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PARALLEL TRADE IN PHARMACEUTICAL
PRODUCTS WITHIN THE EEA: FROM
FIRST TO FINAL MARKETING

- BALANCING THE NEED TO PROTECT AND PROMOTE
PUBLIC HEALTH AND SAFETY WITH THE EC TREATY
OBJECTIVE OF ESTABLISHING A COMMON MARKET

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Thesis submitted in fulfilment of the requirements for the degree of

Doctor of Philosophy (LAW)

by

CARL JOHAN BJÄRN RAM

Department of Law, Durham University

January 2007



17 APR 2007

ABSTRACT

Parallel Trade in Pharmaceutical Products within the EEA: From First to Final Marketing
- *Balancing the Need to Protect and Promote Public Health and Safety with the
EC Treaty Objective of Establishing a Common Market*

by Carl Johan Björnram

This thesis provides a thorough clarification of the rules governing parallel trade in pharmaceutical products within the EEA; from first to final marketing. More specifically, the thesis provides an analysis of the application of EC competition law (Articles 81 and 82 EC Treaty), the free movement of goods provisions (Articles 28-30 EC Treaty), Community measures, and Member State laws to parallel import-restrictive measures.

The EC Treaty and Community measures must, in conjunction with Member State laws, facilitate the establishment of an internal market without compromising public health and safety. For example, the application of Articles 81 and 82 EC Treaty to parallel import-restrictive measures must take into consideration the need to *promote* public health and safety by acknowledging the pharmaceutical industry's reliance on future investments in 'research and development' (R&D). Similarly, the application of Articles 28-30 EC Treaty to repackaging of pharmaceutical products must take into consideration the need to *protect* public health and safety. The importance of balancing the pro-integration objective with the public health and safety objective is particularly evident in relation to the application of the EC Treaty to Member State laws governing the pharmaceutical market-specific and potentially parallel import-restrictive requirement of marketing authorisations.

Parallel trade is, nevertheless, a statistically safe practice, and considered essential to market integration by encouraging intra-brand competition and widening customer choice. Parallel trade is also believed to generate savings to national health authorities, and ultimately patients and taxpayers. The thesis therefore concludes with a set of recommendations aimed at strengthening the protection and promotion of public health and safety *without* having an unduly negative impact on the establishment of an internal market.

DECLARATION

I declare that this thesis is my own work and has not been submitted in any form for another degree or diploma at any university or other institution of tertiary education. Information derived from the published or unpublished work of others has been acknowledged in the text and a list of references is given.

The Copyright of this thesis rests with the author. All information derived from this thesis must be acknowledged appropriately.

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- C-74/03**_____ SmithKline Beecham Plc v. Laegemiddelstyrelsen [2005] E.C.R. 595
- C-207, 252/03**_____ Novartis AG v. Comptroller-General, & Ministre de l'Economie v. Millenium Pharmaceuticals Inc. [2005] E.C.R. 3209
- C-212/03**_____ Commission v. France [2005] E.C.R. 4213
- C-245/03**_____ Merck, Sharp & Dohme BV v. Belgium [2005] E.C.R. 637
- C-348/04**_____ Boehringer Ingelheim KG v. Swingward Ltd. [2004] O.J. C273/11
- T-321/05**_____ AstraZeneca AB v. Commission [2005] O.J. C271/47

T-153/06 _____ EAEPC v. Commission [2006] O.J. C178/38

2. EUROPEAN FREE TRADE AREA COURT (chronological)

Case number:

E-2/97 _____ Mag Instrument Inc. v. California Trading Company [1998] E.T.M.R. 85

E-1/98 _____ Norwegian Government v. Autra Norge A/S [1999] 36 C.M.L.R. 860

E-3/02 _____ Paranova AS v. Merck & Co Inc. [2003] 40 C.M.L.R. 7

3. EC COMMISSION DECISIONS (chronological)

Decision number:

77/66/EEC _____ Gerofabriek [1977] O.J. L16/8

78/163/EEC _____ The Distillers Company [1978] O.J. L50/16

78/823/EEC _____ Kurt Eisele (Maize Seed 1) [1978] O.J. L286/23

80/1283/EEC _____ Johnson & Johnson [1980] O.J. L377/16

82/203/EEC _____ Moët et Chandon [1982] O.J. L94/7

82/267/EEC _____ AEG-Telefunken [1982] O.J. L117/15

82/367/EEC _____ Camera Care/Hasselblad [1982] O.J. L161/18

82/628/EEC _____ Ford [1982] O.J. L256/20

82/853/EEC _____ National Panasonic [1982] O.J. L354/28

84/379/EEC _____ British Leyland [1984] O.J. L207/11

87/406/EEC _____ Tipp-Ex [1987] O.J. L222/1

87/409/EEC _____ Sandoz [1987] O.J. L222/28

87/500/EEC _____ BBI/Boosey & Hawkes [1987] O.J. L286/36

90/38/EEC _____ Bayer (Bayo-n-ox) [1990] O.J. L21/71

90/645/EEC _____ Bayer Dental [1990] O.J. L351/46

92/261/EEC _____ Dunlop [1992] O.J. L131/3

92/426/EEC__Parker Pen [1992] O.J. L233/27
93/82/EEC___Cewal [1993] O.J. L34/20
93/554/EEC___Zera-Agrachemikalien [1993] O.J. L272/28
94/19/EC____Sea Containers Ltd/Stena Sealink [1994] O.J. L15/8
96/478/EC____Adalat [1996] L201/1
97/469/EC___Ciba-Geigy/Sandoz [1997] O.J. L201/1
2001/791/EC__GlaxoWellcome [2001] O.J. L302/1
IV/M.2922___Pfizer/Pharmacia [2003] O.J. C110/24
COMP/A.37.507/F3_AstraZeneca (unreported)

4. NATIONAL CASES (Cronological)

BELGIUM

Reebok International Ltd. v. S.A. Cora & Others [1999] E.T.M.R. 649

Lancome Parfums v. Kruidvat Retail B.V. [2005] E.T.M.R. 26

DENMARK

Bristol-Myers Squibb v. Paranova A/S [2003] (Unreported) (HR(DK)). See Dyekjaer-Hansen K, 'Denmark: Trade Marks –parallel imports – rebranding and repackaging' (2003) 25 E.I.P.R. N183

Case 272/2001 Paranova A/S v. C.H. Boehringer Sohn GmbH & Others [2004] E.T.M.R. 24

Orifarm A/S (unreported). See Dyekjaer-Hansen K, 'Denmark: Trade Marks – Parallel Imports,' (2004) 26 E.I.P.R. N108

FRANCE

Pytheron International SA v. Jean Bowdon SA [1997] E.T.M.R. 211

French Competition Council: Decision No. 05-D-72. See Glatz A and Utzschneider Y, 'France: Anti-competitive agreements – pharmaceuticals,' (2006) 27 E.C.L.R. N58

GREECE

Re. Pfizer Hellas SA and Glaxo SA, Advisory Opinions of the Competition Committee Nos. 81 and 82, Greece, Cases A1-732, A1-733 (August 1989)

Hellenic Competition Commission Decision 318/V/2006 (5 September 2006) (unreported)

NETHERLANDS

Case No. 98/550 Parfums Christian Dior S.A v. Etos B.V (The Appeals Court of the Hague, 15 February, 2000)

SPAIN

1873/98 Difar v. MSD Spain (Servicio de Defensa de la Competencia, el Servicio, SDC)

UNITED KINGDOM

Eurim-Pharm GmbH v. Johnson & Johnson Inc. [1981] 2 C.M.L.R 287

Glaxo v. Europharm, (unreported) (1986) 1078 Scrip 10

Colgate Palmolive v. Markwell Finance [1989] RPC 497

Zino Davidoff S.A. v. A. & G. Imports Limited [1999] C.M.L.R. 1056

Glaxo Group Ltd v. Dowelhurst Ltd [2000] 2 C.M.L.R. 571

Sony Computer Entertainments Inc. v. Tesco Stores Ltd [2000] E.T.M.R 102 (Ch.D)

Napp Pharmaceutical Holdings Ltd v. Director General of Fair Trading [2001] Comp. A.R. 1

R v. The Secretary of State for Health ex parte. BAEPD & Dowelhurst Ltd. v. ABPI [2001] E.W.H.C. 183

Boehringer Ingelheim v. Swingward, & Boehringer Ingelheim v. Dowelhurst [2004] 3 C.M.L.R. 3

Genzyme Ltd v. The Office of Fair Trading [2004] C.A.T. 4

Glaxo Group Ltd v. Dowelhurst Ltd and Richard Taylor [2004] E.W.C.A. (Civ) 290

UNITED STATES

United States v. Parke, Davis & Co., 362 U.S. 29

LIST OF ABBREVIATIONS

ABPI	<i>Association of the British Pharmaceutical Industry</i>
ATC	<i>Anatomical Therapeutic Classification system</i>
BAEPD	<i>British Association of European Pharmaceutical Distributors (Association of British parallel importers)</i>
BMA	<i>British Medical Association</i>
B.M.J.	<i>British Medical Journal</i>
B.S.L.R.	<i>Bio-Science Law Review</i>
C.A.T.	<i>Competition Appeals Tribunal</i>
CEE	<i>Central and East European</i>
CFI	<i>Court of First Instance</i>
C.L.I.	<i>Current Law Index</i>
C.M.L.R.	<i>Common Market Law Review</i>
Comp.A.R.	<i>Competition Appeal Reports</i>
EAEPD	<i>European Association of Euro-Pharmaceutical Companies (Europe-wide parallel importers association)</i>
EC	<i>European Community</i>
ECJ	<i>European Court of Justice</i>
E.C.L.R.	<i>European Competition Law Review</i>
E.C.R.	<i>European Court Reports</i>
EDQM	<i>European Directorate for the Quality of Medicines</i>
EEA	<i>European Economic Area</i>
EEC	<i>European Economic Community</i>
EFPIA	<i>European Federation of Pharmaceutical Industries and Associations</i>
EFTA	<i>European Free Trade Area</i>
EGA	<i>European Generics Medicine Association</i>
E.I.P.R.	<i>European Intellectual Property Review</i>
E.J.P.H.	<i>European Journal of Public Health</i>
E.L.J.	<i>European Law Journal</i>
E.L.Rev.	<i>European Law Review</i>
EMEA	<i>European Medicines Agency (formerly: European Agency for the Evaluation of Medicinal Products)</i>
Ent.L.R.	<i>Entertainment Law Review</i>
EPAR	<i>European Public Assessment Report</i>
EphMRA	<i>European Pharmaceutical Marketing Research Association</i>

ESRC _____ *Economic and Social Research Council*
E.T.M.R. _____ *European Trade Mark Reports*
EU _____ *European Union*
EUF _____ *European Union Focus*
EWCA _____ *Court of Appeal of England and Wales*
EWHC _____ *High Court of England and Wales*
FPL _____ *Föreningen för Paralleldistributörer av Läkemedel* (Swedish parallel importers association)
GDP _____ *Gross Domestic Product*
I.C.C.L.R. _____ *International Company and Commercial Law Review*
IHE _____ *Institutet för Hälso- och sjukvårdsekonomi* (Swedish Health Economics Institute)
INTA _____ *International Trademark Association*
Int.T.L.R. _____ *International Trade Law and Regulation*
I.P.Q. _____ *Intellectual Property Quarterly*
IRPP _____ *Institute for Research on Public Policy*
J.B.L. _____ *Journal of Business Law*
J.I.P.L.P. _____ *Journal of Intellectual Property Law and Practise*
J.E.P.P. _____ *Journal of European Public Policy*
J.I.E.L. _____ *Journal of International Economic Law*
LIF _____ *Läkemedelsindustriföreningen* (Swedish Association of the Pharmaceutical Industry)
LMI _____ *Legemiddelindustriforeningen* (Norwegian Association of the Pharmaceutical Industry)
MAL _____ *Manufacturer's (Assemble) Licence*
MHRA _____ *The Medicines and Healthcare products Regulatory Agency (UK)*
NERA _____ *National Economic Research Associates*
NHS _____ *National Health Service (UK)*
OECD _____ *Organisation for Economic Co-operation and Development*
O.J. _____ *Official Journal of the European Union*
OTC _____ *Over-the-counter Medicine*
PIL _____ *Parallel Import Licence*
P.J. _____ *Pharmaceutical Journal*
POM _____ *Prescription-only-medicine*
PPRS _____ *Pharmaceutical Price Regulation Scheme (UK)*
R&D _____ *Research and Development*
R.A.J. _____ *Regulatory Affairs Journal*
SCRIPT _____ *Journal of the Scottish Centre for Research into Intellectual Property and Technology*

- SFK**_____ *Stichting Farmaceutische Kengetallen* (Dutch Foundation for
Pharmaceutical Statistics)
- SPC**_____ *Supplementary Protection Certificate*
- SSNIP**_____ *Small but Significant Non-transitory Increase in Price*
- TRIP**_____ *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994*
- VFA**_____ *Verband Forschender Arzneimittelhersteller e.V* (German Association of
Research-Based Pharmaceutical Companies)
- WDL**_____ *Wholesale Dealer's Licence*
- WHO**_____ *World Health Organisation*
- WIPO**_____ *World Intellectual Property Organisation*
- WMA**_____ *World Medical Association*
- WTO**_____ *World Trade Organisation*

A NOTE ON FOOTNOTES

Every source is given a full reference the first time it appears in a chapter, with the exception of a small number of documents and Acts. These exceptions are referred to using a system of chapter X, page X, and footnote X in all subsequent chapters. The first (and full) reference in a chapter is the principal footnote to which all subsequent references in the chapter refer to using a system of footnote (n.) X above. *Ibid* is used if the immediate above footnote refers to the same source or the same footnote. The case number is given if the main text does not clearly refer to the source. For example, if the principle footnote refers to Case 104/75 *Officier van Justitie v. de Peijper*, all subsequent footnotes will refer to n. X above, para. X if the main text clearly indicates the case concerned, or to Case 104/75, n. X above, para. X if not clear from the main text. Subsequent Commission Decisions are referred to using a short form of the 'name' of the decision (e.g. *Adalat*, n. X above). Similarly, if the principal footnote refers to a literary work, for example P. Rey and J. Venit, 'Parallel trade and pharmaceuticals: A policy in search of itself,' (2004) 29 E.L.Rev. 153, all subsequent footnotes will refer to Rey and Venit, n. X above, X, with the last X denoting the particular page number. The same principle applies to Community measures, national legislation and agency guidelines, where either the title of the document, name of the author, or an easily identifiable number will be used in all subsequent footnotes. Cross-references to other parts of the thesis are given in the form of *chapter 1(2) above*, referring to section 2 of chapter 1, or, if more specific; chapter X, pp. X-X above.

INTRODUCTION

Parallel trade is the act of purchasing goods in a lower priced market and reselling in a higher priced market without authorisation from the manufacturer and owner of the intellectual property rights. Having identified a price differential in legitimate intellectual property protected products, parallel traders purchase the goods in the lower priced market in the hope of selling the goods in the higher priced market.¹ Parallel traders thus compete with the manufacturer's authorised products on the higher-priced market.

Although organised trade outside the manufacturer's distribution channels occurs within most products groups, parallel traders have found pharmaceutical products a particularly attractive niche market (see *chapter 1*). This may seem strange considering the potential profitability of parallel trade in a wide range of less regulated product groups, such as electronic products and clothing. However, parallel traders' particular interest in pharmaceutical products is easily explained. First, pharmaceutical prices are regulated by national authorities leading to a large disparity in prices between different national markets (see *chapter 1*). Secondly, pharmaceutical products are a non-substitutable necessity for the well-being of any society, guaranteeing a constant and inherent demand.

Parallel trade is not legally or practically possible in most parts of the world. Strict marketing regulations are applied to most pharmaceutical products. Without access to the manufacturer's test-results and product-specific information it is very difficult to obtain marketing authorisation from national authorities. Further, even if marketing authorisation is obtained, importation would be made economically unviable, if not impossible, due to the fact that most pharmaceutical products

¹ See T. Hays, *Parallel importation under European Union law*, (London: Sweet & Maxwell, 2004); and W. Rothnie, *Parallel imports*, (London: Sweet & Maxwell, 1993).



benefit from patent protection for the chemical composition of the product and a trademark affixed on the packaging. National laws allow intellectual property owners to exercise their rights so as to prevent importation or exportation of the intellectual property protected products. There are, however, exceptions. A limited number of States and 'trade zones' restricts the manufacturer's right to exercise intellectual property rights so as to create barriers to trade.²

The most prominent and economically significant of these countries and entities is the European Union (EU) and its 25 Member States. The objective of the EC Treaty is to establish a common market through the free movement of goods, workers and capital and the application of competition rules.³

For this purpose, parallel import-restrictive market strategies, adopted by manufacturers, have traditionally been considered as an obstacle to market integration by the European Commission (the Commission)⁴ (see *chapter 2*). Article 81 EC Treaty prohibits all agreements, concerted practices and decisions by undertakings that may affect trade between Member States and prevent, restrict or distort competition within the common market. Article 82 EC Treaty prohibits any abuse by a dominant undertaking likely to affect trade between Member States. The Commission, the Court of First Instance (CFI), and the European Court of Justice (ECJ) have found a wide variety of parallel import-restrictive agreements and

² For example, the European Union, Australia, Hong Kong, Singapore, and South Africa have all introduced varying forms of exhaustion of trademark rights mechanisms. In late April 2004 a bill was introduced to allow re-importation from Canada and other countries into the US: see J. Arfwedson, 'Parallel trade in pharmaceuticals,' Quickstudy, The Institute for Policy Innovation (27 July 2004), p. 2.

³ The free movement of goods provisions comprise Articles 28 to 30 EC Treaty. Article 28 EC Treaty: '*Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.*' Article 30 EC Treaty: '*The provisions of [Article 28]...shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of...the protection of health and life of humans...;or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.*' The relevant competition rules comprise Articles 81 and 82 EC Treaty.

⁴ The Commission is the competition authority for the European Community.

abuses to be prohibited by Articles 81 and 82 EC Treaty, from refusals to supply,⁵ and applying a system of dual-pricing in order to limit parallel importation,⁶ to the imposition of restrictions through distribution agreements (see *chapter 2*).⁷

Further, the requirement in Directive 2001/83/EC,⁸ that no pharmaceutical product may be placed on the market without benefiting from a marketing authorisation, presents a problem for parallel importers of pharmaceutical products (see *chapter 3*). Without access to the manufacturer's product dossier it is almost impossible to obtain marketing authorisation. However, in *de Peijper*⁹ the ECJ ruled that national measures having this effect hinder intra-Community trade contrary to Article 28 EC Treaty.¹⁰ The Court also ruled that it is unnecessary for the protection of public health and safety to request, from the parallel trader, information which the competent authority in the importing Member State already has in its possession following the original marketing authorisation application. The effect of this ruling was the establishment of a 'first marketing principle' for marketing authorisation applications, commonly referred to as the 'simplified procedure.'¹¹ As explained in *chapter 4*, the reference marketing authorisation holder exhausts the right to prevent future applicants from relying on the information already in the possession of the national authority when the product obtains a first marketing authorisation. A 'parallel import licence' (PIL) will be granted by a competent national authority if the parallel imported product and the reference product already benefiting from a marketing authorisation share a 'common origin' and are 'essentially identical.'

⁵ Case 27/76 *United Brands Co. v. Commission* [1978] E.C.R. I-207; and *Joined Cases 6-7/73 Commercial Solvents v. Commission* [1974] E.C.R. 223.

⁶ See e.g. Commission Decision 2001/791/EC *GlaxoWellcome* [2001] O.J. L302/1.

⁷ See e.g. Commission Decision 87/409/EEC *Sandoz* [1987] O.J. L222/28; Commission Decision 80/1283/EEC *Johnson & Johnson* [1980] O.J. L377/16; and Commission Decision 87/406/EEC *Tipp-Ex* [1987] O.J. L222/1.

⁸ Article 6 of Council Directive 2001/83/EC on the Community code relating to medicinal products for human use [2001] O.J. L311/67.

⁹ Case 104/75 *Officier van Justitie v. de Peijper* [1976] E.C.R. 613. See *chapter 3*(3.1) below.

¹⁰ It should be noted that different rules apply to 'personal imports:' see Case 215/87 *Schumacher v. Hauptzollamt Frankfurt am Main-Ost* [1989] E.C.R. 617; and *chapter 3*, p. 102, n. 91 below.

¹¹ Case 104/75, n. 9 above.

Nevertheless, patent and trademark holders are in effect capable of segmenting the common market along national borders, owing to the territorial nature of intellectual property rights.¹² Manufacturers' may therefore exercise their intellectual property rights vested in the pharmaceutical product so as to restrict parallel trade. This has resulted in the ECJ distinguishing between the 'existence' and the 'exercise' of an intellectual property right (see *chapter 5*). The former is protected by Article 295 EC Treaty¹³ whilst the latter is subject to the severity of the free movement of goods and the competition rules. This tension between national and Community law whereby the existence of national intellectual property rights is recognised but the exploitation thereof is subject to Community law, is known as the 'exhaustion of rights' doctrine (see *chapter 5*). This doctrine allows for 'Community exhaustion' of intellectual property rights once the protected product is placed anywhere in the European Economic Area (EEA) for the first time.¹⁴ The inclusion of a derogation (commonly referred to as the 'specific mechanism') from the 'exhaustion of rights' doctrine in the 2003 Act of Accession¹⁵ of the ten new Member States (Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia) will, however, restrict parallel trade from the new Member States for a dynamic transition period (see *chapter 5*). Its inclusion was largely a result of the low pharmaceutical prices in the new Member States, which are mostly 'central and eastern European' (CEE) countries with struggling economies.

¹² Some limited measures have been adopted by the Community, such as Council Directive 89/104 EEC to approximate the laws of the Member States concerning trademarks [1989] O.J. L40/1, providing for the granting of trademarks valid throughout the Community.

¹³ Article 295 EC Treaty: '*This Treaty shall in no way prejudice the rules in Member States governing the system of property ownership.*' This Article should be read in conjunction with Article 30 EC Treaty.

¹⁴ See Case 15/74 *Centrafarm BV v. Sterling Drug Inc.* [1974] E.C.R. 1174. The EEA is a free trade area established by the Agreement on the European Economic Area [1994] O.J. L344/3. It consists of Norway, Iceland, Liechtenstein, and the 25 EC Member States.

¹⁵ Act Concerning the Conditions of Accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia, and the Slovak Republic and the Adjustments to the Treaties on which the European Union is founded [2003] O.J. L236/33. The 'specific mechanism' is contained in Chapter 2 (Company Law) of Annex IV to the Act.

In consequence, manufacturers are largely unable to exercise their intellectual property rights to prevent parallel trade within the EEA. However, national marketing regulations concerning marketing authorisations, commercial practices, and customer preferences have also undermined parallel importers' ability to fully exploit these opportunities (see *chapter 6*). By way of illustration, goods purchased in bulk originally packaged for sales to hospitals may require repackaging to accommodate smaller quantity consumer sales,¹⁶ and packaging bearing instructions or warnings in one language may need to be translated for sale in another Member State. To prevent the European pharmaceutical market from being partitioned along national borders the ECJ has repeatedly ruled that trademark proprietors are precluded from 'exercising' their intellectual property rights to prevent repackaging of pharmaceutical products if the parallel importer fulfils a set of conditions (see *chapter 6*) These conditions effectively afford the parallel trader a licence for the unauthorised use of the relevant trademark.

However, it is not only the trademark proprietor's rights that must be taken into consideration when repackaging pharmaceutical products (see *chapter 7*). Title V of Directive 2001/83/EC¹⁷ regulates the labelling and package leaflets of pharmaceutical products. In addition, Article 40 of the above Directive requires parallel importers to hold a 'manufacturer's (assemble) licence' before commencing any repackaging.¹⁸ The intellectual property aspect is secondary, and separate from these regulations. As this area of law is sparsely commented upon, chapter 7 analyses the conformity of these regulations with the EC Treaty.

Against this background, this thesis provides a thorough clarification of the rules governing parallel trade in pharmaceutical products within the EEA; from first to final marketing. Focus is on the need to balance the common market objective with the need to *protect* and *promote* public health and safety when interpreting the EC

¹⁶ In the UK for example, medicines usually come in multiples of seven, whereas in other continental Member States medicines are usually packaged in multiples of five or ten. Discussed in chapter 6(1) below.

¹⁷ N. 8 above.

¹⁸ *ibid.*, Art. 40.

Treaty. This balancing act is of utmost importance due to the specific characteristics of the pharmaceutical industry, which largely set it aside from other consumer product groups.

First, the Community-wide diversity in pricing regulations and reimbursement policies has led to a vast disparity in pricing levels for pharmaceutical products between Member States (see *chapter 1*). This has prompted debate on the effect of parallel trade on the need to promote future 'research and development' (R&D) of new pharmaceutical products.¹⁹ The pharmaceutical industry relies heavily upon investments in R&D. The profit made during patent protection will fund the R&D of new products. Parallel traders, however, are simply importing the exporting Member States' pricing policy (see *chapter 2*). The argument is therefore that the profits of parallel traders correlate to the decrease in funds made available for R&D by the patent proprietor.²⁰

Secondly, the pharmaceutical industry is characterised by strict regulations, the majority concerning quality control. This has led to concerns, mostly voiced by manufacturers and patient interest groups, that parallel trade may adversely affect the protection of public health and safety (see *chapter 3*). It is argued that parallel trade, as a result of the relaxation of regulatory control following the establishment of the 'simplified procedure' (see *chapter 4*) and the 'exhaustion of rights' doctrine (see *chapter 5*), may open a gateway to the common market for poor or even counterfeit pharmaceutical products.²¹ In particular, it is argued that repackaging of pharmaceutical products may affect the therapeutic qualities of parallel imported

¹⁹ See for example H. Bale Jr., 'The conflict between parallel trade and product access and innovation: The case of pharmaceuticals,' (1998) 1 J.I.E.L. 637; and P. Rey and J. Venit, 'Parallel trade and pharmaceuticals: A policy in search of itself,' (2004) 29 E.L.Rev. 153.

²⁰ See for example P. Kanavos, J. Costa-Font, S. Merkur and M. Gemmill, 'The economic impact of pharmaceutical parallel trade in European Union Member States: A stakeholder analysis,' Special Research Paper, London School of Economics (January 2004); and P. West and J. Mahon, 'Benefits to payer and patients from parallel trade,' Report, York Health Economics Consortium (May 2003), (<http://www.york.ac.uk/inst/yhec/downloads/ParallelTrade_ExecSumm.pdf>).

²¹ See e.g. A. Clark, 'Parallel imports: A new job for customs?,' (1999) 21 E.I.P.R.; and S. Shallar, 'Spaghetti junction,' *European Pharmaceutical Executive*, 1 March 2005, p. 12.

products (see *chapter 6*), either due to interference with the actual products or to poor packaging providing an inadequate protection (see *chapter 7*).²²

This thesis applies a doctrinal research methodology. Focus is on primary sources such as the EC Treaty, Community Regulations and Directives, ECJ and national case-law interpreting the EC Treaty, and national legislation. The UK will be used as a reference Member State. Secondary sources include peer-reviewed journal articles and other literary works. Guidance notes and other material from competent national authorities and the European Medicines Agency (EMA)²³ are frequently used in order to research the practical implementation of EC measures and national legislation. Chapters 3, 4 and 7 in particular include much EMA and UK Medicines and Healthcare Products Regulatory Agency (MHRA)²⁴ material.

There are three main reasons for not including empirical research in the thesis. First, parallel trade in pharmaceutical products is a very sensitive and contentious business sector. Parallel traders and manufacturers have for nearly three decades been involved in an enduring argument over the legitimacy and public benefit of parallel trade. As a result of the two groups' opposing interests, their willingness to participate in such research would be limited. This was made evident to me by the board of directors of the Association of Swedish Parallel Importers in September 2005.²⁵ Secondly, for the same reason, the objectivity of any primary evidence and information received from the respective interest groups would be questionable. Finally, the diverse interest in the trade, from all parties involved in and affected by it, ensures that any disputes are likely to result in legal proceedings. Similarly,

²² See chapter 7(4) below, and F. Humer, 'A tainted trade – parallel trade medicines are a clear symptom of the failure of Europe's pharmaceutical policy,' *European Pharmaceutical Executive*, 1 November 2005, p. 44.

²³ The acronym EMA originates from the agency's predecessor the 'European Agency for the Evaluation of Medicinal products.' In keeping with the traditionally confusing policy of agency names in the Community, the acronym does not actually match the full name of the (current or former) agency in any European language.

²⁴ On January 1st 2006 the UK Medicine's Control Agency (MCA) and the UK Medical Devices Agency (MDA) merged to form the new MHRA.

²⁵ I was invited by the chairman of the 'Föreningen för Paralleldistributörer av Läkemedel' (FPL), Göran Heintz, in September 2005 to discuss my research, and given an opportunity ask questions.

other interested parties, such as the Commission and individual Member States, will have an incentive to either promote or prevent the trade. The Commission believes parallel trade will help to achieve the EC Treaty objective of establishing a common market,²⁶ whilst the majority of Member States are actively promoting the trade as it is believed to generate savings for national health budgets.²⁷ Thus, any conduct not in accordance with national and Community regulations and measures will most likely be brought to the public's attention. The thesis therefore applies a doctrinal research methodology focusing on primary sources. This has the added benefit of allowing for an objective study of the reasoning applied by the Community courts when balancing the common market objective with the need to promote and protect public health and safety in light of the information available to the Court at the time of giving its judgment or ruling. This will allow for an analytical (as opposed to a mere result-driven) approach that can be applied to other areas of the law.

The thesis is divided into three parts. Part 1 concerns the European pharmaceutical market (chapter 1), competition law (chapter 2), marketing authorisations and PILs (chapters 3 and 4), with special reference to the UK regulatory framework. Part 2 concerns intellectual property – 'exhaustion of rights' and the 'specific mechanism' (chapter 5); repackaging (chapter 6); and labelling and package leaflet regulations (chapter 7). Part 3 (chapter 8) concludes, with a set of recommendations.

The terminology applied in this thesis needs to be briefly explained. First, the term 'pharmaceutical products,' used throughout the thesis, is interchangeable with 'medicinal products' or 'medicines.' Secondly, the terms 'common market,' 'single market,' and 'internal market' are sometimes used interchangeably by EU institutions and commentators. Even though a single market is sometimes differentiated as a more advanced form of common market, the thesis tends to use the term 'common market' for the purpose of clarity and consistency. As the common market extends to the markets of the EEA Member States, the term

²⁶ See chapters 2 and 5 below.

²⁷ See chapter 1(3) below.

'common market' refers to the 25 EC Member States and the EEA Member States.²⁸ Finally, all decisions of national courts, of the ECJ, of the CFI, and of the European Free Trade Association (EFTA) Court²⁹ are referred to as *judgments*. However, national courts are empowered under Article 234 EC Treaty (and national courts against whose decisions there is no judicial remedy under national law are obliged) to refer questions of interpretation or validity of Community law to the ECJ, when necessary before the national court can deliver a judgment. Such preliminary references result in a *ruling* by the ECJ.

The law is stated as of 28th of September 2006.

²⁸ See n. 14 above.

²⁹ The EFTA Court has jurisdiction with regard to EFTA Member States which are parties to the EEA Agreement, currently Iceland, Liechtenstein and Norway.

PART I

REGULATING THE EUROPEAN PHARMACEUTICAL
MARKET: PRICING, DISTRIBUTION AND MARKETING

THE EUROPEAN PHARMACEUTICAL MARKET

Over the last hundred years the pharmaceutical industry has changed our lives and the way we think about diseases and medicine. A century ago the contraction of tuberculosis or meningitis would most likely result in death. The development and progress of the pharmaceutical industry means that today there is a drug to treat most diseases, and a vaccine to prevent most diseases altogether. Everyone agrees that this is a remarkable achievement which is to the benefit of all mankind. Controversy has arisen because most pharmaceutical companies are privately owned profit-making institutions, and profiting from sickness and misery can be difficult to reconcile with human morals. Apart from the particular nature of pharmaceutical products the industry itself is operating under special circumstances and conditions, both in relation to national and Community measures, but also in terms of the development and marketing of pharmaceutical products. A clear understanding of the intricacies of the pharmaceutical industry and the European pharmaceutical market is necessary in order to gain a clear understanding of the conditions under which parallel trade in pharmaceutical products operates.

1. *The intricacies of the pharmaceutical industry*

The pharmaceutical industry relies heavily upon investments in ‘research and development’ (R&D). A new pharmaceutical product starts ‘life’ as a newly-discovered molecule in a research lab. The R&D may have been carried out in the pharmaceutical company’s own facilities or be the result of collaboration with a university, or (as is increasingly the norm) by an R&D contractor.¹ At this stage of

¹ See S. El Feki, ‘Prescription for change – a survey of pharmaceuticals,’ *The Economist*, 18 June 2005, p. 1, 6.

the development the new molecule is patented. After further pre-clinical development the clinical trials start. This is soon followed by a marketing authorisation application and approval. The process of developing a pharmaceutical product is costly and long; it can take as much as 12 years from first discovery to first marketing² and cost upwards of \$802 million.³ At this stage most of the patent period will have expired, only leaving approximately 8 years of patent protection after first marketing. However, this is only for the molecules that survive the different stages of development and reach the final stage of marketing approval, estimated to be only about 1 out of 10 000 molecules.⁴ The implications of this costly process is that 'Big Pharma,' a dozen or so multinational pharmaceutical companies, roughly accounts for half of the world's \$550 billion pharmaceutical sales market.⁵

The next stage in a pharmaceutical product's life-cycle - the marketing stage - is laden with controversy. First, a key issue for the manufacturer is whether the product will be classified as a 'prescription-only-medicine' (POM) or as an 'over-the-counter' (OTC) medicine.⁶ OTC medicines have traditionally been used for

² See The Association of the British Pharmaceutical Industry (ABPI), 'The development of medicines,' (October 2005) (<http://www.abpi.org.uk/publications/briefings/Dev_Medicines.pdf>), p. 1.

³ See J. DiMasi, R. Hansen and H. Grabowski, 'The price of innovation: New estimates of drug development costs,' (2003) 22 *Journal of Health Economics* 151, 182. According to The Swedish Association of the Pharmaceutical Industry (LIF), 'Pharmaceutical market and healthcare,' Fakta (2005), (<<http://www.lif.se/Statistik/stat.asp>>), p. 38, the estimated cost has increased from \$231m in 1991, to \$802m in 2001. However, Steven Paul, head of science and technology at Elli Lilly, estimates that the cost of bringing a new product to the market has now risen to more than \$1.5 billion: See El Feki, n. 1 above, 6.

⁴ ABPI, n. 2 above, 2; and El Feki, *ibid.*, 6. To this should be added that about 20% of new drugs will fail because of safety concerns; see C. Hodges, *European regulation of consumer safety*, (Oxford: OUP, 2000), p. 281.

⁵ See LIF, n. 3 above, 36-37 for the world market figure and the twelve top pharmaceutical companies' ('Big Pharma') world sales figures 2004 (Billion USD): Pfizer (50,7); GlaxoSmithKline (32,8); Sanofi-Aventis (27,5); Johnson & Johnson (24,7); Merck & Co (23,9); Novartis (22,8); AstraZeneca (21,6); Roche (17,7); Bristol-Myers Squibb (15,6); Wyeth (14,2); Abbott (14,2); Elli Lilly (12,7).

⁶ In the UK three classifications are used: POM (requires a prescription from a specified health professional); 'behind-the-counter' (must be sold by, or under the supervision of, a registered pharmacist); and 'off-the-shelf' (available from any sales outlet). The OTC market includes the last two of the abovementioned categories. See The British Medical Association (BMA), 'Over-the-counter medication,' Board of Science (May 2005), (<<http://www.bma.org.uk/ap.nsf/Content/OTCmedication>>), p. 2.

minor ailments, as the documented safety of such products makes them suitable for self-diagnosis and self-care. There is a general recognition that when a new product is granted a marketing authorisation it will be classified as a POM in order to supervise the safety of the product. However, there is a general trend to switch the POM classification to OTC after a few years, when the safety of the drug is documented and established.⁷ Pharmaceutical companies welcome the (de)classification to OTC, especially when the product patent is about to expire, as it is a good way to manage the product life-cycle; perhaps ending with a sale of the brand name altogether. National health services and patients also encourage the (de)classification to OTC as such products are often cheaper and save doctors from having to write prescriptions.⁸

Secondly, Pharmaceutical companies have to balance the immorality of profiting from illness and suffering with share-holders' demands for larger returns on investment. Pharmaceutical companies are accused of rushing the development stage in order to market the products earlier, thus allowing for a longer period of marketing before the patent period expires.⁹ Worse even, the industry is often accused of 'inventing' diseases in order to widen the market for a particular pharmaceutical product.¹⁰ Recent events, such as the Vioxx scandal have not helped to better the reputation of the industry.¹¹ This highlights the difficulties faced by the industry in relation to advertising and marketing.

⁷ BMA, n. 6 above, 6.

⁸ EL Feki, n. 1 above, 10.

⁹ See Appendix 3 of Hodges, n. 4 above, for statistics on drug-related incidents and injuries.

¹⁰ One example is Pfizer's advertising campaign aimed at marketing Viagra for female sexual dysfunction: EL Feki, n. 1 above, 5.

¹¹ Vioxx, a pharmaceutical product marketed by Merck, has recently been subject to a number of Court cases concerning the safety of the product; see below. The industry's reputation was also tarnished when 39 pharmaceutical companies sued the South African government over changes to its patent law to allow for the supply of affordable HIV medicines. See S. EL Feki, 'Why drugmakers should do more for developing countries,' *The Economist*, 2 October 2004, p. 63; and A. van der Merwe, 'Use of pharmaceutical patents without authorisation: Some thoughts from South Africa,' (2004) I.P.Q 198.

Only America and New Zealand allow direct-to-consumer marketing,¹² a practice which helps patients become aware of medical conditions they did not know they had, but may also lead to more self-diagnosis and medication; a practice which may not be in patients best interest in the long run.¹³ It may also run counter to its purpose. Vioxx, a COX-2 inhibitor, was fiercely advertised by Merck. The effect was that the drug, which was of immense benefit to a small number of patients, is now withdrawn from the market due to over usage by patients not in need of its therapeutic effects as a result of over-marketing by Merck.¹⁴ Sales promotion aimed at doctors and health authorities is similarly intensive. However, this practice is much a characteristic of the US market as the European market is much more regulated and state controlled, which will be further discussed below. Nevertheless, this explains the strategy employed by 'Big Pharma' of focusing on a small number of products. As R&D is a risky business, with few molecules reaching the market, and having only 8 or so years of patent protection left, pharmaceutical companies intend to maximise revenues before the patent expires. Meanwhile competitors, realising the value of the product market, introduce so called 'me-too' products (copies or substitutes of the competitor's product).¹⁵ It is questionable whether 'me-too' products actually fill a purpose as the efforts applied by the company could better serve humanity by finding a much-needed cure for another disease, although subsequent research may actually result in a much improved version of the original product. Perhaps this cumulatively explains why pharmaceutical companies spend around three times more on marketing, advertising, and administration as on R&D.¹⁶ This is especially so as in addition to 'me-too' products, R&D companies face competition from generics manufacturers post patent expiration.

¹² El Feki, n. 1 above, 11.

¹³ See B. Mintzes, M. Barer, R. Kravitz, A. Kazanjian and K. Bassett, 'Influence of direct to consumer pharmaceutical advertising and patients' requests on prescribing decisions: two site cross sectional survey,' (2002) 324 B.M.J. 278.

¹⁴ The Court recently ruled in favour of Merck by rejecting a claim that short-term use of Vioxx caused the 2001 death of a Florida man. Vioxx was withdrawn from the market in 2006. See Merck press release of 17 February, 2006:<http://www.vioxx.com/rofecoxib/vioxx/consumer/press_release_02172006.jsp>.

¹⁵ El Feki, n. 1 above, 5.

¹⁶ See D. Light and J. Lexchin, 'Foreign free riders and the high price of US medicines,' (2005) 331 B.M.J. 958, 959.

R&D companies invest a fraction of their revenues back into research and development of new molecules. Generics manufacturers, on the other hand, take advantage of the availability of the product data. Once the patent expires, generics companies are allowed to use this data to produce equivalents of an original product.¹⁷ In some Member State markets, for example Denmark, Germany, the Netherlands and the UK, generic products accounts for upwards or almost 20% of the market sales value.¹⁸ Generic products are often 20-80% cheaper than original patented products and can therefore generate savings for health care providers as well as patients.¹⁹ As generic products bring down prices through increased brand competition, R&D companies (the patent holders) try to generate as much revenue as possible before the patent expires.

This inevitably highlights the fact that the pharmaceutical industry operates under very special conditions. First, the inherent demand for pharmaceutical products is not price sensitive. Admittedly, pharmaceutical products can be a luxury few can afford in developing countries, but demand is genuine, and quite literally, a matter of life or death. As a necessity, and a non-substitutable such, pharmaceutical products will always be in demand. Both poor and rich people will always demand pharmaceutical products, even though rich people may purchase them more readily. Especially since life-expectancy in rich (and to a certain extent developing) countries is increasing and chronic diseases are rapidly becoming a growing burden on society.²⁰ Secondly, profiting from illness and suffering is by some considered unethical or at least immoral. Nevertheless, it must be remembered that without substantial profits there would be no incentive to carry out further R&D. At least a pharmaceutical company provides life-saving products in return for its profits, whilst a generics company only produces copies of already invented pharmaceutical

¹⁷ Discussed in chapter 3(2.3) below.

¹⁸ Denmark 21.1%; Germany 26.8%; the Netherlands 21.1%; and the UK 17.2%: The European Federation of Pharmaceutical Industries and Association (EFPIA), 'The pharmaceutical industry in figures,' Key data (2005), (<http://www.efpia.org/6_publ/infigures2005.pdf>), p. 12.

¹⁹ See The European Generics Medicines Association's website at: <<http://www.egagenerics.com/gen-basics.htm>> for more information.

²⁰ Most of the 7500 products currently under development are aimed at chronic diseases of the rich world, according to El Feki, n. 1 above, 8.

products and as such does not contribute to the R&D of new pharmaceutical products. In other industries, large profits may only mean the sale of even more environmentally harmful or unhealthy products.

2. *The European pharmaceutical market*

The European pharmaceutical market accounts for 29.6% of the world market and is second in size only to the US market.²¹ The pharmaceutical industry is the EU's 5th largest industrial sector²² employing upwards of 588,000 people²³ producing more than €154 billion worth of pharmaceutical products annually.²⁴ This makes the European pharmaceutical industry an important employer and economic actor contributing to the well-being of the European economy in addition to maintaining a healthy society. Further, European pharmaceutical companies invested upwards of €21.5 billion in R&D in 2004.²⁵ Investments in R&D has steadily increased since 1980 reflecting the increase in product development costs, whilst the amount of new chemical or biological entities/products originating on European territory has steadily decreased from 88 in the period 1990-1994 to only 57 in the period 2000-2004.²⁶ Only 7 of the 23 new molecular entities/products launched on the world market in 2004 originated from European territory, whilst 9 originated from the US market.²⁷ The unavoidable analysis seems to be that, compared to the US; Europe seems to be a less attractive location for R&D investment. The Commission has, by setting up the G10 Medicines Group and releasing a Communication on 'a stronger European-based pharmaceutical industry for the benefit of the patient – a call for action,' recognised that the pharmaceutical industry is favouring the US over Europe as a base for R&D.²⁸ It is clear that 'without creating the right environment

²¹ LIF, n. 3 above, 37.

²² Commission Communication on a stronger European-based pharmaceutical industry for the benefit of the patient – a call for action [2003] COM/383/final., p. 12.

²³ As of 2004: EFPIA, n. 18 above, 9.

²⁴ As of 2003: *ibid.*, 6.

²⁵ *ibid.*, 20.

²⁶ *ibid.*

²⁷ LIF, n. 3 above, 41.

²⁸ The High Level Group on Innovation and Provision of Medicines – The G10 Medicines Group – was set up in March 2001 to 'explore ways of improving industry competitiveness in Europe while

for pharmaceutical innovation we will never regain the competitive advantage Europe once enjoyed.²⁹ However, regaining Europe's crown as the world's leading health and research centre will be difficult considering that the pharmaceutical industry regards Europe as 'a hostile and turbulent environment for pharmaceuticals.'³⁰ The industry's main grievance within the EC is Member States' pricing regulations and the trade in pharmaceutical products outside manufacturers' distribution channels, maintaining that parallel trade in medicines 'between EU countries is a key factor in Europe's declining attractiveness for pharmaceutical R&D.'³¹ Member State regulations existing in conjunction with EC measures have created a complex and often non-dynamic market, at least from the pharmaceutical industry's viewpoint, which is likely to differ from that of economic actors – such as parallel importers – actually benefiting from the lack of harmonisation of national pricing regulations. These regulations and measures must be thoroughly accounted for and discussed before the rationale for parallel trade can be outlined.

2.1 *Community measures specific to the pharmaceutical market*

Measures adopted by the Community are primarily concerned with the marketing stage of pharmaceutical products. The Unit responsible for pharmaceuticals in the Commission's Enterprise and Industry Directorate-General is responsible for maintaining, simplifying, and updating Community measures concerning the single market in pharmaceutical products. The first Community pharmaceutical Directive was introduced in 1965, aiming to maintain a high level of protection for public

encouraging high levels of health protection.' The Group published the report; G10 Medicines Group, 'High Level Group on innovation and provision of medicines in the European Union – recommendations for action,' Report, (7 May 2002), (<<http://ec.europa.eu/enterprise/phabiocom/p9.htm>>). The Commission adopted its official response by way of the Commission Communication (2003), n. 22 above, setting out how each recommendation can be taken forward.

²⁹ Günter Verheugen (Vice-President of the European Commission responsible for Enterprise and Industry) at the annual meeting of the EFPIA in Brussels, 1 June 2005. See Commission press release SPEECH/05/311 (1 June 2005), p. 4.

³⁰ Speech by J-F Dehecq, EFPIA Vice-President, G10 Medicines Group's Conference, Rome (10 July 2003), (<http://www.efpia.org/5_conf/DehecqG10RJuly2003.pdf>).

³¹ See F. Humer 'A tainted trade – parallel trade medicines are a clear symptom of the failure of Europe's pharmaceutical policy,' European Pharmaceutical Executive, 1 November 2005, p. 44.

health.³² In 1995 the ‘European Agency for the Evaluation of Medicinal products’ (EMEA) was established,³³ only to be replaced by the new ‘European Medicines Agency’ (EMA) in November 2005.³⁴ The new Agency is responsible for the ‘centralised procedure,’ the ‘mutual recognition procedure’ and the ‘simplified procedure’ (for generic products) for granting marketing authorisations.³⁵

The Community has also introduced a system of pharmacovigilance (the system of monitoring the safety of pharmaceutical products post marketing) requiring Member States to monitor and collect data on adverse reactions to pharmaceutical products and to take action where necessary.³⁶ This system is linked to the Community regulations governing the ‘classification of medicinal products,’ determining whether a pharmaceutical product should be sold as a POM or an OTC medicine.³⁷ Wholesale distribution, packaging and labelling have also been subject to Community measures.³⁸

Finally, Directive 2001/83/EC prohibits any advertising of medicinal products for which a marketing authorisation has not been granted.³⁹ In contrast to the US, direct-to-consumer advertising of POM products and products containing narcotic

³² Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products [1965] O.J. 22/369.

³³ Council Regulation (EEC) 2309/93 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [1993] L214/1.

³⁴ See Council Regulation (EC) 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] O.J. L136/01, Title V and Art. 90. The acronym EMEA remains: see introduction, p. 7, n. 23 above. The functions of the agency are discussed in chapter 3, pp. 89-90 below.

³⁵ See Regulation 726/2004, *ibid.*; and Council Directive 2001/83/EC on the Community code relating to medicinal products for human use [2001] O.J. L311/67. See chapter 3(2) below for discussion of these procedures.

³⁶ Title IX of Directive 2001/83, *ibid.*

³⁷ *ibid.*, Title VI; and BMA, n. 6 above. The G10 Medicines Group recommended that the mechanisms and concepts for moving medicines from POM to OTC should be reviewed, and that the same trademark should be allowed to be used for products moved to OTC status; see Commission Communication (2003), n. 22 above, 31.

³⁸ Directive 2001/83, *ibid.*, Title V and VI. See chapter 7 below.

³⁹ *ibid.*, Title VIII and Article 87(1).

substances is prohibited.⁴⁰ However, a product may be advertised if it is designed 'for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment.'⁴¹ Member States may also prohibit direct-to-consumer advertising of products subject to State reimbursement.⁴² Advertising aimed at persons qualified to prescribe or supply such products, e.g. doctors, is allowed subject to certain restrictions, including certain requirements concerning the training of medical sales representatives.⁴³

However, although these measures may prove important to public health and safety and, to a certain extent, the free movement of pharmaceutical products; the pharmaceutical market is distinct from other markets in respect of the pricing of pharmaceutical products. Member States are allowed to regulate the price and reimbursement levels of pharmaceutical products sold within the national market as the organisation of national social security schemes is under the exclusive competence of Member States.⁴⁴ In effect, this means that Member States are both price regulators and, in most Member States, the largest - if not sole - buyer of pharmaceutical products due to a European tradition of maintaining national health services. However, notwithstanding the exclusive competence of Member States, the Council has adopted Directive 89/105/EEC⁴⁵ in an attempt to increase the transparency of measures regulating the pricing of pharmaceutical products and their inclusion in national health insurance system lists of reimbursable products. Member States must ensure that national measures on the pricing and reimbursement of pharmaceutical products do not create unjustified obstacles to trade by ensuring that a decision on the price is communicated within 90 days to the

⁴⁰ Directive 2001/83, n. 35 above, Article 88(1). The G10 Medicines Group recommended that the restriction on advertising of prescription medicines to the general public should continue. This is endorsed by Commission Communication (2003), n. 22 above, 36.

⁴¹ Directive 2001/83, *ibid.*, Art. 88(2).

⁴² *ibid.*, Art. 88(3).

⁴³ *ibid.*, Arts. 91-93.

⁴⁴ See Case 238/82 *Duphar BV v. The Netherlands* [1984] E.C.R. 523, para. 16; and Case 110/79 *Una Coonan v. Insurance Officer* [1980] E.C.R. 1445, para. 12.

⁴⁵ Council Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems [1989] O.J. L40/8.

applicant.⁴⁶ If the Member State decides not to include the product on the list of reimbursable products the 'decision shall contain a statement of reasons based on objective and verifiable criteria.'⁴⁷ Member States must also ensure that such decisions are capable of judicial review.⁴⁸ These principles are equally applicable to decisions to include certain categories in the list of reimbursable products (positive list),⁴⁹ or excluding certain categories of products from that list (negative list),⁵⁰ as well as decisions concerning a subsequent price increase.⁵¹ Similarly, Member States operating a system of direct or indirect price controls on the profitability of pharmaceutical companies responsible for placing products on the market must both publish information concerning the function of the system in an appropriate publication, and communicate it to the Commission.⁵² Finally, the G10 Medicines Group recommended that Member States should remove price control altogether on authorised pharmaceutical products that are neither purchased nor reimbursed by national health services.⁵³

The Transparency Directive⁵⁴ and the G10 recommendation⁵⁵ may provide for a more transparent and competitive pharmaceutical market. However, the method of price control and the structure of the national market remains the exclusive competence of Member States, resulting in large variations in pharmaceutical prices

⁴⁶ Directive 89/105, n. 45 above, Art. 2(1).

⁴⁷ *ibid.*, Art. 2(2). The Commission has formally asked Spain in a reasoned opinion to introduce a more transparent procedure for the reimbursement of pharmaceutical products. In addition to being included in the list of reimbursable products, Spanish authorities require prior approval of individual prescriptions, in the form of an inspection visa, before reimbursement. According to the Commission this procedure is not based on 'objective and verifiable criteria.' See Commission press release IP/05/1285 (17 October 2005).

⁴⁸ *ibid.*, Art. 2(2). Such appeals must be to judicial bodies and not mere independent experts or supervisory bodies. See Case C-424/99 *Commission v. Austria* [2001] E.C.R. 9285, paras. 42-45.

⁴⁹ *ibid.*, Art. 6. The 90 day time limit is mandatory. However, this does not require the automatic entry of the product to the list where the time limit is exceeded: see Case C-245/03 *Merck, Sharp & Dohme BV v. Belgium* [2005] E.C.R. 637, paras. 20 and 34.

⁵⁰ *ibid.*, Art. 7.

⁵¹ *ibid.*, Art. 3.

⁵² *ibid.*, Art. 5.

⁵³ See Commission Communication (2003), n. 22 above, 32.

⁵⁴ Directive 89/105, n. 45 above.

⁵⁵ N. 53 above.

and market structures throughout the Community.⁵⁶ It is therefore necessary to analyse the conditions under which the pharmaceutical markets of a selected number of Member States operate.

2.2 *Different markets, policies and prices*

Member States have adopted some form of national health care policy over the last 30 years or so.⁵⁷ Some maintain a public national health service, whilst others allow for private health care financed through mandatory health insurance. By illustration, total spending on health care as a percentage of GDP varied from 5.7% in the Slovak Republic to 10.9% in Germany in 2002.⁵⁸

As Member States are often the largest and main provider of health care they have monopsony⁵⁹ power in terms of purchasing and pricing of pharmaceutical products. This is especially so whenever the State is not only the main provider of health care but also the sole supplier of pharmaceutical products due to a long established state-controlled pharmacy monopoly.⁶⁰ However, Member States regulate the price of pharmaceutical products not only by market forces but also through national regulations. The price regulation methods differ between Member States and often overlap, but in general three different approaches can be discerned.

The method of profit control is only applied by the UK. By way of the Pharmaceutical Price Regulation Scheme (PPRS)⁶¹ prices for all pharmaceutical

⁵⁶ The system of price control of pharmaceutical products is generally endorsed by the ECJ as long as it does not discriminate between domestic and imported products: see Case 181/82 *Roussel Laboratoria BV v. The Netherlands* [1983] E.C.R. 3849. See also R. Nazzini, 'Parallel trade in the pharmaceutical market: Current trends and future solutions,' (2003) 26 *World Competition* 53, 59-60.

⁵⁷ M. Kyle, 'Entry in pharmaceutical markets,' Seminar paper, German Institute for Economic Research (4 June 2003), (<http://www.diw.de/deutsch/produkte/veranstaltungen/docs/margaret_kyle.pdf>), p. 4.

⁵⁸ EFPIA, n. 18 above, 24.

⁵⁹ A market similar to a monopoly except that a large buyer not seller controls a large proportion of the market and drives the prices down. Sometimes referred to as the buyer's monopoly.

⁶⁰ For example Sweden and its State owned pharmacy (Apoteket). See Case C-438/02 *Criminal proceedings against Hanner* [2005] E.C.R. 4551, concerning the State monopoly's conformity with the EC Treaty.

⁶¹ Administered by the Department of Health. The statutory powers covering pharmaceutical pricing are contained in sections 33 to 38 of the Health Act 1999. See *R v. The Secretary of State for Health*

products are set so as to ensure that the return on capital is lower than the authorised upper-threshold. In practical terms this means that the government regulates the return on capital instead of the price directly.⁶² The profit control system in conjunction with a strong national pharmaceutical industry, thus encouraging spending on R&D,⁶³ has led to the UK having higher pharmaceutical prices in comparison with other Member States.

A method of 'international price comparison' is applied by most Member States. The price is set in relation to prices in neighbouring countries, the EU-wide average, or by reference to prices in selected countries. Most Member States using this method, however, set the price in relation to an average European price, or the average of prices in a number of selected countries. Table 1 below provides a list of the reference countries Member States use when calculating the price.⁶⁴

Table 1.

Member State	Reference countries	Basis of calculation
Ireland	Denmark, France, Germany, Netherlands, UK	Average
Italy	All EU countries	Average
Portugal	France, Italy, Spain	Average
Slovenia	Italy, France, Germany	85% of the average for most products; 96% of the average for innovative products.
Czech Republic	Greece, Spain, France, Poland	Lowest
Sweden	Norway, Finland, Germany, the Netherlands, and Switzerland	Similar to No. and F, but lower than G, N, and S.
The Netherlands	Belgium, France, Germany, and the UK	Average
Greece	All EU countries	Lowest price
Spain	Originating country, and lowest priced Member State.	Average
France	12 Member States (Ireland, Italy, Spain, and Portugal mandatory)	Average

ex parte BAEPD & Dowelhurst Ltd. v. ABPI [2001] E.W.H.C. 183, where the conformity of the PPRS with the EC Treaty was unsuccessfully challenged by parallel importer Dowelhurst.

⁶² See M. Sedgley, 'Profit or loss? Fulfilling dual aims in pharmaceutical price regulation in the UK,' (2001) 2 *Eurohealth* 13.

⁶³ Together with the Netherlands, Spain and Sweden, the UK provides tax incentives for R&D spending by allowing for deductions of R&D facilities and machinery. See P. Kanavos, 'Pharmaceutical pricing,' Josephinum Lectures seminar paper, Medizinische Universität Wien (5 July 2005), (<<http://www.meduniwien.ac.at/josephinum-lectures/index.php?menu=download>>).

⁶⁴ Data gathered from P. Kanavos, 'Pharmaceutical regulation in Europe,' Towards a national strategy on drug insurance: Challenges and priorities Conference Paper, IRPP (23 September 2004), (<<http://www.irpp.org/events/archive/sep02/kanavos.pdf>>), p. 14; and S. Seget, 'Pharmaceutical pricing strategies: Optimizing returns throughout R&D and marketing,' Reuters Business Insight Report, Datamonitor (2005), pp. 103-115.

Finally, some Member States apply a mixture of direct price control and/or international price comparisons. Spain, for example, requires a price to be negotiated directly with the national authorities in addition to using international price comparisons as a guiding price. The price is supposed to reflect the cost of the product and its value to society. As this is notoriously difficult to estimate, greater emphasis is placed on international price comparisons. A system of direct negotiations, however, provides national authorities with an opportunity to reward companies that have made a contribution to society or the economy.⁶⁵ France applies a similar system. The R&D expenditure and the added-value of the product to society, as well as the above-listed international price comparisons, are taken into consideration by the negotiating national authorities. Negotiations are often lengthy, resulting in a delay of up to 18 months before the product can be launched on the French market.⁶⁶ Finland applies a similar system whereby a 'reasonable price' is set on the basis of the costs and value of the product in conjunction with international price comparisons.⁶⁷ Instead of direct price control through negotiations, Austria has implemented a system of price/volume agreements in addition to rebates on excessive sales.⁶⁸ The only Member State not applying any form of price control - thus allowing free pricing - is Germany. However, reference prices establish the maximum limit up to which the national authorities will reimburse German patients.⁶⁹ Pharmaceutical prices are therefore indirectly affected by reimbursement levels; so-called reference prices.

Reference pricing systems operate by grouping together similar products and specifying a price. The government will only reimburse the patient up to that price;

⁶⁵ Kanavos, 'Pharmaceutical regulation,' n. 64 above, 13.

⁶⁶ Seget, n. 64 above, 112. In R. Minder and D. Pilling, 'Drug companies hit out at French price controls,' *Financial Times*, 10 June 2001, p. 23, Pfizer chairman Hank McKinnell was quoted saying 'we introduce our new products later and later on the French market, and if the government continues to put pressure on prices, there will be no more [new products].'

⁶⁷ Kanavos, 'Pharmaceutical regulation,' n. 64 above, 13.

⁶⁸ *ibid.*, 14. Also used, to some extent, in Belgium, Sweden and France.

⁶⁹ The German Association of Research-Based Pharmaceutical Companies (VFA), 'Reference prices: Jumbo groups discriminate against innovative pharmaceuticals,' Position paper (4 November 2005), (<http://www.vfa.de/en/articles/art_2005-01_001.html>).

any excess above the reference price has to be paid by the patient (insured).⁷⁰ The distinction and relationship between pricing policies and reference prices can be confusing. Simply put, the government regulates the 'retail' price at which pharmaceutical products can be sold using the methods described above. However, for budgetary purposes, the same government decides which - and at what prices - pharmaceutical products are to be reimbursed to patients using a 'reference' price. In effect, the reference price is the maximum as companies will be unable to realise a price above the reference price (reimbursement level). Unless the price is in line with the reference (reimbursement) price, the 'retail' price can only be realised if the product is not subject to reimbursement or the patient agrees to pay the excess price.

A vast majority of Member States have implemented a system of reference pricing.⁷¹ In Germany a so-called 'positive list' is used, covering all products that are reimbursable.⁷² In Italy, the reference price is set using a European average price. Drugs are divided into three groups. Class A includes pharmaceutical products for chronic diseases, which are fully reimbursable. Class B includes 'important' medicines, of which 50% of the price is reimbursable, whilst Class C covers products not reimbursable by the state.⁷³ Similarly, in the UK, all pharmaceutical products not included on a 'limited list' are fully reimbursable.⁷⁴ Reimbursement rates in France are determined by a product's efficacy and value to society. Products not included on the 'negative list' are divided into three groups with a reimbursement level ranging from 100% (AIDS medicines) to 35% for less serious diseases.⁷⁵ Finally, Greece uses a novel system whereby products that are

⁷⁰ Kanavos, 'Pharmaceutical pricing,' n. 63 above.

⁷¹ Note that reference pricing systems are subject to Directive 89/105, n. 45 above.

⁷² Seget, n. 64 above, 105.

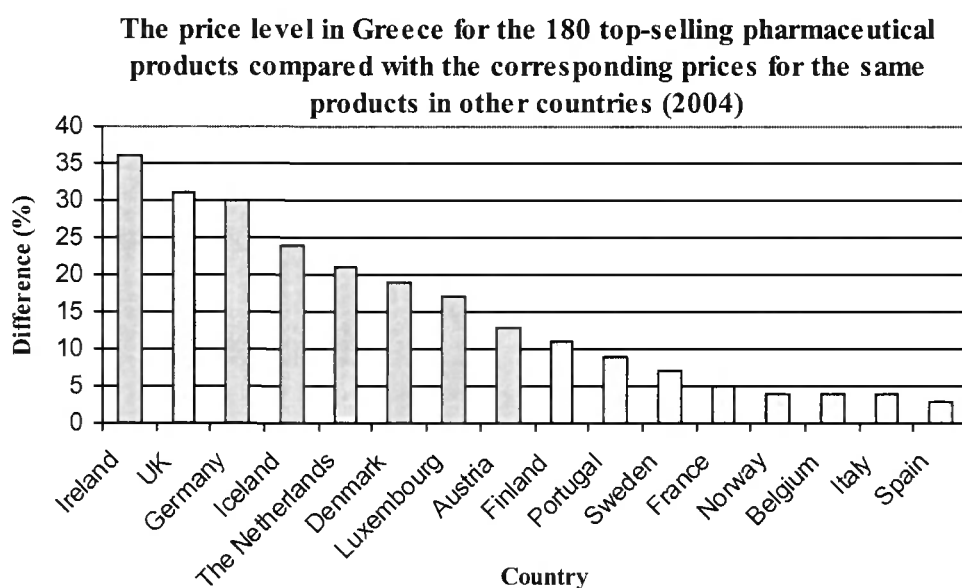
⁷³ *ibid.*, 107.

⁷⁴ *ibid.*, 108-110. Spain uses a similar system, whereby all products not covered by the 'negative list' are reimbursed to a level of 60-90% depending on the classification of the product.

⁷⁵ *ibid.*, 104. These negotiations, headed by the Commission de Transparence, can be very lengthy. See Furniss J, 'Price controls in France: Budgeting for medical benefit?', (2001) 2 *Eurohealth* 9.

considered for reimbursement must be available in two of the following countries; USA, the UK, Sweden, Switzerland, France and Germany.⁷⁶

The diversity in pricing regulations and reimbursement policies throughout the Community has led to vast differences in price levels for pharmaceutical products between Member States. It is possible that prices throughout the Community will, over time, converge due to the use of international price comparisons. The Transparency Directive⁷⁷ may hasten this process, as the flaws of national regulations will be more apparent when transparent. However, the current price differences represent historical and cultural differences in Member States health care policies. These price differences are illustrated by Table 2.⁷⁸



A discernable pattern is that Member States with more intrusive regulations tend to have lower prices. In general, these Member States tend to be southern European countries, with Spain and Greece having the lowest prices in the EC. Northern Member States, such as the UK, Germany, and the Scandinavian Member States,

⁷⁶ Kanavos, 'Pharmaceutical regulation,' n. 64 above, 15.

⁷⁷ Directive 89/105, n. 45 above.

⁷⁸ Gathered from LIF, n. 3 above, 41.

are historically rich countries with a large domestic pharmaceutical industry and therefore tend to have less restrictive regulations and in consequence, higher prices.

3. *Parallel trade in pharmaceutical products*

The large disparity in prices in the Community is the result of national pricing regulations and thus cannot be remedied by market forces. In fact, the disparity in pricing levels in conjunction with the harmonisation of the European pharmaceutical market and the free movement of goods provisions has proved sufficient to sustain a successful parallel trade in pharmaceutical products between low-price and high-price Member States.

This trade, largely a result of the abovementioned pricing regulations, refers to the act of purchasing goods in lower-priced countries and reselling them in a higher-priced country without the authorisation of the manufacturer and owner of the intellectual property rights. Simply put, it is the trade in products outside the manufacturer's distribution channels. However, it does not necessarily include re-importation as parallel importation can be carried out between any two Member States. By way of illustration, Losec manufactured in Sweden may be exported to Spain by the manufacturer, only to be parallel imported into the UK by a Dutch parallel trader.

As illustrated by the formula below, parallel trade is based upon the price difference between the exporting and importing Member State.

$$(PH - PL - T)Q - L > 0$$

where PH is the price in the importing Member State and PL the price in the exporting Member State. T is the transport cost, Q the quantity traded and L is the marketing authorisation fee. A parallel trader will enter the market as long as it

expects to cover its fixed costs (L) with a high enough margin (PH – PL) on a sufficient quantity of products (Q).⁷⁹

The only costs are transportation costs and the marketing authorisation fee, which will be discussed in chapters 3 and 4 below. Parallel traders also have had to overcome claims that such trade is prohibited due to manufacturers' intellectual property rights.⁸⁰ Despite these costs and hurdles parallel trade is highly profitable. Vast price differences between Member States, sometimes as much as 25-35%, allow for a good profit margin and ample opportunity for successful trade. As the Mediterranean Member States tend to have lower prices than the northern Member States they are often the source of parallel imported pharmaceutical products. The Greek and Spanish markets are the main source countries for parallel importers, closely followed by France and Italy.⁸¹ Hence, northern Member States such as Germany,⁸² the UK,⁸³ the Netherlands⁸⁴ and the Scandinavian countries⁸⁵ are net importers of parallel traded pharmaceutical products.

⁷⁹ See M. Kyle, 'Strategic responses to parallel trade,' CEP productivity and innovation seminar paper, London School of Economics (19 January 2006), (<<http://cep.lse.ac.uk/seminarpapers/19-01-06-KYL.pdf>>), pp. 10-11.

⁸⁰ Discussed in chapter 5 below.

⁸¹ Exact figures for parallel exports are difficult to compile, however, it is estimated that parallel exports accounted for 21.6% of the Greek pharmaceutical market in 2002. Data is not available from France, Italy, Spain and Portugal. In 2003 there were only 4 registered parallel import licences in Italy, and 2 in Spain. These Member States are clearly net parallel exporters. See P. Kanavos and J. Costa-Font, 'Pharmaceutical parallel trade in Europe: Stakeholder and competition effects,' (2005) 20 *Economic Policy* 753, 763.

⁸² According to the VFA, 'The pharmaceutical industry in Germany,' Statistics (2005), (<http://www.vfa.de-e_statistics_2005.pdf>), p. 50; parallel imports accounted for 5% of the German pharmacy sales market in 2004.

⁸³ According to the EFPIA, n. 18 above, 5; parallel imports accounted for 17.1% of the UK pharmacy sales market in 2003.

⁸⁴ According to the Foundation for Pharmaceutical Statistics (SFK), 'Facts and figures,' (2004), (<<http://www.sfk.nl/algemeen/2004fandf>>), p. 32; parallel imports accounted for 14.8% of the Netherlands drug costs in 2003.

⁸⁵ According to LIF, n. 3 above, 11; parallel imports accounted for 10.4% of the Swedish pharmacy market in 2004. Parallel imports accounted for 6.2% of the Norwegian pharmacy sales market in 2004 according to the Norwegian Association of Pharmaceutical Manufacturers (Legemiddelindustriforeningen), 'Facts and figures' (2005), p. 31; and 8.5% of the Danish market in 2004 according to its Danish counterpart Lægemedelindustriforeningen (<<http://www.talogdata.dk/sw164.asp>>). This is likely not only the result of the prevailing prices in these Member States, but also due to the State owned pharmacy monopoly in Sweden (and until recently Denmark and Norway) allowing for easy and simultaneous access to the whole of the market: see C. Björnram, 'Parallellimportörerna blir förlorarna,' Dagens Industri, 1 June 2005, p 4.

However, a sufficient price differential need not necessarily be the sole relevant criteria for successful commerce. Parallel importers are also benefiting from national policies mandating dispensing of parallel imported products. These policies are intended to generate savings for national health systems and are mostly applied by high-priced Member States.

Table 3⁸⁶

Policies mandating the dispensing of parallel imports in 2004

Policy	Denmark	Germany	Netherlands	Norway	Sweden	UK
Financial incentive to pharmacy	No	No	Yes	Yes	Yes	Yes
Penalty to pharmacy if not dispensing cheaper PI	No	Yes	No	No	No	No
Obligation to inform patients of cheaper PI	Yes	No	No	No	No	No
Obligation to dispense PI if available	No	No	No	No	Yes	No
Clawback (indirect benefit to health insurance)	No	No	Yes	No	No	Yes

The above policies explain why Norway and Sweden, Member States with modest pharmaceutical prices in comparison with many others, are large purchasers of parallel imported pharmaceutical products. Even with low price margins between the importing and exporting country parallel traders can make a large profit by supplying large quantities due to the abovementioned policies.⁸⁷ In the Netherlands, Norway, Sweden and the UK pharmacists have a financial incentive to dispense parallel imported products. These markets are therefore prime markets for parallel traders. Clawback mechanisms ensure that the discounts (lower prices) pharmacists receive from parallel importers are being returned to the health authorities as savings. Without such policies it is likely that an even larger share of the savings

⁸⁶ Adapted from P. Kanavos, D. Gross and D. Taylor, 'Parallel trading in medicines: Europe's experience and its implications for commercial drug importation in the United States,' Pub ID: 2005-07, The AARP Public Policy Institute (July 2005), (<http://assets.aarp.org/rgcenter/health/2005_07_trade.pdf>), pp. C1-C2; and the author's own research.

⁸⁷ In Sweden, where pharmacies are legally obliged to dispense a parallel imported equivalent if available, 3 of the 12 largest pharmaceutical companies in terms of sales value are parallel importers. Two out of these parallel importers, Orifarm and Paranova, are also the largest parallel importers in Denmark and Norway. See LIF, n. 3 above, 14.

would not accrue to the national health system, but remain with the parallel traders. However, even though parallel trade may have short-term economic benefits, the question is whether the trade is of benefit to society in the long run.

3.1 *Parallel trade – benefit or menace to society?*

Parallel traders argue that parallel imports generate savings to national health authorities, and ultimately patients and taxpayers. Several reports have assessed the benefits from parallel imported pharmaceutical products and to whom these benefits accrue. A report by York Health Economics Consortium, commissioned by the European Association of Euro-Pharmaceutical Companies (EAEPc), estimated that the total direct savings from parallel importation of pharmaceutical products in the UK, Germany, Sweden, the Netherlands and Denmark amounted to €631m in 2002.⁸⁸ However, this finding must be analysed in the light of the EAEPc's description of itself as 'the professional and representative voice of pharmaceutical parallel trade in Europe.'⁸⁹ Similarly, an analysis conducted by the University of Southern Denmark in 2006, partly funded by the EAEPc (£25,000), estimates that the practice of parallel trade in Denmark, Germany, Sweden and the UK alone generated savings of €442m to national health budgets in 2004.⁹⁰

This should be compared to a recent study from the London School of Economics and Political Science (LSE), partly funded by pharmaceutical company Johnson & Johnson, estimating that parallel imports in 2002 generated savings to the Norwegian, German, Swedish, Danish, Dutch and UK national health services of just €99.2m.⁹¹ The savings accruing to the UK National Health Service alone was

⁸⁸ P. West and J. Mahon, 'Benefits to payer and patients from parallel trade,' Report, York Health Economics Consortium (May 2003), (<http://www.york.ac.uk/inst/yhec/downloads/ParallelTrade_ExecSumm.pdf>).

⁸⁹ EAEPc's website: <<http://www.eaepc.org>>.

⁹⁰ See A. Jack, 'Parallel trade in drugs 'saves millions,' *Financial Times*, 24 June, 2006, (<<http://www.ft.com/cms/s/fc877de6-02ce-11db-9231-0000779e2340.html>>). The survey also notes that savings from parallel trade have decreased since 2001.

⁹¹ P. Kanavos, J. Costa-Font, S. Merkur and M. Gemmill, 'The economic impact of pharmaceutical parallel trade in European Union Member States: A stakeholder analysis,' Special Research Paper,

estimated at just €55.9m.⁹² By comparison, the UK Department of Health estimates ‘that parallel imports save the NHS...approximately £60m per year.’⁹³ This strengthens the credibility of the LSE survey, as it should be in the interest of the Department of Health to present large savings in order to justify its parallel trade mandating policies. £60m is far more conservative than the York Health Economics Consortium’s estimate of €201.3m for the UK alone.⁹⁴ In conclusion it can be said that parallel imports generate savings to national health authorities. The lack of objectivity and impartiality of these surveys, however, makes it difficult to reach a conclusion on exactly how large or small these savings really are. A more relevant question is if these savings are in proportion to the profit made by parallel importers, pharmacists and the costs to society in terms of less funding made available for R&D.

A closer look at the economics of parallel trade is needed, for which the UK market will serve as an example. The price difference between the importing and exporting Member States is the base of the business. This has been estimated to range between 21% and 26.3%, or €414m and €518m for the 19 most parallel traded pharmaceutical products in the UK in 2002.⁹⁵ It is difficult to estimate the revenue that accrues to pharmacists, but it is likely that pharmacists retain a certain margin over the UK government’s clawback which average 10.4% of the sales price.⁹⁶ This means that after the effect of the clawback is included gross financial benefits ranging between €365m and €469m accrue to parallel traders and, to a lesser extent,

London School of Economics (January 2004), (<<http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/Workingpapers/Paper.pdf>>).

⁹² Kanavos et al. (LSE Report), n. 91 above, 181. This figure includes the clawback mechanism.

⁹³ *Hansard*, HC, Vol. 434, Column 436W, 6 June 2005; *per* Jane Kennedy on behalf of the Secretary of State for Health.

⁹⁴ West and Mahon, n. 88 above, ‘Executive Summary.’ See also B. Irvine (ed.), P. Kanavos and P. Holmes, ‘Pharmaceutical parallel trade in the UK,’ Report, The Institute for the Study of Civil Society (2005), (<<http://www.civitas.org.uk/pdf/ParallelTradeUK.pdf>>), p. 48, for a compilation of all findings. This figure excludes the benefit to pharmacies.

⁹⁵ Kanavos et al. (LSE Report), n. 91 above, 124. The former figure relates to the average of the three lowest EU Public Purchasing Parity Prices (PPP), whereas the latter refers to the lowest PPP price in the EU.

⁹⁶ *ibid.*, 123. By comparison, the York Health Economics Consortium estimated the total direct savings to pharmacies at €141m (See Irvine et al. (Civitas), n. 94 above, p. 48).

pharmacists.⁹⁷ Even though these figures fail to take parallel importers transportation and administrative costs into consideration, it is likely that ‘most, but not all, of the financial benefit accrues to the parallel trader rather than to the health care system or the patient.’⁹⁸ Logically, this also means that the total loss of direct profits to the pharmaceutical industry in the UK amounts to the total price difference between the low- and high-priced Member States, ranging between €414m and €518m in 2002.⁹⁹

The pharmaceutical industry claims that this has serious effects on the ‘research-based industry’s ability to fund research for new, innovative and life-saving drugs – to the overall detriment of patients and medical progress.’¹⁰⁰ The industry also refutes the argument that parallel trade will lead to price convergence in the Community. Price convergence can only be achieved by harmonising Member States’ pricing regulations, and in any case, will never be achieved through parallel trade as long as most of the profit from the trade remains with the importers. As parallel traders are simply importing the exporting Member States’ pricing policy, this form of trade comes at a cost. It reduces the funds available for future R&D and is therefore ‘a key factor in Europe’s declining attractiveness for pharmaceutical R&D.’¹⁰¹ Parallel traders retaliate by claiming that there is no ‘quantifiable evidence that parallel distribution negatively affects R&D spending. Parallel trade simply generates large savings for national health services which can be invested in other parts of the health service.’¹⁰²

⁹⁷ Kanavos et al. (LSE Report), n. 91 above, 124.

⁹⁸ Commission Communication on the single market in pharmaceuticals [1998] COM/588/final, p. 4.

⁹⁹ Kanavos et al. (LSE Report), n. 91 above, 125. This is a very low estimate, and only includes the direct loss to profits. The indirect effects, such as a loss of sales due to the increased parallel importation of generic products, would add significantly to this figure. In S. Hall and S. Szymanski, ‘Intellectual property rights and parallel trading in pharmaceuticals,’ Full Report of Research Activities and Result, ESRC (10 March 2003) p. 10: Professor Stephen Hall estimates the total loss to the UK industry at about £770m, and a gain of up to £480m for the UK economy from parallel trade, leading to a net loss of £290m.

¹⁰⁰ Humer, n. 31 above, 44.

¹⁰¹ *ibid.*

¹⁰² R. Freudenberg (President of the British Association of European Pharmaceutical Distributors (BAEPD)), ‘Dispelling the myths,’ European Pharmaceutical Executive, 1 January 2006, p. 58.

4. *Conclusion*

Parallel importation of pharmaceutical products is built upon two market anomalies. First, in contrast to most product markets, pharmaceutical prices are regulated by national authorities, giving rise to vast price differences between Member States. Secondly, Member States tend to prefer parallel imported products over nationally sourced products, despite the potential impact parallel trade may have on future investments in the R&D of new products. In fact, many Member States have adopted policies mandating the dispensing of parallel imported products even though recent studies suggest that the (net) savings generated by parallel imports to national health authorities, taking into account the overall effect the trade has on the national economy, are far lower than first anticipated. This disjunctive approach – encouraging parallel imports instead of simply lower (or, if a low price Member State, increase) the pharmaceutical prices directly so as to make parallel trade unprofitable – is contributing to the unattractiveness of Europe as a location for carrying out R&D, and could eventually result in a decline in the introduction of new substances.

In the absence of Community-wide harmonisation of national pricing and reimbursement regulations, parallel trade in pharmaceutical products will remain a profitable business. Unable to influence the main prerequisite for successful parallel trading - the price divergences - manufacturers are considering other ways in which parallel trade can be restricted. However, as the next chapter will show, restricting parallel trade is difficult considering the application of Articles 81 and 82 EC Treaty to the European pharmaceutical market.

PARALLEL TRADE IN PHARMACEUTICAL PRODUCTS AND ARTICLES 81 AND 82 EC TREATY

The objective of competition law is to enhance efficiency and facilitate the creation of a single market while protecting consumers and competition.¹ Article 81 EC Treaty prohibits all agreements, concerted practices and decisions by undertakings that may affect trade between Member States and prevent, restrict or distort competition within the common market.² Article 82 EC Treaty prohibits any abuse by a dominant undertaking likely to affect trade between Member States.³ As such, competition law is a vast subject. This chapter therefore only discusses specific issues relevant to the trade in pharmaceutical products, in particular the export and import of pharmaceutical products by parallel traders. Focus is on restrictive agreements between manufacturers and distributors of pharmaceutical products and abusive behaviour by dominant manufacturers which aims to restrict further trade in their products. The Commission has traditionally adopted a very pro-integration policy towards parallel import-restrictive measures. The Community courts and Advocate General Jacobs, however, have lately taken a critical approach to the Commission's very pro-integration application of Articles 81 and 82 EC Treaty in

¹ Neelie Kroes (Commissioner for competition) was quoted saying that 'first, it is competition, and not competitors, that is to be protected, secondly, ultimately the aim is to avoid consumers harm,' in a speech delivered at the Fordham Corporate Law Institute on 23rd September 2005: see Commission press release SPEECH/05/537. See also K. Ehlermann, 'The contribution of EC competition policy to the single market,' (1992) 29 C.M.L.R. 257; and R. Whish, *Competition Law*, 4th ed., (London: Butterworths, 2001), pp. 15-21 for further discussion.

² Article 81 EC Treaty: '*The following shall be prohibited as incompatible with the common market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market.*'

³ Article 82 EC Treaty: '*Any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between Member States.*'

relation to such measures, which will be evident following the discussion of *Bayer*,⁴ *GlaxoWellcome*,⁵ and *Syfait*.⁶

1. *Article 81 EC Treaty*

The application of Article 81 EC Treaty can be divided into three steps. First, is there a valid agreement or concerted practice between two or more undertakings? Secondly, does this agreement or concerted practice distort competition within the common market? Thirdly, does it affect trade between Member States?

The Commission and to a lesser extent the ECJ have traditionally adopted a very wide definition of an agreement or concerted practice.⁷ Agreements can be inferred from mere acquiescence and do not necessarily require any formal documents.⁸ No distinction is made in relation to agreements between competitors active at the same level of commercialisation (horizontal agreements), and agreements between parties at a different level of commercialisation (vertical agreements), such as between a manufacturer and a distributor.⁹ For the purpose of this chapter an undertaking can be sufficiently defined as an entity engaging in trade within the market, which will certainly include manufacturers, distributors and parallel importers. The undertaking does not have to be physically present, but must have commercial presence within the market.¹⁰ A distortion or restriction of trade between Member

⁴ See Commission Decision 96/478/EC *Adalat* [1996] L201/1; the CFI judgment in Case T-41/96 *Bayer AG v. Commission* [2000] E.C.R. II-3383; and the ECJ judgment in Joined Cases C-2-3/01 P *Bundesverband der Arzneimittel-Importeure & Commission v. Bayer AG* [2004] E.C.R. 23.

⁵ See Case T-168/01 *GlaxoWellcome plc v. Commission* [2006] E.C.R. (unreported: delivered on 27 September 2006). See also Commission Decision 2001/791/EC *GlaxoWellcome* [2001] O.J. L302/1.

⁶ See Opinion of Advocate General Jacobs and the ECJ ruling in Case C-53/03 *Synetairismos Farmakopoiion Aitolias (Syfait) & Others v. GlaxoSmithKline AEEVE* [2005] E.C.R. 4609.

⁷ See Joined Cases 41, 44-45/69 *ACF Chemiefarma NV v. Commission* [1970] E.C.R. 661, and Joined Cases 89, 104, 114, 116-117, 125-129/85 *Ahlström Oy v. Commission* (Woodpulp) [1993] E.C.R. 1307.

⁸ *ibid.*; and Commission Decision 82/853/EEC *National Panasonic* [1982] O.J. L354/28.

⁹ See Joined Cases 56 and 58/64 *Consten SARL & Grundig-Verkaufs GmbH v. Commission* [1966] E.C.R. 299, and Case C-70/93 *BMW AG v. Ald Autoleasing D GmbH* [1995] E.C.R. 3439, para. 15. Article 81 EC Treaty does not, however, apply to agreements between an undertaking and its subsidiary: Case 15/74 *Centrafarm BV v. Sterling Drug Inc.* [1974] E.C.R. 1174. See also T. Hays, 'Anti-competitive agreements and extra-market parallel importation,' (2001) 26 E.L.Rev. 468, 469.

¹⁰ Commonly referred to as 'the effects doctrine.' See Case 48/69 *ICI Ltd v. Commission* (Dyestuffs) [1972] E.C.R. 619; and Cases 89, 104/85 etc., n. 7 above.

States is evident when, typically, the agreement directly or indirectly restricts imports or exports as a result of supply restrictions, distribution restrictions, or price fixing as a means to segment the common market.¹¹ The provisions of Article 81(1) EC Treaty may be declared inapplicable under Article 81(3) EC Treaty if the agreement has minor effects and ‘contributes to improving the production or distribution of goods,’ otherwise the agreement will be void and attract a fine of up to 10% of the participating undertakings’ turnover. However, when the effect of the agreement is to restrict intra-Community trade, even a small market-share may support the finding of a violation of Article 81 EC Treaty.¹² The Block Exemption Regulations,¹³ providing a safe harbour from the prohibition under Article 81(1) EC Treaty for certain categories of agreements, are important to technology transfer agreements and research and development agreements between manufacturers of pharmaceutical products, but less relevant to distribution agreements. Regulation 2790/99 covers all vertical agreements that fall, prima facie, within Article 81(1) EC Treaty.¹⁴ However, territorial and customer restrictions are listed as ‘hard core regulations’ in Article 4(1)(b), rendering any agreements as to where products may be exported or imported from, or to whom products may or may not be sold, ineligible for an exemption. Refusals to meet demand from a reseller who would market the products in a different Member State/market are prohibited by Regulation 2659/2000.¹⁵ This Regulation also explicitly prohibits contractual obligations aimed at preventing parallel imports.

¹¹ See e.g. Case 56/65 *STM v. Maschinenbau Ulm GmbH* [1966] E.C.R. 235. However if the effect on competition within the common market is negligible, the agreement may fall outside Article 81(1) EC Treaty due to the *de minimis* doctrine: see Case 5/69 *Völk v. Vervaecke* [1969] E.C.R. 295 and Commission Notice on agreements of minor importance which do not appreciably restrict competition under Article 81(1) of the Treaty establishing the European Community [2001] O.J. C368/13.

¹² A market share of as little as 3.18% was not considered insignificant in Joined Cases 100-103/80 *Musique Diffusion Francaise SA v. Commission* [1983] E.C.R. 1825.

¹³ See Commission Regulation (EC) 2659/2000 on the application of Article 81(3) of the Treaty to categories of research and development agreements [2000] O.J. L304/7; and Commission Regulation (EC) 772/2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements [2004] O.J. L123/11.

¹⁴ Commission Regulation (EC) 2790/1999 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices [1999] O.J. L336/21.

¹⁵ N. 13 above, Art 5(1)(i).

1.1 *Parallel imports and Article 81 EC Treaty*

Measures to restrict parallel trade by manufacturers have traditionally been considered an obstacle to market integration by the Commission. Parallel trade, the Commission believes, will bring about harmonisation and market integration. The first case to discuss the application of Article 81 EC Treaty to transactions involving intellectual property was *Consten & Grundig*.¹⁶ As intellectual property holders, which may include pharmaceutical manufacturers, would be able to segment the market along national boundaries if free to exercise the territorially based intellectual property rights, a distinction was made between the 'exercise' and the 'existence' of such rights.¹⁷ The 'existence' of rights granted through national legislation was to remain protected by national legislation by way of Articles 295 and 30 EC Treaty, whilst the exercise of such rights is subject to the application of the free movement of goods provisions and the competition law framework of the EC Treaty.¹⁸ The practice of using intellectual property rights to enforce agreements brings such agreements within Article 81 EC Treaty.¹⁹ However, as a result of this principle, manufacturers were no longer able to segment the common market by territorially-based exclusive distribution agreements,²⁰ and were forced to find other solutions to prevent parallel imports.

The Commission has found a wide variety of parallel import-restrictive agreements to be prohibited by Article 81 EC Treaty, from (tacitly accepted) refusals to supply,²¹ to the imposition of restrictions through distribution agreements,²² and

¹⁶ N. 9 above. See Hays, n. 9 above, 469 for a thorough discussion.

¹⁷ See chapter 5 below for a further discussion.

¹⁸ See Case 15/74, n. 9 above; and the 'exhaustion of rights doctrine' discussed in *ibid*.

¹⁹ Cases 56 and 58/64, n. 9 above. It is worth noting that, even though not relevant to the direct argument at issue, an agreement or concertation between several competitors to bring a course of intellectual property infringement litigation against parallel importers so as to prevent exports or imports is not likely to infringe Article 81 EC Treaty: see S. Preece, 'Glaxo and others v Dowelhurst and Swingward: Litigation and the scope of Article 81,' (2000) 21 E.C.L.R. 330.

²⁰ Case 161/84 *Pronuptia de Paris GmbH v. Pronuptia de Paris Irmgard Schillgallis* [1986] E.C.R. 353.

²¹ See Commission Decision 87/406/EEC *Tipp-Ex* [1987] O.J. L222/1; Commission Decision 92/261/EEC *Dunlop* [1992] O.J. L131/3; and Commission Decision 82/628/EEC *Ford* [1982] O.J. L256/20.

applying a system of dual-pricing in order to limit parallel importation.²³ Manufacturers try to *prevent* parallel importation in various ways, in particular by maintaining an effective distribution network,²⁴ to prevent parallel importers from entering the market. However, this chapter will focus on the much narrower issue of *restricting* parallel imports from or to a particular market. Restrictive measures affect particular existing parallel importers on particular markets after the trade has started to affect the manufacturer's sales. Such measures are not implemented in a *preventative* capacity, but in order to *restrict* parallel imports after the general preventative measures have failed to achieve their objective.

1.2 *Pricing policies*

Pricing restrictions can generally be divided into two main policies. The first, and perhaps most obvious, is fixing the resale price of the products. In order to restrict parallel imports, manufacturers impose restrictions on the price at which the distributor is allowed to resell the products. Such measures, often imposed through supply agreements, are prohibited by Article 81 EC Treaty as they distort competition by artificially segmenting the common market along low-priced and high-priced Member States.²⁵ However, the pharmaceutical market is distinct from most other markets as pharmaceutical prices are set by national authorities, rendering manufacturers unable to fix or even influence distributors' resale prices in a given Member State.

²² Commission Decision 92/426/EEC *Parker Pen* [1992] O.J. L233/27; Commission Decision 87/409/EEC *Sandoz* [1987] O.J. L222/28; and Commission Decision 80/1283/EEC *Johnson & Johnson* [1980] O.J. L377/16.

²³ *GlaxoWellcome*, n. 5 above.

²⁴ Such as the tactics applied by AEG in relation to its selective distribution network: see Commission Decision 82/267/EEC *AEG-Telefunken* [1982] O.J. L117/15.

²⁵ See Commission Decision 77/66/EEC *Gerofabriek* [1977] O.J. L16/8; Commission Decision 78/823/EEC *Kurt Eisele (Maize Seed 1)* [1978] O.J. L286/23; and Hays, *Parallel importation under European Union law*, (London: Sweet & Maxwell, 2004) p. 141. Similarly, the imposition of a minimum price in the supply agreement is prohibited by Article 81 EC Treaty as it could potentially prevent entry into a large number of Member State markets: see Commission Decision 82/367/EEC *Camera Care/Hasselblad* [1982] O.J. L161/18.

The second pricing policy that can be implemented by manufacturers is a system of dual-pricing intended to discourage parallel importers from capitalising on price differences between Member States. Instead of restricting the distributor's subsequent resale price, the manufacturer directly restricts the price at which it sells the products to the distributor: one price for products intended for the domestic market and another for products intended for export.²⁶ The nature of the pharmaceutical industry makes it particularly prone to such measures as the distributor's customers are easily identifiable and often few in number, and as such, easily monitored. Further, as pharmaceutical prices are largely regulated by Member State authorities, a single price can be set for all products regardless of destination, but allowing for a rebate for products sold on the domestic market. The manufacturer's reimbursement level (rebate) is thus linked to the national authority's reimbursement level.²⁷ For example, the measure at issue in *Organon*²⁸ was Organon's offer of a 12.5% discount on the contraceptive pills 'Marvelon' and 'Mercilon' to UK distributors intending to resell the products only within the UK. The Commission applied Article 81 EC Treaty, and found that an agreement existed between Organon and its distributors which would restrict parallel imports and divide the common market along national boundaries. Similarly, a dual pricing system was set up by GlaxoWellcome in Spain.²⁹ The pricing mechanism involved a different price for pharmaceutical products subsidised by the Spanish social security funds and sold on the Spanish market, and a much higher price for products destined for export. The price of the product was thus determined by its geographic destination. As in *Organon*,³⁰ the Commission found the measure to restrict parallel

²⁶ See Commission Decision 78/163/EEC *The Distillers Company* [1978] O.J. L50/16; and Commission Decision 82/203/EEC *Moët et Chandon* [1982] O.J. L94/7.

²⁷ See chapter 1(2.2) above on reference prices.

²⁸ The Commission made it known that it wanted to issue a Decision withdrawing immunity from fines that ensued from Organon's notification (Article 81(3) EC Treaty). In the end this was not necessary as Organon voluntarily decided to abandon the pricing regime; see Commission press release IP/95/1345; and S. Kon and F. Schaeffer, 'Parallel imports of pharmaceutical products: A new realism, or back to basics,' (1997) 18 E.C.L.R. 123, 127-129.

²⁹ *GlaxoWellcome*, n. 5 above.

³⁰ N. 28 above.

importation and distort competition within the common market.³¹ GlaxoWellcome did not dispute the Commission's finding of an agreement between GlaxoWellcome and the distributors.³²

GlaxoWellcome and Organon, however, argued that the pricing mechanisms could be justified with reference to economic arguments. The price of Marvelon, the contraceptive pill subject to Organon's discount, was at the time subject to the UK Pharmaceutical Price Regulation Scheme (PPRS) and could therefore be supplied almost without charge to UK patients.³³ The price difference between Marvelon on the UK market and Marvelon on the Dutch market was therefore almost completely a result of national pricing policies, as Marvelon was not fully reimbursable under the Dutch social security scheme. The argument is therefore that competition law is not the appropriate tool to remedy distortions to the market which are caused not by the actions of the undertakings subject to the agreement but by national pricing regulations. Further, Dutch patients were not affected by the discount scheme as the price and availability of Marvelon remained stable. Similarly, GlaxoWellcome maintained that its dual pricing policy did not have an anti-competitive effect as it only remedied a distortion of the pharmaceutical market caused by the divergence in national pricing regulations.³⁴ The Commission, however, argued that as the disparity in national pricing regulations does not exempt the pharmaceutical sector from the free movement of goods provisions,³⁵ the same argument cannot warrant an exemption from the competition provisions. The relevant argument could, moreover, be refuted by the fact that the price difference was mainly the result of

³¹ The Commission drew an analogy with Commission Decision 80/789/EEC *Distillers* [1980] O.J. L233/43 concerning a prohibition to supply customers who would not use the goods for their own consumption, but to resell the goods in the non-duty-free market. The low-priced Spanish market was compared with a duty free market, and the non-duty free market with the export markets. See *GlaxoWellcome*, n. 5 above, recital 81.

³² See C. Stothers, 'Who needs intellectual property? Competition law and restrictions on parallel trade within the European Economic Area,' (2005) 27 E.I.P.R. 458, 460-462.

³³ See chapter 1(2.2) above on the UK pricing system.

³⁴ See A. Kliemann, 'Commission Decision prohibits Glaxo Wellcome's Spanish pricing system,' (2001) 2 *Competition Policy Newsletter* 30, 31; and Kon and Schaeffer, n. 28 above, 129.

³⁵ See Joined Cases C-267-268/95 *Merck & Co. Inc. v. Primecrown Ltd.* [1996] E.C.R. 6285; and chapter 5 below.

currency fluctuations.³⁶ However, regardless of the cause of the price difference, the agreement sought to distort competition in the common market by restricting parallel imports, and ‘in any event, it is not for a private company to safeguard governmental policy choices by restricting competition.’³⁷

GlaxoWellcome decided to appeal the Commission Decision to ‘keep the issue [of parallel trading] alive.’³⁸ The CFI’s judgment is important and, in relation to the pharmaceutical market and Article 81 EC Treaty, can be seen as indicating a change in the Court’s traditionally pro-integration approach to parallel import-restrictive agreements.³⁹ The Court did not dispute the Commission’s finding of an agreement between GlaxoWellcome and its distributors.⁴⁰ However, the Court held that the Commission did not take adequate account of the specific nature of the pharmaceuticals market when considering the dual-pricing scheme to have as its objective the restriction of competition. ‘As the prices of the medicines concerned are to a large extent shielded from the free play of supply and demand owing to the applicable regulations and are set or controlled by the public authorities, it cannot be taken for granted at the outset that parallel trade tends to reduce those prices and thus to increase the welfare of final consumers.’⁴¹ It can therefore not be presumed that parallel trade reduces prices, and that the dual-pricing clause deprives final consumers of a benefit which would have been present in the absence of the potentially parallel import-restrictive agreement.⁴² However, the Court held that GlaxoWellcome had failed to show that the dual-pricing clause did not have as its effect the restriction of competition. Even though the dual-pricing clause has the

³⁶ Kliemann, n. 34 above, 31; and *GlaxoWellcome*, n. 5 above, recitals 141-143: the British pound appreciated by 30% against the Spanish Peseta between October 1996 and April 1998, and 27% between January 1996 and December 1998.

³⁷ *GlaxoWellcome*, *ibid.*, recital 179.

³⁸ Case T-168/01, n. 5 above. See S. Pautke and K. Jones, ‘Competition law limitations for the distribution of pharmaceuticals – rough guide to the brave new world,’ (2005) 26 E.C.L.R. 24, 34.

³⁹ The judgment was, however, delivered after Cases C-2-3/01 *Bayer* (n. 4 above) and Advocate General Jacobs’s Opinion in *Syfait* (n. 6 above), which is further discussed in section 2.5 below.

⁴⁰ Case T-168/01, n. 5 above, paras. 89-90.

⁴¹ *ibid.*, para. 147. This can be seen as endorsing Advocate General Jacobs’s Opinion in *Syfait*, n. 6 above: see pp. 77-79 below for the Advocate General’s discussion of the effects of parallel trade on the final consumer.

⁴² *ibid.*, paras. 121-122.

effect of limiting the freedom of GlaxoWellcome and its distributor's to choose their customers, 'not every agreement which restricts the freedom of action of the participating undertakings...necessarily falls within the prohibition in Article 81(1) [EC Treaty].'⁴³ Nevertheless, the Court held that GlaxoWellcome had not succeeded in calling into question the Commission's finding that the dual-pricing clause had as its effect to deprive national health budgets, and therefore final consumers, of a benefit in the form of a reduction in prices which they would have derived in the absence of the parallel import-restrictive agreement.⁴⁴

However, even though the agreement had as its effect the restriction of competition, the Court found that the Commission had failed to adequately consider whether the dual-pricing clause might give rise to an economic advantage by contributing to innovation so as to be capable of benefiting from an Article 81(3) EC Treaty exemption. GlaxoWellcome's argument that parallel trade leads to a loss in efficiency by reducing the capacities for financing R&D cannot be disregarded in light of GlaxoWellcome's evidence to this effect.⁴⁵ 'Such an omission is particularly serious where the Commission is required to determine whether the conditions for the application Article 81(3) [EC Treaty] are satisfied in a legal and economic context, such as that characteristic of the pharmaceutical sector, where competition is distorted by the presence of national regulations.'⁴⁶ It cannot be assumed that the loss in efficiency only stems from the variations in exchange rates, as, even though currency fluctuations may have an impact on price differentials between two Member States, parallel trade is linked to the coexistence of different national pricing regulations. Further, the Commission had erred in not considering that the dual-pricing clause could lead to a gain in efficiency. In particular, the

⁴³ Case T-168/01, n. 5 above, para. 170-171. The Court referred to *inter alia* Case C-309/99 *Wouters and Others v. Nederlandse Orden van Advocaten* [2002] E.C.R. 1577.

⁴⁴ Case T-168/01, *ibid.*, para. 189-190. The Court, however, acknowledged that the savings derived from parallel trade are minimal (para. 190). See also chapter 1(3.1) above.

⁴⁵ *ibid.*, paras. 258 and 264. This is particularly so considering that the contents of GlaxoWellcome's arguments and supporting evidence is 'corroborated on a number of significant aspects by documents originating with the Commission' (at para 263), as, for example, Commission Communication on the single market in pharmaceuticals [1998] COM/588/final.

⁴⁶ *ibid.*, para. 276.

measure would not only lead to an increase in revenues for GlaxoWellcome, but has the secondary effect of increasing the funds available for future R&D. Parallel importers, on the other hand, do not engage in competition among themselves, but only reduce prices to an extent necessary to attract customers. In consequence, most of the price differentials remain with the parallel importers instead of being re-invested into innovation.⁴⁷ The Commission could therefore not lawfully conclude that the dual-pricing clause did not contribute to the promotion of technical progress for the purpose of the first condition for the application of Article 81(3) EC Treaty.⁴⁸ Accordingly, as the Commission did not further clarify and consider the other conditions which must be satisfied in order to be eligible for an exemption under Article 81(3) EC Treaty, the Decision was annulled. Due to the retro-active effect of the annulment, the Commission must reconsider GlaxoWellcome's request for an exemption.

By considering the specific nature of the pharmaceutical market, the judgment can be seen as endorsing Advocate General Jacobs's Opinion in *Syfait*,⁴⁹ which will be discussed in section 2.5 below. The Commission must acknowledge that certain practices that facilitate price discrimination by preventing parallel imports, such as dual-pricing mechanisms, may lead to a gain in efficiency, providing an added benefit to consumers and strengthen the competitiveness of the European pharmaceutical industry.⁵⁰ The pharmaceutical industry is characterised by high investments, which are largely sunk costs, while the variable costs are fairly low. As a result, it is commercially sensible to market the products wherever the variable costs can be recovered, even though the sunk costs cannot be recovered if all products are sold at the lowest price.⁵¹ The Court can be interpreted as giving its approval of Ramsey pricing by ordering the Commission to take this aspect into

⁴⁷ Case T-168/01, n. 5 above, para. 300. See also chapter 1(3.1) above.

⁴⁸ *ibid.*, para. 308.

⁴⁹ N. 6 above. See also section 2.5 below.

⁵⁰ See D. Glynn, 'Article 82 and price discrimination in patented pharmaceuticals: The economics,' (2005) 26 E.C.L.R. 135, for a very convincing discussion of the benefits of price discrimination and measures that facilitate such price discrimination within the common market.

⁵¹ Case T-168/01, n. 5 above, para. 271. See also Advocate General Jacobs's Opinion in *Syfait*, n. 6 above, para. 89.

consideration, which contradicts earlier findings by the Commission and the ECJ.⁵² The inability to recover the overhead sunk costs in the low price Member States may result in manufacturers delaying the launch of new pharmaceutical products in these Member States. In fact, parallel trade may seriously affect the incentive to carry out further R&D if the overhead sunk costs cannot be recovered. The conclusion must therefore be that competition law shifts the funds available for R&D to parallel importers no-value adding business. Whether manufacturers in fact choose to make the funds available for R&D is irrelevant. Manufacturers have the option, if needs be, to invest the funds into R&D, whilst an increase in parallel importers' profits will have no, even potential, impact on R&D. The agreement may therefore remedy a loss in efficiency, as well as providing a gain in efficiency by allowing for an increase in funds made available by the pharmaceutical company for future inventions (R&D). It is therefore hoped that the Commission will consider the agreement eligible for an Article 81(3) exemption.

Coincidentally, the European Association of Euro-Pharmaceutical Companies (EAEP), the European-wide parallel importers association, has filed a complaint with the Commission alleging that Pfizer's recently implemented dual-pricing system in Spain – similar to GlaxoWellcome's - is incompatible with Article 81 EC Treaty.⁵³ The outcome of the Commission's re-examination of GlaxoWellcome's request for an exemption, or, if appealed, the ECJ's judgment, is eagerly waited for

⁵² See V. Korah, 'The interface between intellectual property rights and competition in developed countries,' (2005) 2:4 *Script-ed* 463, 472, discussed in the context of Advocate General Jacobs's Opinion in *Syfait* (n. 6 above), where the Advocate General invoked the same argument. See F. Ramsey, 'A contribution to the theory of taxation,' (1929) 37 *Economic Journal* 47, 47-61: provided that if no price is below variable costs, no-one is worse off, and the sunk overhead costs will be recovered from the markets willing to pay a high price.

⁵³ EAEP, 'Pfizer breaking EU competition rules,' (October 2005), (<http://www.eaepc.org/news_and_press/current_articles.php?n=3&id=274>), Pfizer's dual-pricing system entails a 'regulated' price for products intended for the Spanish market, and a higher 'Pfizer price' for products intended for other markets. Distributors will have to sign a detailed contract creating an information system whereby the distributors will have to inform Pfizer of their sales data, allowing Pfizer to determine which of the two prices should apply. There is therefore a distinct possibility that the Commission will conclude that there is a valid agreement between Pfizer and the distributors. Alternatively, the EAEP claims that the dual pricing system can be considered an abuse by a dominant undertaking, and thus not compatible with Article 82 EC Treaty: see p. 66 below.

by commentators.⁵⁴ It must be remembered, however, that the CFI did not dispute the Commission's finding of a valid agreement between GlaxoWellcome and its distributors. The 'concept of an agreement,' which will be further discussed in section 1.4 below, has been the subject of much case-law by the ECJ, culminating in the *Bayer*⁵⁵ judgment.

1.3 *Export and resale bans*

The demand for pharmaceutical products is not price sensitive due to the lack of substitutes and special nature of such products. Despite a lack of commercial viability, manufacturers fulfil their ethical duties by continuing to supply pharmaceutical products in low-priced Member States in order to satisfy inherent domestic demand. Manufacturers hope that those products will saturate the local demand and not be re-exported to higher-priced Member States. The most obvious way of preventing parallel imports from low-priced Member States is to impose an export or resale ban in the sales contract, and make the further commercial relationship and the delivery of products contingent upon the distributor's agreement not to export or resell the products to higher-priced markets. In order to guarantee the parallel importer's adherence with the ban, working as a deterrent, the manufacturer may penalise any breach of the agreement with a refusal to supply.

Resale bans can potentially segment the common market along national boundaries and distort competition by preventing the flow of goods from low-priced to high-priced Member States. Agreements between manufacturers and distributors that prevent the distributor from reselling the products, by for example requiring that the supplies be used only for the distributor's own requirements, are not compatible with Article 81 EC Treaty.⁵⁶ Even resale bans that are not directly aimed at

⁵⁴ The EAEPC said in a comment to the judgment: 'we are confident that a full analysis of the economic impact of parallel trade will confirm pharma manufacturers are in the wrong,' in S. Boseley, 'GSK claims victory in battle over drug prices,' *The Guardian*, 28 September 2006, p. 15.

⁵⁵ Cases C-2-3/01, n. 4 above.

⁵⁶ See Commission Decision 90/38/EEC *Bayer* (Bayo-n-ox) [1990] O.J. L21/71. This case was complicated by the fact that Bayer was using a selective distribution system; but as the resale ban

preventing parallel imports per se, but nevertheless have an indirect effect on intra-Community trade, may violate Article 81 EC Treaty. A resale ban on opened forms of original packages carrying the manufacturer's trademark was held to be in violation of Article 81 EC Treaty by the Commission.⁵⁷ Bayer, the manufacturer, claimed that the prohibition was not aimed at preventing parallel imports, but was a pure health and safety measure.⁵⁸ The Commission nevertheless held the measure to amount to an export ban, as the prohibition did not take into account that certain types of packaging, if opened, do not affect the safety of the product, and even though several Member States prohibit trade in opened forms of packaging the resale ban effectively prevents trade to the remaining Member States.⁵⁹

A less restrictive measure to prevent parallel imports is to include an export ban in the supply contract. The effects of an export ban are similar to that of a complete resale ban. It segments the common market along national borders and prevents parallel imports; even though, hypothetically, a distributor may potentially still resell the products to another distributor based within the same Member State who in turn exports the products to a higher-priced Member State.⁶⁰ For example, Sandoz, a pharmaceutical manufacturer, sought to prevent products marketed in Italy from being parallel exported to other higher-priced Member States by simply including the term 'export prohibited' on the distributors' invoices. This is clearly the most obvious way to restrict exports. There is also no doubt that the insertion of such a condition distorts competition and trade between Member States. In fact, even an export ban to non-EEA countries may be seen as distorting competition

prevented intra-system sales it was nevertheless in violation of Article 81 EC Treaty. See Hays, 'Parallel importation,' n. 25 above, 83-84.

⁵⁷ Commission Decision 90/645/EEC *Bayer Dental* [1990] O.J. L351/46.

⁵⁸ *ibid.*, recital 8. Further, as prices for dental products were at the time freely determined throughout the Community, prices were almost the same in all Member States. Hence, Bayer argued that the prohibition was not aimed at preventing parallel imports.

⁵⁹ *ibid.*, recitals 11 and 16. See chapters 6 and 7 below on repackaging.

⁶⁰ Similarly, sending the products out of the common market and enforcing an import ban in the supply contract in order to keep the products out of the common market would have the same effect on trade between Member States. The manufacturer may, however, be able to assert his patent rights in order to prevent such importation. See chapter 5(4) on 'international exhaustion.'

within the common market if the effects of the export ban and the manufacturer's behaviour are such that in reality the export ban prevents parallel imports.⁶¹

An export ban, however, does not amount to an infringement of Article 81 EC Treaty in the absence of an agreement between the manufacturer and distributors. As the insertion of an export ban on the invoices can be seen as a unilateral action, the Commission had to adopt a very wide interpretation of an 'agreement.' Although the Commission recognised that no formal agreement between Sandoz and the distributors existed, it maintained that the inclusion of the contested condition on the invoices was part of the normal commercial relationship between Sandoz and its customers. 'Consequently, the invoice cannot be seen as the expression of a merely unilateral act...the fact that the invoices have been constantly and systematically used leads to the conclusion that Sandoz PF's clients implicitly agreed with it and accepted it.'⁶² When Sandoz subsequently challenged the decision before the ECJ the Court upheld the Commission Decision by ruling that the distributors' failure to object to the contested condition amounted to a tacit acceptance of the condition.⁶³ The Court held that this practice had been repeated to the extent that it had become an established part of Sandoz's business relations, and as such, together with the Italian distributors' tacit acceptance of the terms by the distributors, amounted to an agreement to restrict exports between Sandoz and its distributors.⁶⁴ As Broberg and Jacobsen rightly observe, 'the idea that the distributors tacitly accept the anti-competitive clause irrespective of the fact that the clause is clearly contrary to their interests, and irrespective of the fact that several of

⁶¹ *Johnson & Johnson*, n 22 above, recital 28: after amending the wording of the agreement, only exports to non-EEA countries were prohibited. However, the supplier's behaviour gave evidence to the fact that exports to EEA Member States were in practise still prohibited.

⁶² *Sandoz*, n. 22 above, recital 26.

⁶³ Case C-277/87 *Sandoz SpA v. Commission* [1990] E.C.R. 45, para. 1 (only a summary has been published).

⁶⁴ An agreement was held to exist even though the customers were not informed of the condition until the invoice arrived. Cf. *Johnson & Johnson*, n. 22 above, where a similar condition was included in the price list. Further, the Court held that an agreement existed even though Sandoz had taken no any action against customers in order to ensure compliance with the condition. See also Case 86/82 *Hasselblad v. Commission* [1984] E.C.R. 883; and M. Broberg and P. Jakobsen, 'The concept of agreement in Article 81 EC: On the manufacturers' right to prevent parallel trade within the European Community,' (2002) 23 E.C.L.R. 127, 130.

the distributors did re-export the products is...an unusually broad interpretation of the concept of agreement.⁶⁵ Nevertheless, the insertion of the export ban on the invoices was a fundamental error by Sandoz, enabling the Commission and the ECJ to discern Sandoz's underlying intention to restrict parallel imports. This leads to the question whether a unilateral decision to restrict parallel imports, in the absence of any written or otherwise communicated requirements, will violate Article 81 EC Treaty.

1.4 *Refusals to supply and the 'concept of agreement'*

Resale bans and export bans are often contained in the manufacturer's supply contract or otherwise communicated to the distributor by the manufacturer. The Commission will readily show that this amounts to an agreement to restrict parallel imports between the manufacturer and the distributor. To circumvent this finding, manufacturers may simply refuse to supply selected distributors altogether, or at least implement some sort of supply quota, in order to restrict parallel imports without violating Article 81 EC Treaty. The manufacturer may trace parallel imported products back through the distribution chain in order to identify which distributors are supplying parallel importers, or, alternatively, will be able to identify such distributors by the unusually large amount of products ordered.⁶⁶ Like a resale or export ban, refusing to supply a distributor clearly distorts competition and will segment the common market along national boundaries as it prevents trade between Member States. However, unlike resale and export bans, often expressly included in the supply or sales contract, a refusal to supply is arguably a unilateral decision by the manufacturer. In the absence of a valid agreement such measures

⁶⁵ Broberg and Jakobsen, n. 64 above, 131.

⁶⁶ See inter alia, *Johnson & Johnson*, n. 22 above. Another practice is to supply the same drug for the same price in the importing Member State. The manufacturer will do this for six or seven weeks and then suddenly cut off supply. During this time the manufacturer will be able to ascertain the demand for products in the importing Member State, and the inherent domestic demand in the exporting Member State, subsequently limiting supplies on the exporting market accordingly. See Morais R, 'Pssst... Wanna buy some Augmentin?', *Forbes*, 12 April 2004, (<<http://www.forbes.com/forbes/2004/0412/086/html>>).

will be compatible with Article 81 EC Treaty. This spurred the Commission to focus on the definition of an agreement, widening the concept when convenient.

The Commission's and the ECJ's wide interpretation of an agreement in *Sandoz*⁶⁷ has been applied to a wide range of practices aimed at preventing parallel imports, including a car manufacturer's refusal to supply right-hand driven cars to German distributors in an attempt to prevent re-importation into the UK.⁶⁸ The ECJ held that although the act of refusing to supply the distributor did not itself constitute an agreement between the manufacturer and the distributor, the manufacturer's practice could be seen as part of the original selective distribution agreement signed and agreed long before the manufacturer's refusal to supply.⁶⁹ According to the ECJ, technological developments leave room for certain matters to be decided by the manufacturer at any point during the duration of the agreement.⁷⁰ Thus, refusing to supply the distributor could not be seen as a unilateral decision by the manufacturer.

The Commission's and the Community courts' willingness to infer an agreement between a manufacturer and its distributors, albeit an agreement of benefit only to the manufacturer, resulted in manufacturers being unable to refuse to supply distributors. As will be discussed below, the Commission's approach was unsatisfactory as it blurred the distinction between Articles 81 and 82 EC Treaty, with the former being used as a substitute for the latter whenever the manufacturer was non-dominant. To manufacturers' widespread relief this was recognised by the CFI and the ECJ in the landmark case of *Bayer*.⁷¹

Bayer, a large multinational pharmaceutical company, manufactures and markets 'adalat,' for the treatment of coronary heart disease. Due to national regulations the price for 'adalat' was almost 40% lower in Spain and France than in the UK.

⁶⁷ N. 22 and 63 above.

⁶⁸ See Joined Cases 25-26/84 *Ford Inc. v. Commission* [1985] E.C.R. 2725.

⁶⁹ *ibid.*, paras. 30-33.

⁷⁰ *ibid.*, para. 20.

⁷¹ N. 4 above.

Bayer's distributors engaged in parallel exporting 'adalat' from Spain and France to the UK. As, by law, distributors must keep a reserve stock of pharmaceutical products, they began to order huge amounts of 'adalat' so as to be able to satisfy the needs of local pharmacies as well as those in the UK. This led to a significant loss of revenue for Bayer's British subsidiary, as a result of a huge increase in 'adalat' dispensed by Bayer's French and Spanish subsidiaries.⁷² Bayer, concerned by this loss, implemented a supply quota system in order to restrict the flow of 'adalat' from Spain and France onto the UK market. The quota was calculated on basis of the distributors' orders in the previous year, allowing a 10% annual increase to cover the general rise in consumption. The distributors tried to circumvent Bayer's quota system by convincing their local subsidiaries to increase their orders and send the excess supply to the distributors for later parallel export to the UK. Bayer discovered this widespread practice and refused the orders in excess of the decided quota.

The Commission, considering that there was an agreement between the distributors and Bayer capable of restricting trade between Member States, issued a Decision ordering Bayer to inform the distributors that exports are allowed within the common market.⁷³ In addition Bayer was fined 3 million ECUs.⁷⁴ The Commission tried to extend the principle in *Sandoz*,⁷⁵ and in the ECJ's judgment in *Ford*,⁷⁶ to a situation like that in *Bayer*⁷⁷ where there was no explicit export ban or selective distribution agreement. Thus, the Commission effectively argued that the EC Treaty imposes a general prohibition on parallel import-restrictive measures.

Bayer appealed the decision to the CFI. The subsequent judgment would have a far-reaching impact on manufacturer's ability to prevent parallel imports. The CFI referred to established case-law and held that it is sufficient that undertakings have

⁷² Cases C-2-3/01, n. 5 above, para. 5. According to Bayer, its British subsidiary saw a fall in turnover of DEM 230 million as a direct result of the parallel imports from Spain and Portugal. This represented a loss of revenue for the mother company of DEM 100 million.

⁷³ *Adalat*, n. 5 above.

⁷⁴ *ibid.*, recital 3.

⁷⁵ N. 22 above.

⁷⁶ N. 68 above.

⁷⁷ N. 4 above.

expressed a joint intention to conduct themselves in a specific way for there to be an agreement.⁷⁸ However, it is also clear from that case-law that the Commission cannot hold that apparently unilateral conduct on the part of a manufacturer, adopted in the context of the contractual relations which he maintains with his dealers, in reality forms the basis of an agreement between undertakings...if it does not establish the existence of an acquiescence by the other partners, express or implied, in the attitude adopted by the manufacturer.⁷⁹ The CFI held that the evidence put forward by the Commission was not enough to prove that there was tacit acquiescence on behalf of the distributors. The fact that the distributors actively tried to circumvent the system set up by Bayer negates the Commission's finding of an agreement. The facts of the case can also be distinguished from the judgment in *Sandoz*.⁸⁰ In *Sandoz*,⁸¹ the manufacturer had clearly included the phrase 'export prohibited' on the invoices, which set the tone of the underlying intention. Bayer, on the other hand, did not make its intentions clear to the distributors. Secondly, the distributors in *Sandoz*⁸² complied with the clause de facto and without discussion, thereby giving their tacit acquiescence.⁸³ The second case relied on by the Commission, *Tipp-Ex*,⁸⁴ concerned an exclusive distribution agreement between Tipp-Ex and its distributor DMI. In order to achieve its object of preventing parallel imports, Tipp-Ex implemented a monitoring system to give DMI an incentive to increase its prices to the parallel importers. Unlike the distributors in *Bayer*,⁸⁵ DMI gave its acquiescence by following Tipp-Ex's demands so as to increase the resale prices eventually culminating in a refusal to supply altogether.⁸⁶ The Court held that this amounted to an agreement between Tipp-Ex and DMI. Similarly, in *Johnson & Johnson*, a monitoring system set up in order to trace exported goods back to the distributor coupled with an express warning to reduce supplies to the distributor

⁷⁸ Case T-41/96, n. 4 above, para. 67; referring to Cases 41, 44-45/69, n. 7 above.

⁷⁹ Case T-41/96, *ibid.*, para. 72.

⁸⁰ N. 63 above.

⁸¹ *ibid.*

⁸² *ibid.*

⁸³ See Case T-41/96, n. 4 above, para. 163.

⁸⁴ Case C-279/87 *Tipp-Ex GmbH v. Commission* [1981] E.C.R. I-261. See K. Lasok, 'Article 85 – definition of an agreement,' [1990] 11 E.C.L.R. R59.

⁸⁵ N. 4 above.

⁸⁶ Case C-279/87, n. 84 above.

amounted to an export ban.⁸⁷ Therefore, as the distributors in *Bayer* failed to give their tacit acquiescence by trying to circumvent the resale ban, Bayer's conduct did not amount to an agreement but merely a unilateral act.⁸⁸ The CFI therefore held that the Commission had failed to prove the existence of an agreement between Bayer and the distributors.⁸⁹ On appeal, the ECJ upheld the CFI judgment, noting that the mere finding of a continuous business relationship between the manufacturer and its distributors is not sufficient for a finding that an agreement to restrict parallel exports exists.⁹⁰

The *Bayer*⁹¹ judgment has severely restricted the Commission's practice of using Article 81 EC Treaty as a tool to penalise 'parallel import-restrictive' conduct by manufacturers. Unilateral conduct cannot and should not come within the scope of Article 81 EC Treaty. It is likely that the Commission widened the concept of an agreement under Article 81 EC Treaty as a direct result of not being able to classify Bayer as a dominant undertaking.⁹² The almost religious belief that restricting parallel imports is *per se* prohibited by Community competition law had obliterated the concept of an agreement under Article 81 EC Treaty. The ECJ observed that if an agreement could be inferred from the facts of *Bayer* it 'would have the effect of confusing the scope of that provision [Art. 81] with that of Article 82 EC Treaty.'⁹³ The result, until *Bayer*,⁹⁴ was that a manufacturer could not refuse to supply a distributor. If the manufacturer were in a dominant position the 'abuse' could be

⁸⁷ *Johnson & Johnson*, n. 22 above, recital 15-17; and *Eurim-Pharm GmbH v. Johnson & Johnson Inc.* [1981] 2 C.M.L.R. 287. See M. Noor, 'The Bayer Case: New hope for manufacturers,' (2002) 23 E.I.P.R. 158, 159. This follows US policy (under the Sherman Antitrust Act 15 U.S. §§), where an agreement does not necessarily require contractual arrangements, but may be inferred from the actions of the manufacturer. If the manufacturer's actions go beyond mere announcement of his policy, and he employs other means to enforce his policy, this may amount to an agreement. See *United States v. Parke, Davis & Co.*, 362 U.S. 29; and H. Lidgaard, 'Unilateral refusal to supply: An agreement in disguise?,' (1997) 17 E.C.L.R. 352, 358.

⁸⁸ Case T-41/96, n. 4 above, para. 182.

⁸⁹ *ibid.*, para. 183.

⁹⁰ Cases C-2-3/01, n. 4 above, para. 141. See C. Brown, 'Bayer v Commission: The ECJ agrees,' (2004) 25 E.C.L.R. 386.

⁹¹ *ibid.*

⁹² M. Jephcott, 'Commentary on Case T-41/96 Bayer AG v. Commission,' (2001) 22 E.C.L.R. 469, 476.

⁹³ Case C-2-3/01, n. 4 above, para. 101.

⁹⁴ *ibid.*

caught by Article 82 EC Treaty, if not; the Commission would infer an agreement to restrict parallel imports from the continuous business relationship between the manufacturer and the distributors so as to come within Article 81 EC Treaty. This would lead to the illogicality of a refusal to supply being more heavily penalised under Article 81 EC Treaty than under Article 82 EC Treaty, since Article 82 EC Treaty only prohibits a dominant undertaking from ‘abusing’ its position, which does not necessarily encompass all forms of a refusal to supply.⁹⁵

The *Bayer*⁹⁶ judgment provided non-dominant manufacturers with a glimpse of hope.⁹⁷ The Court made it clear that the concept of an agreement is restricted to at least a ‘concurrence of wills,’ albeit the form in ‘which it is manifested being unimportant so long as it constitutes the faithful expression of the parties’ intention.’⁹⁸ However, manufacturers should be aware that the judgment must be applied with care.

First, it should be remembered that the ECJ did not rely on *Ford*⁹⁹ and *AEG v. Commission*¹⁰⁰ since those cases concerned selective distribution agreements.¹⁰¹ For example, the issue in *Ford*¹⁰² was not to establish that there was an agreement, but rather whether the export ban was part of the original agreement. Manufacturers should therefore be aware that the principle in *Bayer*¹⁰³ may not apply to a relationship between a manufacturer and a selective distributor.

Secondly, the manufacturer must not make its intentions, as to the refusal to supply, known to the distributor or indeed to any other party. This was the ‘mistake’ Sandoz

⁹⁵ N. 4 above: Cases C-2-3/01, para. 139; and Case T-41/96, para. 180. See Case 27/76 *United Brands Co. v. Commission* [1978] E.C.R. I-207, paras. 182-191. See also section 2.4 below.

⁹⁶ Cases C-2-3/01, n. 4 above.

⁹⁷ See A. Dawes, ‘Neither head nor tail: The confused application of EC competition law to the pharmaceutical sector,’ (2006) 27 E.C.L.R. 269, 276.

⁹⁸ Case T-41/96, n. 4 above, para. 69.

⁹⁹ N. 68 above.

¹⁰⁰ Case 107/82 *AEG-Telefunken AG v. Commission* [1983] E.C.R. 3151.

¹⁰¹ N. 4 above: Cases C-2-3/01, paras. 143-144; and Case T-41/96, paras. 170-171.

¹⁰² N. 68 above.

¹⁰³ Cases C-2-3/01, n. 4 above.

made when printing 'export prohibited' on the invoices.¹⁰⁴ Similarly, manufacturers will have to ensure that no documents or memos in their possession set out their covert intentions.¹⁰⁵ Further, Bayer was in a position to argue that the sales quota was justified as the distributors had to order enormous amounts of products to satisfy national legislation requiring distributors to keep a full range of products.¹⁰⁶ A legally or commercially viable explanation for the refusal to supply could be enough to negate anti-competitive behaviour.¹⁰⁷

Thirdly, manufacturers must refrain from monitoring and tracing parallel exported goods back through the distribution chain, as this can be seen as a means to enforce the 'export ban' from which an agreement can be inferred from if the distributors adhere to the manufacturer's policy.¹⁰⁸ Manufacturers may trace parallel exported goods back to the original distributors and warn, penalise, or refuse to supply them. However, not only may this lead to the inference of an agreement if the distributor adheres to the manufacturer's threats, but the manufacturer's covert intention of restricting parallel imports may be discernable from the manufacturer's selective approach by refusing to supply only certain distributors. It is important to remember that Bayer's quota system universally applied to all distributors.

¹⁰⁴ *Sandoz*, n. 22 above. Similarly, Johnson & Johnson made the mistake of including the condition: 'Export prohibited except by prior arrangement' under the 'terms of trading;' see *Johnson & Johnson*, n. 22 above, recital 13.

¹⁰⁵ In this respect *Ford*, n. 68 above, can be distinguished from Cases C-2-3/01 *Bayer*, n. 4 above, by the 'smoking memo' setting out Ford's intentions to prevent parallel exports. See Jephcott, n. 92 above, 476.

¹⁰⁶ For example, Bayer claimed that one Spanish distributor suddenly ordered a quantity representing nearly half of the total yearly consumption in Spain: see Case T-41/96, n. 4 above, para. 32; and *Adalat*, n. 4 above, recital 114. As national legislation requires distributors to keep a full range of products in reserve quantities, the distributors had to order huge quantities so as to satisfy the domestic market as well as the parallel exporters. Bayer's quota system did therefore only amount to an export ban when coupled with the national legislation. As a consequence, parallel exporters and distributors supplying such are likely to try to have this legislation amended or removed.

¹⁰⁷ For example in *Re. Pfizer Hellas SA and Glaxo SA, Advisory Opinions of the Competition Committee* Nos 81 and 82, Greece, Cases A1-732, A1-733 (August 1989), Pfizer and Glaxo successfully managed to justify a refusal to supply a potential parallel importer. Greek law required manufacturers to maintain a three month reserve stock of pharmaceutical products in the country. As the manufacturers' laboratories were operating at full capacity, the Hellenic Competition Commission excused Pfizer and Glaxo for refusing to supply the potential parallel exporter with the large amount of products ordered, as this would have placed the two undertakings in breach of Greek national law. See Hays, 'Parallel importation,' n. 25 above, 83.

¹⁰⁸ *Johnson & Johnson*, n. 22 above, recitals 15-17.

Finally, *Bayer*¹⁰⁹ was distinguished from *Sandoz*¹¹⁰ on the fact that the distributors in *Bayer*¹¹¹ sought to circumvent Bayer's quota system. This means that, ironically, a manufacturer may benefit from a dishonest relationship with its distributors. If the distributor 'agrees' to the unilateral policy the Commission may regard this as an agreement. Distributors may also take full advantage of this 'loophole' and willingly accept any conditions, even though this may be to their detriment in the short run, so as to argue that there is a valid agreement with the manufacturer. Manufacturers are therefore well advised not to discuss the policy with distributors, and not to attempt to justify its implementation even though this may have a negative impact on their commercial relationship with the distributors.¹¹²

Although the Commission suffered a great setback in terms of its ability to apply Article 81 EC Treaty by the ECJ's judgment in *Bayer*,¹¹³ the effects of *Bayer*¹¹⁴ may turn out to be far more extensive for the Commission than first anticipated. The Commission's misapplication of Article 81 EC Treaty may have spurred the Court to consider the peculiarities of the pharmaceutical trade in the context of parallel imports and competition law. The CFI in *Bayer* held that the Commission cannot 'rely in support of its argument upon its conviction, which is, moreover, devoid of all foundation, that parallel imports will in the long term bring about the harmonisation of the price of medicinal products.'¹¹⁵ This reasoning is further supported by Advocate General Jacobs's Opinion to the first case before the ECJ concerning a unilateral refusal to supply distributors in order to restrict parallel imports under Article 82 EC Treaty.¹¹⁶ This case is important at a time when the Commission is facing significant difficulty in applying Article 81 EC Treaty, following *GlaxoWellcome*¹¹⁷ and *Bayer*.¹¹⁸ By narrowing market definitions the

¹⁰⁹ Cases C-2-3/01, n. 4 above.

¹¹⁰ N. 63 above.

¹¹¹ N. 4 above.

¹¹² S. Pautke and K. Jones, 'Competition law limitations for the distribution of pharmaceuticals – rough guide to the brave new world,' (2005) 26 E.C.L.R. 24, 34.

¹¹³ N. 4 above.

¹¹⁴ *ibid.*

¹¹⁵ Case T-41/96, n. 4 above, para. 181.

¹¹⁶ Case C-53/03, n. 6 above.

¹¹⁷ Case T-168/01, n. 5 above.

Commission set out to prevent such restrictive practices using Article 82 instead of Article 81 EC Treaty.¹¹⁹

2. *Article 82 EC Treaty*

The costly and difficult task of proving a dominant position on behalf of the manufacturer is a possible explanation to why the Commission has traditionally focused on Article 81 EC Treaty in relation to parallel import-restrictive measures.¹²⁰ The *Bayer*¹²¹ and *GlaxoWellcome*¹²² judgments, however, may leave the Commission with little choice but to consider the application of Article 82 EC Treaty to such measures by pharmaceutical manufacturers in a dominant position. This can be a daunting exercise as the Commission must not only show that the undertaking holds a dominant position on the market, but also that the measure amounts to an abuse of this position. This involves a three stage approach. First, the relevant market must be defined; secondly, it must be assessed whether the undertaking holds a dominant position on this market. Finally, as dominance is not in itself an abuse, consideration of what behaviour is likely to be abusive must be undertaken.

2.1 *Article 82 EC Treaty and parallel trade*

The eagerly awaited ruling by the ECJ in *Syfait*¹²³ did not provide the guidance hoped for in relation to the application of Article 82 EC Treaty to parallel import-restrictive measures in the field of pharmaceutical products. The ECJ was asked to provide guidance on whether the refusal to meet fully the orders of its distributors

¹¹⁸ N. 4 above.

¹¹⁹ Following Case C-2-3/01, *ibid.*, the Commission spokeswoman Amelia Torres said that the Commission has received numerous requests for clearance of supply quota systems and is considering them under 'the antitrust rules.' Clearly, the Commission turned the focus to Article 82 EC Treaty following this judgment. See Morais, n. 66 above, p. 4.

¹²⁰ J. Nazerli, S. Hocking and U. Ranasinghe, 'Parallel imports of pharmaceuticals – a prescription for success or a free market overdose?', [1998] 19 E.C.L.R. 332, 338.

¹²¹ Cases C-2-3/01, n. 4 above.

¹²² Case T-168/01, n. 5 above.

¹²³ N. 6 above.

constitutes a per se abuse of Article 82 EC Treaty when done with the intention of restricting parallel exports. Advocate General Jacobs delivered a much debated Opinion where it is argued that such measures can be objectively justified 'given the combined circumstances of the European pharmaceutical sector at the current stage of its development.'¹²⁴ However, the ECJ never considered these arguments as the reference was held to be inadmissible.¹²⁵ Similarly, the Commission's Decision in *AstraZeneca*¹²⁶ provides little guidance on the application of Article 82 EC Treaty to parallel import-restrictive measures. The decision concerns an abuse by a dominant position as a result of withdrawing a marketing authorisation so as to prevent the further marketing of generic and parallel imported products, as well as giving misleading information to the authorities delaying the access of generic products to the market. The Commission Decision is therefore limited to its facts, and primarily concerns a *preventative* (exclusionary) rather than restrictive measure.

This unfortunately left the issues of substance as a matter of EC law concerning the application of Article 82 EC Treaty to parallel import-restrictive practices by pharmaceutical manufacturers unresolved. Secondly, the issue of market definition and dominance was not part of the reference to the ECJ in *Syfait*.¹²⁷ A definition and discussion of the factors that must be present in order for Article 82 EC Treaty to be applicable is therefore necessary. Finally, a thorough analysis of conduct that might be objectively justified will be carried out with reference to Advocate General Jacobs's Opinion in *Syfait*.¹²⁸

¹²⁴ Advocate General Jacobs, n. 6 above, para. 105.

¹²⁵ Case 53/03, n. 6 above, para. 37.

¹²⁶ Commission Decision COMP/A.37.507/F3-AstraZeneca of 15 July 2005 (not yet reported, but a non-confidential version is available on DG Competition's website: <http://ec.europa.eu/comm/competition/index_en.html>). See also Commission press release IP/05/737, and N. Fagerlund and S. Rasmussen, 'AstraZeneca: The first abuse case in the pharmaceutical sector,' (2005) 3 *Competition News Letter* 54, 54-56. The decision has been appealed: Case T-321/05 *AstraZeneca v. Commission* [2005] O.J. C271/47. See also pp. 70-72 below.

¹²⁷ N. 6 above.

¹²⁸ *ibid.*

2.2 *Defining the relevant market*

The relevant market for the purpose of Article 82 EC Treaty can be defined as a geographically delimited product market. The product market comprises 'all those products and/or services which are regarded as interchangeable or substitutable by the consumer, by reason of the products' characteristics, their prices and their intended use.'¹²⁹ The key is interchangeability; involving demand-side and supply-side substitution.¹³⁰ An undertaking or a group of undertakings cannot be in a dominant position if its customers can switch to available substitutes in the event of a change in the sales conditions or price.¹³¹ The most widely used test to measure demand-side substitution is the so called "Small but Significant Non-transitory Increase in Price" (SSNIP) test. This test measures whether a hypothetical small but permanent price increase (5-10%) in the product considered would incur a loss of sales of such magnitude that the price increase would be unprofitable for the manufacturer.¹³² Interchangeability may also be a factor on the supply-side. The undertaking (or its competitors) may be able to adapt its production/supply to the manufacture of a product sold by its competitors. If so, the additional substitutable goods will be included in the relevant product market.¹³³

Before applying these tests to pharmaceutical products it must be recognised that the pharmaceutical sector is a very distinct market with four specific attributes. First, pharmaceutical products are neither trend nor price sensitive as there is an inherent demand for such products. Secondly, pharmaceutical products are rarely substitutable as they are intrinsically linked to a particular treatment. Thirdly, virtually all pharmaceutical products are patent protected, or/and must be linked to a marketing authorisation in order to be placed on the market. Finally, prices are

¹²⁹ Commission Notice on the definition of relevant market for the purposes of the Community competition law [1997] O.J. C372/5, recital 2.

¹³⁰ See Case 85/76 *Hoffman-La Roche & Co. AG v. Commission* [1979] E.C.R. 641; and Case 322/81 *Michelin NV v. Commission* [1983] E.C.R. 3461.

¹³¹ Case 27/76, n. 95 above. See Whish, n. 1 above, 26-30 for discussion.

¹³² Commission Notice, n. 129 above, recital 17.

¹³³ See Case 6/72 *Europemballage Corp. and Continental Can Co. Inc. v. Commission* [1973] E.C.R. 215; and Case 322/81, n. 130 above.

regulated by national authorities by way of reimbursement levels. For example, the SSNIP test does not take into account state intervention in the pharmaceutical sector, making it difficult to apply the test to pharmaceutical products as end consumers are not sensitive to price increases as a result of state regulated reimbursement levels.¹³⁴ The SSNIP test may also be irrelevant to the pharmaceutical industry as manufacturers cannot increase prices due to national pricing regulations. Besides, only in limited cases, as for example when there are a number of similar products for the treatment of a particular illness, will demand-side substitutability be relevant and practically possible.¹³⁵ Similarly, supply-side substitutability may not be relevant to the pharmaceutical sector as it will require significant investments in production capability (including 'research and development' (R&D)) or intangible assets (intellectual property) in order to switch to production of another pharmaceutical product.

There are very few cases on market definition involving the pharmaceutical market outside the field of merger control. Unfortunately, the issue of dominance was not part of the reference to the ECJ in *Syfait*,¹³⁶ as the Hellenic Competition Commission assumed that GlaxoSmithKline was holding a dominant position in at least one of its products; Lamictal. However, a handful of Article 81 EC Treaty decisions¹³⁷ and one Article 82 EC Treaty decision¹³⁸ have discussed market definition, and as in the merger control cases, the Commission used the 'Anatomical Therapeutic Classification' system (ATC) as the basis for defining the

¹³⁴ For a discussion on pricing and reimbursement levels see chapter 1(2.2) above. Further, this attribute of the pharmaceutical sector makes product substitution very difficult as demand should be assessed with reference to pharmacists and doctors and not end consumers. See Commission Decision 97/469/EC *Ciba-Geigy/Sandoz* [1997] O.J. L201/1, recital 21. See also *GlaxoWellcome*, n. 5 above, recital 185, in relation to Article 81 EC Treaty. By comparison, see the 'customer preference test' in chapter 6(4.1) below.

¹³⁵ The intensity of competition in the pharmaceutical industry means that a patented product sometimes competes with rival patented products; often referred to as 'fast followers.' See EFPIA, 'Article 82 EC: Can it be applied to control sales by pharmaceutical manufacturers to wholesalers?', (November 2004), (<http://www.efpia.org/6_publ/Article82ECNov04.pdf>), p. 26.

¹³⁶ N. 6 above.

¹³⁷ See in particular *GlaxoWellcome*, n. 5 above, and *Adalat*, n. 4 above.

¹³⁸ *AstraZeneca*, n. 126 above. See also *Napp Pharmaceutical Holdings Ltd v. Director General of Fair Trading* [2001] Comp. A.R. 1, concerning a dominant position on the UK market.

relevant market.¹³⁹ In pharmaceutical cases the third ATC level is used, which determines the therapeutic and pharmacological subgroups of pharmaceutical products – i.e. their intended use and characteristics. However, in specific cases the product market definition may be narrower or wider than the ATC 3 level, as ultimately, the definition depends on the indication for which the pharmaceutical products are prescribed.¹⁴⁰ The ATC 3 level may also be further subdivided between (i) over-the-counter products and prescription only products, and (ii) products subject to state reimbursement, and those not reimbursed.¹⁴¹

The geographical market in all Commission Decisions using the ATC classification has hitherto been defined as national.¹⁴² The relevant geographic market therefore comprises the exporting as well as all importing national markets. However, even though ATC classification is the right method for defining the relevant market in merger control and Article 81 EC Treaty cases, it does not necessarily mean that this is the right approach in parallel import cases.

Parallel traders choose their products not on basis of their therapeutic qualities but on the margin of price difference between the product on the exporting market and the importing market. Therefore, in addition to the ‘ATC classification approach,’ the so-called ‘arbitrage approach’ to the definition of the relevant market must be

¹³⁹ Recognised by the World Health Organisation (WHO), (<<http://www.who.int/classifications/atcddd/en/>>). Occasionally, and lately, the Commission has also relied on the ATC system drawn up by the European Pharmaceutical Marketing Research Association (EphMRA). See *Ciba-Geigy*, n. 134 above, and *GlaxoWellcome*, n. 5 above, recital 110. See also J-P. Gunther, ‘Misuse of patent and drug regulatory approval systems in the pharmaceutical industry: An analysis of US and EU converging approaches,’ (2005) 26 E.C.L.R. 669, 680.

¹⁴⁰ In *AstraZeneca*, n. 126 above, recitals 371 and 504, the Commission used the ATC 4 level, defining the relevant market as prescription-only proton pump inhibitors as all such products were used for the same treatment. See Fagerlund and Rasmussen, n. 126 above, 56.

¹⁴¹ See e.g. *Ciba-Geigy*, n. 134 above. See also Commission Notice, n. 129 above, para. 16; and Gunther, n. 139 above, 680. See also chapter 1(1 and 2.2.) above

¹⁴² See e.g. *Adalat*, n. 4 above; *GlaxoWellcome*, n. 5 above; and *AstraZeneca*, n. 126 above. See Commission Decision IV/M.2922-*Pfizer/Pharmacia* [2003] O.J. C110/24 in relation to mergers. See also M. Kerckhove, ‘Parallel trade in pharmaceutical products following the ECJ’s Bayer judgment: Can a case be made under Article 82 of the EC Treaty?’, (2005) *The European Antitrust Review* 83, 84.

discussed.¹⁴³ The (economics) term ‘arbitrage’ refers to ‘the simultaneous buying and selling of assets in different markets or in derivative forms, taking advantage of the differing prices.’¹⁴⁴ The basis of this approach to the definition of the relevant market is the fact that the parallel importer is in the business of arbitrage and not of manufacturing and providing pharmaceutical products for the downstream market of treating bad health. Secondly, the parallel importer and the manufacturer are not competitors since doctors are often unaware whether the product is ‘original’ or parallel imported; the doctor’s only interest is that the product possess certain therapeutic attributes.¹⁴⁵ Thirdly, a parallel trader can easily end parallel importation of a certain product, and commence parallel importation of a different product with a higher price margin. Very small investments, or none, in tangible and intangible assets will be necessary. Strictly speaking, parallel importers choose their products on basis of the price difference, and thus the scope for successful short-term trade between the exporting and the importing Member State.¹⁴⁶ Parallel traders’ demand-side substitutability is therefore based on existing price differences, and not limited to the relevant ATC level.¹⁴⁷ When a price difference disappears between two Member States, parallel importers will substitute the loss in profits by finding a new product or a new export market.¹⁴⁸ Whether the new

¹⁴³ This term was first used by Frédéric Jenny, Judge at the French Cour de Cassation, in F. Jenny, ‘Pharmaceuticals competition and free movement of goods,’ EU competition law and policy conference report, Hellenic Competition Commission (19 April 2002), p. 77. See also EAEPC, ‘Understanding competition in the distribution of pharmaceutical products in Europe,’ (September 2005), (<http://www.eaepc.org/admin/files/eaepc_article_82_study_september_2005.pdf>), pp. 30-31, where, unsurprisingly, this theory is refuted by the EAEPC.

¹⁴⁴ See *The Concise Oxford English Dictionary*, 10th ed., (Oxford: Oxford University Press, 2002), p. 67.

¹⁴⁵ EFPIA, n. 135 above, 32.

¹⁴⁶ *ibid.*, 33.

¹⁴⁷ Jenny, n. 143 above, 82. In Case T-168/01, n. 5 above, the CFI said: ‘it is not manifestly incorrect to accept that all the medicines... which are capable of being sold at a profit owing to the price differential between [the exporting Member State] and the Member State of destination constitute a product market.’ (at para. 159). This could serve as good *obiter dicta* in support of this argument.

¹⁴⁸ Luc Gyselen, (at the time) Head of the Unit responsible for pharmaceuticals in DG Competition stated, at the IBC’s 12th annual ‘EU Pharmaceutical Law conference’ (May 13 2004), that the conclusion reached after receiving the answers from a questionnaire sent out to parallel importers in connection with a quota system implemented by a manufacturer, was that, although the search costs for new products was more expensive than usual as a result of the quota system, the parallel importers could get ‘round this by diversifying.’ Substitutes were thus available. See EFPIA, n. 135 above, 33.

product belongs to the same ATC class as the previously traded product is of no relevance to the parallel importer. In other words, the relevant product market comprises all pharmaceutical products for which a similar profit can be generated, taking account of both volume and price margin, if parallel imported within the EEA.¹⁴⁹ By illustration, if a pharmaceutical product, for example an antibiotic, is 50% more expensive in Member State A than in Member State B, the relevant market is not all antibiotics coming within the same ATC class, but all pharmaceutical products with at least a 50% price difference between the two Member States and the same volume market on the two markets.

Analysing the relevant geographical market for parallel imported pharmaceutical products under the ‘arbitrage’ approach is a novel task. First, the geographical market can only be comprised of Member States in which the product in question benefits from a marketing authorisation. Without a marketing authorisation the parallel importer will not be able to apply for a parallel import licence; thus rendering parallel importation impossible and unlawful.¹⁵⁰ Focus should therefore be on Member State markets where the manufacturer is active, and not necessarily where the parallel importer is, as of yet, active.¹⁵¹ Similarly, regulatory and legal obstacles restrict the geographic scope of the market to EEA Member State markets. It can be argued that the relevant market should only comprise the exporting market (where the abusive behaviour is conducted) and Member State markets with a higher price – that is to say where a profit from arbitrage can be made.¹⁵² However, as discussed in relation to the relevant product market, parallel importers can readily switch from one product to another, and similarly, source the products from another Member State. Parallel importation does not require overt investments, and the regulatory barriers faced when entering a new Member State market are negligible. As the number of combinations of different products that can be

¹⁴⁹ Kerchove, n. 142 above, 84.

¹⁵⁰ See chapters 3 and 4 below for a further discussion on marketing authorisations and parallel import licences.

¹⁵¹ However, Jenny, n. 143 above, 83, is focusing on the markets where the parallel importer is currently active.

¹⁵² However, cf. *ibid.*

imported and exported to/from different Member States with a profit is, in theory, almost endless, the relevant geographic market should be defined as comprising all Member States where the product is benefiting from a marketing authorisation.¹⁵³

2.3 *Dominance*

To be in a dominant position the undertaking must be able to prevent competition and have the ability to behave independently within the above defined 'relevant market.' The EC Treaty does not provide a definition of a 'dominant position' but the ECJ and the Commission have provided vast guidelines. The ECJ has defined a dominant position as relating 'to a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers.'¹⁵⁴ In other words, a dominant undertaking is able to increase prices to an uncompetitive level without losing sales to its competitors so as to make the price rise profitable. There is no single factor which is conclusively indicative of a dominant position. Instead the Commission and the ECJ have identified a number of separate factors which are cumulatively indicative of a dominant position.¹⁵⁵ These include the size of the undertaking's market share, the product substitutability, barriers to entry and buyer power.

The size of the undertaking's market share becomes relevant if the relevant market is limited to products within the same ATC group marketed on the national market.

¹⁵³ Prices may also fluctuate throughout the Community as a result of patent expirations, changes to national pharmaceutical pricing policies or currency rates, changing the market conditions over time. See Case T-30/89 *Hilti AG v. Commission* [1991] E.C.R. II-1439, where the relevant geographical market was defined as the entire Community by the CFI, due to large price differences between Member States and low transportation costs making parallel importation likely.

¹⁵⁴ See Case 85/76, n. 130 above, para. 38.

¹⁵⁵ However, as the case-law on parallel trade in pharmaceutical products and Article 82 EC Treaty is limited to *AstraZeneca*, n. 126 above, and Case C-53/03, n. 6 above; most cases concerning dominance within the pharmaceutical sector have been decided under Council Regulation (EC) 139/2004 on the control of concentrations between undertakings [the EC Merger Control Regulation] [2004] O.J. L204/01.

Evidence of a large market share, over 50%, can be indicative of a dominant position, but the significance of a large market share varies depending on the market structure and is not conclusive if viewed independently of other factors.¹⁵⁶ The market share is likely to depend on whether the product is a ‘first mover,’ i.e. still patent protected and recently commercialised, or an off-patent product subject to competition from a number of generic substitutes.¹⁵⁷ The novelty required for patent protection is indicative of a large market share, indeed as large as 50% or more. As such, the size of the market share is often proportionate to the amount of available substitute products. Off-patent products often face competition from generic substitutes, which may be indicative of a non-dominant position.¹⁵⁸ The barriers to entry into the market are also lower for off-patent products, as the product data is available and patent protection is not longer a barrier to entry. Nevertheless, this analysis may be more applicable to merger cases than to cases concerning parallel imports and Article 82 EC Treaty, as the important question in such a situation is whether the undertaking is able to maintain the uncompetitive price even in the absence of the alleged anti-competitive abuse.¹⁵⁹ The specific market structure of the pharmaceutical market suggests that pharmaceutical manufacturers do not possess such market power. First, entry to the market is strictly controlled by way of marketing authorisations, and pharmaceutical companies can be said to be bound by an ethical duty to continue marketing their products due to the special nature of pharmaceutical products.¹⁶⁰ Secondly, pharmaceutical companies have little or no room for manoeuvre as prices are regulated by national authorities.¹⁶¹ Manufacturers may thus not possess the power

¹⁵⁶ In Case C-62/86 *AKZO BV v. Commission* [1991] E.C.R. 3359, the Court held that a market share of 50% or more is indicative of a dominant position in the absence of exceptional circumstances.

¹⁵⁷ In *AstraZeneca*, n. 126 above, recital 548, the Commission noticed that a ‘first mover’ can often maintain higher prices than later entrants. This is a result of having a large market share, and thus more power to maintain higher prices. See *Fagerlund and Rasmussen*, n. 126 above, 56.

¹⁵⁸ Currently over 50% of the value of the EU market consists of off-patented products, making dominance difficult to establish: see J. Attridge, ‘A single European market for pharmaceuticals: Could less regulation and more negotiation be the answer?’, (2003) *European Business Journal* 122, 132.

¹⁵⁹ *Kerckhove*, n. 142 above, 84.

¹⁶⁰ See Glynn, n. 50 above, 137. See also chapter 5, pp. 148-150 below.

¹⁶¹ G. Robert and S. Ridley, ‘Parallel trade in the pharmaceutical sector: Scourge or benefit,’ (2006) 27 *E.C.L.R.* 91, 94.

to increase prices. In any event, it can be argued that parallel import-restrictive behaviour does not have an impact on pharmaceutical prices, because ‘most, but not all, of the financial benefit accrues to the parallel trader rather than to the health care system or the patient.’¹⁶²

Thirdly, the number of pharmaceutical buyers on the national market is often very limited. Indeed, in some Member States the national health authority is the sole buyer of pharmaceutical products.¹⁶³ This may place pharmaceutical buyers in a monopsonistic position due to their market power and solitude, although this power may be undermined by the inherent demand in pharmaceutical products.¹⁶⁴ As purchasing health authorities’ main aim is to provide the best health service from their available budgets, certain product groups, at the detriment of others, may be favoured at certain times, undermining the manufacturer’s dominant position.¹⁶⁵ Thus, national health authorities’ demand is subject to budgetary constraints, affecting subsequent supply to end-consumers. Glynn therefore rightly observes that ‘the correct way of understanding the situation is likely to be that both the supplier and the customer have dominant positions – a monopsonist facing a monopolist.’¹⁶⁶

Proving dominance on the ‘arbitrage approach’ market may be equally difficult. In theory, the same reasoning applies to this market, but not only to products within the ATC 3 group, but to all products and product groups within the ‘arbitrage approach’ market. It is almost inconceivable that a manufacturer would hold a

¹⁶² See Commission Communication (1998), n. 45 above, 43. See also chapter 1(3.1) above.

¹⁶³ An example is Sweden, where pharmaceutical sales are limited to Apoteket AB (a state monopoly): See chapter 1, p. 26, n. 85 above.

¹⁶⁴ See EFPIA, n. 135 above, 44. However, this argument was rejected by the UK Competition Appeal Tribunal in *Genzyme Ltd. v. The Office of Fair Trading* [2004] C.A.T. 4, on the particular facts of the case. Genzyme asserted that the buyer power of NHS and the Department of Health’s price fixing powers prevented any alleged abuse. The Tribunal held that, even though the NHS is the only purchaser of the drug in question, the fact that there were no substitutable goods on the market meant that the NHS bargaining power is weak in comparison to Genzyme’s monopolistic position (at para. 250). It should, however, be remembered that this case did not concern parallel imports, and was decided on its facts. See also chapter 1, p. 20, n. 59, re: monopsony power.

¹⁶⁵ Glynn, n. 50 above, 135. This is another reason why the ‘relevant market’ should not be limited to a particular ATC group.

¹⁶⁶ *ibid.*, 137.

dominant position within a market comprising all products that can be parallel imported with the same arbitrage profit between two Member States. This analysis is strengthened by the parallel importers' own submission that parallel trade is not necessarily curtailed by refusals to supply or dual-pricing policies.¹⁶⁷

Finally, a number of undertakings can be seen as collectively (or jointly) holding a dominant position on the market.¹⁶⁸ Collective dominance requires tacit coordination between suppliers in an oligopoly that 'would make each member of the dominant oligopoly...consider it possible, economically rational, and hence preferable, to adopt on a lasting basis a common policy on the market...without having to enter into an agreement or resort to a concerted practice...and without any actual or potential competitors, let alone customers or consumers, being able to react effectively.'¹⁶⁹ In order to present themselves as a collective entity the undertakings must have strong economical and structural links.¹⁷⁰ However, in comparison with other sectors, it may prove difficult to show collective dominance in the pharmaceutical sector. The number of suppliers of any given substitutable pharmaceutical product is limited; in many cases (especially during the patent protection period) there is only one supplier of the product. Thus, there may be a very limited economical rationale for engaging in tacit collusion in relation to parallel import-restrictive practices, such as refusal to supply and dual-pricing policies.¹⁷¹ Of course, if the market is defined using the 'arbitrage' approach, it could be possible for suppliers to adopt identical dual-pricing policies for all of their products on all EEA markets. Nevertheless, the difficulty of finding evidence of

¹⁶⁷ See EFPIA, n. 135 above, 33; and Kerchove, n. 142 above, 84. However, cf. EAEPD, n. 143 above, 46-53.

¹⁶⁸ See Case T-342/99 *Airtours plc v. Commission* [2002] E.C.R. II-2585; and the CFI's rejection of the Commission's finding of collective dominance in Joined Cases T-68, 77-78/89 etc. *Societa Italiana Vetro v. Commission* [1992] E.C.R. II-1403.

¹⁶⁹ Case T-342/99, *ibid.*, para. 62. See also S. Baxter and F. Dethmers, 'Collective dominance under EC merger control – after *Airtours* and the introduction of unilateral effects: Is there still a future for collective dominance,' (2006) 27 E.C.L.R. 148, 149-150.

¹⁷⁰ See Joined Cases C-395-396/96 P *Compagnie Maritime Belge Transports SA v. Commission* [2000] E.C.R. 1365.

¹⁷¹ However, see *ibid.*; and Commission Decision 93/82/EEC *Cewal* [1993] O.J. L34/20, in relation to selective price cutting and the granting of loyalty rebates.

economical and structural links between the undertakings¹⁷² so as to show that the undertakings collectively hold a dominant position is further aggravated by the fact that pharmaceutical buyers may be in a monopsonistic position.¹⁷³ In conclusion, the Commission is more likely to apply Article 81 EC Treaty, as collective dominance would be more difficult to prove than concerted behaviour or an agreement.

The above mentioned characteristics of the narrowly defined ATC classification market, and the much wider 'arbitrage approach' market - which is arguably the correct market definition - show the difficulties of proving a dominant position. This is likely to explain why the Commission has historically focused on Article 81 EC Treaty when addressing parallel import-restrictive practices. However, assessing an undertaking's dominant position is only the first hurdle the Commission must overcome, as the issue of proving abuse may be an equally insurmountable task.

2.4 *Abuse*

Article 82 EC Treaty does not prohibit undertakings from holding a dominant position; only the abuse of such a position. To this end, the ECJ has recognised that a dominant undertaking's commercial activity is restricted by its 'special responsibility' brought about by its dominant position, and thus must fulfil certain duties in addition to those of a non-dominant undertaking.¹⁷⁴ In general, abusive behaviour can be divided into two types; exploitative abuses affecting consumers of the dominant undertaking, and exclusionary abuses detrimental to the competitors of the dominant undertaking. Parallel import-restrictive measures generally fall

¹⁷² In Decision No. 05-D-72 of the French Competition Council the referring parties, engaging in parallel trade, contended that the defendant pharmaceutical companies had colluded to restrict their deliveries to other Member States so as to prevent parallel exports. The Competition Council held that 'a simple parallelism of behaviour was not enough to establish the existence of an agreement in the absence of serious, precise and concordant indicators evidencing it.' See A. Glatz and Y. Utzschneider, 'France: Anti-competitive agreements – pharmaceuticals,' (2006) 27 E.C.L.R. N58.

¹⁷³ See Case T-342/99, n. 168 above, para. 62, on buyer power.

¹⁷⁴ See Case 322/81, n. 130 above, para. 57.

under the latter category. This section will discuss the range of abuses aimed at restricting parallel importation, including pricing policies, regulatory abuses, and refusals to supply that may be considered abusive. This will be followed by an analysis of the possibility of an objective justification for such behaviour, as proposed by Advocate General Jacobs in *Syfait*.¹⁷⁵

2.4.1 Pricing policies

Article 82(c) EC Treaty explicitly prohibits dominant undertakings from ‘applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage.’ Dual pricing schemes, charging one price for products intended for the domestic market and another price for products intended for the export market, may fall within this prohibition. As discussed above in relation to Article 81 EC Treaty, such measures are clearly intended to restrict parallel exports by discouraging trade between low-price and high-price Member States.¹⁷⁶ This means that, hypothetically, the Commission could have instigated infringement proceedings under Article 82 EC instead of Article 81 EC Treaty against GlaxoWellcome and Organon in response to the undertakings’ respective dual pricing policies, had the Commission been able to establish dominance.¹⁷⁷ Indeed, the EAEPC has recently filed a complaint with the Commission alleging that Pfizer is in breach of Article 82 EC Treaty by implementing a rebate system in Spain, effectively amounting to a dual-pricing regime.¹⁷⁸

There is limited guidance from the Commission and the ECJ on discriminatory pricing in relation to parallel exports and Article 82 EC Treaty. Rebates and similar practices that have the effect of restricting exports are prohibited by Article 82 EC

¹⁷⁵ N. 6 above.

¹⁷⁶ See section 1.2 above: in particular *GlaxoWellcome* and Case T-168/01, n. 5 above; and *Organon*, n. 28 above.

¹⁷⁷ *ibid.*

¹⁷⁸ See EAEPC, ‘Pfizer,’ n. 53 above: EAEPC also claims that this behaviour is prohibited by Article 81 EC Treaty.

Treaty,¹⁷⁹ as are measures discriminating between customers active within the same Member State, or indeed different Member States.¹⁸⁰ Similarly, charging excessive prices in an effort to impede parallel exports and imports has been held to violate Article 82 EC Treaty.¹⁸¹ Article 82(c) EC Treaty may arguably not apply to geographical discriminatory pricing if the customers are not acting within the same geographical market in the absence of a specific prohibition on parallel exports.¹⁸² However, the pricing scheme applied by Pfizer does discriminate between customers on the same geographical market as the price is determined according to the destination of the product.¹⁸³ Nevertheless, unlike in *United Brands*,¹⁸⁴ the pricing scheme set up by Pfizer is not intended to maintain the price differences between Member States as prices are set by national authorities (and thus it is not in the manufacturers' power to do so); but to restrict parallel exports.¹⁸⁵ However, if the undertaking can point to an objective justification for its conduct, and it is proportionate, the conduct may potentially be exempt from the Article 82 EC Treaty prohibition.¹⁸⁶ This is supported by the CFI's judgment in *GlaxoWellcome*, where the Court considered dual-pricing agreements to be potentially eligible for exemption under Article 81(3) EC Treaty due to the specific nature of the pharmaceutical market.¹⁸⁷ The objective justifications given by Advocate General

¹⁷⁹ See Case T-65/89 *BPB Industries plc & British Gypsum v. Commission* [1993] E.C.R. II-389; and Case T-228/97 *Irish Sugar plc. v. Commission* [1999] E.C.R. II-2969, where the CFI upheld the Commission's Decision that Irish Sugar's 'border rebates,' which were implemented in order to restrict importation of sugar from Northern Ireland, constituted an abuse of a dominant position under Article 82 EC Treaty. See H-G. Kamann and E. Bergmann, 'The granting of rebates by market dominant undertakings under Article 82 of the EC Treaty,' (2005) 26 E.C.L.R. 83, 88.

¹⁸⁰ See Case T-83/91 *Tetra Pak International SA v. Commission* [1994] E.C.R. II-755; and Case 27/76, n. 95 above. However, there is no per se prohibition of price discrimination. See Whish, n. 1 above, 659.

¹⁸¹ See Commission Decision 84/379 *British Leyland* [1984] O.J. L207/11, recital 29; and Case 226/84 *British Leyland Plc. v. Commission* [1986] E.C.R. 3263.

¹⁸² Case 27/76, n. 95 above. The geographic price discrimination was intensified by the export/import prohibition. See D. Gerardin and N. Petit, 'Price discrimination under EC competition law: The need for a case-by-case approach,' GCLC Working Paper 07/05, The Global Competition Law Centre Brugge, GCLC Working Paper (7 May 2005), p. 44.

¹⁸³ See n. 53 above.

¹⁸⁴ N. 95 above.

¹⁸⁵ N. 53 above.

¹⁸⁶ In the absence of an equivalent to Article 81(3) EC Treaty, the Court has developed a doctrine of objective justification: see e.g. *ibid.* For a discussion: see P. Craig and G. de Burca, *EU law: Text, cases, and materials*, 2nd ed., (Oxford: Oxford University Press, 1998), 975-976.

¹⁸⁷ Case T-168/01, n. 5 above. See pp. 39-42 above for further discussion.

Jacobs in his Opinion in *Syfait*¹⁸⁸ are, in theory, equably applicable to dual-pricing regimes and refusals to supply. This reasoning will be further discussed in section 2.5 below.

2.4.2 *Refusals to supply*

A more direct way of restricting parallel imports is to refuse to supply parallel importers on the exporting market. *Syfait*¹⁸⁹ concerned pharmaceutical products manufactured and sold by GlaxoSmithKline on the Greek market. The facts of the case were as follows. As a consequence of discovering that a large amount of the products on the Greek market were parallel exported, GlaxoSmithKline stopped meeting orders from distributors and started supplying pharmacies and hospitals directly. Subsequently, as a response to an interim decision by the Hellenic Competition Commission, GlaxoSmithKline reinstated supplies to the distributors but limited supplies to the amount necessary to satisfy national demand. GlaxoSmithKline admitted that the practice was implemented in order to restrict parallel imports, but argued that its unilateral action could be objectively justified with reference to the specific circumstances of the pharmaceutical market. Although Advocate General Jacobs delivered an Opinion¹⁹⁰ which has since been the source of much debate, the referral provides little guidance as the ECJ failed to answer the questions due to the inadmissibility of the Hellenic Competition Commission reference. This section will discuss the actual (alleged) abuse, focusing on the question whether a refusal to supply in order to restrict parallel exports is a per se abuse, whilst the objective justification argument, as proposed by Advocate General Jacobs, will be discussed separately in the next section.

In general, an undertaking is free to decide which third parties it wants to deal with, and conversely, which parties it does not want to deal with.¹⁹¹ From this outset, the

¹⁸⁸ N. 6 above.

¹⁸⁹ *ibid.*

¹⁹⁰ *ibid.*

¹⁹¹ Case 210/81 *Demo-Studio Schmidt v. Commission* [1983] E.C.J. 3045.

CFI was correct to state that ‘even an undertaking in a dominant position may, in certain cases, refuse to sell or change its supply or delivery policy without falling under the prohibition laid down in Article [82].’¹⁹² However, the notion that dominant undertakings are in general free to decide over commercial decisions when pursuing a profit maximising strategy, is subject to certain restrictions.¹⁹³ In *United Brands* the ECJ made it clear that an undertaking ‘cannot stop supplying a long-standing customer who abides by regular commercial practice, if the orders placed by that customer are in no way out of the ordinary.’¹⁹⁴ The Court added that such refusal must have the possible consequence of eliminating a trading party from the relevant market,¹⁹⁵ although this does not prevent a dominant undertaking from prioritising long-standing customers over occasional customers in times of scarcity of supply.¹⁹⁶ A refusal to supply would therefore only be an abuse of a dominant position where the customer has suffered a competitive disadvantage, or is placed at the risk of elimination.¹⁹⁷ In terms of existing competitors, a dominant undertaking is not allowed to abuse its dominant position by limiting the output of competitors.¹⁹⁸ In this context, however, it should be remembered that the aim of competition law is to protect competition and consumers, not necessarily competitors.¹⁹⁹ An undertaking is therefore not under an obligation to subsidise competition to itself by supplying an existing competitor. If the refusal to supply is proportionate to the harm suffered by the competitor, and the dominant undertaking has given reasonable notice to the customer, a refusal to supply will not be considered abusive.²⁰⁰

¹⁹² Case T-41/96, n. 4 above, para. 180.

¹⁹³ See Case 27/76, n. 95 above, para. 189. For a good discussion on refusals to supply, see R. Subiotto and R. O’Donoghue, ‘Defining the scope of the duty of dominant firms to deal with existing customers under Article 82 EC,’ (2003) 24 E.C.L.R. 683.

¹⁹⁴ *ibid.*, para. 182.

¹⁹⁵ *ibid.*, para. 183.

¹⁹⁶ Case 77/77 *BP BV v. Commission* [1978] E.C.R. 1513, para. 32. It may also be objectively justifiable for a dominant undertaking to terminate supplies if it is a direct response to internal reorganisation: para. 28. See Subiotto and O’Donoghue, n. 193 above, 685.

¹⁹⁷ Case 77/77, *ibid.*, para. 32

¹⁹⁸ Joined Cases 6-7/73 *Commercial Solvents v. Commission* [1974] E.C.R. 223.

¹⁹⁹ N. 1 above. See also Subiotto and O’Donoghue, n. 193 above, 684.

²⁰⁰ See Commission Decision 87/500/EEC *BBI/Boosey & Hawkes* [1987] O.J. L286/36. Boosey & Hawkes stopped supplying a customer who had changed its main activity to that of the promotion of a rival brand. The Commission held that in principle there is no obligation on a dominant

The situation is slightly different in respect of refusing to supply a new customer. A dominant undertaking, as mentioned above, is under no obligation to enter into contract with a third party against its will. As such, a potential customer cannot demand to be supplied by the dominant undertaking. In *Commercial Solvents*,²⁰¹ one of the earliest cases on refusals to supply, the ECJ laid down the basis for what has come to be known as the ‘essential-facilities’ doctrine. *Commercial Solvents*²⁰² concerned a refusal to supply an existing customer with an indispensable raw material, effectively eliminating all competition on the downstream market. This doctrine is equally applicable to existing and new customers, effectively establishing a system whereby access to essential facilities can be achieved by invoking competition law. The facility must have ‘no real or potential substitutes’ in order to be classified as an ‘essential facility,’ thus precluding competitors from demanding access to the facility on grounds of suitability or mere economic convenience.²⁰³ Secondly, the relevant market for the purpose of the application of the doctrine is not the market for the ‘essential facility,’ but the downstream market for which the facility is indispensable. For example, in *Sea Containers Ltd/Stena Sealink*²⁰⁴ the requesting party did not intend to set itself up as a port facilities provider, but wished to provide ferry services on the downstream market for which the port facilities were seen as an ‘essential facility.’

Applying these findings to the parallel trade sector shows the complexities of the doctrine. By way of illustration, *AstraZeneca*²⁰⁵ concerned the marketing authorisations pharmaceutical manufacturers must possess in order to market their

undertaking to subsidise competition to itself. In *Filtrona/Tabacalera* the Commission held that vertical integration without an anticompetitive purpose is not in itself an abuse. Increasing production of its own requirements, so as to achieve economies of scale is not an abuse of a dominant position even though a refusal to supply existing customers may be an unavoidable consequence: see Commission ‘Nineteenth Report on Competition Policy,’ (1989), point 61; and EFPIA, n. 135 above, 54.

²⁰¹ N. 198 above.

²⁰² *ibid.*

²⁰³ Case C-7/97 *Oscar Brönnner GmbH v. Mediaprint GmbH* [1998] E.C.R. 7791. See Whish, n. 1 above, 611-613, for discussion.

²⁰⁴ See Commission Decision 94/19/EC *Sea Containers Ltd/Stena Sealink* [1994] O.J. L15/8.

²⁰⁵ N. 126 above. See chapter 4, p. 130 below for further discussion.

products within the EC.²⁰⁶ Parallel importers must also apply for a marketing authorisation, but can benefit from a simplified procedure whereby a parallel import licence (PIL) is granted on the back of the manufacturer's marketing authorisation.²⁰⁷ The Commission held that AstraZeneca's withdrawal of its marketing authorisation for Losec, upon obtaining a marketing authorisation for a new variation of the product, constituted an abuse of a dominant position because it was intended to prevent or delay entry of generic and parallel imported products to the concerned Member State markets.²⁰⁸ First, it may be argued that the Commission's reasoning in *AstraZeneca*²⁰⁹ shares similarities with the case-law on 'essential facilities.'²¹⁰ AstraZeneca abused its position not by refusing to supply the actual products, but by (in effect) refusing to supply the national authorities with information needed in order to grant PILs. This was a refusal to licence rather than supply.²¹¹ However, the essential facilities doctrine can only apply if such refusal to

²⁰⁶ See chapter 3 below for further discussion of marketing authorisations.

²⁰⁷ See chapter 4 below.

²⁰⁸ See *AstraZeneca*, n. 126 above, recitals 860-862; and Press release IP/05737, n. 126 above. Further, apart from this the second infringement, the Commission alleged that AstraZeneca had misused the patent system by giving false information so as to obtain an extra period of patent protection; (recital 773-776). It is conceivable that the Commission was inspired by the US antitrust authority's focus on alleged attempts at preventing or delaying generic entry. See M. Kerckhove, 'The application of Article 82 EC Treaty to the pharmaceutical sector – some recent EC guidance,' (2006) *The European Antitrust Review* 5, 6. See also Commission Decision 93/554/EEC *Zera-Agrachemikalien* [1993] O.J. L272/28 (abusing national marketing requirements so as to prevent parallel importation of agro-chemicals was considered a violation of Article 81 EC Treaty: note; was decided on the particular facts of the case).

²⁰⁹ *ibid.*

²¹⁰ See Case C-7/97, n. 203 above; and in particular Cases C-241-242/91 P *RTE & ITP (Magill) v. Commission* [1995] E.C.R. I-743. The marketing authorisation, which is a prerequisite for the granting of a PIL, can be compared with the data information at issue in *Magill*. See S. Lawrance and P. Treacy, 'The Commission's AstraZeneca decision: Delaying generic entry is an abuse of a dominant position,' (2005) 1 J.I.P.L.P. 7, 8.

²¹¹ A distinction can be made between this case and Case 226/84 (*Leyland*), n. 181 above, where the ECJ upheld the Commission's definition of the market as that of issuance of certificates needed for importation into the UK; (para. 4-5). The difference between such certificates and marketing authorisations for pharmaceutical products is that secondary certificates are issued (and charged for) by the car manufacturer, whilst a secondary marketing authorisation, a PIL, is granted by the national Medicines Control Agency. Thus, in the Commission's view, AstraZeneca abused its position by indirectly preventing access to the national market of its products by withdrawing the marketing authorisation, whilst the certificates at issue in *Leyland* were seen as a product in itself. Such certificates could possibly be seen as an 'essential facility' for the downstream market of marketing Leyland cars. However, as the relevant market in *AstraZeneca* was defined as proton pump inhibitors (i.e. the actual products) the 'essential facilities' doctrine did not apply as there is not a downstream market: see Fagerlund and Rasmussen, n. 126 above, 56.

supply will result in the elimination of all competition on the downstream market,²¹² which is not necessarily the case in relation to refusal to supply parallel importers. First, a parallel imported product is arguably not a new product, and parallel importation may not amount to an ancillary market but is only a form of trade in the same product. Secondly, a valid marketing authorisation may not be indispensable to carrying on business so as to be classified as an ‘essential facility,’ as, depending on the definition of the relevant market, there are actual and potential substitutes.²¹³ If the relevant market is defined using the ‘arbitrage approach’ (i.e. parallel imported products) there will be many substitutes in the form of products with similar price differentials, and if the relevant market is defined using the ‘ATC classification approach’ the potential substitutes will be newly developed products (replacing the withdrawn product on the particular market) for which a marketing authorisation and subsequently a PIL can be applied for. It can therefore be argued that the Commission introduced a new form of abuse of a dominant position with its decision in *AstraZeneca*.²¹⁴

After considering the facts of *AstraZeneca*,²¹⁵ and the reasoning in the preceding paragraph, it seems clear that *Syfait*²¹⁶ is not an ‘essential facilities’ case. GlaxoSmithKline was not keeping the products for internal use, and was not refusing to supply wholesalers who supplied the Greek market.²¹⁷ Thus, a refusal to supply did not eliminate all competition on the Greek market. Further, there are many substitutes to be traded by the parallel importer if the market is defined using

²¹² Case C-418/01 *IMS Health GmbH v. NDS Health GmbH* [2004] E.C.R. 5039.

²¹³ Lawrance and Treacy, n. 210 above, 9.

²¹⁴ See *ibid.*, 8. Due to recent case-law and changes to the Community’s pharmaceutical framework, it may well be the first and the last time the Commission will face similar facts. See *AstraZeneca*, n. 126 above, recital 847; and chapter 4(3) below. Nevertheless, *AstraZeneca*’s appeal is eagerly awaited by commentators.

²¹⁵ N. 126 above.

²¹⁶ N. 6 above.

²¹⁷ However, the fact that the refusal affects existing as well as new trading partners (distributors) would not preclude the application of the ‘essential facilities’ doctrine. See Case 6-7/73, n. 198 above.

the ‘arbitrage approach.’²¹⁸ Secondly, as elaborated upon in relation to *AstraZeneca*,²¹⁹ it is debatable whether parallel trade is a downstream market. Even if the market is as narrowly defined as one particular product manufactured and supplied by GlaxoSmithKline, the parallel trade in this product would not be an ancillary or downstream market, as both parties are acting in the same market – the supply of product X.²²⁰ Thus, parallel trade does not give rise to an ancillary product market, and does not give rise to added value, regardless of the market definition.²²¹

If the ‘essential facilities’ doctrine does not apply, the second question is whether a refusal to supply in order to restrict parallel imports is a *per se* abuse. Advocate General Jacobs is of the view that a ‘dominant pharmaceutical undertaking will not necessarily abuse its dominant position by reason of its refusal to supply in full the orders placed with it by pharmaceutical wholesalers even when its intention is thereby to limit parallel trade.’²²² This analysis follows a rather detailed survey of the case-law on refusals to supply,²²³ focusing on *United Brands*,²²⁴ *Commercial Solvents*,²²⁵ and the most important ‘essential facility’ cases.²²⁶ These cases, however, did not refer to a foreclosure of national markets. The ECJ has held

²¹⁸ Case C-7/97, n. 203 above. See also Case 1873/98 *Difar v. MSD Spain* (see EFPIA, n. 135 above, 68) where the Spanish Competition Service held that the refusal could not be an abuse since Difar could purchase products from other distributors.

²¹⁹ N. 126 above.

²²⁰ EAEPC’s argument that the importing market will qualify as a ‘downstream geographic market’ for the purpose of the ‘essential facility’ doctrine is misleading. That would mean that the ‘essential facility’ doctrine would apply as long as the products are traded between two Member States. The downstream market must be a different product market; not merely a different geographical market: see EAEPC, n. 143 above, 55.

²²¹ Temple Lang states that there must be ‘scope for substantial non-price competition on the [downstream] market, that is, it is not merely simple resale or distribution of products or services, and a refusal to contract would prejudice consumers,’ in T. Lang, ‘International antitrust law & policy,’ in Hawk (ed.) (2003) *Fordham Corp. L. Inst.*, p. 270. Referred to in C. Koenig and C. Engelmann, ‘Parallel trade restrictions in the pharmaceuticals sector on the test stand of Article 82 EC – Commentary on the Opinion of Advocate General Jacobs in the case Syfait/GlaxoSmithKline,’ (2005) 26 E.C.L.R. 338, 339.

²²² Advocate General Jacobs, n. 6 above, para. 53

²²³ *ibid.*, paras. 54-69.

²²⁴ N. 95 above.

²²⁵ N. 198 above.

²²⁶ Case C-7/97, n. 203 above; Case 311/84 *Telemarketing (CBEM) v. CLT & IPB* [1985] E.C.R. 3261; Case 238/87 *Volvo AB v. Erik Veng Ltd.* [1988] E.C.R. 6211; Cases C-241-242/91, n. 210 above; and Case 418/01, n. 212 above.

measures by a dominating undertaking, intended to prevent imports and exports, to be incompatible with Article 82 EC Treaty. In *British Leyland*²²⁷ and *United Brands*²²⁸ the ECJ focused on the intention to foreclose national markets, and in *AAMS*²²⁹ the Court held as abusive measures that were aimed at restricting imports of cigarettes.²³⁰ However, *British Leyland*,²³¹ *AAMS*,²³² and even *AstraZeneca*,²³³ concerned measures directly aimed at preventing/restricting parallel imports, whilst GlaxoSmithKline did not actively prevent or restrict parallel imports, but merely stopped facilitating such trade by refusing to supply. Further, the measure at issue in *United Brands*²³⁴ threatened to force the distributor out of business altogether. It should also be remembered that in the same case the ECJ stated that a dominant undertaking ‘cannot stop supplying a long-standing customer who abides by regular commercial practice, if the orders placed by that customer are in no way out of the ordinary.’²³⁵ It is unclear exactly what type of reaction would have been considered proportionate, but the Court’s reasoning can be interpreted as implying that a refusal to supply, or as in *Syfait* only supplying a ‘reasonable amount,’²³⁶ may be a proportionate response if the orders placed are out of the ordinary.²³⁷ It is also clear that a dominant undertaking ‘must be conceded the right to take such reasonable steps as it deems appropriate to protect its said interests,’²³⁸ although such behaviour cannot be deemed justified if its actual purpose is to strengthen and abuse the undertaking’s dominant position. Advocate General Jacobs therefore correctly admits that an ‘intention to limit parallel trade should be one of the circumstances which will ordinarily render abusive a refusal to supply on the part of a dominant

²²⁷ N. 181 above.

²²⁸ N. 95 above.

²²⁹ Case T-139/98 *AAMS v. Commission* [2001] E.C.R. 3413.

²³⁰ The Commission found that AAMS had unilaterally refused to authorise increases in imports of cigarettes, and had engaged in various activities aimed at increasing sales of domestic cigarettes and to limiting sales of foreign cigarettes. See EUF (ed.), ‘Court upholds fine on Italian cigarette distribution monopoly,’ (2001) 90 E.U.F 10.

²³¹ N. 181 above.

²³² N. 230 above.

²³³ N. 126 above.

²³⁴ N. 95 above.

²³⁵ *ibid.*, para. 182.

²³⁶ Satisfying domestic demand and the public service obligation. See Advocate General Jacobs, n. 6 above, para. 17.

²³⁷ Craig and de Burca, n. 186 above, 960.

²³⁸ Case 27/76, n. 95 above, para. 189.

undertaking.²³⁹ Thus, a refusal to supply with the intention of restricting parallel imports is not in all cases abusive. Even though an intention to prevent parallel imports is present, ‘the partitioning of the market is not the primary intent, but rather an inevitable consequence, given the characteristics of the market, of the attempt by [GlaxoSmithKline] to protect what it sees as its legitimate commercial interest, by refusing to meet in full the orders which it receives.’²⁴⁰ If such conduct were a *per se* abuse all customers could declare an intention to export in the sole interest of receiving all additional quantities requested. This would arguably be detrimental to legal certainty, and could potentially be exploited by parallel importers to the detriment of public health and safety if the national market does not receive adequate supplies.²⁴¹

A refusal to supply with the intention of restricting parallel imports is therefore not necessarily a *per se* abuse. If the measure is under the circumstances proportionate, given that the orders placed by the parallel importer are out of the ordinary, a refusal to supply may not be abusive and thus not incompatible with Article 82 EC Treaty in line with *United Brands*.²⁴² However, as Advocate General Jacobs observes, ‘in any event....it is clear that the Community case-law provides dominant undertakings with the possibility of demonstrating an objective justification for their conduct, even if it is *prima facie* an abuse.’²⁴³

2.5 *Objective justification*

Indeed, most abuses intended to restrict parallel imports may not be objectively justified. The Commission believes that parallel trade is essential to the EC Treaty objective of market integration. This may hold true for parallel trade in general, but the European pharmaceutical market operates under very particular conditions on a market which is already distorted and thus not affected by anti-competitive

²³⁹ Advocate General Jacobs, n. 6 above, para. 70.

²⁴⁰ *ibid.*, para. 71.

²⁴¹ Subiotto and O’Donoghue, n. 193 above, 692.

²⁴² N. 95 above, para. 182.

²⁴³ Advocate General Jacobs, n. 6 above, para. 72.

measures. Further, the same arguments may not only make the abuse objectively justified, but deem the conduct under the circumstances proportionate to the effects on competition so as to make it non-abusive.²⁴⁴ To this end, Advocate General Jacobs identifies three factors which cumulatively justify refusals to supply in order to restrict parallel imports; (i) the regulation of price and distribution in the European pharmaceutical sector, (ii) the economics of the innovative pharmaceutical industry, and (iii) the consequences of parallel trade for consumers and purchasers in the Member State of importation.

The pharmaceutical market is subject to extensive price regulation giving rise to substantial price differences throughout the Community. Prices are set by national authorities and are not the result of market forces or commercial strategy on behalf of the manufacturer.²⁴⁵ As a result, manufacturers are not attempting to maintain price differentials of their own making when refusing to supply parallel importers, but are merely trying to avoid the economic consequences which would follow if the low prices prevailing in the exporting Member State were to be 'generalised across the Community.'²⁴⁶ Member States and Community measures also impose stringent public service obligations on manufacturers and wholesalers which require wholesalers to maintain an adequate supply to meet domestic demand.²⁴⁷ As a result, Advocate General Jacobs believes that manufacturers may have difficulty maintaining a sufficient stock of products in the domestic market if required to supply parallel importers with excessive supplies of products aimed for exports.²⁴⁸ The situation is further aggravated by the fact that manufacturers can be said to have an ethical and moral, albeit not legal, obligation to maintain supply in each Member State, and are thus restricted from mitigating losses incurred on the importing market by withdrawing from low-price Member States acting as

²⁴⁴ Case 27/76, n. 95 above, para. 182.

²⁴⁵ See chapter 1(2.2) above on the European pharmaceutical market.

²⁴⁶ Advocate General Jacobs, n. 6 above, para. 84.

²⁴⁷ See, in particular, Article 81 of Council Directive 2001/83/EC on the Community code relating to medicinal products for human use [2001] O.J. L311/67.

²⁴⁸ Advocate General Jacobs, n. 6 above, para. 87. Note: this is refuted by Koenig and Engelmann, n. 221 above, 342, claiming that there is no verifiable evidence that parallel trade is preventing manufacturers and wholesalers from fulfilling their supply obligations.

exporting markets.²⁴⁹ Hypothetically, if it were not for this moral obligation and the public service obligations, low-priced Member States would not be supplied at all as the entire stock would be exported by parallel traders.

Advocate General Jacobs continued by considering the economics of the innovative pharmaceutical industry. Advocate General Jacobs gave his approval of Ramsey pricing by considering the pharmaceutical industry to be characterised by large investments in R&D, which are largely sunk costs, while the variable costs are fairly low.²⁵⁰ As discussed in section 1.2 above regarding *GlaxoWellcome*, where the CFI can be interpreted as tacitly approving of Advocate General Jacobs's Opinion,²⁵¹ parallel trade may seriously affect future R&D if manufacturers are not able to recover the sunk costs. Even though the variable costs can be recovered in low-price Member States, the sunk costs can only be recovered by marketing the remaining products in high-price Member States. By, in effect, importing the exporting Member State's pricing policy; parallel trade may have a detrimental effect on future R&D. This is linked to Advocate General Jacobs's discussion on the consequences of parallel trade for consumers and purchasers in the Member State of importation.

Parallel trade in pharmaceutical products does not contribute to price competition beneficial to the end consumer.²⁵² Prices are regulated by national authorities, and consumers do not pay for the full amount of the products. Nor do taxpayers benefit from parallel trade, as pharmacists receive payment for parallel traded products at the same rate as products supplied by the original manufacturer.²⁵³ As a result, the profit from the trade largely remains with the parallel trader and the pharmacists. Given that Member States act as both price regulators and purchasers of pharmaceutical products, 'it cannot be assumed that the sole concern of the

²⁴⁹ See Advocate General Jacobs, n. 6 above, para. 86. See also n. 160 above for further discussion.

²⁵⁰ See n. 52 above; and pp. 41- 42 above, for further discussion.

²⁵¹ Case T-168/01, n. 5 above, para. 271; and *ibid.*

²⁵² Advocate General Jacobs, n. 6 above, para. 97.

²⁵³ *ibid.*, para 98. See also Commission Communication (1998), n. 45 above, para. 4.

purchaser in a high-price Member State is to obtain lower prices.’²⁵⁴ As Advocate General Jacobs observes; if Member States’ main concern is to lower the funds spent on pharmaceutical products, they could have lowered the prices directly instead of promoting parallel trade.²⁵⁵

The arguments in favour of an objective justification, as proposed by Advocate General Jacobs, have been thoroughly analysed and scrutinised by several commentators.²⁵⁶ It is argued that Advocate General Jacobs’s analysis is erroneous as parallel trade actually results in considerable direct and indirect savings for health authorities.²⁵⁷ According to the EAEPC, there is no evidence to show that parallel trade affects future R&D, nor that it has a negative impact on the supply structure.²⁵⁸ However, Advocate General Jacobs’s conclusion is to be endorsed irrespective of these claims and arguments. Competition law serves to protect competition and consumers, not certain competitors.²⁵⁹ Although national health authorities may generate savings from parallel trade, there is no conclusive evidence of end-consumers benefiting from parallel trade. If the aim was to generate savings to the national health authorities there is nothing to prevent a Member State from amending its pricing regulations.²⁶⁰ On the contrary, it is clear that end-consumers suffer no harm from a refusal to supply parallel importers;

²⁵⁴ According to Advocate General Jacobs, n. 6 above, para. 99.

²⁵⁵ *ibid.*: the Hellenic Competition Commission came to the same conclusion: (para. 13).

²⁵⁶ Koenig and Engelmann, n. 221 above; Korah, n. 52 above; D. McCann, ‘Syfait v GlaxoSmithKline: Article 82 and parallel trade of pharmaceutical,’ (2005) 26 E.C.L.R. 373; and Stothers, n. 32 above, 458.

²⁵⁷ See e.g. Koenig and Engelmann, *ibid.*, 345-347. A reference is made to P. West and J. Mahon, ‘Benefits to payer and patients from parallel trade,’ Report, York Health Economics Consortium (May 2003), (<http://www.york.ac.uk/inst/yhec/downloads/ParallelTrade_ExecSumm.pdf>), which reached the conclusion that parallel trade could result in substantial savings to national health authorities. The study’s objectivity must be questioned as it was commissioned by the EAEPC. See Chapter 1(3.1) above for further discussion.

²⁵⁸ EAEPC, n. 143 above, 65. Conversely, see also P. Rey and J. Venit, ‘Parallel trade and pharmaceuticals: A policy in search of itself,’ (2004) 29 E.L.Rev. 153, 177: ‘parallel trade does not appear to be a good way to “harmonise” Member States’ health policies, since it tends to generate a unilateral alignment on the lowest level of R&D incentives.’ See chapter 1(3.1) above for an extended discussion on the benefits of parallel trade.

²⁵⁹ See n. 1 above; and DG Competition discussion paper on the application of Article 82 of the Treaty to exclusionary abuses – public consultation, DG Competition (December 2005), (<<http://ec.europa.eu/comm/competition/antitrust/others/discpaper2005.pdf>>), para. 54: ‘this means that it is competition, and not competitors as such, that is to be protected.’

²⁶⁰ Advocate General Jacobs, n. 6 above, para. 99.

indeed, parallel trade may actually be harmful to consumers' well-being as it may restrict the funds available for future R&D. Therefore, the essential question in *Syfai*²⁶¹ seems to be whether the parallel importer or the manufacturer should be allowed to keep the profits resulting from the price difference between the importing and exporting Member State, rather than one to protect consumers.²⁶² Using Article 82 EC Treaty to protect certain competitors is a misapplication of competition law.²⁶³

Advocate General Jacobs's Opinion must, however, be analysed against the background of the specific facts of the case. Refusing to supply distributors altogether, by for example supplying pharmacists and hospitals directly, may affect distributors not engaging in parallel trade and have a negative impact on the supply structure in the market.²⁶⁴ In this regard, it should be noted that where the refusal to supply is aimed at punishing a customer for its export activities, it cannot be objectively justified.²⁶⁵ Similarly, where the refusal to supply is associated with other abusive conduct, it will not be subject to objective justification; and will, accordingly, be classified as an abuse under Article 82 EC Treaty.²⁶⁶ It is therefore advisable to apply Advocate General Jacobs's Opinion with care in order to preserve legal certainty.

The refusal to supply must not be perceived as an attempt to harm competitors so as to affect competition in the pharmaceutical market, but rather as a proportionate step to protect commercial interests. Implementing supply quotas instead of a total refusal to supply will strengthen this assumption due to its less harmful effects on

²⁶¹ N. 6 above.

²⁶² Subiotto and O'Donoghue, n. 193 above, 690.

²⁶³ See n. 249 above. Cf. Cases 6-7/73, n. 198 above, where the Court signalled its intent to protect the competitor before the consumer.

²⁶⁴ Allegedly, Pfizer is considering a system of direct sales in Germany which would eliminate the need for distributors' altogether. The EAEPC has filed a complaint with the Commission: see EAEPC, 'Pfizer,' n. 53 above.

²⁶⁵ See *Johnson & Johnson*, n. 22 above, and *Tipp-EX*, n. 21 above, in relation to Article 81 EC Treaty.

²⁶⁶ See, e.g., Case T-30/89, n. 153 above, where a refusal to supply was coupled with intent to tie the sales of Hilti nail guns with Hilti nails.

the domestic supply system. Advocate General Jacobs's Opinion must also be limited to the pharmaceutical industry. The suggestion that Advocate General Jacobs's reasoning could have wider implications for other industry sectors (such as the auto trade) that are subject to considerable price differences between Member States due to national tax rates, fails to consider the extent to which the pharmaceutical market is regulated.²⁶⁷ Further, focusing on the consumer benefit aspect (i.e. the industry's reliance on investments in R&D) will justify the special treatment of the pharmaceutical industry and uphold legal certainty. As stated above, competition law protects competition and consumers, and not certain competitors. Instead of arguing that the characteristics of the pharmaceutical industry are capable of being objectively justified, Advocate General Jacobs's reasoning can be drawn upon to show that the special nature of the pharmaceutical market precludes a finding of consumer harm, thus negating a finding of abuse in the first place. Instead of characterising certain abusive behaviour as objectively justified, it is 'more accurate to say that certain types of conduct on the part of a dominant undertaking do not fall within the category of abuse at all,' according to Advocate General Jacobs.²⁶⁸ This approach is also proposed by the Commission in a recent DG Competition Discussion paper on the application of Article 82 EC Treaty to exclusionary abuses.²⁶⁹ The Commission proposes the introduction of an Article 81(3) EC Treaty-type mechanism to Article 82 EC Treaty. There are two types of objective justification relevant to parallel import-restrictive measures. The proposed 'meeting competition defence' could be relevant to refusals to supply and dual-pricing policies by pharmaceutical companies in order to 'minimise the short run losses resulting directly from competitors actions,' even though this justification is only proposed to apply to behaviour which otherwise would constitute a pricing abuse.²⁷⁰ In relation to (strict) refusals to supply, the Commission proposes that dominant undertakings should be allowed to exclude others for a period of time in

²⁶⁷ This comparison is made in Koenig and Engelmann, n. 221 above, p. 342. See e.g. Case T-62/98 *Volkswagen AG v. Commission* [2000] E.C.R. II-2707.

²⁶⁸ Advocate General Jacobs, n. 6 above, para. 72.

²⁶⁹ DG Competition, n. 259 above.

²⁷⁰ *ibid.*, para. 81.

order to recoup an adequate return on their investments.²⁷¹ If this justification would apply not only to ‘refusal to start supplying an input,’ but also to ‘termination of an existing supply relationship,’²⁷² it could justify conduct similar to that at issue in *Syfait*.²⁷³

In conclusion it can be said that Advocate General Jacobs’s Opinion, contrary to previous case-law²⁷⁴ and Commission Decisions,²⁷⁵ shows a willingness to consider the specific characteristics of the pharmaceutical market. It was unfortunate that the ECJ failed to consider these arguments due to the inadmissibility of the Hellenic Competition Commission’s reference.²⁷⁶ However, despite the absence of clear guidance from the ECJ, the Hellenic Competition Commission decided to follow the Opinion of Advocate General Jacobs and ruled in September 2006 that GlaxoSmithKline did not infringe Greek competition laws or Article 82 EC Treaty by its refusal to meet fully the orders sent to it by pharmaceutical distributors.²⁷⁷ Similarly, as discussed in section 1.2 above, the CFI tacitly endorsed Advocate General Jacobs’s Opinion by taking the specific nature of the pharmaceutical market into consideration in *GlaxoWellcome*.²⁷⁸ Advocate General Jacobs’s Opinion should therefore not be underestimated as a valuable guideline and food for thought for the Commission and the Community courts in relation to future decisions and referrals. The Commission and the ECJ must recognise that pharmaceutical markets are of a national and not of a Community

²⁷¹ DG Competition, n. 259 above, para. 235.

²⁷² *ibid.*, paras. 207 and 225.

²⁷³ N. 6 above.

²⁷⁴ See e.g. Cases C-267-268/95, n. 37 above.

²⁷⁵ For example, *GlaxoWellcome*, n. 5 above.

²⁷⁶ Case C-53/03, n. 6 above, para. 37.

²⁷⁷ See Hellenic Competition Commission Decision 318/V/2006 (unreported: delivered on 5 September 2006); and Hellenic Competition Commission press release (5 September 2006) (<http://www.epant.gr/Photos/20060905_pressrelease_glaxo.pdf>). See also C. Seib, ‘GSK hails judgment as blow to parallel trading,’ *The Times*, 6 September 2006, p. 52. Incidentally, see Case T-153/06 *EAEP v. Commission* [2006] O.J. C178/38 (pending before the CFI) seeking the annulment of Commission Decision D/201953 (10 April 2006), rejecting three complaints of the EAEP against GlaxoSmithKline for the reason that the Hellenic Competition Commission is already dealing with the case (which resulted in Decision 318/V/2006 above).

²⁷⁸ Case T-168/01, n. 5 above. See also section 1.2 above.

dimension as a first step to prompt a Community-wide harmonisation of national regulations.²⁷⁹

3. Conclusion

The *Bayer*²⁸⁰ and *GlaxoWellcome*²⁸¹ judgments were welcomed by pharmaceutical manufacturers, having long suffered from the pro-integration policy adopted by the Commission and the ECJ to the benefit of parallel importers. This will be even more evident following the discussion of parallel trade and the free movement of goods provisions in chapter 5.

First, and foremost, *Bayer*²⁸² signalled a change in the Court's approach to parallel import-restrictive measures. Mere unilateral decisions are not prohibited by Article 81 EC Treaty, and its application cannot be justified by the Treaty objective of market integration, as restricting parallel imports is not a per se violation of Article 81 EC Treaty. Manufacturers must, however, apply the Court's findings with care. Unilateral decisions to restrict parallel imports may still be prohibited by Article 81 EC Treaty if the manufacturer has entered into a selective distribution agreement with the distributor. The manufacturer should also refrain from making its intentions clear to the distributor and avoid any attempts at monitoring and tracing parallel exported goods back through the distribution chain as this may be interpreted as a means to enforce the export/resale ban. Ironically, manufacturers may benefit from a dishonest relationship with distributors as any attempt by a distributor to circumvent the ban may be seen as evidence of the unilateral nature of the decision, to the detriment of the distributor.

Further, certain dual-pricing agreements may be capable of benefiting from an Article 81(3) EC Treaty exemption despite having a parallel import-restrictive

²⁷⁹ See C. Vicien, 'Why parallel imports of pharmaceutical products should be forbidden,' (1996) 17 E.C.L.R. 219, 224.

²⁸⁰ Cases C-2-3/01, n. 4 above.

²⁸¹ Case T-168/01, n. 5 above.

²⁸² Cases C-2-3/01, n. 4 above.

effect. Such agreements may remedy a loss in efficiency, as well as providing a gain in efficiency by allowing for an increase in funds made available by the pharmaceutical company for future R&D. The Commission may therefore find it increasingly difficult to apply Article 81 EC Treaty to parallel import-restrictive agreements following *GlaxoWellcome*.²⁸³ Coincidentally, the EAEPD has filed a complaint with the Commission alleging that Pfizer's dual-pricing system in Spain is incompatible with Articles 81 and/or 82 EC Treaty.²⁸⁴ The outcome of the Commission's re-examination of GlaxoWellcome's request for an exemption, or, if appealed, the ECJ's judgment, is therefore eagerly waited for by commentators.

It is likely that the CFI was influenced by Advocate General Jacobs's Opinion in *Syfait*²⁸⁵ when giving judgment in *GlaxoWellcome*.²⁸⁶ Advocate General Jacobs argued that the special characteristics of the European pharmaceutical market provide an objective justification from Article 82 EC Treaty for parallel import-restrictive measures. The Opinion should be endorsed and national and Community courts should follow the example set to them by the Hellenic Competition Commission²⁸⁷ and the CFI in *GlaxoWellcome*,²⁸⁸ and follow Advocate General Jacobs's Opinion as its substance was not rejected by the ECJ. Unfortunately, however, the issue of dominance was not considered by the Advocate General or the ECJ in *Syfait*.²⁸⁹ Nevertheless, it is likely that the Commission will have difficulties in proving a dominant position on behalf of the manufacturer in relation to parallel import-restrictive measures, as the relevant market must be defined using the 'arbitrage approach' method giving rise to a very wide market definition. This will be further complicated considering the market position of pharmaceutical manufacturers versus national health authorities; a monopolist facing a monopsonist.²⁹⁰

²⁸³ Case C-168/01, n. 5 above.

²⁸⁴ See n. 53 above.

²⁸⁵ N. 6 above.

²⁸⁶ Case C-168/01, n. 5 above.

²⁸⁷ See (Greek) Decision 318/V/2006, n. 277 above.

²⁸⁸ Case C-168/01, n. 5 above.

²⁸⁹ N. 6 above.

²⁹⁰ See section 2.3 above.

This is a great setback for parallel traders, as acquiring products for onward sale is merely the first in a series of hurdles parallel traders must overcome in order to carry out successful cross-border trade. The following chapter will discuss the pharmaceutical market-specific and potentially parallel import-restrictive requirement of marketing authorisations.

MARKETING AUTHORISATIONS AND PARALLEL IMPORT LICENCES

A pharmaceutical product may not be placed on the Community market without a marketing authorisation.¹ This requirement is another hurdle for traders and manufacturers of pharmaceutical products. However, it is part of the 'research and development' (R&D) process, and enables authorities to maintain and record a steady flow of quality drugs being put on the market.

To protect public health and safety and avoid disasters such as the Thalidomide tragedy, pharmaceutical products must be tested and controlled before they can be marketed to the public. Marketing authorisation applications must therefore contain extensive information concerning the particulars of the product as well as test results. As parallel importers do not have access to this information it essentially prevents traders from obtaining marketing authorisation, even though the products imported are already benefiting from the manufacturer's marketing authorisation and, consequently, have already been tested and quality assured.

This chapter will clarify the national and Community measures governing the need to obtain a marketing authorisation. It is important to have a clear understanding of how Community and national measures regulates the marketing stage and safety of

¹ Article 6(1) of Council Directive 2001/83/EC on the Community code relating to medicinal products for human use [2001] O.J. L311/67.

the pharmaceutical industry as this regulatory framework forms the basis of the below discussed simplified procedure for parallel imported products.

1. *National authorisations*

National Medicines Control Agencies grant national marketing authorisations. There are no major differences between regulations adopted by Member States since most of the laws and regulations have been harmonised by Community measures. The UK legal framework will therefore serve as a good example.

The marketing of pharmaceutical products in the UK, exercised by the granting of marketing authorisations and licences, is largely governed by EC measures and the Medicines Act 1968.² The Medicines Act collated most previous legislation and aimed to introduce provisions for the control of medicines. It established a licensing system affecting the manufacture, sale, supply and importation of medicinal products into the UK. The Medicines Act matched or even exceeded the requirements of Directive 65/65/EEC.³ In 1995 the UK medicines legislation was brought into line with EC measures concerning marketing authorisations by 'The Marketing Authorisations Regulations 1994.'⁴ Other aspects of medicine control, such as wholesale dealer's licences and manufacturer's licences, and promotion of pharmaceutical products, are regulated by the Medicines Act 1968 and its secondary legislation, amended so as to conform to Community measures.⁵ The 'Medicines and Healthcare products Regulatory Agency' (MHRA) is responsible

² The Medicines Act 1968, c. 67.

³ Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products [1965] O.J. 22/369. This is quite remarkable since, of course, the UK was not yet a Member State in 1968.

⁴ The Medicines for Human Use (Marketing Authorisation Etc.) Regulations 1994, implementing Council Regulation (EEC) 2309/93 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [1993] L214/1. See also The Medicines for Human Use and Medicinal Devices (Fees and Miscellaneous Amendments) Regulations 2001, implementing Directive 2001/83, n. 1 above.

⁵ *ibid.*; and note 2 above. See also chapter 1(2.1) above on advertising of pharmaceutical products.

for enforcing the Medicines Act 1968, and therefore for granting licences relating to marketing and wholesale distribution of pharmaceuticals.

A marketing authorisation application requires a vast amount of information regarding the product characteristics: inter alia, the qualitative and quantitative composition, clinical particulars, pharmacological properties, pharmaceutical particulars and administrative data. Furthermore, results of clinical trials, and the manufacturing procedure must be extensively described by the applicant and approved by the MHRA. The early stages of development of a new pharmaceutical product are of no interest to the MHRA when assessing applications for marketing authorisations. It is when the applicant commences clinical trials that the safety and efficacy of the pharmaceutical products can be shown. The results of the clinical trials will eventually become part of the marketing authorisation application.

National marketing authorisation procedures have since 1998 been limited to the initial phase of the 'mutual recognition' procedure, i.e. the work undertaken by the reference Member State.⁶ National marketing authorisations can also be used for pharmaceutical products which are only to be authorised in one Member State, and for products with a 'well-established' use under the 'abridged procedure' laid down by Article 10 of Directive 2001/83/EC.⁷ A national marketing authorisation is granted for a period of 5 years after which it must be renewed.

⁶ Commission, 'Notice to Applicants - The Rules governing Medicinal Products in the European Community,' (Volume 2A: Chapter 1) ENTR/F2/BL D(2002) Rev 2, p. 4. The 'mutual recognition' procedure allows for a bundle of national marketing authorisations. The assessment by the reference Member State (the first Member State to grant the marketing authorisation) has to be mutually recognised by other Member State Medicines Control Agencies. See Section 2.2 below

⁷ N. 1 above. The abridged procedure is intended for generic pharmaceutical products. See section 2.3 below.

2. *The Community framework*

The Community has been involved in the pharmaceutical market since the early 1960s.⁸ Directive 65/65/EEC⁹ was the first Community measure concerning the marketing stage of pharmaceutical products. Following the thalidomide disaster, and its gruesome effects that shocked society, the Community and lawmakers were determined to ensure a high level of public security and safety in the pharmaceutical context. The first step was to ensure that no pharmaceutical product is placed on the European market without a marketing authorisation. Directive 65/65/EEC,¹⁰ subsequently amended and replaced by Directive 2001/83/EC,¹¹ defined a 'medicinal product' and subcategories of 'medicinal products.'¹² This term is, for the purpose of the thesis, interchangeable with the term 'pharmaceutical product.' Nevertheless, the harmonised definition of a 'medicinal product' following Directive 65/65/EEC¹³ does not in practice ease the workload for Member State Medicines Control Agencies.¹⁴ The definition is useful to determine whether a product is required to have a marketing authorisation. However, once it is established that the product is in fact a medicinal product, the definition has lost its use. Medicinal products have many shapes, functions, effects, and contain a range of different chemicals and natural compounds. The harmonised definition of 'medicinal products' as products placed on the market under a 'special name,' presented for 'treating or preventing disease in human beings,'¹⁵ does not remove the need to examine each marketing authorisation application in detail. Naturally, the definition of chemical compounds, and what can and cannot be included within a 'medicinal product' limits the definition of a medicinal product. However, once a

⁸ See Commission 'Pharmaceuticals in the European Union' (Brussels: Office for Official Publications of the European Communities, 2000), for a general introduction.

⁹ N. 3 above.

¹⁰ *ibid.*

¹¹ N. 1 above.

¹² *ibid.*, Art. 1.

¹³ N. 3 above.

¹⁴ See Case 227/82 *Criminal proceedings against Bennekom* [1983] E.C.R. 3883, for further discussion of the definition of 'medicinal products.'

¹⁵ Directive 2001/83, n. 1 above, Art. 1.

product has been classified, a thorough examination of its content and safety must be made before a marketing authorisation can be granted.

Almost 20 years later, Council Regulation EEC/2309/93¹⁶ established the 'European Agency for the Evaluation of Medicinal Products' (EMEA).¹⁷ Together with Directive 93/41/EEC¹⁸ the Regulation laid down two new procedures for the authorisation of pharmaceutical products, in order to assure safety and quick access to pharmaceuticals for the public. The two new procedures are the 'centralised' procedure and the 'mutual recognition' procedure (of which the latter draw upon the 'multi-state' procedure from 1975), which will be discussed below.¹⁹

The EMEA was set up in order to grant Community marketing authorisations, and assist the free movement of pharmaceutical products within the Community. Its work was based upon cooperation between Member State Medicines Control Agencies, the EMEA, and various institutions within the EC, for example the Committee for Proprietary Medicinal Products²⁰ and the Pharmaceutical Committee,²¹ as well as the European Commission. In November 2005 the EMEA was officially replaced by the new 'European Medicines Agency' (EMA).²² The new Agency broadly carries on the work of the 'old' EMEA, administering applications for Community marketing authorisations using the centralised procedure, discussed below.

¹⁶ N. 4 above.

¹⁷ See chapter 1, p. 17, n. 34 above; and introduction, p. 7, n. 23 above.

¹⁸ Council Directive 93/41/EEC repealing Directive 87/22/EEC on the approximation of national measures relating to the placing on the national market of high-technology medicinal products, particularly those derived from biotechnology [1993] O.J. L214/40.

¹⁹ See S. Grubb, 'Development of a trans-national European licensing system for pharmaceutical products,' (1992) 3 I.C.C.L.R 77, for a good introduction to the changes brought about by the 1993 legislation, forming the first attempt at creating a centralised and de-centralised procedure.

²⁰ Second Council Directive 75/319/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products [1975] O.J. L147/13 established the Committee for Proprietary Medicinal Products in order to ensure the proper implementation of Directive 65/65, n. 3 above.

²¹ Council Decision 75/320/EEC establishing a Pharmaceutical Committee [1975] O.J. L147/23.

²² Council Regulation (EC) 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] O.J. L136/01, Title V and Art. 90. The acronym EMEA remains. See also n. 17 above.

However, it is not only the marketing stage of pharmaceutical products that must be controlled and regulated. Pharmacovigilance, or the surveillance of the safety of a product during its time on the market, is also regulated by the Community.²³ Directive 75/319/EEC²⁴ and Regulation EEC/2309/93²⁵ required Member States to set up national pharmacovigilance systems to collect and evaluate information in order to assess the possible side-effects and adverse reactions of products on national markets. The 'new' EMEA is responsible for ensuring pharmacovigilance in the Community by issuing guidance notes and cooperating with national Medicines Control Agencies. Pharmacovigilance is indirectly relevant to the validity of marketing authorisations: if marketed products do not fulfil the safety requirements they may be revoked.

Directive 2001/83/EC²⁶ amended the rules relating to the mutual recognition and centralised procedures, and established a third procedure, the 'abridged marketing authorisation' procedure for generic and well-established products. All three procedures must be discussed before the regulations governing the importation of products benefiting from marketing authorisations can be analysed.

2.1 *The 'centralised procedure'*

This procedure is compulsory for all biotechnology products. Under the 2004 legislation the procedure is now also compulsory for all medicines to treat AIDS, cancer, diabetes, neurodegenerative disorders, orphan diseases and, from 2008, auto-immune and viral diseases.²⁷

²³ See C. Hodges, *European regulation of consumer safety*, (Oxford: OUP, 200) p. 138, 142, and Appendix 1, for a good introduction to the concept of pharmacovigilance.

²⁴ N. 20 above.

²⁵ N. 4 above.

²⁶ N. 1 above.

²⁷ Regulation 726/2004, n. 22 above, Annex. See also L. Horton J. Mailly and K. Goecke, 'Prognosis on pharmaceuticals is progress – new legislation on pharmaceuticals that was published in April includes many important changes in the EU legislative framework for regulation of product quality, safety and efficacy,' (2004) 101 *Law Society Gazette* 35, 36.

Applications for marketing authorisations are submitted directly to the EMEA.²⁸ The Committee of Proprietary Medicinal Products (CPMP) evaluates the application and selects a Member State to assess the application. On return, the CPMP evaluates the findings of the Member State Medicines Control Agency (the 'rapporteur') and decides whether or not to grant a marketing authorisation. This process should take no more than 210 days.²⁹ The findings of the CPMP are then forwarded to the EMEA, which, within 30 days, forwards its decision to the Commission which will take the final decision. The decision is binding on all Member States. A centrally authorised Community marketing authorisation remains valid for 5 years, and the authorised product can be marketed in all Member States. Applications for extension must be made to the EMEA three months before the date of expiration of the marketing authorisation.³⁰

Even though obtaining a marketing authorisation through the centralised procedure should be beneficial and time-efficient for pharmaceutical companies, the number of medicinal products approved under the centralised procedure has remained low. In 1995 the Commission approved three medicinal products, reaching the peak in 2001 when 44 medicinal products were granted a centralised Community marketing authorisation. However, in 2003 the Commission only approved 20 applications, rising to 42 in 2004.³¹ Hopefully the numbers will increase in pace with the ongoing harmonisation. However, following the Community enlargement in 2004, existing (national) marketing authorisations in the new Member States that were in conflict with existing Community marketing authorisations, i.e. for the benefit of the same product, have been annexed/transformed to the relevant Community marketing authorisation.³² Further, as the new Member States had to apply the *acquis* by the

²⁸ See Commission Notice, n. 6 above; and Commission Communication on the Community marketing authorisation procedures for medicinal products [1998] O.J. C229/4, for detailed information relating to this sub-heading.

²⁹ Regulation 726/2004, n. 22 above, Art. 6(3).

³⁰ See Commission, 'Pharmaceuticals,' n. 8 above, 11.

³¹ See The Community Register of medicinal products (<<http://pharmacos.europa.org/F2/register/alfregister.htm>>). See also The Swedish Association of the Pharmaceutical Industry (LIF), 'Pharmaceutical market and healthcare,' Fakta (2005), (<<http://www.lif.se/Statistik/stat.asp>>), p. 18.

³² Disputes may arise as to whether the product benefiting from a national marketing authorisation in a new Member State is identical to the product benefiting from the Community marketing

date of accession, Commission Decisions (including Community marketing authorisations) extend automatically to the territory of the new Member States.³³ The effect of this is that national marketing authorisations in the new Member States that do not comply with the safety standards in Directive 2001/83/EC became illegal on the day of accession of the new Member States.³⁴

It has been contested whether a product benefiting from a centrally authorised Community marketing authorisation must be marketed under the same brand name and in the same packaging throughout the Community. In *Thomae* the ECJ was asked to decide whether the notification and upholding of a Community marketing authorisation requires a universal brand name and packaging throughout the Community.³⁵ The ECJ found that the relevant Community measures refer to a singular name, implying that a Community marketing authorisation should only be granted for one brand name.³⁶ Allowing a marketing authorisation holder to use different brand names throughout the Community may lead to segmentation along national borders affecting the free movement of pharmaceutical products within the Community, and thus amount to a measure having equivalent effect to a quantitative restriction under Article 28 EC Treaty, or amount to an abuse of a

authorisation. The products must be considered to be the 'same medicinal product.' See EMEA, 'PERF II Acquis Working Group: Reflection Paper on phasing in issues,' (EMEA-PERF-Acq-1041-02-Final).

³³ See EMEA, 'PERF II Acquis Working Group: Achieving Compliance of Medicinal Products Authorised in CC with the Acquis,' (EMEA-PERF-Acq-1043-02-final), p. 4.

³⁴ However, the 2003 Act of Accession [2003] O.J. L236/33 (see introduction, p. 4, n. 15 above for a full reference), provides for transition periods during which Directive 2001/83 (n. 1 above) do not apply to the following Member States and dates in relation to upgrading of product dossiers: Lithuania – 1st January 2007 (Annex IX, para. 2); Poland – 31st December 2008 (Annex XII, para. 5); Malta – 31st December 2006 (Annex XI, para. 2); and Slovenia – 31 December 2007 (Annex XIII, para. 1). This means that national marketing authorisations for certain pharmaceutical products issued under national law granted prior to accession will remain valid until renewed in compliance with the *acquis*. These marketing authorisations will not benefit from the mutual recognition procedure (discussed below), and can not be parallel imported unless the exporting and importing Member State Medicines Control Agencies certifies that the two products are identical and approves of such importation. See M. Struys, 'Practical implications of EU enlargement,' Allen & Overy publication (January 2004), (<<http://www.allenoverly.com/pdf/EUIP.pdf>>). See also chapter 5(5) below.

³⁵ Case T-123/00 *Thomae GmbH v. Commission* [2002] ECR II-5193. See also Case T-179/00 *A. Menarini Srl v. Commission* [2002] E.C.R. II-2879 (universal packaging); Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted [2003] COM/839/final., para. 3; and chapter 7(3.1) below.

³⁶ Case T-123/00, *ibid.*, para. 63.

dominant position under Article 82 EC Treaty.³⁷ However, the ECJ held that in exceptional circumstances relating to the protection of health and human life, variations to the package layout may be allowed. National laws precluding the use of a particular brand name, which may prevent market access, may be such an exception if necessary for the protection of public health and safety.

*Thomae*³⁸ exemplifies a typical Community problem, namely discrepancy in the Community harmonisation framework. The effectiveness of the centralised procedure is affected by the lack of complete harmonisation in relation to trademarks. The European Federation of Pharmaceutical Industries and Associations (EFPIA) considers it important for the pharmaceutical industry to be allowed to use different brand names in different Member States for the same product, particularly in situations where legal, linguistic or practical complications prevent the use of a universal brand name throughout the Community.³⁹ An argument is that the process of obtaining a trademark available throughout the Community is difficult, costly and time consuming, and may delay the marketing of pharmaceutical products much in demand.⁴⁰

2.1.1 *The Centralised procedure and parallel imports*

Centrally authorised pharmaceuticals distributed in parallel benefit from the Community marketing authorisation granted to the manufacturer, and do not need to apply for a 'parallel import licence' (PIL).⁴¹ This may be done even if the marketing authorisation holder has not yet placed the authorised products on the market.⁴² It is therefore only products benefiting from a national marketing

³⁷ See EMEA, 'Post-authorisation guidance on parallel distribution,' (EMEA/Ho/2368/04/Rev 2), para. 9.

³⁸ N. 35 above.

³⁹ EFPIA 'The single trademark issue – the importance of trade mark rights for medicines,' Position paper (June 2002), (<http://www.efpia.org/4_pos/legal/Trademarks0602.pdf>). See also chapter 6(3), pp. 184-185 below.

⁴⁰ See International Trademark Association (INTA), 'Single trademark requirement,' Position paper (June 2003), (<http://www.inta.org/downloads/tap_singletm2003.pdf>).

⁴¹ PILs are discussed in section 3.2 below.

⁴² See Commission Communication (2003), n. 35 above, for detailed information.

authorisation, issued by a national Medicines Control Agency or using the ‘mutual recognition’ procedure, that need to benefit from a PIL.⁴³ In parallel trade in centrally authorised pharmaceutical products, the marketing authorisation holder remains the same. The marketing authorisation holder is therefore responsible for the pharmaceutical product even when the product is subject to parallel trade. Trade in centrally authorised pharmaceutical products is therefore commonly referred to as ‘parallel distribution.’ A trader is free to distribute the product in any Member State without applying for a PIL – provided the labelling, package leaflet and blue-box have been amended so as to comply with national legislation in the Member State of importation.⁴⁴ However, following *Thomae*,⁴⁵ the parallel importer is not allowed to change the brand name of the product. Similarly, parallel importers are not allowed to bundle together products which benefit from different Community marketing authorisations so as to create a smaller or larger package.⁴⁶

However, all parallel distribution of centrally authorised medicinal products within the Community must be notified to the EMEA before the products are placed on the market. According to Article 57 of Regulation 726/2004, ‘checking that the conditions laid down in Community legislation...and in the marketing authorizations are observed in the case of parallel distribution...’⁴⁷ is one of the official tasks of the EMEA. The notification takes the form of a ‘Notification of parallel distribution of a centrally authorized medicinal product.’⁴⁸ The notification form must include details of the parallel distributor; the Member State of destination; the repackager; certification that the condition of the product has not

⁴³ EMEA, ‘Post-authorisation,’ n. 37 above, 1.

⁴⁴ See F-J. Braun, ‘The Legal Framework for Parallel Trade in Pharmaceuticals for Human Use in the European Economic Area,’ Master of Drug Regulatory Affairs Thesis, Friedrich-Willhelms-Universität Bonn (2004), p. 8. See chapter 7(3.1) below for a further discussion on the blue-box and repackaging of centrally authorised pharmaceutical products.

⁴⁵ N. 35 above.

⁴⁶ Case C-433/00 *Aventis GmbH v. Kohlpharma GmbH & MTK GmbH* [2002] E.C.R. 7761. See also EUF (ed.), ‘Repackaging of medicines must respect marketing authorisations,’ (2002) 109 E.U.F. 16; and the lengthy discussion of this case in chapter 7(3.1) below.

⁴⁷ N. 22 above, Art. 57.

⁴⁸ EMEA, ‘Post-authorisation,’ n. 37 above.

been affected; and a confirmation that the administrative fee has been paid.⁴⁹ Mock-ups of the package and package leaflet, as well as a copy of the ‘wholesale dealer’s licence’ or a copy of the marketing authorisation must be annexed to the notification form.⁵⁰ The EMEA no longer requires a specimen of the repackaged product to be submitted with the Notification.⁵¹ A colour copy of the repackaged sales presentation must, however, accompany the Notification.⁵² According to the EMEA, the average time taken to obtain the Notice is around three months.⁵³ When the EMEA has no objections to the parallel distribution and repackaging, it will issue a Notice and send it to the parallel distributor, the relevant national authority, and the original marketing authorisation holder.

In essence, notice to the EMEA is a form of PIL. An official PIL is not needed, but it needs to be confirmed that the imported product is identical to the product already benefiting from a Community marketing authorisation. It is also important that national authorities be notified as to when, where, what, and by whom a pharmaceutical product is being imported. In the event of a product recall or a withdrawal of the marketing authorisation for safety reasons, it is vital that national authorities know whom to contact, and where and when the products have been marketed.

2.2 *The ‘mutual recognition’ procedure*

Directives 75/318/EEC⁵⁴ and 75/319/EEC⁵⁵ established the ‘multi-state’ procedure which allows Member States to take account of previous marketing authorisations

⁴⁹ EMEA, ‘Post-authorisation,’ n. 37 above, 12: this fee is currently € 3 480.

⁵⁰ *ibid.*, 3. If the products are imported from a new Member State subject to the ‘specific mechanism’ in the 2003 Act of Accession (see n. 34 above), the applicant must prove that adequate notice has been given to the patent proprietor. See Regulation 726/2004, n. 22 above, Art. 57; and chapter 5(5.2.3) below.

⁵¹ *ibid.*, 18.

⁵² *ibid.*

⁵³ *ibid.*, 5.

⁵⁴ Council Directive 75/318/EEC on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products [1975] O.J. L147/01.

in other Member States. Following the entering into force of Directive 2001/83/EC⁵⁶ this became the 'mutual recognition' procedure. The principle of mutual recognition of products legally marketed in the exporting Member State by the importing Member State was established in *Cassis de Dijon*.⁵⁷ The mutual recognition procedure implements this case-law by enabling the mutual recognition of marketing authorisations. Since all pharmaceutical products marketed in the Community must benefit from a marketing authorisation, it is not possible to have a system of mutual recognition of pharmaceutical products *per se*, as this could lead to a product being marketed in a country where it does not benefit from a marketing authorisation. Instead it is the mutual recognition of the marketing authorisations, not the products, which forms the basis of this procedure.

Article 8(3)(j) of Directive 2001/83/EC states that 'copies of any authorisation obtained in another Member State or in a third country to place the medicinal product on the market, together with a list of those Member States in which an application for authorisation submitted in accordance with this Directive is under examination'⁵⁸ shall be submitted. Following this, the Member State where the marketing authorisation is sought shall 'approve the assessment report, the summary of product characteristics and the labelling and package leaflet and shall inform the reference Member State accordingly.'⁵⁹ This is the basis upon which the 'mutual recognition' procedure for marketing authorisations is founded.

An application for a marketing authorisation may be addressed to several Member States. The first Member State to start processing the application will become the 'reference' Member State. The reference Member State then notifies the other Member States having received identical applications, which may then stop their investigations, and await the result from the reference Member State. When the

⁵⁵ N. 20 above.

⁵⁶ N. 1 above.

⁵⁷ Case 120/78 *Rewe-Zentral AG v. Bundesmonopolverwaltung für Branntwein* (Cassis) [1979] E.C.R. 649.

⁵⁸ N. 1 above, Art. 8(3)(i).

⁵⁹ *ibid.*, Art. 28(4).

reference Member State authority has reached a decision, it sends its findings to the other Member States. The Member States then have 90 days to recognise the decision of the reference Member State and grant the applicant marketing authorisation.⁶⁰ In this way the applicant will be granted several national marketing authorisations by only making one application. It is important to remember that the set of marketing authorisations granted does not have the status of a Community marketing authorisation, but remains a bundle of individual national marketing authorisations.⁶¹ As such it is beneficial to large pharmaceutical companies as it allows them to use initially different brand names across the Community, acting as a preventative measure against parallel imports, as well as providing more flexibility in products roll-out.⁶²

2.3 *The 'abridged procedure'*

This provides a speedier marketing authorisation procedure for generic products. Since manufacturers of generics (i.e. 'copies' of pharmaceutical products already in well-established use) do not have access to the test results and other information concerning the pharmaceutical product, and the 'reference' pharmaceutical product already benefits from a marketing authorisation, manufacturers of generics do not have to submit all test results.

Article 10 of Directive 2001/83/EC,⁶³ which derogates from Article 8(3)(i), is the basis of the so-called 'abridged application' procedure. According to Article 10 the 'applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product, which is or has been authorized under Article 6 for not

⁶⁰ In accordance with Directive 2001/83, n. 1 above, Art. 28(4).

⁶¹ It should also be noted that national marketing authorisations in the new Member States cannot benefit from the mutual recognition procedure during the transition period: see n. 34 above.

⁶² See IMS Insights (ed.), 'New EU Drug regulations positioned to boost new introductions and competition,' IMS Insights, 12 June 2003, (<<http://www.ims-global.com>>); and EFPIA, 'Single trademark,' n. 39 above.

⁶³ N. 1 above.

less than eight years in a Member State or in the Community.’⁶⁴ ‘Generic medicinal product’ shall mean a medicinal product that has the same ‘qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.’⁶⁵ This definition is often referred to as the ‘essentially similar’ test.

In the case of generic products that are marketed in a Member State other than the one intended for importation, Article 10(a) becomes relevant. It states that ‘the applicant shall not be required to provide the results of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Community for at least ten years, with recognised efficacy and an acceptable level of safety...’⁶⁶ This procedure is often referred to as the ‘informed consent application.’⁶⁷ An application using the abridged procedure does not result in a marketing authorisation with any specific attributes. Rather, the procedure is only a procedure being applied by the national Medicines Control Agency, subsequently resulting in the granting of a national marketing authorisation. The procedure can also be applied in conjunction with the mutual recognition procedure.⁶⁸

The recent Directive 2004/27/EC⁶⁹ changed the procedures concerning regulatory data exclusivity. Data submitted by pharmaceutical companies will be protected for 10 years from the first time of first authorisation. However, it is possible for a

⁶⁴ *ibid.*, Art. 10.

⁶⁵ Directive 2001/83, n. 1 above, Art. 10(2)(b). See also Case C-368/96 *R. v. Licensing Authority, ex parte Generics* [1998] E.C.R. I-7967.

⁶⁶ *ibid.*, Art. 10(a).

⁶⁷ Commission Notice, n. 6 above, 9.

⁶⁸ Note, however, that nationally authorised generic versions of centrally authorised products cannot legally stay on the market in the new Member States after accession. Similarly, due to the transition periods during which Directive 2001/83 (n. 1 above) do not apply to the new Member States in accordance with the 2003 Act of Accession (see n. 34 above), a generic product cannot be imported from a new Member State to an ‘old’ Member States even if the products are identical unless express consent is given by the respective national Medicines Control Agencies in the Member States of importation and exportation. See pp. 91-92 above; and PERF, ‘Reflection paper,’ n. 33 above, 7.

⁶⁹ Council Directive 2004/27/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use [2004] O.J. L136/34.

generic company to submit an abridged application for a marketing authorisation relying on the innovator's data eight years after the issue of first marketing authorisation, although the applicant will have to wait a further two years before the product may be placed on the market – hence the expression 'the 8+2' formula.⁷⁰ The protection of the innovator's data is to allow for a recoup of investments – a form of reward for the innovator's investments in research and development.

3. *Imported pharmaceutical products*

A trader wishing to import pharmaceutical products into the UK (or any other Member State) must normally possess a 'wholesale dealer's licence' (WDL) issued by the MHRA, regardless of whether the parallel imported product benefits from a Community or a national marketing authorisation.⁷¹ This means that a WDL must normally be obtained before a PIL can be granted.

However, parallel importers who import pharmaceuticals from another Member State do not need to possess a WDL as long as the products are subject to a PIL⁷² and the importer is in possession of a 'manufacturer's (assemble) licence' (MAL) in the Member State of importation, subject to the products not having left the premises of the licensed manufacturer or assembler before sold or supplied.⁷³ This is embodied in Article 77(3) of Directive 2001/83/EC, which states that 'possession of a manufacturing authorization shall include authorization to distribute by wholesale the medicinal products covered by that authorization.'⁷⁴

⁷⁰ Horton, Mailly and Goecke, n. 27 above, 36. This rule is only applicable to products patented after the entry into force of Directive 2004/27, n. 69 above.

⁷¹ EMEA, 'Post-authorisation,' n. 37 above, 14.

⁷² See section 3.2 below.

⁷³ See the Medicines Act 1968, n. 2 above, Art. 8(3)(c); The Medicines (Exemption from Licences) (Wholesale Dealing) Order 1990; and MHRA, 'Notes for applicants and holders of a wholesale dealer's licence,' (MHRA Guidance Note No. 6), para. 19. MALs are further discussed in chapter 7(2) below.

⁷⁴ Directive 2001/83, n. 1 above, Art. 77(3).

The procedures and laws governing the granting of WDLs are laid down in Directive 2001/83/EC.⁷⁵ Article 80(g) of Directive 2001/83/EC requires holders of a WDL to comply with the Guidelines on Good Distribution Practice of Medicinal Products for Human Use,⁷⁶ as prepared in accordance with Article 10 of Directive 92/25/EEC⁷⁷ on the wholesale distribution of pharmaceutical products for human use. These Directives have been implemented by UK law.⁷⁸

A WDL can be divided into three parts. The company (and qualified person) must be authorised, the products for which wholesale distribution is intended must be specified, and finally, the premises where the products intended for wholesale distribution will be stored must be authorised. The applicant must have a ‘qualified person’ designated as the responsible person.⁷⁹ The MHRA Guidelines state that it is not required that the responsible person is a pharmacist, but it is recommended.⁸⁰ The designated person need not be an employee of the licence holder, but must be at the licence holder’s disposal, as he could be liable to take action in Court on behalf of the licence holder. The ‘qualified person’ must ensure that the products supplied under a WDL have been obtained from another company benefiting from a WDL, and that the products are only supplied to another WDL licensee.⁸¹ Further, the storage conditions, including transportation, observing that the right temperature is maintained, and protecting the products from contamination and/or mixing with other products intended for distribution, must be adequate.⁸²

⁷⁵ *ibid.*

⁷⁶ Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use (94/C 63/03).

⁷⁷ Council Directive 92/25/EEC on the wholesale distribution of medicinal products for human use [1992] O.J. L113/1.

⁷⁸ See The Standard Provisions for Wholesale Dealer’s Licences and Wholesale Dealer’s Import licences laid down in the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971, as amended.

⁷⁹ See Hodges, n. 23 above, 157, for a further discussion of the ‘qualified person.’

⁸⁰ MHRA Guidance Note No. 6, n. 73 above, paras. 6.3-6.4.

⁸¹ Directive 2001/83, n. 1 above, Art. 80(b) and (c). See also MHRA Guidance Note No. 6, *ibid.*, paras. 5.2(d) – 5.2(e).

⁸² See Commission, ‘Good distribution,’ n. 76 above, paras. 9-16; and MHRA Guidance Note No. 6, *ibid.*, Appendix 1.

A WDL holder must also establish an emergency and recall plan.⁸³ In order to be able to execute an effective recall, the distributor is required to keep records for any transaction including pharmaceutical products over the last five years. Under the Guidelines on Good Distribution, the wholesaler must also record the batch number of the products supplied, so as to ensure an effective recall process in case of an emergency. This plan should apply without any difference to deliveries in the Member State where the licence was granted and in other Member States where the batch was supplied, which entails a certain amount of cooperation between Member States.

Further cooperation between Member States is also needed due to the fact that the wholesale dealer's premises (where the products are stored) need not be located in the Member State of importation (where the licence is granted).⁸⁴ It would amount to a measure having equivalent effect to a quantitative restriction under Article 28 EC to require an applicant of a WDL to maintain premises for storage and technical equipment in the Member State where the application is made, if the applicant already has access to adequate premises in another Member State.⁸⁵ If the premises conform to the laws and regulations in the second Member State, it would be an additional cost for the applicant to maintain additional premises in the Member State where the application is made, even if such a requirement applied without distinction to all applicants.⁸⁶ Safety can still be assured by means of cooperation, and additional checks at borders and in pharmacies.⁸⁷ The argument that the requirement is merely intended to guarantee regular supplies of foreign pharmaceutical products to the market is not valid, since this requirement can be met without the need for the applicant to maintain premises in the Member State of importation.⁸⁸ The Member State which issued the WDL will have to cooperate

⁸³ See Commission, 'Good distribution,' *ibid.*, paras. 25-30, for the rules relating to emergency plans and recalls discussed in the paragraph below.

⁸⁴ See Joined Cases 87-88/85 *Legia & Gyselinx v. Minister for Health* [1986] E.C.R. 1707. See also chapter 7(2) below for further discussion of this case.

⁸⁵ *ibid.*, para. 16.

⁸⁶ *ibid.*

⁸⁷ *ibid.*, paras. 18 and 20.

⁸⁸ *ibid.*, para. 22.



with the authorities in the Member State where the wholesale dealer's premises are located.⁸⁹ If effective cooperation is not possible, this will affect public health and safety. It will also mean added expenses for the Member State granting the WDL, which will have to carry out inspections in pharmacies and at borders in order to maintain safety. The Member State where the premises are located may not be so rigid in its inspections of the premises, as (national) public health and safety is not at risk since the products are being supplied in another Member State. Nevertheless, a WDL is a normal requirement for importers of pharmaceutical products, and despite having to rely on effective cooperation between Member States to maintain public health and safety, it provide some safety guarantees.

3.1 *Marketing authorisations and imported pharmaceutical products*

Even if a parallel importer benefits from a WDL, Directive 2001/83/EC⁹⁰ makes it clear that no pharmaceutical product may be placed on the market without a marketing authorisation. A problem therefore presents itself for parallel importers of pharmaceutical products not benefiting from a Community marketing authorisation: without access to the results of pre-clinical studies and chemical data it is almost impossible to obtain a marketing authorisation, especially since many pharmaceutical products intended for parallel importation are still patent protected and the data protection period has not yet expired.

In consequence, the requirement of marketing authorisation effectively hinders the free movement of pharmaceutical products within the Community. It is also debatable whether importers should be required to go through the same application process as this would entail unnecessary risks and suffering to test animals and humans taking part in the clinical trials required for a successful marketing authorisation application.⁹¹

⁸⁹ *ibid.*, para. 20.

⁹⁰ N. 1 above, Art. 6.1.

⁹¹ It should be noted that different rules apply to 'personal imports.' Following Case 215/87 *Schumacher v. Hauptzollamt Frankfurt am Main-Ost* [1989] E.C.R. 617, rules restricting

This was first discussed by the ECJ in *Adriaan de Peijper*.⁹² Adriaan de Peijper was the managing director of Centrafarm, a parallel importer distributing pharmaceutical products imported from the United Kingdom to Dutch pharmacies. The Officier van Justitie considered that de Peijper infringed national public health legislation on two grounds. First, the Netherlands authorities had not consented to such importation being carried out by Centrafarm. Secondly, certain essential documents concerning the preparation of the concerned products, namely the 'records' and the 'file' as defined by Dutch legislation, were not available. In this context, 'file' means a document which the importer must keep for 'every pharmaceutical packaging of a pharmaceutical preparation which he imports...and which must contain detailed particulars concerning the said packaging and especially of the quantitative and qualitative composition as well as the method of preparation.'⁹³ These documents and particulars must then be endorsed by the person or persons responsible for the manufacture of the said pharmaceutical product abroad. When applying for marketing authorisation, the 'file' must be shown in order to obtain a certification. Only the holder of a 'file' will be able to obtain effective marketing authorisation. 'Record' means a document the importer must show when he markets the pharmaceutical products in the Netherlands to certify that the products have actually been manufactured and checked in accordance with the 'file.' The 'file' therefore seems to refer to the product and its manufacturing process in general, whereas the 'record' refers to specific batches of the product.

De Peijper claimed that the Dutch legislation was in breach of Article 28 EC Treaty. By requesting the delivery of documents identical to documents already in their

importation by private individuals of non-prescription pharmaceutical products authorised and available in the Member State of importation, but purchased in a pharmacy in another Member State, is not compatible with the Community's free movement of goods provisions. Neither is a prior authorisation procedure to personal imports, not effected by personal transport, of products being lawfully prescribed in the Member State of importation compatible with Articles 28 and 30 EC Treaty: Case C-212/03 *Commission v. French Republic* [2005] E.C.R. 4213, para. 49. See also M. Mäkinen, P. Rautava and J. Forsström, 'Restrictions on import of drugs for personal use within the European single market,' (2002) 12 E.J.P.H. 244.

⁹² Case 104/75 *Officier van Justitie v. de Peijper* [1976] E.C.R. 613.

⁹³ *ibid.*, para. 3.

possession (previously supplied by the holder of the reference marketing authorisation) the legislation created an obstacle 'capable of hindering, directly or indirectly, actually or potentially, intra-Community trade.'⁹⁴ The *Kartongerecht* made a preliminary reference to the ECJ.

The ECJ restated the well-established definition of a measure equivalent to a quantitative restriction,⁹⁵ and held that 'imports being channelled in such a way that only certain traders can effect these imports, whereas others are prevented from doing so, constitute such an obstacle to imports.'⁹⁶ Measures such as these can however fall within the derogations provided by Article 30 EC Treaty if adopted for 'the protection of health and the life of humans.'⁹⁷ The ECJ applied a proportionality test.

Article 30 EC Treaty cannot be relied upon to justify measures adopted to 'lighten the administrative burden' of national authorities, unless without the measure the burden would in essence be unbearable for the national authorities.⁹⁸ The Court, however, found that it is unnecessary for the protection of public health and life of humans to require a parallel importer to supply the authorities with documents identical to documents already in their possession produced to them by the manufacturer, laying down the specifics of a product identical to the one being imported by the parallel importer.⁹⁹ However, if the products are not identical, i.e. do not possess the same therapeutic effects or manufacturing process, a request for a 'file' may be in conformity with Article 30 EC Treaty.¹⁰⁰ 'Nevertheless, having regard to the nature of the market for the pharmaceutical product in question, it is necessary to ask whether this objective cannot be equally well achieved if the national administrations, instead of waiting passively for the desired evidence to be produced to them – and in a form calculated to give the manufacturer of the product

⁹⁴ Case 8/74 *Procureur du Roi v. Dassonville* [1974] E.C.R. 837, para. 5.

⁹⁵ Case 104/75, n. 92 above, para. 12.

⁹⁶ *ibid.*, para. 13.

⁹⁷ *ibid.*, para. 14.

⁹⁸ *ibid.*, paras. 18 and 32.

⁹⁹ *ibid.*, para. 21.

¹⁰⁰ *ibid.*, paras. 35 and 36.

and his duly appointed representative an advantage – were to admit, where appropriate, similar evidence and, in particular, to adopt a more active policy which could enable every trader to obtain the necessary evidence.’¹⁰¹ According to the Court, this objective can be achieved by cooperation between Member States in obtaining the documents necessary to make checks on ‘largely standardised and widely distributed products.’¹⁰²

The objective of safeguarding public health and safety pursued by the Community legislation can only be justified in relation to products being put on the market for the first time. It can therefore be argued that *de Peijper*,¹⁰³ in essence, established a ‘first marketing principle’ similar to the ‘exhaustion of rights doctrine’ for intellectual property rights.¹⁰⁴ When the product has obtained a first marketing authorisation, national authorities and the original marketing authorisation holder have lost their right to prevent future applicants from relying on the information already in the possession of national authorities. The ECJ thus established a simplified procedure for parallel imported pharmaceutical products.

Since the marketing and importation of pharmaceutical products still need to be subject to a certain control system, *de Peijper*¹⁰⁵ led to the implementation of a system for granting PILs by Member State Medicines Control Agencies. The system draws upon the ECJ’s ruling and allows parallel importers to rely on the product dossier already in the possession of the national Medicines Control Agency following the marketing authorisation application of the reference product. This system prevents marketing authorisation holders from effectively hindering market access for parallel imported products by refusing to supply them with the product information necessary to obtain a marketing authorisation. Before discussing the

¹⁰¹ Case 104/75, n. 92 above, para. 24.

¹⁰² *ibid.*, para. 27.

¹⁰³ *ibid.*

¹⁰⁴ See chapter 5 below for discussion of the ‘exhaustion of rights doctrine.’

¹⁰⁵ N. 92 above.

exceptions and limitations to the *de Peijper*¹⁰⁶ ruling, the effects of this ruling must be discussed.

3.2 *Parallel Import Licences (PILs)*

Following the *de Peijper*¹⁰⁷ ruling, the Commission published a Communication on importation of medicines already benefiting from a marketing authorisation.¹⁰⁸ This prompted the MHRA to issue the 'Notes on Application for Product Licences (Parallel Importing)' in 1984.¹⁰⁹

The MHRA defines a PIL as a 'United Kingdom marketing authorisation granted by the licensing authority under these Regulations in respect of a relevant medicinal product which is imported into the United Kingdom from another EEA State in accordance with the rules of Community law relating to parallel imports.'¹¹⁰ The UK application form for a PIL is fairly straightforward.¹¹¹ Information is required regarding the product for which the application is made, as well as information concerning the marketing authorisation in the exporting Member State and the manufacturer of the product. Information regarding the marketing authorisation and its holder in the UK must also be submitted, with full details of the relabelling/repackaging procedure, and the name, address and manufacturing authorisation number of the relabeller/repackager. In an attempt to verify and assess the quality of the product, full details of the specifications and quality control test methods applied by the applicant must also be included in the application. Finally, a

¹⁰⁶ *ibid.*

¹⁰⁷ N. 92 above.

¹⁰⁸ Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted [1982] O.J. C115/5. See also Commission Communication (2003), n. 35 above.

¹⁰⁹ MHRA, 'Notes on Application for Product Licences (Parallel Importing) (Medicines for Human Use),' (MAL2(PI)). This is no longer available from the MHRA. However, a new unofficial version is available upon request: MHRA, 'Guidance notes on applications for product licenses for parallel imported medicinal products,' (Unofficial) (2005).

¹¹⁰ Medicine (Fees) Regulations 2001, n. 2 above, Art. 2(1)(a).

¹¹¹ For the following paragraph see: MHRA, 'Application for a Product Licence (Parallel Importing),' (Form MLA 201(PI)).

specimen of the product and specimens of all the containers (in all sizes) intended for importation from the exporting Member State must be enclosed.

Directive 2001/83/EC provides for a 90-day time limit within which the Member State may decide upon the mutual recognition of a marketing authorisation already granted by another Member State authority.¹¹² The Commission, in its 2003 Communication, therefore suggests that '45 days is a reasonable time-limit for applying a simplified procedure to decide on a [PIL] application.'¹¹³ In the UK, all new PILs will be published in the MHRA's updating journal for medicines, and will also be available on the Agency's website. The MHRA notifies the relevant marketing authorisation holder of the granting of a PIL.¹¹⁴

This is the basis of the 'simplified procedure.' The system may seem straightforward and efficient at a first glance. But the definition of 'parallel imported,' discussed in the next chapter, will show that there are still many questions left unanswered concerning the intricacies of the 'simplified procedure.'

4. *Conclusion and analysis*

The Community's marketing authorisation framework aims to integrate Member State markets into a single European market for pharmaceutical products. Community legislation therefore provides for three different marketing authorisation procedures; the centrally authorised Community procedure, the mutual recognition procedure, and the abridged application procedure. The centralised procedure grants Community marketing authorisations, valid throughout the Community. The mutual recognition procedure provides a bundle of national marketing authorisations granted by way of mutual recognition, and the abridged

¹¹² N. 1 above, Art. 18.

¹¹³ Commission Communication (2003), n. 35 above, para. 3.

¹¹⁴ The current fee for a parallel import licence is £1,483. The ECJ has held that such fees, charged in order to check whether the products 'subsequently marketed are identical to the registered product do not constitute charges having an effect equivalent to customs duties where those fees form part of a general system of internal fees:' Case 32/80 *Criminal proceedings against Kortmann* [1981] E.C.R. 251, para. 3.

procedure provides a simplified procedure for generic pharmaceutical products. In order to facilitate the free movement of pharmaceutical products, the Community also demands that Member States provide a 'simplified procedure' for parallel imported pharmaceutical products. The Community market for pharmaceutical products therefore consists of pharmaceutical products benefiting from a range of different marketing authorisations and licences granted using different procedures. This complicated system threatens, to an extent, the safety and efficiency of the pharmaceutical trade. Safety and efficacy is weakened due to the fact that there is no centralisation. This means that Member States must not only cooperate with each other, but also with the EMEA, which can have an effect on pharmacovigilance. Instead of a Member State only monitoring and maintaining safety of the pharmaceutical products benefiting from a marketing authorisation in its own territory, it must rely on the EMEA and other Member State Medicines Control Agencies, which means national agencies require a lot of trust in each other, as well as in the EMEA.

The system also threatens free movement. When applying for national marketing authorisations, pharmaceutical companies can still use different names in different Member States, even when using the mutual recognition procedure. The mutual recognition procedure has therefore not made it easier for parallel importers, which must still apply for a PIL. Only when products are benefiting from a Community marketing authorisation is a PIL unnecessary. However, the requirement of a single brand name throughout the Community reduces the popularity of the centrally authorised marketing authorisation. In practice, therefore, the situation for parallel importers has not changed significantly over the last 20 years.

This could be solved by gradually making the centrally authorised Community marketing authorisation procedure compulsory for more categories of pharmaceuticals.¹¹⁵ A Community marketing authorisation should be seen as possessing positive attributes. Once the product has obtained a Community

¹¹⁵ See section 2.1 above on the centralised Community procedure.

marketing authorisation it can be marketed throughout the Community. But also, once a product is withdrawn, it is withdrawn from the entire Community market. The marketing authorisation holder is therefore able to focus on the new product, recouping the R&D costs. The marketing authorisation holder would not have to compete with parallel imported versions either, since parallel trade in a product benefiting from a Community marketing authorisation is dependant on the marketing authorisation being in force. Making the centralised Community marketing authorisation procedure compulsory for more pharmaceutical categories would also benefit parallel importers, since a PIL is not needed as a result of all the relevant information already being submitted to the EMEA by the Community marketing authorisation holder. There would only be one marketing authorisation for the product, making safety and quality checks more effective and origin controls far more time-efficient. Making the Community marketing authorisation compulsory for all new medicinal products would therefore benefit society as a whole, since it would increase safety and lead to a more cost effective marketing authorisation system.

Regulation 726/2004, stating that, 'after 20 May 2008, the Commission, having consulted the Agency, may present any appropriate proposal modifying' the list of product groups for which the centralised procedure shall be compulsory,¹¹⁶ indeed suggests that the Community marketing authorisation procedure may gradually become compulsory for more product groups. This is supported by the fact that, as of 20 May 2008, the procedure will be compulsory for auto-immune diseases, immune dysfunctions and viral diseases.¹¹⁷

Objections to such a reform are likely to come from, first, national Medicines Control Agencies, and indirectly Member States, since it would lead to a decrease in responsibilities, and possible down-sizing, of such agencies. Since the regulation of the national pharmaceutical industry and market falls under the retained national competence over the protection of public health and safety in accordance with Article 30 EC Treaty, Member State objections will be difficult to overcome.

¹¹⁶ N. 22 above, Annex.

¹¹⁷ *ibid.*

Applying the mutual recognition principle to national marketing authorisations (in effect making the mutual recognition procedure compulsory for all pharmaceutical products) would perhaps be more welcomed by Member States than making the centralised procedure compulsory. Even though this would potentially increase safety, it would still require certain cooperation and exchange of information between Member States, while not solving the issue of PILs, as a PIL would still be needed in order to guarantee safety in the absence of a centralised procedure only allowing for the marketing of one version of the authorised product. Secondly, manufacturers may oppose a proposal to make the centralised procedure compulsory due to the negative impact it will have on the ability to foreclose markets, as will be evident in the following chapter. However, the benefit of only having to apply for one marketing authorisation is likely to outweigh this disadvantage. Similarly, parallel importers may object to the proposal due to its centralisation. If the Community marketing authorisation is withdrawn, it will be withdrawn throughout the Community. However, this argument is likely to be outweighed by the benefit of not having to apply for a PIL in the first place.

Hopefully, the current system is only a temporary solution adopted under a transition period until the centralised procedure for Community marketing authorisations becomes standard. This will increase efficiency, public health and safety, and provide legal certainty. Making the centralised procedure for marketing authorisations compulsory would solve many unanswered questions, and would be an efficient way of stimulating free movement of pharmaceutical products within the Community. This will be even more evident following the complicated definition of 'parallel imported' in relation to the 'simplified procedure,' carried out in the next chapter.

THE SCOPE OF THE SIMPLIFIED PROCEDURE

As established in the preceding chapter, the product for which a ‘parallel import licence’ (PIL) is applied for must be a parallel imported version of a product already benefiting from a marketing authorisation in the Member State of importation. The key question is therefore how the ECJ and Community measures have defined the term ‘parallel imported,’ as the normal procedure for obtaining a marketing authorisation will apply if the product is not considered to be a ‘parallel imported’ version of such a product. The two main criteria are, first, that the parallel imported and the reference product share a ‘common origin,’ and, secondly, that they can be regarded as ‘essentially identical.’ The ECJ has also had to consider whether the automatic revocation of the PIL upon the withdrawal of the reference marketing authorisation is compatible with Articles 28 and 30 EC Treaty. This will be discussed in section 3. The following section will focus on the definition of ‘common origin’ and ‘essentially identical.’

A good introduction to these two definitions is the UK ‘Medicines and Healthcare products Regulatory Agency’s’ (MHRA) guidelines for PIL applications: MAL2(PI).¹ Paragraph 4 of MAL2(PI) provides that; ‘all the following conditions must be met before an application can be considered under these arrangements i.e. the product concerned must:

¹ MHRA, (MAL2(PI)); and MHRA, (Unofficial) (2005): see chapter 3, p. 106, n. 109 above, for full references.

- a) Be a product which is to be imported from a Member State of the European Community;
- b) Be a proprietary medicinal product (as defined in Article 1 of EC Directive 65/65) for human use...;
- c) Be covered by a currently valid marketing authorisation granted, in accordance with Article 3 of EC Directive 65/65, by the regulatory authority of an EC Member State;
- d) ...have no differences, having therapeutic effect, from a product covered by a UK [marketing authorisation]...;
- e) Be made by, or under licence to;
 - i) the manufacturer who made the product covered by the UK [marketing authorisation] or;
 - (ii) a member of the same group of companies as the manufacturer who made the product covered by the UK [marketing authorisation].

If any of these conditions are not met the applicant will be invited to apply for a [marketing authorisation] in the normal way under the [established] procedures.²

First, it should be remembered that the parallel imported product must already benefit from a marketing authorisation in a Member State other than the Member State of application/importation. Secondly, the parallel imported product must use an existing marketing authorisation in the Member State of application/importation as a reference when applying for a PIL. Community measures at the very least require that this reference marketing authorisation be in force at time of the application for a PIL.³ This is not only an additional condition, but a sufficient

² MAL2(PI), n. 1 above, para. 4. See also Case C-94/98 *R, ex parte Rhone-Poulenc Rorer v. The Licensing Authority* [1999] E.C.R. I-8789, paras. 9-13.

³ Case C-223/01 *AstraZeneca A/S v. Laegemiddelstyrelsen* [2003] E.C.R. I-11809 concerning an application for a marketing authorisation for a generic product under the 'abridged' application procedure (see chapter 3.2.3. above), but this may be equally important in relation to the simplified procedure for parallel imports.

condition.⁴ The product need not be marketed: it suffices that the marketing authorisation is in force, enabling the MHRA to take part of the data and documents from the reference marketing authorisation.⁵ The applicant must also show that the product is a parallel imported version of the product benefiting from the reference marketing authorisation. The granting of a PIL by the MHRA is very straightforward if the product is in every aspect identical to a product already benefiting from a marketing authorisation.

1. 'Common origin'

The easiest way to show that the product for which a PIL is applied for is a true parallel import is to show that it shares a 'common origin' with the product benefiting from the reference marketing authorisation, i.e. was manufactured by the same company, at the same factory. In this way the products will be considered to conform with paragraph e(ii) of MAL2(PI),⁶ which requires the parallel importer and manufacturer to be members of the same group of companies.

In *Smith & Nephew v. The Medicines Control Agency*⁷ the ECJ was asked to define 'common origin.' In brief, the facts were that Smith & Nephew had been licenced by a US firm to market the drug 'Ditropan' in the UK. Primecrown, a parallel importer, was granted a PIL from the MHRA⁸ for products manufactured by a Belgian subsidiary of the US company which had granted the licence to Smith & Nephew. The products benefited from a Belgian marketing authorisation, and were considered 'essentially identical' to those marketed by Smith & Nephew.

⁴ Case C-223/01, n. 3 above, paras. 49-50; and Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted [2003] COM/839/final., para. 6.

⁵ See Article 10(1) of Council Directive 2001/83/EC on the Community code relating to medicinal products for human use [2001] O.J. L311/67, in relation to the abridged procedure. It is likely that this is equally applicable to PILs. See also section 2.1 below.

⁶ N. 1 above, para. e(ii); see also MHRA (unofficial), n. 1 above, para. 6(e).

⁷ Case C-201/94 *Smith & Nephew Ltd v. The Medicines Control Agency* [1996] E.C.R. I-5819.

⁸ The thesis refers to the MHRA for the sake of clarity, even though this agency was, at the time, known as the Medicines Control Agency: see introduction, p. 7, n. 24 above.

However, the US company claimed that it did not supervise or control Smith & Nephew's manufacture of Ditropan in the UK. Thus, it could not guarantee that the product specifications for the products marketed by Smith & Nephew and those manufactured by the Belgian subsidiary were in all respects identical. When the MHRA became aware of the fact that the requisite link between the two products was non-existent it withdrew the licence granted to Primecrown. Primecrown brought proceedings to quash the MHRA's decision to withdraw the licence.

The ECJ compared these facts to those in *de Peijper*.⁹ The products at issue in *de Peijper*¹⁰ were in all respects identical, and were produced by the same group of companies. The products imported by Primecrown and the products produced by Smith & Nephew were, according to tests, identical. However, they did not originate from the same producer. What nexus is required between the two sets of products?

The ECJ addressed the issue by stating that:

'That case-law [*de Peijper*]¹¹ can be applied to a situation such as at issue in the main proceedings, in which independent companies produce proprietary medicinal products, which have a common origin by virtue of the fact that they are manufactured pursuant to agreements concluded with the same licensor. Otherwise, such agreements could lead to partitioning of the national markets of the various Member States.'¹²

When two 'essentially identical' products benefit from marketing authorisations in two different Member States, the competent authority must treat the products as benefiting from both marketing authorisations. The two independent companies must be joined by agreements concluded with the same licensor in order to benefit

⁹ Case 104/75 *Officier van Justitie v. de Peijper* [1976] E.C.R. 613. See chapter 3(3.2) for the facts.

¹⁰ *ibid.*

¹¹ *ibid.*

¹² Case C-201/94, n. 7 above, para. 25.

from the ‘cross-reference,’ which national authorities can carry out ‘unless there are countervailing considerations relating to the effective protection of the life and health of humans.’¹³ The fact that the licensor is situated outside the European Community is not relevant.¹⁴

*Smith & Nephew*¹⁵ clarified as many questions as it created. The two products must have a common origin; however, they do not have to be manufactured by the same group of companies. The requirement of a common origin was therefore not relaxed. The ECJ merely defined ‘the same group of companies’ to include two manufacturers bound together by a licensing agreement.¹⁶

The PIL system was set up in order to facilitate the free movement of parallel imported pharmaceuticals. The crucial factor is therefore how to define such products. In *Smith & Nephew*¹⁷ the ECJ defined parallel imported products as including products produced by two separate manufacturers bound by a licensing agreement. However, can products that are ‘essentially identical’ but which lack a common origin be defined as parallel imports?¹⁸ After all, ‘parallel imported’ means that the products are simply traded in parallel with the original manufacturer’s distribution network.¹⁹ Allowing products, no matter how ‘essentially identical’ they may be, to benefit from a PIL if they do not share a common origin will undermine the intention of the ECJ’s ruling in *de Peijper*.²⁰

¹³ Case C-201/94, n. 7 above, para. 32.

¹⁴ *ibid.*, para. 34.

¹⁵ *ibid.*

¹⁶ This is now included in MHRA (unofficial), n.1 above, defining a ‘common origin’ as being ‘made under licence to a company (inside or outside the EEA) which has also licensed the manufacture of the UK product.’ (para. 6(e)).

¹⁷ N. 7 above.

¹⁸ In Case C-94/98, n. 2 above, the Court held, in line with *Smith & Nephew (ibid)* that the marketing authorisation holders and the manufacturers of the reference products, as well as for the product for which a PIL is applied for, must be members of the same group of companies. Thus it seems *Smith & Nephew* did not have an impact on the importance of a ‘common origin.’

¹⁹ See chapter 1(3) above.

²⁰ N. 9 above.

The ECJ needed to decide which direction to take, either to reserve the simplified procedure for parallel imports in the strict sense, or to use the simplified procedure as a vehicle for the free movement of pharmaceutical products in general. The ECJ was given an opportunity in *Kohlpharma*.²¹ The facts were as follows.

Jumex was a medicinal product authorised in Italy, and Movergan was a medicinal product authorised in Germany. The connection between the two products was that the same Hungarian producer supplied the active ingredient used in both. Kohlpharma, a German parallel importer, applied for a PIL for Jumex, relying on Movergan as the reference product. The German authorities refused the PIL, citing a lack of common origin between the two products as the main reason.

Kohlpharma claimed that the principle in *Smith & Nephew*²² should apply. If the possibility of a common origin is ruled out solely on the ground that the companies are joined by a supply agreement, and not a licensing agreement, as in *Smith & Nephew*,²³ pharmaceutical undertakings could effectively prevent parallel imports by replacing licensing agreements with supply agreements.

The ECJ agreed, applying a pro-integration view to the facts. The crucial issue in *Smith & Nephew*,²⁴ according to the ECJ, was not whether there was a common origin. The Court in *Smith & Nephew*²⁵ stated that the provisions of Directive 2001/83/EC²⁶ concerning the procedure for issue of marketing authorisations cannot apply to a case such as *de Peijper*²⁷ where the two products under examination were 'in every respect' identical.²⁸ The Court, in *Smith & Nephew*,²⁹ later added; 'moreover, the proprietary medicinal products at issue in...[*de Peijper*] had been

²¹ Case C-112/02 *Kohlpharma GmbH v. Germany* [2004] E.C.R. 3369

²² N. 7 above.

²³ *ibid.*

²⁴ *ibid.*

²⁵ *ibid.*

²⁶ N. 5 above.

²⁷ N. 8 above.

²⁸ Case C-201/94, n. 7 above, paras. 21-23.

²⁹ *ibid.*

manufactured by the same group of companies and therefore had a common origin.³⁰ This implies that a ‘common origin’ is not a decisive factor, but can strengthen the finding that the goods are essentially identical, if all other criteria are fulfilled.³¹

This suggests that the primary purpose is to protect public health and safety.³² The Court, in *Kohlpharma*,³³ therefore drew the conclusion that public health and safety is protected if a product complies with the same safety and efficacy standards to a product already benefiting from a marketing authorisation. National authorities should use all available information, including information available through cooperation with authorities in other Member States.³⁴

If the primary purpose is to protect public health and safety, and that requirement is fulfilled by way of showing that the products are ‘essentially identical,’ the requirement of a ‘common origin’ will not be decisive in determining whether to grant a PIL.³⁵ However, it may constitute an important ‘aspect in establishing that such is the case.’³⁶

A PIL can therefore not be precluded solely on the ground that there is no ‘common origin’ between the product for which an application is sought and the reference medicinal product, where;³⁷

- a) the application is submitted with reference to a medicinal product which already benefits from a marketing authorisation;

³⁰ Case C-201/94, n. 7 above, para. 24.

³¹ Advocate General Tizzano in Case C-112/02, n. 21 above, paras. 56-58.

³² Supported by Article 2 of the Preamble to Directive 2001/83, n. 5 above: ‘The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.’

³³ N. 21 above.

³⁴ *ibid.*, para. 20.

³⁵ *ibid.*, para. 15.

³⁶ *ibid.*, para. 17.

³⁷ *ibid.*, para. 21.

- b) the medicinal product for which a licence is sought is imported from a Member State in which it already benefits from a marketing authorisation, and;
- c) the safety and efficacy assessment carried out for the reference marketing authorisation can be used in the application for a PIL for the applicant product without any risk to public health and safety.³⁸

Following *Kohlpharma*,³⁹ a common origin between the parallel imported pharmaceutical product and the reference product cannot be a decisive factor for the granting of a PIL. However, it should be noted that the ECJ has not yet ruled on facts where no common origin, however remote, exists. There was a common origin, to a certain extent, in *de Peijper*,⁴⁰ *Smith & Nephew*,⁴¹ and *Kohlpharma*.⁴² Even though the Court used different reasoning in *Kohlpharma*,⁴³ it did not overturn any earlier rulings, but merely expanded the definition of ‘common origin.’ A PIL has not been denied solely on the ground of an absence of ‘common origin,’ and has not been granted in absence of a ‘common origin’ however remote, either before or after *Kohlpharma*.⁴⁴ A ‘common origin’ therefore remains highly relevant. If there is a total lack of ‘common origin’ between the parallel imported product and the reference marketing authorisation it will be hard to prove that the products are ‘essentially identical.’ It is therefore an advantage for the parallel importer if he can demonstrate a common origin between the two products.

However, the law is characterised by uncertainty. This disturbing tendency of the ECJ to act as lawmaker rather than interpreter, by departing from previous rulings without an explanation as in *Kohlpharma*,⁴⁵ should give food for thought.⁴⁶ In *Smith*

³⁸ Case C-112/02, n. 21 above, para. 21.

³⁹ *ibid.*

⁴⁰ N. 9 above.

⁴¹ N. 7 above.

⁴² N. 21 above.

⁴³ *ibid.*

⁴⁴ *ibid.*

⁴⁵ *ibid.*

& Nephew⁴⁷ and *de Peijper*,⁴⁸ the ECJ acknowledged the importance of the common origin test, but sought to expand it. By merely considering ‘common origin’ to be an additional condition to ‘essentially identical’ in *Kohlpharma*,⁴⁹ the ECJ failed to realise the importance of a ‘common origin.’ It is precisely because parallel imports satisfy the ‘common origin’ test that the simplified procedure for parallel imported medicinal products was implemented. If ‘essentially identical’ were the only relevant test, a generic product could be imported from a Member State where the data period has expired into a Member State where the data protection period has not yet expired, subject to the two products being ‘essentially identical.’⁵⁰ This would undermine the abridged procedure for generic products.⁵¹ Conversely, it is important not to confuse the ‘essentially identical’ test under the simplified procedure with the ‘essentially similar’ test under the abridged procedure, as this would eradicate the purpose of the simplified procedure for parallel imported products.⁵² If products do not need to share an obvious ‘common origin,’ the conditions and requirements that need to be fulfilled in order for two products to be considered ‘essentially identical’ must be discussed.

2. ‘Essentially identical’

A PIL will only be granted if the national Medicines Control Agency already has access to the product characteristics and results of clinical trials, having previously granted a marketing authorisation for the same pharmaceutical product. Otherwise the trade could not be classified as parallel imports. However, this gives the

⁴⁶ See O. Lemaire, ‘Regulatory data protection: From essential similarity to not dissimilar?’, (2003/2004) 5 B.S.L.R. 197

⁴⁷ N. 7 above.

⁴⁸ N. 9 above.

⁴⁹ N. 21 above.

⁵⁰ See O. Lemaire and M. Meulenbelt, ‘Adalat and Kohlpharma – where now for parallel trade in the European Union,’ (2004) R.A.J. 499, 504.

⁵¹ See A. Wearing, I. Kirby, M. Kerckhove and W. Vodra, ‘Parallel trade in the EU and US pharmaceutical markets,’ (2004/05) *PLC Global Counsel Life Sciences Handbook* 117, 118. See also chapter 3(2.3) above, and section 2.1 below, for further discussion of the definition of ‘essentially similar’ and the abridged procedure for generic pharmaceutical products.

⁵² See S. Kon and F. Schaeffer, ‘Parallel imports of pharmaceutical products: A new realism, or back to basics,’ (1997) 18 E.C.L.R. 123, 142 for a further discussion of the need to maintain the distinction between the two tests. See also section 2.1 below.

reference marketing authorisation holder a potential leeway to differentiate pharmaceutical products, i.e. produce slightly different variations of the same pharmaceutical product for different Member States. The ECJ has therefore clarified that the variations of a pharmaceutical product are only to be classified as different where the documentation concerning the particulars (in the Medicines Control Agency's possession) of the variations shows that the differences will result in a different therapeutic effect.⁵³

Smith & Nephew clarified the meaning of 'essentially identical,' establishing that the products 'need not be identical in all respects,' but should at least be manufactured according to the same formulation, using the same active ingredient, and have the same therapeutic effects.⁵⁴ If the products are not considered 'essentially identical,' the parallel imported product must apply for a marketing authorisation under the normal procedure. This is reflected in the MHRA's guidelines stating that the parallel imported product should 'have no differences, having therapeutic effect, from a product covered by a UK [marketing authorisation].'⁵⁵

2.1 '*Essentially identical*' or '*essentially similar*'

A common mistake is to confuse the 'essentially similar' criteria under the abridged procedure for generic products with the 'essentially identical' criteria under the simplified procedure.⁵⁶ The two concepts therefore require clarification before a detailed definition of 'essentially identical' can be carried out.

⁵³ Case 104/75, n. 9 above.

⁵⁴ N. 7 above, para. 26. See also Commission Communication (2003), n. 4 above, 5.

⁵⁵ MAL2(PI), n. 1 above, para. 4(e); and MHRA (unofficial), n. 1 above, para 6(d).

⁵⁶ The 'abridged' procedure and the concept of 'essentially similar' are discussed in chapter 3(2.3) above. Chapter 3(3.1-3.2) above discussed the origins and workings of the 'simplified procedure' for parallel imported products. The abridged procedure allows for a speedier application procedure for generic products, resulting in the granting of a valid marketing authorisation. The simplified procedure, however, results in a PIL, as the product is not a copy (i.e. generic) but identical to the reference product, and thus already benefits from a marketing authorisation.

Article 10 of Directive 2001/83/EC (as amended) defines, for the purpose of the abridged marketing authorisation procedure that a ‘generic medicinal product’ ‘shall mean a medicinal product which has the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.’⁵⁷

This concerns generic products applying for a marketing authorisation using the abridged procedure. However, the Article serves as a good guideline for determining whether a parallel imported product is ‘essentially identical’ to a reference product.⁵⁸ As the objective of Directive 2001/83⁵⁹ and the rules governing national Medicines Control Agencies when issuing marketing authorisations is to protect public health and safety,⁶⁰ the conditions to be fulfilled by parallel imported products in order to be considered ‘essentially identical’ need not be more stringent than for generic products to be considered ‘essentially similar.’

The case-law surrounding the abridged procedure’s ‘essentially similar’ test can therefore serve as guidance. However, it must be remembered that these two tests should not be confused. Only the conditions under the ‘essentially identical’ test can be defined by the case-law surrounding the ‘essentially similar’ test as the latter test does need to be more stringent. The main objective may be to protect public health, but the simplified procedure exists to licence a product which already benefits from a marketing authorisation for importation,⁶¹ whilst the purpose of the abridged procedure is to issue a *new* marketing authorisation for a product similar to an existing marketing authorisation.⁶²

⁵⁷ N. 5 above, Art. 10(2)(b). See also chapter 3(2.3) above.

⁵⁸ It does not, however, mean that the two tests are related or apply to the same products. This comparison only serves as an exercise in order to understand and define the ‘essentially identical’ test.

⁵⁹ N. 5 above.

⁶⁰ See n. 32 above; and Case 94/98, n. 2 above, para, 40.

⁶¹ See chapter 3(3.1) above.

⁶² See chapter 3(2.3) above.

2.2 *The definition of 'essentially identical'*

The two products must have the same therapeutic effect in order to be considered 'essentially identical.'⁶³ The therapeutic effect is the effect the drug has on the body – i.e. the extent to which it cures a disease. This condition is closely linked to the condition concerning 'active ingredients' and the same 'pharmaceutical formulation.'⁶⁴ In fact, the three criteria are closely interlinked. If the products have the same pharmaceutical formulation it is very likely that they will have the same active ingredients, and will most likely have the same therapeutic effect.

The active ingredient is the part of the product that provides the effect intended by the manufacturer – a chemical reaction creating the desired effect within the body. It is the primary ingredient in a medicine, all other ingredients only serve to assist the active ingredient when creating the therapeutic effect intended. In *Kohlpharma*,⁶⁵ the common ground between the two products was the active ingredient, produced by the same producer. This suggests that the 'same active ingredient' is the core criterion in 'essentially identical.' If two products are considered to contain the same active ingredients, it is likely that the active ingredients have to contain the same chemically active compound (quality), and possess the same strength (quantitatively).

In *SmithKline Beecham v. Laegemiddelstyrelsen*,⁶⁶ the ECJ discussed to what extent the products require the same composition of 'active ingredients' in order to be considered 'essentially similar' under the abridged application procedure.⁶⁷ The ECJ distinguished between the therapeutically active part of an active substance and the active substance itself. The active substance of the drug in question could be

⁶³ Case 104/75, n. 9 above; and Case C-201/94, n. 7 above, para. 26. See Communication (2003), n. 4 above, 5.

⁶⁴ Case C-201/94, *ibid.*, para. 26.

⁶⁵ N. 21 above.

⁶⁶ Case C-74/03 *SmithKline Beecham Plc v. Laegemiddelstyrelsen* [2005] E.C.R. 595. See also EUF (ed.), 'Products may be essentially similar with same active substance in different salts,' (2005) 159 EUF 19.

⁶⁷ See chapter 3(2.3) above on the abridged application procedure.

divided into two groups – the active moiety and the salt. According to the ECJ, neither Article 4(8)(a)(iii) of Directive 65/65/EEC⁶⁸ nor the Court’s judgment in *Generics*,⁶⁹ preclude two products from being at least ‘essentially similar’ despite the fact that their active ingredients contain different salts, as long as the active moiety of both products is identical.⁷⁰ When considering whether two products are ‘essentially similar,’ it is more realistic to base that enquiry on the therapeutic effect than on the precise molecular structure of the active ingredients.⁷¹

In *Smith & Nephew*, the Court stated that the products should at least have been manufactured according to the same formulation, using the same active ingredients, in order to be considered ‘essentially identical.’⁷² The most likely meaning of this phrase, in light of the above discussion of ‘essentially similar,’ is that the products should have been manufactured according to the same formulation in terms of the active ingredient, not the same formulation and the same active ingredients. The core definition is therefore that of ‘active ingredient,’ on the condition that the products have the same therapeutic effect.

The question is therefore whether the active ingredient includes all the substances of the chemical compound, or only the active moiety in line with *SmithKline Beecham*.⁷³ If the definition is to include all parts of the ‘active ingredient’ this is likely to include the ‘excipients’ as well. ‘Excipients’ are substances used as diluents or a vehicle for a drug. Naturally, it is hard to differentiate between the ‘composition of active ingredients’ and ‘excipients’ as they often complement each other to such an extent that they become almost indistinguishable. However, *Rhone-*

⁶⁸ Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products [1965] O.J. 22/369: Replaced by Directive 2001/83, n. 5 above.

⁶⁹ Case C-368/96 *R. v. Licensing Authority, ex parte Generics* [1998] E.C.R. 7967.

⁷⁰ Case C-74/03, n. 66 above, para. 34. See also Directive 2001/83, n. 5 above, Art. 10(2)(b), which provides that the different salts, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance unless they differ significantly in properties with regard to safety and efficacy.

⁷¹ *ibid.*, paras. 35 and 44.

⁷² N. 7 above, paras. 25-26; and Case C-94/98, n. 2 above, para. 28.

⁷³ N. 66 above.

*Poulenc Rorer*⁷⁴ provided useful guidance on the definition of ‘essentially identical’ in terms of active ingredients and excipients. The basic facts were as follows.

In 1989 and 1993 the MHRA granted a marketing authorisation to M & B for ‘Zimovane.’ M & B appointed Rhone-Poulenc Rorer as their sole agent. After more than three years of additional research, Rhone-Poulenc Rorer developed a new, improved, version of ‘Zimovane.’ The new version contained the same active ingredients and had the same therapeutic effect, but was manufactured by a different manufacturing process and used different excipients which allegedly provided a particular benefit to public health compared with the old version. Rhone-Poulenc Rorer applied to the MHRA for a variation to the marketing authorisation for Zimovane. The MHRA allowed the variation and subsequently, at the request of Rhone-Poulenc Rorer, revoked the old marketing authorisation for the original Zimovane. The relevant question was whether the new and old version of Zimovane could be considered ‘essentially identical’ for the purpose of the appended PIL.

The ECJ, referring to *Smith & Nephew*,⁷⁵ ruled that in order to ascertain whether imports of a pharmaceutical product constitute parallel imports the competent authority must verify that the products, if not identical in all respects, ‘have at least been manufactured according to the same formulation, using the same active ingredient, and have the same therapeutic effect.’⁷⁶ However, Rhone-Poulenc Rorer argued that the condition of ‘manufactured according to the same formulation’ was not met, both in relation to active ingredients and excipients.⁷⁷ The Court agreed that all components of the product - including the excipients - are important to its quality, efficacy, and safety, and form part of the reference marketing authorisation’s product summary as required under Article 4(a) of Directive 65/65/EEC.⁷⁸

⁷⁴ N. 2 above.

⁷⁵ N. 7 above.

⁷⁶ Case C-94/98, n. 2 above, para. 28.

⁷⁷ *ibid.*, para. 31.

⁷⁸ *ibid.*, para. 33. Directive 65/65, n. 68 above.

However, according to the Court, it is also true that changes in excipients do not *normally* alter the products therapeutic effect.⁷⁹ Nevertheless, it is still possible for a parallel imported product, containing the same active ingredients and having the same therapeutic effect, but not using the same excipients as the reference product, to show marked differences in terms of safety due to the effect on the product's shelf-life and bioavailability, 'for example in relation to the rates at which the medicinal product dissolves or is absorbed.'⁸⁰ Measuring the bioequivalence of two such products generally provides the best method of establishing therapeutic equivalence, since the excipients and the manufacturing method may have an impact on the bioavailability, i.e. the rate at which the body responds to the chemical compound.⁸¹ However, the possibility of such effects does not mean that national authorities may never issue a PIL in such a scenario, since a change in excipients does not normally affect safety.⁸²

Consequently, national authorities must grant a PIL, in line with Community measures, when the parallel imported product has the same active ingredients (in terms of active moiety) and therapeutic effect as the reference medicinal product, but does not use the same excipients and is manufactured by a different process, where the competent national authority is able to verify that the parallel imported product complies with the requirements relating to 'quality, efficacy and safety in normal conditions of use and is in a position to ensure normal pharmacovigilance.'⁸³ This effectively took excipients out of the 'essentially identical' test.

⁷⁹ Case C-94/98, n. 2 above, para. 34.

⁸⁰ *ibid.*, para. 43.

⁸¹ Advocate General Ruiz-Jarabo Colomer in Case C-368/96, n. 69 above, para. 37.

⁸² Case C-94/98, n. 2 above, para. 44. This is in contrast to the 'abridged application' procedure which, according to Directive 2001/83, n. 5 above, Art. 10(2)(b), requires that the bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.

⁸³ Case C-94/98, n. 2 above, para. 48. This confirmed, or rather extended, the ECJ's ruling in Case C-368/96, n. 69 above - a case which concerned the 'essentially similar' test for generic products - to parallel imported products under the simplified procedure. Following (C-368/96) *Generics*, a generic product is considered 'essentially similar' to a reference product despite differences in excipients, as long as the quality and efficacy is not compromised, and the products have the same composition in terms of active ingredients, the same pharmaceutical form, and are bioequivalents.

However, a change in excipients may have an impact on the product's characteristics, despite the two products having the same therapeutic effect.⁸⁴ In such a scenario, when the products only differ in respect of modified excipients, leading to e.g. improved temperature stability and thus making storage in the refrigerator unnecessary, two products can be considered 'essentially identical' as long as the quality and safety is not affected. It is for the national court to decide if public health and safety is put at risk by allowing the two products to be marketed side by side simultaneously.

This leads to the question whether two products can be considered 'essentially identical' if they do not have the same pharmaceutical form. In the words of the Council of Europe under the auspices of the European Pharmacopoeia; 'the pharmaceutical form is the combination of the form in which a pharmaceutical product is presented by the manufacturer (form of presentation) and the form in which it is administered including the physical form (form of administration).'⁸⁵ Differences in terms of active substances and excipients are usually not visible to the human eye. The consumer would therefore not be able to tell that the products are not identical. However, if two products (containing the same active ingredients and having the same therapeutic effects) can be considered 'essentially identical' even though they do not have the same pharmaceutical form this would affect the consumer's view of the product.

It should, however, be noted that case-law and Community measures do not mention pharmaceutical form in relation to PILs. It is therefore not an established condition for the purpose of showing that two products are 'essentially identical.' However, the 'same pharmaceutical form' is one of the 'core' conditions of the abridged procedure's 'essentially similar' test,⁸⁶ as defined in Directive

⁸⁴ See Case C-172/00 *Ferring GmbH v. Eurim-Pharm GmbH* [2002] E.C.R. 6891.

⁸⁵ European Directorate for the Quality of Medicines (EDQM), *List of standard terms*, 5th ed., (EDQM: 2004). See also Advocate General Ruiz Jarabo Colomer in Case C-368/96, n. 69 above, para. 37.

⁸⁶ See chapter 3(2.3) above on the abridged procedure.

2001/83/EC⁸⁷ and *Generics*.⁸⁸ It is possible for two products to contain the same active moiety and have the same therapeutic effect even though they have different pharmaceutical forms. The ‘change in form’ is usually due to a change in excipients and/or design carried out to facilitate the transportation through the body. The question therefore remains whether a product would be considered ‘essentially identical’ to a reference product with a different pharmaceutical form upon the first granting of a PIL.⁸⁹ Following *Rhone-Poulenc Rorer*⁹⁰ it seems as if the answer would be positive; even though a different form could entail a different pharmaceutical formulation this does not always preclude the finding of ‘essentially identical.’ This presumption is further supported by recent case-law concerning the abridged marketing authorisation procedure for generic products, which can serve as a guideline for the simplified procedure. In *Approved Prescription Services Ltd*⁹¹ the ECJ held that an abridged marketing authorisation can be granted for a product C, even though the reference product B is a line extension of product A, ‘but has a different pharmaceutical form from product A or is otherwise not essentially similar to product A within the meaning of Article 10(1)(iii)’⁹² of Directive 2001/83/EC.⁹³

In conclusion, it can be said that two products will be considered ‘essentially identical’ if they have the same therapeutic effects. In order to have the same therapeutic effects, the products must possess the same active ingredients, in particular the same active moiety. The excipients need not be identical, if it can be shown that the difference in excipients does not affect quality and safety assurance. The implication is that it is not unlikely that two products could be considered

⁸⁷ N. 5 above.

⁸⁸ N. 69 above, para. 36.

⁸⁹ Incidentally, PILs have been allowed to remain valid even in circumstances where the reference marketing authorisation is withdrawn and replaced by a new marketing authorisation for a product with a different pharmaceutical form than the parallel imported version. See Case C-15/01 *Paranova AB v. Läkemedelsverket* [2003] E.C.R. I-4175, and Case C-113/01 *Paranova Oy* [2003] E.C.R. 4243. This will be further discussed in section 3 below.

⁹⁰ N. 2 above.

⁹¹ Case C-36/03 *Approved Prescription Services Ltd v. Licensing Authority* [2004] E.C.R. 11583

⁹² *ibid.*, para. 16

⁹³ N. 5 above. See chapter 3(2.3) above.

‘essentially identical’ even if they have different pharmaceutical forms, and possess different storage requirements.

The ECJ has therefore expanded the definition of ‘parallel imported’ as set out in *de Peijper*.⁹⁴ The PIL system has moved away from being a system for strictly parallel imported products to ‘essentially identical’ products that do not necessarily need to share a common origin with the reference products. Slight differences between the imported version and the reference products were allowed in order to preclude manufacturers from segmenting the Community market along national lines by marketing slightly different pharmaceutical products throughout the Community. Unfortunately, it now seems as if the ‘simplified procedure,’ by allowing for a lack of common origin and differences in the pharmaceutical formulation, has been relaxed so as to create an authorisation procedure for imported products in general, sharing some similarities with a product already benefiting from a marketing authorisation, instead of a licensing system strictly for the benefit of products imported in parallel. The effects this may have on public health and safety will be further discussed below.

However, potential risks to public health and safety may also occur when the two ‘essentially identical’ products are sold simultaneously on the market, and in particular when the reference marketing authorisation is withdrawn and replaced by a marketing authorisation for a new and different, albeit improved, product.

3. *Withdrawal of the reference marketing authorisation*

Withdrawing a marketing authorisation by a pharmaceutical company is a common practice. It is often the result of having obtained marketing authorisation for an improved version of the product, rendering the marketing authorisation for the old version superfluous. It can also be done for reason of profit maximisation as it is easier to market a product when the old version is no longer available. A new

⁹⁴ N. 9 above.

version of a drug can recover costs spent on ‘research and development’ (R&D) by income from the period of exclusivity granted by patent protection. If the old version is allowed to coexist on the market the profit derived from exclusivity will not be maximised. Thus, pharmaceutical companies are not interested in continuing to market the old version, and do not want parallel importers to market the old version alongside the new version.

Withdrawing a marketing authorisation can also be a response to public health and safety concerns. The competent national authority may revoke the marketing authorisation if marketing of the product may pose a risk to public health and safety. Likewise, the holder may decide to voluntarily withdraw the marketing authorisation if continuous marketing of the product is likely to harm the public’s perception of the product and the goodwill of the manufacturer.

Paragraph 12 of the MHRA’s MAL2(PI) established that a PIL continues in force only as long as the reference UK marketing authorisation to which it is linked remain in force. If it ceases to be valid for any reason (for example, through expiration or revocation) the PIL also ceases to be valid.⁹⁵

Revoking the PIL as a result of the *revocation* of the reference marketing authorisation by the national Medicines Control Agency on grounds of public health and safety can be justified under Article 30 EC Treaty. If the product under the reference marketing authorisation presents a risk to public health and safety, so will the product under the PIL. However, revoking the PIL upon the mere *withdrawal* of the reference marketing authorisation (by its holder) will obstruct the free movement of goods under Article 28 EC Treaty, and cannot be justified under Article 30 EC Treaty, since marketing of the parallel imported product presents no risk to public health and safety.⁹⁶ Similarly, in *Ferring*,⁹⁷ the ECJ noted that the

⁹⁵ MAL2(PI), n. 1 above, para. 12.

⁹⁶ See Case C-94/98, n. 2 above, para. 48. The MHRA (unofficial), n. 1 above, has been amended so as to take into account this (and subsequent) case-law by adding that: ‘If a marketing authorisation is withdrawn, it may be possible to continue to market the product in the UK, but only if ‘the [PIL]

withdrawal of the reference marketing authorisation does not mean that the safety and quality of the product has been called into question. In fact, the products continue to be marketed in the Member State of exportation.⁹⁸ Therefore, when the reference marketing authorisation is withdrawn for reasons other than the protection of public health, the automatic cessation of the linked PIL cannot be justified.⁹⁹

The fact that it is not the act of withdrawal by the marketing authorisation holder that is questioned, but the act of the State-regulated Medicines Control Agency when revoking the PIL, supports the argument that national Medicines Control Agencies, when granting PILs, may not restrict duration of the PIL until the expiry date of the reference marketing authorisation. The expiry of a PIL, for reasons not relating to health and safety, at a time when the reference marketing authorisation remains valid, should have the same effect on the free movement of goods as a revocation.¹⁰⁰

Conversely, withdrawing the marketing authorisation in the Member State of exportation will have the same effect on the free movement of goods. If the supply chain is broken, this will prevent intra-Community trade. However, the difference is that it will be difficult to link this restriction to a State measure, as the Member State will not be responsible for the revocation of the PIL. It is however possible that the marketing authorisation holder could be liable under competition law, if intending to prevent parallel trade.¹⁰¹ It will be interesting to note the ECJ's and the Commission's reaction to such a situation.

satisfies the strict criteria that the [ECJ] have set for the survival of [PILs] in these circumstances. Otherwise, the [PIL] will automatically fall:' (para. 13).

⁹⁷ N. 84 above. By way of an Article 234 EC Treaty reference from a German Court, the ECJ was asked to rule upon the conformity of a law demanding that all PILs have to be automatically revoked upon the withdrawal of the reference marketing authorisation with Articles 28 and 30 EC Treaty: see p. 132 below.

⁹⁸ *ibid.*, para 36.

⁹⁹ *ibid.*, para 33.

¹⁰⁰ See Commission Communication (2003), n. 4 above, 17.

¹⁰¹ See Commission Decision COMP/A.37.507/F3-AstraZeneca of 15 July 2005 ((not yet reported, but a non-confidential version is available on DG Competition's website: <http://ec.europa.eu/comm/competition/index_en.html>); and Commission Press Release IP/05/737. The decision has been appealed: Case T-321/05 *AstraZeneca AB v. Commission* [2005] O.J. C271/47. The Commission

However, a voluntarily-withdrawn marketing authorisation is normally replaced by a new marketing authorisation for a new, improved product. If the national Medicines Control Agency considers the new and old versions to be ‘essentially identical,’ it will append the PIL to the new marketing authorisation. By doing this, the national Medicines Control Agency in effect avoids the ‘question of lawfulness in the light of free movement of goods of the automatic revocation of PILs as a result of the revocation of a parent authorisation at the request of the holder of that authorisation.’¹⁰²

If, however, the PIL is not appended to the new marketing authorisation, but is nevertheless allowed to remain in force; the Member State Medicines Control Agency is not required to take into consideration that the new version of the product may provide a particular public benefit to public health, and that this may not be achieved if the two products are allowed to be sold simultaneously on the market.¹⁰³ The safety of the old version is not being questioned considering that the old version is still marketed in other Member States, not least the exporting Member State. Revoking the PIL in such circumstances may only lead to a loss of benefit to public health, as opposed to creating a risk to public health. However, there may be a risk to public health if consumers are likely to confuse the two versions.

In *Ferring*,¹⁰⁴ the ECJ ruled that ‘if it is demonstrated that there is in fact a risk to public health arising from the coexistence of two versions of the same pharmaceutical product on the market in a Member State such a risk may justify

fined AstraZeneca €60 million for, *inter alia*, ‘misusing rules and procedures applied by the national Medicines Control Agencies which issue market authorisations for medicines by selectively deregistering the marketing authorisations for Losec...with the intent of blocking or delaying entry by generic firms and parallel traders;’ (Press release, above). Thus, withdrawing marketing authorisations, with the intention of blocking parallel imports, infringes Article 82 EC Treaty if the undertaking holds a dominant position. This shows that competition law is a relevant factor. However, subsequent changes in the EU legislation have made it impossible to repeat the specific conduct. See the below discussion on Cases C-15/01 and C-113/01, n. 89 above. It should be noted that the decision concerned the withdrawal of marketing authorisations on the importing market, and not on the exporting market as discussed in this paragraph. See chapter 2, pp. 70-72 above, for further discussion of this Commission Decision and Article 82 EC Treaty.

¹⁰² Case C-94/98, n. 2 above, para. 39.

¹⁰³ *ibid.*, para. 48.

¹⁰⁴ N. 84 above. See n. 97 above for the facts of the case.

restrictions on the importation of the old version of the pharmaceutical product in consequence of the withdrawal of the marketing authorisation of reference by the holder thereof in relation to that market.¹⁰⁵ The difference between the new and old version (still being parallel imported) in *Ferring*¹⁰⁶ was that the old version needed to be stored in a cool place in order to preserve its therapeutic qualities, whereas the improved thermostability of the new version means that it can be stored at room temperature. As a result, is it relevant to the ruling that marketing the two products simultaneously means that there is a danger of incorrect storage of the ‘old’ version, which may have consequences to public health and safety?

If it can be demonstrated that there is a risk to public health arising from the coexistence of the new and old versions, such a risk may justify restrictions on the old version.¹⁰⁷ It is for the competent national authorities to determine whether the coexistence of the two versions poses a risk to public health and safety. Mere reliance on the reference marketing authorisation holder’s assertion cannot justify such a prohibition.¹⁰⁸ In consequence, the national court must apply the principle of proportionality. For example, it may be possible to avert this risk by adequate labelling, or by providing relevant information to patients and pharmaceutical dispensers.¹⁰⁹

Shortly after *Ferring*,¹¹⁰ the ECJ was faced with similar facts in the related cases of *Paranova Oy*¹¹¹ and *Paranova AB*.¹¹² Astra held the Swedish and Finnish marketing authorisations for Losec ENTERO, notably the best-selling pharmaceutical product in the world. Astra improved the product and applied for marketing authorisations

¹⁰⁵ Case C-172/00, n. 84 above, para 46.

¹⁰⁶ *ibid.*

¹⁰⁷ *ibid.*, para. 43.

¹⁰⁸ *ibid.*, para. 44.

¹⁰⁹ *ibid.*, para. 45. On the facts, however, the ECJ thought it conceivable that adequate labelling would not suffice to avert this risk.

¹¹⁰ N. 84 above.

¹¹¹ Case C-113/01, n. 89 above.

¹¹² Case C-15/01, n. 89 above. For a thorough discussion of both cases, see F. Wiraeus, ‘Parallelimport och försäljning av läkemedel – fallet Losec,’ Examensarbete, University of Lund (2000).

in Sweden and Finland for the new variant, called Losec MUPS. The difference between the two variants is that ENTERO comes in the form of capsules with omeprazole acid as the active ingredient, whilst MUPS is in the pharmaceutical form of tablets with the active ingredient consisting of magnesium salt of omeprazole acid. The tablet was made up by thousands of small grains, each having a diameter of 0.5 mm, whilst the capsule consists of one hundred small grains with a diameter of 0.7 – 1.6 mm. Moreover, the tablets and capsules differ in size and colour.¹¹³ As a result of introducing a new variant, Astra Oy and Hässle withdrew the marketing authorisations for Losec ENTERO in Sweden and Finland. In response, the relevant national Medicines Control Agencies (the Swedish and Finnish Läkemedelsverket) notified the holders of the PILs for Losec ENTERO that the PILs would cease to be valid as a result of the withdrawal of the reference marketing authorisations. Paranova appealed against the Agencies decisions, subsequently resulting in an Article 234 EC Treaty referral to the ECJ by the Swedish Supreme Court.

The ECJ ruled, in line with *Ferring*,¹¹⁴ that Articles 28 and 30 preclude national legislation under which the withdrawal of the reference marketing authorisation entails the withdrawal of the PIL.¹¹⁵ However, partly as a consequence of the differences between the two products, the important parts of these rulings concern the issue of pharmacovigilance, since as a consequence of the withdrawal of the marketing authorisation for the old version of the product, the previous marketing authorisation holder would not be under an obligation to submit the information necessary to carry out effective pharmacovigilance. Due to the differences between the two products it was even more important to monitor their safety; individually as well as the potential consequences of allowing the two products to be sold side-by-side. However, despite these obstacles, the ECJ considered that adequate pharmacovigilance can still be effectively carried out, even though certain information may have to be requested from the parallel importer.

¹¹³ Wiraeus, n. 112 above, 24.

¹¹⁴ N. 84 above.

¹¹⁵ Case C-15/01, n. 89 above, para. 33.

Pharmacovigilance satisfying Directive 75/319¹¹⁶ can be guaranteed by requesting information and documentation from national authorities in the Member States where the products are still marketed and benefiting from a marketing authorisation,¹¹⁷ in line with the decision in *de Peijper*¹¹⁸ when establishing the simplified procedure. The ‘Note for Guidance on Procedure for competent Authorities on the Undertaking of Pharmacovigilance Activities’¹¹⁹ requires information to be submitted to a database using international or mutually recognisable codes and languages, so as to ensure effective pharmacovigilance accessible for all Member State authorities throughout the Community.¹²⁰ Effective pharmacovigilance can therefore be achieved by cooperation with other Member States. Information necessary to maintain an effective pharmacovigilance system will still be obtainable since the product is still marketed in other Member States. However, this does not preclude specific reasons relating to the protection of public health and safety which may justify the withdrawal of a PIL, in line with *Ferring*.¹²¹

First, it can be argued that this ‘forced cooperation’ may have a positive side-effect on integration. By leaving the PIL valid following the withdrawal of the reference marketing authorisation, the ECJ forces Member State Medicines Control Agencies to rely solely on information provided by agencies in other Member States. In consequence, it encourages Member States into stronger co-operation, as well as indicating that licences based on separate national procedures are no longer sufficient to satisfy Community integration and public health.

Secondly, the *Paranova* cases may, as discussed in section 2.2 above, have an impact on the definition of ‘essentially identical.’ Losec ENTERO and Losec MUPS differ in terms of active ingredients. It may be argued that the products have

¹¹⁶ Council Directive 75/319/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products [1975] O.J. L147/13.

¹¹⁷ Case C-15/01, n. 89 above, para. 28.

¹¹⁸ N. 9 above.

¹¹⁹ The European Medicines Agency (EMA), ‘Note for Guidance on Procedure for competent Authorities on the Undertaking of Pharmacovigilance Activities,’ (CPMP/PhVWP/175/95 Rev. 1).

¹²⁰ Case C-15/01, n. 89 above, para. 29.

¹²¹ N. 84 above.

the same active ingredient, and the difference lay in the excipients used. Nevertheless, the products differ in terms of ‘pharmaceutical form.’ However, it should be noted that the cases were concerned with the revocation of PILs, and so may not have an impact on the definition of ‘essentially identical’ per se. The PILs were not appended to the new marketing authorisations, as in *Rhone-Poulenc*,¹²² but were merely allowed to co-exist with the new marketing authorisations. If the products had been appended to the new marketing authorisations, this would *de facto* have confirmed that the two products were ‘essentially identical’ despite having different pharmaceutical forms.¹²³ Nevertheless, the practical effect of the two rulings mean that a parallel imported version may be sold alongside a reference product having a different ‘pharmaceutical form,’ thus strengthening the theory that the ECJ would rule that the ‘same pharmaceutical form’ is not part of the definition of the term ‘essentially identical,’ should it be asked to rule on this question in the future.¹²⁴

The rules regarding the revocation of PILs as a response to the withdrawal of the reference marketing authorisation can therefore be summarised as follows;

- Articles 28 and 30 EC Treaty preclude national legislation under which the withdrawal of the reference product marketing authorisation on application of the holder entails the automatic cessation of the PIL for that product;¹²⁵
- the fact that a new version of the product has been put on the national market and is also found in other Community markets does not alter this outcome;¹²⁶
- However, those provisions do not apply if there is a risk to public health and safety by allowing the two products to coexist on the market.¹²⁷

¹²² N. 2 above.

¹²³ See section 2.2 above.

¹²⁴ See *ibid.*, and in particular Case C-36/03, n. 91 above, para. 16, concerning the ‘same pharmaceutical form’ in the context of the abridged marketing authorisation.

¹²⁵ Case C-172/00, n. 84 above, para 46; Case C-15/01, n. 89 above, para. 33; and C-113/01, n. 89 above, para 34.

¹²⁶ Case C-172/00, *ibid.*, para 46.

4. *Conclusion and analysis*

Following *de Peijper*¹²⁸ and the ECJ's subsequent case-law concerning the simplified procedure, there are no real obstacles remaining for parallel importers in relation to marketing authorisations. The definition of 'parallel imported' is very generous, and manufacturers can no longer prevent parallel imports by withdrawing reference marketing authorisations. The question is instead whether the ECJ has in fact adopted a stronger pro-integration policy than is necessary in order to establish a common market, and whether this can be justified despite the ensuing risks to public health and safety.

The *de Peijper*¹²⁹ case was equally important to the development of parallel trade in pharmaceutical products as the case-law establishing the 'exhaustion of rights' principle in relation to intellectual property rights, which will be discussed in the next chapter.¹³⁰ By establishing a simplified procedure for parallel imported pharmaceutical products in order to allow for the importation of products 'essentially identical' to products which already benefit from a marketing authorisation the ECJ, in essence, created an 'exhaustion of rights' principle for marketing authorisations. In order to preclude marketing authorisation holders from preventing parallel trade in their products by marketing slightly different variations throughout the Community, the ECJ held that it would be sufficient if the parallel imported product and the reference product are 'essentially identical.' In theory, this system does not constitute a risk to public health and safety since the information relating to the pharmaceutical product is already in the relevant national Medicines Control Agency's possession as a result of the reference marketing authorisation application.

¹²⁷ Case C-172/00, n. 84 above, para. 46; and Case C-15/01, n. 89 above, paras. 31-32.

¹²⁸ N. 9 above. See chapter 3(3.1) above.

¹²⁹ *ibid.*

¹³⁰ See chapter 5 below.

However, the ECJ's pro-integration policy has led to a system whereby the two products, albeit being 'essentially identical,' need not have a common origin and the PIL cannot be revoked even after the withdrawal of the reference marketing authorisation. The definition of 'essentially identical' has also expanded to encompass a difference in excipients and, possibly, pharmaceutical form. This has eradicated the initial purpose of the simplified procedure. It seems as if the procedure has turned into a fifth procedure for marketing authorisations allowing for a speedier procedure for imported pharmaceutical products being closely linked to the abridged procedure.¹³¹

It is likely that this was not the intention of the ECJ when establishing the simplified procedure in *de Peijper*.¹³² The Court's intention was to establish a procedure which enables 'parallel importation' in the term's historical and true meaning, and not for 'normally imported' products, even though they are 'essentially identical' to products which already benefit from marketing authorisations. Products that fit this description should use the abridged application procedure when applying for marketing authorisation.

The current system can indirectly risk public health and safety. Member State Medicines Control Agencies will find it harder to carry out effective pharmacovigilance when all the information is not in their hands and they have to cooperate with agencies in other Member States in order to find the information and particulars that cover the differences between the reference product and the parallel imported product. This may be positive for the integration of the single market, forcing Member States to cooperate, but it will also lead to an increasing risk of errors by national Medicines Control Agencies when carrying out pharmacovigilance due to the extra workload associated with cooperation.

¹³¹ See chapter 3(2.3) above on the abridged procedure.

¹³² N. 9 above. See chapter 3(3.1) above.

A solution would be to go back to the ruling in *de Peijper*.¹³³ The particulars and conditions could be laid down in Community measures, thus limiting the procedure to products imported in parallel. Products not originating from the same manufacturer, thus not having an absolutely common origin with the reference product, should be restricted to the abridged marketing authorisation procedure.¹³⁴ But in order not to affect legal certainty, the best solution is to gradually make the Community marketing authorisation compulsory for more categories of pharmaceutical product. This would solve many problems for all three involved parties; the marketing authorisation holder, the parallel importer, and society at large, not to mention the Community which would benefit from the centralisation and further integration, which would result from only having one marketing authorisation procedure throughout the Community.¹³⁵ Only one marketing authorisation would be needed, and a PIL would not be necessary. Once the marketing authorisation is withdrawn, parallel importation will not be possible. But since most withdrawn marketing authorisations are replaced by new marketing authorisations for similar products, parallel importation of the replacing product can commence instantly. As discussed in chapter 3 section 4, the wording of Regulation 726/2004 indeed suggest that the Community marketing authorisation procedure may gradually become compulsory for more product groups.¹³⁶ Unfortunately, however, the objections to such a reform may be difficult to overcome despite its many benefits.¹³⁷

However, even though the parallel importer is eligible to apply for a parallel import licence under the current system, and indeed may be granted such a licence, the manufacturer may exercise the intellectual property rights linked to the pharmaceutical product to prevent such importation. Intellectual property right holders are therefore in theory capable of segmenting the common market along

¹³³ N. 9 above.

¹³⁴ See chapter 3(2.3) above.

¹³⁵ See chapter 3(4) above.

¹³⁶ See *ibid.*; and the Annex to Council Regulation (EC) 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] O.J. L136/01.

¹³⁷ See chapter 3(4) above for discussion of the possible objections to such a reform.

national boundaries. The relationship between parallel trade and intellectual property rights, discussed in the next chapter, is therefore linked to the hurdle of marketing authorisations as successful parallel importation requires that the free movement of goods provisions prevail over both of these barriers to trade simultaneously.

PART II

PARALLEL TRADE IN INTELLECTUAL PROPERTY
PROTECTED PRODUCTS AND REPACKAGING OF
PHARMACEUTICAL PRODUCTS

THE EC TREATY AND INTELLECTUAL PROPERTY RIGHTS: THE 'EXHAUSTION OF RIGHTS' DOCTRINE

Intellectual property rights are granted by national legislation conferring exclusive and territorial property rights upon the holders thereof. A typical pharmaceutical product is likely to benefit from a patent protection for its chemical composition, and a trademark affixed on its packaging. The latter will ensure to the holder of the trademark the goodwill associated with the product, and guarantee the origin of the trademarked product to consumers. Owing to the territorial nature of intellectual property rights, patent and trademark holders are capable of segmenting the common market along national borders. Some limited measures have been adopted by the Community, such as the Trade Mark Directive¹ providing for the grant of a trademark valid throughout the EEA. However, the debate as to whether national intellectual property rights are compatible with the EC Treaty was left to be resolved by the ECJ, resulting in the distinction between the 'existence' and the 'exercise' of an intellectual property right. The former is protected by Article 295 EC Treaty² whilst the latter is subject to the severity of the free movement of goods and competition rules.³ This tension between national and Community law whereby the existence of national intellectual property rights is recognised but the

¹ Council Directive 89/104 EEC to approximate the laws of the Member States relating to trade marks [1989] O.J. L40/1.

² See introduction, p. 4, n. 13 above, for a full recital. This Article should be read in conjunction with Article 30 EC Treaty (see n. 3 below). Article 295 originates from article 83 EC Treaty establishing the Coal and Steel Community, whose function was to determine whether an undertaking was privately or public owned. The application of Article 295 EC Treaty to intellectual property rights, so as to make a distinction between the existence and the exercise of intellectual property rights, is therefore a somewhat elaborate exercise. See G. Tritton, 'Articles 30 and 36 and intellectual property: Is the jurisprudence of the ECJ now at an ideal standard,' (1994) 16 E.I.P.R. 422, 423.

³ The free movement of goods provisions consists of Articles 28-30 EC Treaty: see introduction, p. 2, n. 3 above, for full recitals. The competition rules comprise Articles 81 and 82 EC Treaty, discussed in chapter 2 above.

exploitation thereof is subject to Community law, has been further developed by the ECJ in the context of interpreting Articles 28 and 30 EC Treaty. The 'exhaustion of rights' doctrine defines the limitations imposed upon the exercise of the right by Community law. The implications of this doctrine subsequently resulted in a 'specific mechanism' in the 2003 Act of Accession,⁴ allowing intellectual property rights holders to derogate from the doctrine if the products imported from the ten new Member States possess certain characteristics.

This chapter will discuss the compatibility of the free movement of goods provisions and parallel trade in pharmaceutical products within the EEA. Discussion of the controversial issue of allowing for international exhaustion, as opposed to merely Community exhaustion of intellectual property rights, will be followed by discussion of the application of these principles in the 'EFTA-EEA' Member States. Finally, a thorough analysis of the derogation in the 2003 Act of Accession⁵ will be undertaken to provide a complete account of the free movement of intellectual property protected pharmaceutical products within the enlarged EEA.

1. *The existence/exercise distinction*

If a European common market is to be achieved goods must be imported and exported between Member States without restrictions. However, as Member States tend to adopt protectionist measures that directly or indirectly favour national interests, the ECJ is frequently asked to rule on the compatibility of national legislation with the free movement of goods provisions in the EC Treaty. Article 28 EC Treaty prohibits all restrictions on the free movement of goods and all measures having equivalent effect between Member States.⁶ National intellectual property rights, if exercised according to national law, may prevent this freedom of movement owing to their inherently territorial nature. The EC Treaty provides for an express derogation to the free movement of goods provision in Article 30 EC

⁴ Act of Accession [2003] O.J. L236/33: see introduction, p. 4, n. 15 above for a full reference.

⁵ See *ibid.*; and n. 138 below.

⁶ See n. 3 above.

Treaty, stating that Article 28 EC Treaty shall not preclude prohibitions or restrictions on imports or exports which are justified for, *inter alia*, the protection of industrial and commercial property. 'Such prohibitions and restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.'⁷ Save for the limited protection of property ownership afforded under Article 295 EC Treaty,⁸ the Treaty provides no further guidance concerning intellectual property rights. The traditional function of a patent, in the context of the pharmaceutical industry, is to grant the inventor of a new pharmaceutical product a time-restricted monopoly right over the invention, while the risk premium is compensated for and the financial investment made during its development recovered.⁹ Equally, it cannot be disputed that a trademark owner who has invested much time and funds in building up goodwill and following for a trademark should be able to prevent a third party from illegally capitalising on the trademark's reputation.

Consequently, the ECJ has been forced to strike a balance, when interpreting the EC Treaty, between the traditional function of national intellectual property rights and the common market objective. In *Deutsche Grammophon*, a case concerning parallel importation of copyright protected music records, the Court stated that; 'although the Treaty does not affect the existence of industrial property rights conferred by the national legislation of a Member State, the exercise of these rights may come within the prohibitions of the Treaty.'¹⁰ The origin of this 'existence-exercise' distinction can be traced to two earlier judgments concerning the relationship between Article 81 EC Treaty and intellectual property rights.¹¹ This leads to the question of how the concepts of 'existence' and 'exercise' are defined.

⁷ Article 30 EC Treaty: see n. 3 above.

⁸ See n. 2 above.

⁹ See D. Bainbridge, *Intellectual property*, 5th ed., (London: Longman, 2002), chapter 12, for discussion of the traditional functions of a patent.

¹⁰ Case 78/70 *Deutsche Grammophon v. Metro* [1971] E.C.R. 487, para. 11.

¹¹ Joined Cases 56 and 58/64 *Consten SARL & Grundig-Verkaufs GmbH v. Commission* [1966] E.C.R. 299 and Case 24/67 *Parke Davis & Co. Ltd. v. Probel & Centrafarm* [1968] E.C.R. 55. See chapter 2(1) above for a further discussion.

2. *The 'specific subject matter' of intellectual property rights*

The existence/exercise distinction in relation to intellectual property rights only functions if the different attributes of an intellectual property right can be divided into separate categories. Following *Deutsche Grammophon*¹² a line of cases focusing on the definition of the existence and the exercise of an intellectual property right emerged. For intellectual property proprietors this is commercially a very important issue. *Centrafarm v. Sterling Drug*¹³ defined the 'specific subject matter' of a patent. The term 'specific subject matter' is, for the purpose of this chapter, interchangeable with 'existence,' and will be used throughout the chapter. The facts were as follows: Sterling held the patent for a drug marketed in the UK and Germany. Centrafarm, a parallel importer, discovered that the drug was considerably more expensive in the Netherlands, and started to import it from the UK and Germany. Sterling sought injunctive relief preventing Centrafarm from importing it into the Netherlands. After referral to the ECJ by the Dutch Court, the ECJ confirmed the 'existence/exercise' principle from *Deutsche Grammophon*¹⁴ and then held that the specific subject matter of a patent is 'the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licences to third parties, as well as the right to oppose infringements.'¹⁵ The specific subject matter serves to 'reward the creative effort of the inventor,'¹⁶ which is the function of a patent. A patent therefore gives its proprietor the inherent right to manufacture and put the patented products into circulation for the first time. All other actions of the patent proprietor fall into the category of 'exercising' the patent.

The distinction between the specific subject matter and the exercise of trademark rights is similar. Trademark rights granted by national legislation are State 'measures' within the scope of Articles 28 and 30 EC Treaty. The ECJ has

¹² N. 10 above.

¹³ Case 15/74 *Centrafarm BV v. Sterling Drug Inc.* [1974] E.C.R. 1147.

¹⁴ N. 10 above.

¹⁵ Case 15/74, n. 13 above, para. 11.

¹⁶ *ibid.*, para. 9.

recognised that the exercise of trademark rights may affect intra-Community trade and held in *Centrafarm v. Winthrop* that the specific subject matter ‘is the guarantee that the owner of the trade mark has the exclusive right to use that trade mark, for the purpose of putting products protected by the trademark into circulation for the first time.’¹⁷ The Court has further held that the ‘essential function’ of a trademark is to guarantee the origin of the trademarked product to the end consumer, thus guaranteeing that the product has not been subject to interference by a third party at a previous stage of marketing so as to affect the original condition of the product.¹⁸ The right to prevent any interference by a third party with the ‘essential function’ of the trademark is also part of the trademark’s specific subject matter. Trademark proprietors thus have two rights constituting the specific subject matter of the trademark. First, to market the trademarked product for the first time, and secondly, to prevent any misuse by a third party of the trademark that is likely to impair the quality and the guarantee of origin of the trademarked product.

3. *The ‘exhaustion of rights’ doctrine*

As the specific subject matter of intellectual property rights includes the right to market a product for the first time, once the product is first put into circulation within the Community, the right-holder will be deemed to have exhausted the right to prevent the products from moving freely within the EEA. This rule is commonly referred to as the ‘exhaustion of rights’ doctrine, or simply the exhaustion doctrine.¹⁹

The exhaustion doctrine essentially opened the door for parallel trade, a practice which had earlier been prohibited due to the territorial nature of intellectual property rights. But the doctrine also led to a debate on the effect of parallel trade

¹⁷ Case 16/74 *Centrafarm BV v. Winthrop BV* [1974] E.C.R. 1183, para. 8.

¹⁸ Case 102/77 *Hoffman-La Roche & Co AG v. Centrafarm mbH* [1978] E.C.R. 1139, para. 7; and Case C-3/78 *Centrafarm BV v. American Home Products Corp.* [1978] E.C.R. 1823, para. 12.

¹⁹ In practice, this means that so long as a patent is valid, only the proprietor has the right to manufacture the product. After the product is marketed the right to prevent any subsequent trade will have been exhausted. See Case C-316/95 *Generics BV v. Smith Kline Ltd.* [1997] E.C.R. 3929.

on 'research and development' (R&D).²⁰ The specific subject matter of a patent as defined by the ECJ failed to take into consideration all the functions of a patent. Commentators argue that the Court also failed to consider the underlying policy objectives of the patent system: the importance of adequately protecting scientific progress; and providing a commercial incentive for carrying out effective R&D.²¹ Patent protection bestows a monopoly limited by time on the inventor as a form of reward for his efforts, allowing for a recoup of the investments.²² As such, patents create a financial incentive for carrying out R&D as well as providing a means for publishing the specifics of the patent in the public domain after its expiration. Patent proprietors retain the right to first marketing, but the exhaustion doctrine prevents them from capitalising on the different price levels throughout the Community as parallel importers export the products from low-priced Member States to higher-priced markets. Due to national pricing regulations patent proprietors cannot counter parallel imports by harmonising the price throughout the Community and thus make parallel trade commercially unsound.²³

Instead of recognising the pharmaceutical industry's concerns regarding the exhaustion doctrine the ECJ, in true pro-integration spirit, has held that this doctrine applies even though the patent protected-product was first marketed and put into circulation in a Member State where patent protection was not available at the time of marketing.²⁴ The function of a patent is to reward the inventor without, however,

²⁰ See chapter 1(3.1) above; and, inter alia, T. Boorer, P. Edmonds, D. Glynn and C. Ogialoro, 'Economic aspects of the single European market in pharmaceuticals,' (1999) 22 E.C.L.R. 256.

²¹ See e.g. C. Vicien, 'Why parallel imports of pharmaceutical products should be forbidden,' (1996) 17 E.C.L.R. 219, 222; H. Bale, 'The conflicts between parallel trade and product access and innovation: The case of pharmaceuticals,' (1998) J.I.E.L 637, 647; P. Rey and J. Venit, 'Parallel trade and pharmaceuticals: A policy in search of itself,' (2004) 29 E.L.Rev. 153, 165-168; and L. Hancher, 'The European pharmaceutical market: Problems of partial harmonisation,' (1990) 15 E.L.Rev. 9, 24.

²² In Case 15/74, n. 13 above, para. 9, the Court acknowledged that patents serve to reward the creative effort of the inventor. But the question is if the specific subject matter is substantial enough to compensate for this effort.

²³ See chapter 1(2.2) above; and chapter 2 above on the application of Articles 81 and 82 EC Treaty to parallel import-restrictive pricing measures.

²⁴ Case 187/80 *Merck & Co. v. Stephar BV* [1981] E.C.R. 2063; and Joined Cases C-267-268/95 *Merck & Co. Inc. v. Primecrown Ltd* [1996] E.C.R. 6285.

guaranteeing that the inventor will obtain such a reward in all circumstances.²⁵ Considering that the proprietor was fully aware that patent protection was not available in the Member State in question, and fully aware of the implications of the free movement of goods, the proprietor must accept the consequences of his decision to market the product in that Member State. Intellectual property proprietors are free to choose where in the Community to market their products, but once that decision is made, the intellectual property rights are exhausted throughout the Community whether or not first marketing took place in a Member State not providing for intellectual property protection.²⁶ This should be contrasted, however, to a situation where a patent proprietor is legally bound to market the product in another Member State, as in *Pharmon v. Hoechst*.²⁷ Hoechst, a pharmaceutical company, held the patent for a drug in Germany, the UK and the Netherlands. Subsequently a UK company obtained a compulsory licence²⁸ from the UK authorities. In breach of the prohibition against exporting the drug, the UK company sold the manufactured drugs to a Dutch parallel importer, which led to

²⁵ Case 187/80, n. 24 above, para. 10. Merck marketed a pharmaceutical product in the Netherlands, for which it was also the patent proprietor. Merck also marketed the product in Italy, where patent protection was then unavailable. Stephar, a parallel importer, imported the drug from Italy and marketed it in the Netherlands. Merck claimed unsuccessfully that the exhaustion doctrine is not applicable when the product is placed on a market where patent protection is not available.

²⁶ *ibid.*, para. 11. 'To prevent the importation of the product freely marketed by him in another Member State where that product is not patentable would bring about a partitioning of the national markets which would be contrary to the aims of the Treaty:'(para. 13). See also S. Kon and F. Schaeffer, 'Parallel imports of pharmaceutical products: A new realism, or back to basics,' [1997] 18 E.C.L.R. 123, 133. This principle has been extended to copyright rights; Joined Cases 55 and 57/80 *Musik-Vertrieb Membran GmbH v. GEMA* [1981] E.C.R. 147; however, see the distinction made between material and non-material copyright rights in Case 262/81 *Coditel v. Cine Vog Films SA* [1982] E.C.R. 3381. The *Merck v. Stephar* (*ibid.*) principle has been criticised as being inconsistent with subsequent case-law generated by the ECJ; most notably Case 158/86 *Warner Bros and Metronome Video ApS v. Christiansen* [1988] E.C.R. 2605, where the Court recognised that the market for selling video cassettes is distinct from hiring out video cassettes, and that both functions needed separate consent for the exhaustion principle to apply if the rental right would not completely lose its substance. The distinction between *Merck v. Stephar* and *Warner* is that the sale of pharmaceutical products only involves marketing and not any subsequent rental rights. Thus, even if the patent proprietor cannot prevent re-importation, he still has a right to first marketing, whereas if consent was not needed for the exhaustion of the rental rights of video cassettes the entire video rental business would collapse.

²⁷ Case 19/84 *Pharmon BV v. Hoechst AG* [1985] E.C.R. 2281.

²⁸ A licence granted by national governments to manufacture products still protected by patent law, subject to the payment of royalty fees to the patent proprietor. See Commission Communication on the proposal for a Regulation of the European Parliament and of the Council on the compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems [2004] COM/737/final.

Hoechst taking action against the Dutch company under its Dutch patent. Hoechst argued that its patent rights were not exhausted since it had not consented to such marketing in the Netherlands. A compulsory licence is an act of the State which leaves no room for negotiations, whilst a contractual licence is the result of negotiations between the licensee and the licensor. If marketing a product in a Member State where no patent protection is available is the result of a contractual licence, the patent proprietor cannot claim that there was a lack of consent as he freely entered into the negotiations, exhausting his exclusive right on the exporting market.²⁹ However, when a Member State grants a compulsory licence to a third party, so as to be able to manufacture and market the product subject to the licence, the patent proprietor cannot be said to have consented to the actions of the third party.³⁰ The case was thus decided on the basis of lack of consent from the patent proprietor, and not on technicalities relating to whether or not the product was actually put on the market in the first Member State. *Pharmon v. Hoechst* therefore confirmed the ruling in *Merck v. Stephar*³¹ in relation to the consent aspect.³²

Whether *Merck v. Stephar*³³ was rightly decided was finally to be resolved in yet another case involving Merck: *Merck v. Primecrown*.³⁴ Again Merck tried to prevent parallel imports, this time from Spain and Portugal. First, Merck claimed that the exhaustion of rights doctrine should not apply since patent protection was not available in those Member States at the time of marketing. The ECJ rejected this argument, stating that manufacturers are prohibited from opposing importation 'by a third party of that product from another Member State in circumstances where the holder first put the product on the market in that State after its accession to the European Community but before the product could be protected by a patent in that

²⁹ However, in relation to trademarks, this reasoning is negated by the ruling in Case C-9/93 *IHT Internationale Heiztechnik GmbH v. Ideal-Standard GmbH* [1994] E.C.R. 2789; see p. 151 below.

³⁰ 'Such a measure deprives the patent proprietor of his right to determine freely the conditions under which he markets his products.' Case 19/84, n. 27 above, para. 25.

³¹ N. 24 above.

³² Case 19/84, n. 27 above, para. 26-27. See D. Guy, 'Pharmon v Hoechst: Compulsory licences clarified,' (1986) 8 E.I.P.R. 252.

³³ N. 24 above

³⁴ *ibid.*

State.³⁵ Secondly, Merck claimed that the prevalingly low prices for pharmaceutical products in the two Iberian States is the result of national legislation, which has a serious impact on the economic value of the patent and affects the ability to carry out future R&D.³⁶ The ECJ responded by ruling that price regulations may indeed, in certain circumstances, distort competition, but 'it is well settled that distortions caused by different price legislation in a Member State must be remedied by measures taken by the Community authorities and not by the adoption by another Member State of measures incompatible with the rules on free movement of goods.'³⁷ The second Merck case thus confirmed *Merck v. Stephar*.³⁸

However, Merck also argued that, since pharmaceutical companies have an ethical obligation to continue to market products on a Member State market after first marketing, the exhaustion doctrine should not apply under these circumstances.³⁹ This argument appears rather desperate. It is true that the holder of a marketing authorisation is under an obligation to supply pharmaceutical products so that the needs of the patients in the Member State in question are satisfied, but this does not preclude the marketing authorisation holder from withdrawing the marketing authorisation (exiting the market), or indeed, never apply for a marketing authorisation in the first place.⁴⁰ No pharmaceutical company would ever market a

³⁵ Cases C-267-268/95, n. 24 above, para. 54 (emphasis added). The case also concerned the derogation in the Act of Accession of Spain and Portugal, and is further discussed in section 5 below in relation to the derogation mechanism in the 2003 Act of Accession (n. 4 above).

³⁶ *ibid.*, para. 46. See also R. Nazzini, 'Parallel trade in the pharmaceutical market – current trends and future solutions,' (2003) 26 World Competition 53, 62; V. Korah, 'The exhaustion of patents by sale in a Member State where a monopoly profit could not be earned,' (1997) 18 E.C.L.R. 265; and I. Stamatoudi and P. Torremans, 'Merck v Stephar survives the test,' (1997) 22 E.L.Rev 228, for a discussion.

³⁷ *ibid.*, para. 53. See also Nazzini, *ibid.*, 62. Advocate General Fennelly considered that the effect of the ruling in *Merck v. Stephar* (Case 187/80, n. 24 above), and therefore the effect of upholding that view in *ibid.* is 'to export not merely the product but also the commercial consequences of the legislative choice made by the exporting State to the importing State because the patentee has made a commercial choice to sell the product even in a less protected environment.' Advocate General Fennelly in *ibid.*, para. 108.

³⁸ N. 24 above.

³⁹ Cases C-267-268/95, n. 24 above, para. 15.

⁴⁰ See Article 81 of Council Directive 2001/83/EC on the Community code relating to medicinal products for human use [2001] O.J. L311/67: 'The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued

product if it could not see at least the potential for making a profit,⁴¹ and ethical, as opposed to legal, obligations are hard to differentiate from commercial considerations. It can also be questioned whether a truly ethical obligation would take patent protection into consideration – after all it is not a commercial obligation. Moreover, despite having full knowledge of the impact of the ruling in the first Merck case,⁴² Merck still decided to market the products where patent protection was not available, surely anticipating that the products would be subject to parallel exportation.⁴³ The ECJ acknowledged this, and held that an ethical obligation cannot be the ‘basis for derogating from the rule on free movement of goods.’⁴⁴ If, however, a patent proprietor has a legal obligation to market the products on the exporting Member State market he cannot be said to have consented to such marketing and is therefore free to oppose importation and marketing of the products in Member States where the products are benefiting from patent protection.⁴⁵ The distinction between ethical and legal obligations is in line with the Court’s previous

supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.’ See chapter 3 above for discussion of marketing authorisations. See also Case C-249/88 *Commission v. Belgium* [1991] E.C.R. 1275, para. 20, where the ECJ held that pharmaceutical undertakings are under no legal obligation to continue marketing their products in a Member State, i.e. it is only marketing authorisation holders that are under an obligation to supply authorised products. However, in Commission Decision A.37.507/F3-AstraZeneca (not yet reported, but non-confidential version available on DG Competition’s website: <http://ec.europa.eu/comm/competition/index_en.html>); the Commission held that AstraZeneca infringed Article 82 EC Treaty by abusing its dominant position when withdrawing the marketing authorisation for ‘Losec capsules’ and replacing it with a new marketing authorisation for ‘Losec tablets.’ The Commission alleges that this was done in order to prevent competition from parallel importers and generics companies. See Chapter 2, pp. 70-72 above.

⁴¹ For example, when several South American countries demanded that a national trademark must be registered in addition to the multinational trademark, a number of international pharmaceutical companies withdrew from the countries in question or at least sympathised with that tactic. See Stamatouli and Torremans, n. 36 above, 255; and M. Blakeney, *Legal aspects of the transfer of technology to developing countries*, (Oxford: ESC Publishing, 1989), p. 129. Further, Primecrown, the defendants in Case C-267-268/95 (n. 24 above), relied on a report by the National Economic Research Associates (NERA) which showed that only 40 of the 50 most commonly prescribed medicines in Europe were marketed in all Member States. Thus, the industry did not seem to act as if an ethical obligation existed. See I. Stamatouli and P. Torremans, ‘Merck is back to stay: The Court of Justice’s judgment in Merck v Primecrown,’ (1997) 19 E.I.P.R. 545, 548.

⁴² Case 187/80, n. 24 above.

⁴³ Stamatouli and Torremans, ‘Merck is back,’ n. 41 above, 548. However, this should be read in conjunction with the ECJ’s case-law on Articles 81 and 82 EC Treaty, as a refusal to supply can potentially amount to an infringement of the Community’s competition law provisions. See chapters 2(1.4) and 2(2.4) above.

⁴⁴ Cases C-267-268/95, n. 24 above, para. 53.

⁴⁵ *ibid.*, para. 50

rulings in *Merck v. Stephar*⁴⁶ and *Pharmon v. Hoechst*,⁴⁷ as a compulsory licence is a legal obligation and an ethical obligation was not more obvious in *Merck v. Primecrown*⁴⁸ than in *Merck v. Stephar*.⁴⁹ However, except for declaring a compulsory licence to come within the notion, the ECJ failed to provide an adequate definition of the notion of a 'legal obligation' in relation to the exhaustion doctrine. According to the ECJ, the patent proprietor must prove, by way of reference to decisions by 'national authorities or courts or of the competent Community authorities, that there is a genuine, existing [legal] obligation.'⁵⁰ The legal obligation must, most likely, lead to a 'first marketing' of the protected products by the patent proprietor, which, if done without a 'legal obligation,' would have exhausted the proprietary right. For example, a compulsory licence is a 'legal obligation' because the patentee agreed to the national law which provides for the issuance of a compulsory licence, if/where the innovation is not being applied, when applying for patent protection. The patent proprietor therefore never consented to the first marketing of the product in this Member State, but was under a legal obligation to allow a third party to put the product on the market under a compulsory licence. Negative legal obligations, not involving a first marketing, as for example continuing to market the products under the patent in order to avoid allegations of abuse of a dominant position under Article 82 EC Treaty,⁵¹ cannot be considered to be 'legal obligations' in relation to the exhaustion doctrine and the first marketing principle. It is not an abuse of a dominant position not to put a new product on the market for the first time. However, if the undertaking decides to market the product, the undertaking will have exhausted its right to exercise the patent rights after first marketing. Continuing to market the products in order to avoid allegations of abuse of a dominant position can therefore not be considered a 'legal obligation,' but only a consequence of the commercial decision to market the products for the first time.

⁴⁶ N. 24 above.

⁴⁷ N. 27 above.

⁴⁸ N. 24 above.

⁴⁹ N. 24 above

⁵⁰ Cases C-267-268/95, n. 24 above, para. 50.

⁵¹ See chapter 2(2.4.2) above.

It should be noted that, at the time of *Merck v. Primecrown*,⁵² those Member States that did not offer patent protection were the exceptions.⁵³ Allowing patent proprietors to exercise their patent rights so as to prevent parallel exports from these Member States would not have had a great impact on Community integration, but would in fact have acted as a transition measure until such patent protection was in place in the remaining Member States.⁵⁴ This should be compared to *Merck v. Stephar*,⁵⁵ which was decided at a time when a number of Member States did not provide for patent protection. However, the fact that most Member States provide for patent protection ‘does not mean that the reasoning underlying the rule in [*Merck v. Stephar*] is superseded.’⁵⁶ Legal certainty and consistency outweighed the argument that *Merck v. Stephar*⁵⁷ should be overturned because the rule had lost in importance and applicability. The Court nevertheless pointed out that Member States can adopt transitional measures so as to prevent parallel imports from acceding countries to the Community if such acceding Member States do not yet provide for patent protection.⁵⁸

Merck’s campaign to make the ECJ recognise the special nature of the pharmaceutical trade, the lack of pricing harmonisation and its reliance on investments in R&D, therefore came to an end without significant impact on

⁵² N. 24 above.

⁵³ *ibid.*, para 34: ‘It is true, as Merck and Beecham points out, that it is now the norm for pharmaceutical products to be patentable.’

⁵⁴ Pharmaceutical products were for a long time excluded from patent protection in many countries on the basis of public health considerations (as for example Italy). However, following Article 27(1) of the Agreement on Trade-Related Aspects of Intellectual Property Rights: Annex 1(c) of the World Trade Agreement 1994 (establishing the WTO and including GATT Uruguay 1994) (TRIPs) all Member States are now obliged to provide for patent protection for inventions in all fields of technology, including pharmaceutical products. See I. Govaere, ‘The quest for a master key to control parallel imports,’ (2001) 4 *Cambridge Yearbook for European Studies* 192, 203; and C. Tuosto, ‘The TRIPS Council decision of August 30, 2003 on the import of pharmaceuticals under compulsory licences,’ 26 (2004) *E.I.P.R.* 542.

⁵⁵ N. 24 above.

⁵⁶ Cases C-267-268/95, n. 24 above, para. 34.

⁵⁷ N. 24 above.

⁵⁸ See Cases C-267-268/95, n. 24 above, para. 39. This will be discussed below (section 5) in relation to the accession to the Community of Spain and Portugal, and the accession of the ten new Member States in 2004.

parallel trade in pharmaceutical products.⁵⁹ The ECJ did not accept Merck's argument that parallel importation will not promote price harmonisation within the Community in the absence of further integration and harmonisation brought about by Community measures. In consequence, not only products, but also national pricing policies are still being exported and imported within the Community.⁶⁰

The ECJ has had to consider similar intricacies of the exhaustion doctrine in relation to trademarks. As will be evident, the Court has taken a more pragmatic approach to the degree of consent needed for the exhaustion of trademarks in comparison with their pro-integration policy in relation to patents, established in *Merck v. Stephar*.⁶¹

In *Hag I*⁶² the Court concluded that to prohibit the importation of trademarked products simply because the same trademark was registered and protected in the Member State of importation by a third party was not compatible with Articles 28 and 30 EC Treaty.⁶³ This peculiar situation was brought about by the sequestering by the Belgian State of the Belgian section of the German instant coffee company Hag during the Second World War, i.e. as a result of expropriation. Due to later case-law, notably *Pharmon v. Hoechst*,⁶⁴ the Court took the opportunity to overturn its decision in, ironically, a case involving the same facts but another issue – *Hag II*.⁶⁵ Even if allowing the trademark owner to exercise his national trademark rights

⁵⁹ However, see *inter alia* Advocate General Jacobs's Opinion in Case C-53/03 *Synetairismos Farmakopoion Aitolias (Syfait) & Others v. GlaxoSmithKline A EVE* [2005] E.C.R. 4609, proposing a special application of Article 82 EC Treaty to pharmaceutical products due to the special characteristics of the pharmaceutical sector in order to promote future R&D. The issue is, therefore, still very much alive. See chapter 2(2.5) above.

⁶⁰ Advocate General Fennelly in Cases C-267-268/95, n. 24 above, para. 108.

⁶¹ N. 24 above.

⁶² Case 192/73 *Van Zuylen Frères v. Hag AG (Hag I)* [1974] E.C.R. 731.

⁶³ This principle is commonly referred to as the 'common origin' doctrine. The doctrine, established in *ibid.*, was heavily criticised on grounds that the trademark proprietor had not consented to such marketing; see R. Joliet, 'Trade mark law and the free movement of goods: The overruling of Hag I,' (1992) I.I.C. 303, 317; and Case 119/75 *Terrapin Ltd. v. Terranova Industrie CA* [1976] E.C.R. 1039.

⁶⁴ N. 27 above.

⁶⁵ Case C-10/89 *SA CNL-Sucal NV v Hag GF AG (Hag II)* [1990] E.C.R. 3711. Incidentally, the Rapporteur in the case was Professor Rene Joliet, author of Joliet, n. 63 above, and one of the strongest critics of the 'common origin' doctrine.

will partition the Community market along national borders, the trademark owner must be allowed to do so as he has not given his consent to such marketing, in line with *Pharmon v. Hoechst*.⁶⁶ Further, the 'essential function' of a trademark, which is part of the specific subject matter, is to guarantee the origin of the trademarked products. With two identical trademarks, divided as a result of national legislation (expropriation), neither of the trademarks serves to guarantee the origin of the products to the end consumer.⁶⁷ Thus, the 'common origin' doctrine lost all its importance in respect of expropriated trademarks when *Hag II*⁶⁸ was decided in line with *Pharmon v. Hoechst*.⁶⁹ After all, it is hard to see a difference between the act of a government in expropriating a trademark right as part of enemy property and the act of a government in granting a compulsory licence under a patent.⁷⁰

However, at present, the division of ownership of trademarks has presumably come about more often as a result of freely negotiated agreements, rather than government expropriation. Whilst expropriation can be compared to the granting of a compulsory licence, division of ownership as a result of freely negotiated agreements cannot be compared to the facts of *Merck v. Primecrown*,⁷¹ where Merck was the sole proprietor of the intellectual property right, and could therefore be seen as having full control of its specific subject matter. Following a division of ownership the proprietor will no longer be the sole proprietor, and cannot be said to be in full control of the specific subject matter of the intellectual property right. In *Ideal Standard*⁷² the Court therefore held that the principle in *Hag II*⁷³ should not only apply to trademarks sharing a common origin due to expropriation but also to trademarks sharing a common origin as a result of a freely negotiated transfer of

⁶⁶ N. 27 above.

⁶⁷ Case C-10/89 (*Hag II*), n. 65 above, para. 16; the Court stated that 'consumers being able to identify the origin of the marked good and the proprietor could be held responsible for the poor quality of the goods for which he was in no way accountable,' similarly Advocate General Jacobs stated in his Opinion to *Hag II*, para. 26, that 'the consumer is not interested in the genealogy of trade marks...he is interested in knowing who made the goods that he purchased.'

⁶⁸ N. 65 above.

⁶⁹ N. 27 above.

⁷⁰ See Guy, n. 32 above, 253.

⁷¹ N. 24 above.

⁷² N. 29 above. See Tritton, n. 2 above, for a thorough discussion on this case.

⁷³ N. 65 above.

ownership. The Court's ruling has been criticised for not taking into consideration that, in contrast to expropriated trademarks, the original trademark owner freely consented to the marketing of the products when transferring ownership of the identical trademark.⁷⁴ In response to this argument the Court held that 'that view must be rejected. The consent implicit in any assignment is not the consent required for application of the doctrine of exhaustion of rights...if, by assignment, control over the trade mark is surrendered to a third party having no economic link with the assignor.' The argument that the trademark proprietor(s) freely consented to the marketing of the products, so as to be sold side-by-side on the same market, fails to take into consideration the essential function of trademarks which is part of their specific subject matter. Departing from the traditional concept of intellectual property rights as primarily a right to protect the intellectual property owner,⁷⁵ which was argued by the claimant in *Merck v. Primecrown*,⁷⁶ the Court stated that a trademark 'must offer a guarantee that all goods bearing it have been produced under the control of a single undertaking which is accountable for their quality.'⁷⁷ The Court therefore made it clear that its reasoning in *Hag II*⁷⁸ equally applies to trademarks divided through freely negotiated agreements as long as the two trademark owners are not economically linked. Thus, following *Hag II*⁷⁹ and *Ideal Standard*⁸⁰ it can now be claimed that it is irrelevant whether a trademark has a common origin in considering the application of the exhaustion of rights doctrine.⁸¹ In abolishing the common origin doctrine the Court in essence created a potential

⁷⁴ Case C-9/93, n. 29 above, para. 43. See also H. Cohen Jehoram, 'The Ideal-Standard Judgment: An unheeded warning,' (1999) I.P.Q. 114, 119 for further discussion.

⁷⁵ Cohen Jehoram, *ibid.*, 118.

⁷⁶ N. 24 above.

⁷⁷ Case C-9/93, n. 29 above, para. 37. By way of illustration, due to the territoriality of trademark rights, the English Court of Appeal held in *Colgate Palmolive v. Markwell Finance* [1989] RPC 497, that an English manufacturer of toothpaste had not given his consent to the importation of toothpaste from Brazil bearing the same trademark, but not containing the same ingredients as the English version, even though the trademark shared a common origin with the English owned trademark.

⁷⁸ N. 65 above.

⁷⁹ *ibid.*

⁸⁰ N. 29 above.

⁸¹ See G. Tritton, *Intellectual property in Europe*, 2nd ed., (London: Sweet & Maxwell, 2002), p. 518.

circumvention of the exhaustion of rights doctrine, in that it effectively allows for the trademark to be used for voluntary division of the common market.⁸²

The foregoing has concerned the application of the exhaustion doctrine to products first put into circulation, and subsequently traded, within the common market. The suggestion that the exhaustion of rights doctrine also applies to non-Member States (third countries), creating a doctrine of international exhaustion, has been severely criticised by European intellectual property proprietors. As will be evident in the next section, introducing international exhaustion would cause severe damage to Europe's pharmaceutical industry, which is why the ECJ has had to adopt a pragmatic approach to this concept.

4. *International exhaustion*

It is now firmly established that once a product is marketed and put into circulation within the common market the intellectual property rights holder will have exhausted the right to prevent further trading in the product within the common market.⁸³ In this respect, Article 7(1) of the Trade Mark Directive⁸⁴ and subsequent case-law only allows for 'Community exhaustion.' The issue of international exhaustion, i.e. allowing for exhaustion of rights for goods entering the common market from a third country, is highly controversial as it would preclude intellectual property proprietors from preventing importation of trademark protected pharmaceutical products into the Community regardless of geographical origin.

⁸² Case C-9/93, n. 29 above, para. 59. However, as the trademark owners must not be economically linked, there is limited freedom to make such arrangements. Article 81 EC Treaty may, however, apply in such circumstances. See Case 40/70 *Sirena Srl v. Eda Srl* [1971] E.C.R. 3169 where the Court held that a contract for assignment could fall within Article 81 EC Treaty if the assignment continues to produce restrictive effects to the common market after its fulfilment. See M. Jarvis, 'The ideal standard in Court of Justice case-law,' (1995) 20 E.L.Rev. 195; and chapter 2(1) above for further discussion of the application of Article 81 EC Treaty.

⁸³ Case 15/74, 13 above; and Cases C-267-268/95, n. 24 above. Following Article 24 EC Treaty and Case 41/76 *Crirel v. Procureur de la Republique* [1976] E.C.R. 1921, goods imported from outside the common market are to be treated as domestic goods once put into circulation within the common market, i.e. in the same manner as goods originating from within the common market. See T. Hays, *Parallel importation under European Union law*, (London: Sweet & Maxwell, 2004) p. 48.

⁸⁴ N. 1 above, Art. 7(1).

Hence, parallel traders may locate the lowest-priced country for any given pharmaceutical product before exporting the products to the highest-priced Member State market in the Community. In *EMI*⁸⁵ the ECJ held that ‘the exercise of a trade mark right in order to prevent the marketing of products coming from a third country under an identical mark, even if this constitutes a measure having an effect equivalent to a quantitative restriction, does not affect the free movement of goods between Member States and thus does not come under the prohibitions set out in the Articles [28 and 30] of the Treaty.’⁸⁶ The facts of the case share many similarities with *Ideal Standard*,⁸⁷ with the difference that the defendant imported the products from a third country. The products in question were similar goods bearing the same trademark manufactured by a third party, no longer directly or indirectly, legally or economically linked with the national trademark owner. The argument that *EMI*⁸⁸ effectively established that the EC Treaty does not provide for international exhaustion, but merely Community exhaustion, is therefore debatable.⁸⁹ In this respect, the ruling may only be seen as an early formulation of the principle subsequently established by the Court in *Ideal Standard*.⁹⁰ As long as the two trademark proprietors are not economically linked, the essential function of the trademark will be undermined if the goods are allowed to be sold side-by-side on the common market, regardless of the geographical origin of the imported products.

The question of whether the EC Treaty provides for international exhaustion or merely Community exhaustion was eventually addressed by the Trade Mark Directive,⁹¹ which of course must be interpreted within the scope of the EC Treaty. The Trade Mark Directive seeks to harmonise national trademark laws, in particular concerning trademark exhaustion. Article 7(1) of the Directive states that a

⁸⁵ Case 51/75 *EMI Records Ltd. v. CBS Ltd.* [1976] E.C.R. 811.

⁸⁶ *ibid.*, para. 10. See J. Jones, ‘Does an opportunity still exist for the development of a doctrine of international exhaustion at a Community level under Articles 28 and 30,’ (2000) 22 E.I.P.R. 171, for a good discussion of this case.

⁸⁷ N. 29 above.

⁸⁸ N. 85 above.

⁸⁹ Jones, n. 86 above, 171.

⁹⁰ N. 29 above.

⁹¹ N. 1 above.

'trademark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trademark by the proprietor or with his consent.'⁹² Although the Directive seems reasonably clear on the matter of Community exhaustion, doubts still existed as to whether Community exhaustion is only a stipulated minimum, and therefore individual Member States were free to implement a principle of international exhaustion.⁹³ The obvious risk entailed with leaving it up to individual Member States to legislate on international exhaustion became evident in the French case of *Pytheron*,⁹⁴ where the French court held that once a product has been legally imported into a Member State providing for international exhaustion Member States are prohibited from preventing further trade in the trademarked product once the product is put into circulation within the common market. In this respect, it would not make a real difference whether the Community would provide for international exhaustion in its entirety, or if only one Member State would provide for such exhaustion, as the Member State providing for international exhaustion would act as a gateway for all goods entering the common market from third countries.⁹⁵

The ECJ, much to the delight of intellectual property proprietors, adopted a more restrictive interpretation of the Trade Mark Directive in *Silhouette*.⁹⁶ The facts were as follows: Silhouette, an Austrian producer of frames for spectacles, sold the previous year's fashion frames to a Bulgarian trader. Even though the Bulgarian trader had agreed only to market the frames in Bulgaria and a number of other ex-Soviet States the frames nevertheless found a way back into Austria. Silhouette brought an action to prohibit the importation and marketing of the frames in Austria

⁹² Directive 89/104, n. 1 above, Art. 7(1).

⁹³ See R. Goldberg and J. Lonbay (ed.), *Pharmaceutical medicine, biotechnology and European law*, (Cambridge: Cambridge University Press, 2000), p. 37; and A. Carboni, 'Cases past the post on trade mark exhaustion: An English perspective,' (1997) 19 E.I.P.R. 198.

⁹⁴ *Pytheron International SA v. Jean Bowdon SA* [1997] E.T.M.R. 211.

⁹⁵ However, see pp. 155-157 below in relation to the 'EFTA-EEA' Member States.

⁹⁶ Case C-355/96 *Silhouette International GmbH v. Hartlauer mbH* [1998] E.C.R. 4799. See W. Alexander, 'Exhaustion of trade mark rights in the European Economic Area,' (1999) 24 E.L.Rev. 56; W. Cornish, 'Trade Marks: Portcullis for the EEA?,' (1998) 20 E.I.P.R. 172; and T. Hays and P. Hansen, 'Silhouette is not the proper case upon which to decide the parallel importation question,' (1998) 20 E.I.P.R. 277.

relying on the fact that the products had never been placed in circulation within the common market. The ECJ held that the exhaustion doctrine only applies to goods being imported and exported within the common market. Since the goods had not been put into circulation within the common market, and Silhouette had not consented to the re-importation of the products, the Austrian trademark proprietor had the right to prevent importation from third countries.⁹⁷ This interpretation of Article 7 of the Trade Mark Directive provides for Community wide exhaustion, but not for international exhaustion. The Court stated that this ‘is the only interpretation which is fully capable of ensuring that the purpose of the Directive is achieved, namely to safeguard the functioning of the internal market.’⁹⁸ If some Member States were allowed to adopt a principle of international exhaustion, while other Member States chose not to, this would create barriers to intra-Community trade by segmenting the common market along national boundaries. Thus the pharmaceutical industry can take comfort in the fact that the Trade Mark Directive⁹⁹ does not provide for international exhaustion, restricting the(ir) problem of parallel trade to the EEA common market.¹⁰⁰

However, three EEA Member States; Liechtenstein, Iceland and Norway, are in a unique position as they are Members of the European Free Trade Area (EFTA) and the EEA simultaneously (‘EFTA-EEA’ Member States). Point 4(c) of Annex XVII to the EEA Agreement¹⁰¹ implements Article 7(1) of the Trade Mark Directive,¹⁰² inserting the words ‘in a Contracting Party’ in place of the Trade Mark Directive’s

⁹⁷ Case C-355/96, n. 96 above, para. 18.

⁹⁸ *ibid.*, para. 27.

⁹⁹ N. 1 above.

¹⁰⁰ This is likely to remain the case unless the Trade Mark Directive, *ibid.*, is amended so as to provide for international exhaustion. Nothing in the TRIP agreement (n. 54 above) prohibits Member States from imposing a narrow intellectual property regime. Further, Article 6 of TRIP states that: ‘for the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4, nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.’ See D. Kallay, ‘Levi Strauss v Tesco: At a difficult juncture of competition, IP and free trade policies,’ (2002) 23 E.C.L.R. 193, 198; and L. Brazell, ‘The protection of pharmaceutical products and regulatory data: EU enlargement update,’ (2002) 24 E.I.P.R. 155, 158-159.

¹⁰¹ The Agreement on the European Economic Area [1994] O.J. L344/3.

¹⁰² N. 1 above.

'in the Community.'¹⁰³ In addition, Article 2 of Protocol 28 to the EEA Agreement stipulates that 'this provision shall be interpreted in accordance with the meaning established in relevant rulings of the ECJ prior to the signing of the Agreement.'¹⁰⁴ *Silhouette*¹⁰⁵ (decided after the signing of the EEA Agreement) is therefore not relevant to the interpretation of the exhaustion provisions of the EEA Agreement. Although the 'EFTA-EEA' Member States are not a prime source for pharmaceutical products destined for parallel exports, this sparked a fear that an 'EFTA-EEA' Member State might be used as an 'open-gate' into the Community for pharmaceutical products never intended for marketing in the Member State, but aimed for onward trading into the EC common market.¹⁰⁶

To this end the Norwegian Court asked the EFTA Court for an advisory opinion on the compatibility of the EEA Agreement and national laws providing for international exhaustion in *Mag Instrument*.¹⁰⁷ The EFTA Court held that the aim of the EEA is to create a free trade area, and not, as is the EC, a customs union. EEA-wide exhaustion is a minimum and applies to all goods irrespective of origin, whilst EEA Member States are free to implement a policy of international exhaustion as the provisions do not stipulate a maximum.¹⁰⁸ However, according to article 8 of the EEA Agreement the free movement of goods provisions in Article 11 and 13 of the EEA Agreement¹⁰⁹ applies only to goods originating from within the EEA.¹¹⁰ As the free movement provisions are not applicable to goods originating from outside the EEA the parallel importer must show that the trademark proprietor consented to

¹⁰³ N. 1 above, Art. 7(1).

¹⁰⁴ N. 101 above, Protocol 28 Art. 2.

¹⁰⁵ N. 96 above.

¹⁰⁶ See e.g. A. Toutoungi, 'EFTA: Fortress Europe's soft underbelly?', (2006) 28 E.C.L.R. 110.

¹⁰⁷ Case E-2/97 *Mag Instrument Inc. v. California Trading Company* [1998] E.T.M.R. 85. The case was much the result of the Norwegian Trade Mark Act (Act No. 4 of March 3. 1961), which is silent on the issue of exhaustion even though it is well established that Norwegian law in general provides for international exhaustion of trademark rights.

¹⁰⁸ *ibid.*, para. 22. However, the Commission argued that the 'EFTA-EEA' and the EC Member States must adopt the same rule in relation to international exhaustion, as otherwise it may lead to 'internal disparities:' (paras. 12-13 and 24). See Toutoungi, n. 106 above, 112-114. See also Advocate General Jacobs's Opinion in C-355/96, n. 96 above, where a similar argument is presented.

¹⁰⁹ N. 101 above.

¹¹⁰ See Alexander, n. 96 above, 66.

such importation into an EC Member State. In conclusion, the ‘EFTA-EEA’ Member States are free to implement a policy of international exhaustion on the national market, but, as the free movement of goods provision do not apply to goods originating from outside the EEA, the intellectual property proprietor must give his consent to any subsequent exportation or importation of the goods within the common market.¹¹¹

The definition of ‘consent’ and the distribution of the ‘burden of proof’ is therefore very important since the trademark proprietor may be deemed to have exhausted his rights, and therefore unable to prevent further dealing in the products if he can be considered to have ‘consented’ to the importation into the EEA from a non-Member State or an ‘EFTA-EEA’ Member State providing for international exhaustion. The issue of consent and the ‘burden of proof’ will be discussed in the following section.

4.1 *Consent and the ‘burden of proof’*

It is clear that consent will not be implied merely from the fact that the trademark proprietor has sold the same type of products within the common market before importation was commenced by the trader. Thus consent is required for every batch of products, i.e. the ascertainable products under the control of the importer.¹¹²

In *Davidoff*¹¹³ the Court held that, under a proper construction of the Trade Mark Directive,¹¹⁴ the trademark proprietor’s consent must be expressed positively, or in the alternative, ‘the factors taken into consideration in finding implied consent must

¹¹¹ See *Toutoungi*, n. 106 above, 112.

¹¹² Case C-173/98 *Sebago Inc. v. G-B Unic SA* [1999] E.C.R. 4103. Sebago had consented to the marketing in the EEA of one batch of goods, and the issue was whether or not, in absence of an express prohibition, this amounted to implied consent to market other batches of the same goods within the EEA. See also Case No. 98/550 *Parfums Christian Dior S.A. v. Etos B.V.* (The Appeals Court of the Hague, 15 February, 2000); and T. Hays, ‘The burden of proof in parallel-importation cases,’ [2000] 22 E.I.P.R. 353.

¹¹³ Joined Cases C-414-416/99 *Zino Davidoff SA v. A&G Imports Ltd. & Levi Strauss & Co v. Tesco Stores* [2001] E.C.R. 8691.

¹¹⁴ N. 1 above.

unequivocally demonstrate that the trade mark proprietor has renounced any intention to enforce his exclusive rights.’¹¹⁵ In view of this, ‘consent must be so expressed that an intention to renounce those rights is unequivocally demonstrated.’¹¹⁶ Although it can do no harm to include a clause in the contract of sale containing restrictions upon where the products might ultimately be sold, refraining from doing so will not amount to consent,¹¹⁷ as consent cannot be inferred from mere silence on behalf of the trademark proprietor.¹¹⁸ This shows the different approach to consent taken by the ECJ in relation to products that have first been put on the market outside, as opposed to inside, the EEA. The sale by a licensee, a parent company, or a subsidiary implies consent when the marketing takes place within the EEA so as to trigger Community exhaustion, but does not imply consent when the first marketing is outside the EEA.¹¹⁹

The Court has made it clear that the burden of proof rests with the defendant, meaning that it is for the trader ‘alleging consent to prove it and not for the trade mark proprietor to demonstrate its absence.’¹²⁰ However, if the burden of proof rests with the parallel trader, the trader would be faced with the dilemma of either winning the case by revealing his source of supply and subsequently losing the source as the proprietor will block it, or losing the case despite the fact that the goods actually had been marketed within the EEA.¹²¹ The ECJ has recognised that

¹¹⁵ Cases C-414-416/99, n. 113 above, para. 53.

¹¹⁶ *ibid.*, para. 45.

¹¹⁷ See the (UK) Chancery Division ruling in *Quiksilver Pty Ltd v. Charles Robertson (Developments) Ltd (t/a Trago Mills)* [2005] 1 C.M.L.R. 36. The Court followed the approach adopted in *Davidoff (ibid.)* and held that consent cannot be inferred merely from the fact that the contract of sale did not contain any restrictions upon where the goods might ultimately be sold. See J. Smith and V. Noy, ‘Trade marks – parallel imports,’ (2004) 26 E.I.P.R. N194, for a comment on the case. However, a prohibition on reselling in the EEA does not ‘preclude the exhaustion of the proprietor’s exclusive rights in the event of a resale in the EEA in breach of the prohibition.’ Case C-16/03 *Peak Holding AB v. Axolin-Elinor AB* [2004] E.C.R. 11313, para. 56.

¹¹⁸ Cases C-414-416/99, n. 113 above, para. 53.

¹¹⁹ See G. Petursson and P. Dyrberg, ‘What is consent? A note on Davidoff and Levi Strauss,’ (2002) 27 E.L.Rev. 464, 470. The authors also note that trademark owners may only bring trademark infringement claims in Member States where the trademark is registered. As a result, there is nothing to prevent a trader from importing trademarked products from a third country into an EEA Member State where the trademark is not registered.

¹²⁰ Cases C-414-416/99, n. 113 above, para. 54.

¹²¹ See P. Dyrberg, ‘For EEA exhaustion to apply, who has to prove the marketing of the trade marked goods in the EEA – the trade mark owner or the defendant,’ (2004) 26 E.I.P.R. 81, 82.

such an arrangement may in fact amount to a barrier to intra-Community trade by obstructing parallel trade, becoming even more obvious when the trademark owner is marketing the products using an exclusive distribution network, as the products must have been sourced from a small number of suppliers to which the trademark proprietor is closely aligned. The ECJ's solution to this problem was to shift the burden of proof to the trademark proprietor if the trader could establish that there is such a risk if he himself bears the burden of proving consent. If the trader manages to establish this, the burden will revert back to the trademark proprietor who must prove that the goods were initially marketed outside the EEA with his consent, after which the burden will shift back to the trader who has to prove that the trademark owner indeed had given his consent to the importation and subsequent marketing of the products within the EEA.¹²² As a result it will become more burdensome for trademark proprietors to prove trademark infringement, in particular when an exclusive distribution network is the preferred choice of distribution and marketing. A possible precautionary measure that can be adopted by trademark proprietors is to market products using different boxes in different regions, thus allowing the proprietor to easily identify where and incidentally by whom the goods were first put on the market.¹²³ Another arrangement would be for trademark proprietors to print 'for export only' or 'not for sale in the EEA' on the outer packaging of the product, in an attempt to rebut any presumptions of consent on their part.¹²⁴ This would rebut any presumptions at the time of sale without interfering with the sale transaction.

¹²² This was established in Case C-244/00 *Van Doren + Q GmbH v. Lifestyle Sports mbH* [2003] E.C.R. 3051. Van Doren brought an action for trademark infringement against the defendant for marketing products in Germany under Van Doren's trademark. The products had, according to Van Doren, been marketed in the US before being exported so as to be marketed in Germany. As the defendant claimed that the products had been purchased from an intermediary who had obtained the goods from an authorised distributor in the EEA, the Court was forced to answer the question as to which party had to prove the place of marketing of the products. See Dyrberg, 'EEA exhaustion,' n. 121 above, 83.

¹²³ See J. Wessel, 'Germany: Trade marks – exhaustion of rights in the EC – exclusive distribution system,' (2004) 26 E.I.P.R. N152, N153. In December 2003 Glaxo (the pharmaceutical company) announced that it was to colour pharmaceutical products that are destined for non-EEA States. This was a response to the UK High Court and, subsequently, the UK Court of Appeal's decision in *Glaxo Group Limited v. Dowelhurst Limited and Richard Taylor* [2004] E.W.C.A. (Civ) 290. See also C. Davies, 'Glaxo v Dowelhurst: A new twist in the tale,' [2005] 27 E.I.P.R. 127.

¹²⁴ See Hays, 'burden of proof,' n. 112 above, 357. This may however be in breach of Article 81 EC Treaty: see chapter 2(1.3) above.

5. *The new Member States and the exhaustion of rights doctrine*

The absence of international exhaustion in conjunction with the exhaustion of rights doctrine for goods first marketed within the common market has given rise to the expression 'Fortress Europe.' It cannot be denied that it is a very accurate description of the common market in terms of the bottleneck effect it applies to imports from third countries – the difficulties in gaining entry into the Community is compensated for by the Community's free movement provisions giving rise to ample opportunities for traders to capitalise on price differences. However, it is hard to identify a direct analogy between transforming regional markets into a national market, and integrating national markets into a Community market, which can be illustrated by the judgment in *Merck v. Primecrown*¹²⁵ and not least by the common origin doctrine.¹²⁶ If 'Fortress Europe' is impenetrable by intellectual property protected goods from third countries due to the non-applicability of international exhaustion, an enlargement of 'Fortress Europe' is the only option left in order to allow goods placed on other markets access to the common market. The latest enlargement of the Community, in 2004, saw ten new countries gaining access to the exclusive club of Member States. The new Member States, mostly central and eastern European (CEE), have struggling economies and pharmaceutical prices are normally far lower than in the 15 'old' Member States. As a result, the Act of Accession¹²⁷ provided for a 'specific mechanism' in relation to the exhaustion of rights doctrine, the effects of which will be discussed below.

5.1 *The new Member States*

The new Member States are Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia. This is the first time CEE countries have been admitted as Member States. Economic differences between the

¹²⁵ N. 24 above.

¹²⁶ See D. Edward, 'Trade marks, descriptions of origin and the internal market: The Stephen Stewart Memorial Lecture 2000,' (2001) I.P.Q. 135, 138, for an extended discussion.

¹²⁷ N. 4 above.

ten new and the 15 'old' Member States are inherent. At the time of the accession negotiations the new Member States accounted for roughly 8.5% of the GDP generated by the old, with GDP per capita averaging about 55% of the GDP per capita in the old Member States.¹²⁸ Despite the fact that the Community's expansion to a population of nearly half a billion citizens does present significant market opportunities for pharmaceutical manufacturers, the public health expenditure per capita was on average 2.5 times lower than in the 15 old Member States pre-accession.¹²⁹ The New Member States therefore have a strong focus on generics, as the low government health expenditure affects the choice and availability of new pharmaceutical products entering the markets.¹³⁰ Consequently, the new Member States will most likely become a source for low-priced pharmaceutical products exported to higher-priced Member States as the UK, Germany and the Scandinavian Member States by parallel importers.

5.2 *The 'specific mechanism'*

On the accession date the *acquis communautaire* automatically became part of the national laws of the new Member States.¹³¹ Due to the inherent price differentials, and the fact that patent protection for pharmaceutical products was only recently introduced in the new Member States, the pharmaceutical industry and the new Member States (except for Malta and Cyprus) negotiated for derogations and transitional provisions in relation to the exhaustion of rights doctrine. As the price level of pharmaceutical products is significantly lower in the new Member States than in the rest of the Community, and as a result of the inevitable competing

¹²⁸ The statistics exclude Malta and Cyprus. See Commission Communication - Strategy Paper 'Towards the Enlarged Union' [2002] COM/700/final.

¹²⁹ N. Wong, 'Accession impact on pharma,' Datamonitor (October 2005), (<<http://www.drugresearcher.com/news/news-ng.asp?id=50138>>). Even at purchasing power parity levels, the health expenditure is only about one third of the health expenditure per capita in the 15 old Member States according to the World Health Organisation (WHO), 'World Health Report,' (2002), pp. 210-216.

¹³⁰ See the European Generics Medicine Association's website: (<<http://www.egagenerics.com>>). The average market share (value) for generics in the new CEE Member States is almost 37%, whilst only 12% in the old Member States. Currently Poland has the highest market share, with generics accounting for nearly 87% of the total volume.

¹³¹ Existing patents and marketing authorisations were automatically extended so as to be effective in the new Member States. See chapter 3, pp. 91-92 above.

interests between the pharmaceutical industry in the old Member States and the established generics industry in the new Member States, the negotiations resulted in a compromise between competing interests.¹³² The pharmaceutical industry's concern was that the effect of applying the exhaustion of rights doctrine in the new Member States would result in an inflow of pharmaceutical products from the new Member States destined for Member States with a higher price level.¹³³ The concern chiefly stems from the ECJ rulings in *Merck v. Stephar*¹³⁴ and *Merck v. Primecrown*,¹³⁵ precluding patent proprietors from exercising their patent rights even though patent protection was not available at the time of marketing. Parallel importers took the opposing view, claiming that the insertion of any kind of derogation from the exhaustion doctrine in the Act of Accession would in effect be nothing more than 'an export ban intended to benefit the EU-15 pharmaceutical industry.'¹³⁶ The negotiations resulted in the insertion of a derogation mechanism (the 'specific mechanism') in the Act of Accession¹³⁷ which reads as follows:

¹³² See S. Bruun-Nielsen, 'Into the great wide open...? Aspects of the accession process of countries in eastern and central Europe,' (1998) *Int. T.L.R.* 198; and R. Kobia, 'Reflections on the effects of future enlargements of the EU on industrial property: The case of trade marks,' (1998) *E.I.P.R.* 183 for an understanding of the general concerns and debates pre-accession.

¹³³ See, e.g. The European Federation of Pharmaceutical Industries and Associations (EFPIA), 'EU enlargement and pharmaceuticals: Key issues,' Position paper (October 2000), (<http://www.efpia.org/2_indust/topic_2.PDF>): 'Therefore, to ensure the flow and availability of innovative therapies in the newly acceding EU States...a sound basis for the progressive introduction of innovative medicines in these states needs to be provided for.' The Act of Accession must ensure that the manufacturers business 'in the existing EU pharmaceutical market [is not] compromised by re-exports into the current Member States with their higher economic standards.'

¹³⁴ N. 24 above.

¹³⁵ N. 24 above.

¹³⁶ D. MacArthur, 'EU enlargement and free trade with Medicines,' (2002) *R.A.J.* 4, 9: 'it is a thinly disguised restriction on free trade, one of the fundamental pillars of the EU, and should be deleted.'

¹³⁷ N. 4 above.

'With regards to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia and Slovakia, the holder or his beneficiary, of a patent or supplementary protection certificate for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the abovementioned new Member States for the product, may rely on the rights granted by that patent or supplementary protection certificate in order to prevent the import and marketing of the product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent.

*Any person intending to import or market a pharmaceutical product covered by the above paragraph in a Member State where the product enjoys patent or supplementary protection shall demonstrate to the competent authorities in the application regarding that import that one month's prior notification has been given to the holder or beneficiary of such protection.'*¹³⁸

This means that the principle in *Merck v. Stephar*¹³⁹ is temporarily suspended for all products within the scope of the derogation. If the exhaustion of rights doctrine would have applied products could have been acquired in the new Member States and re-imported back to the old Member State markets. By suspending the exhaustion of rights doctrine, the pharmaceutical market and pharmaceutical traders will be given extra time to adjust pharmaceutical prices, distribution networks and patent protection; thus in essence creating a transition period. There is however a significant difference between placing a product on a Member State market where patent protection is not available, and marketing a product in one of the new Member States before it provided for patent protection and before becoming a Member of the Community. A patent proprietor who, fully aware of the consequences in terms of the exhaustion of rights doctrine, markets a product in a Member State where patent protection is not available can be said to have consented to the marketing and the aforementioned consequences. However, a patent proprietor who decided to market a product in one of the new Member States before patent protection became available cannot be said to have consented to the subsequent consequences of the decision to market the product as he could not possibly have predicted that the country in question would one day join the

¹³⁸ 2003 Act of Accession, n. 4 above, Chapter 2 (Company Law) of Annex IV. This section is referred to as the 'specific mechanism.'

¹³⁹ N. 24 above.

European Community. Allowing parallel imports in a scenario like the one just described would therefore be 'inequitable.' In fact, the 'specific mechanism' can be justified with reference to *Pharmon v. Hoechst*.¹⁴⁰ Just as a patent proprietor cannot be said to have consented to the granting of a compulsory licence, a patent proprietor marketing a product in a country which subsequently joined the Community cannot be said to have consented to the future consequences of that marketing, in contrast to *Merck v. Stephar*¹⁴¹ where the patent proprietor must necessarily have been aware of the consequences of marketing the products in a Member State not providing for patent protection.¹⁴²

In order to analyse the scope and applicability of the 'specific mechanism' that provision can be divided into three main sections; the temporal scope, the geographical scope and the notification requirement. Prior derogation mechanisms, notably the derogation in the Act of Accession of Spain and Portugal,¹⁴³ will provide a useful analytical and comparative background to the applicability of the 'specific mechanism.'

¹⁴⁰ N. 27 above.

¹⁴¹ N. 24 above.

¹⁴² In *Merck v. Primecrown*, (Cases C-267-268/95, n. 24 above), the products concerned were marketed after Spain had acceded to the EC, but before patent protection was made available. Also, the derogation period had expired by the time of the ECJ ruling. The new (2004) Member States, on the other hand, made patent protection available before accession. *Merck v. Primecrown* therefore does not contradict the 'specific mechanism,' regardless of the interpretation of this case in respect of the validity of the concerned derogation.

¹⁴³ Art 47 and 209 of the Act Concerning the Conditions of Accession of the Kingdom of Spain and the Portuguese Republic to the European Communities and Adjustments to the Treaties [1985] O.J. L302/23 provide that '*the holder, or his beneficiary, of a patent for a chemical or pharmaceutical product or a product relating to plant health, filed in a Member State at a time when a product patent could not be obtained [in Spain and Portugal] for that product may rely on the rights granted by that patent in order to prevent the import and marketing of that product in the present Member State or States where that product enjoys patent protection even if that product was put on the market [in Spain or Portugal] for the first time by him or with his consent.*' '*This right may be invoked for [pharmaceutical products] ... until the end of the third year after [Spain and Portugal] has made these products patentable.*'

5.2.1 *Temporal and product scope*

The 'specific mechanism' provides that a patent and 'supplementary protection certificate' (SPC) holder may exercise the patent rights for the duration of its validity to prevent parallel imports from the new Member States (excluding Malta and Cyprus) if 'such' protection was not available in the new Member State at the time of filing the patent in the old Member State. In absence of clear guidance in the 'specific mechanism,' the definition of 'such' protection is not clear. It is evident from the wording of the 'specific mechanism' that 'such' protection includes 'a patent or supplementary protection certificate for a pharmaceutical product.'¹⁴⁴ SPCs aim to compensate patent holders for time lost in the commercialisation of pharmaceutical products due to the delay in obtaining marketing authorisation.¹⁴⁵ They last for up to five years and were designed to provide a maximum of 15 years of marketing monopoly. The SPC period is calculated by subtracting five years from the time difference between the patent application date and the date of the first granting of a marketing authorisation in the Community. As an SPC must be lodged within six months after the date the first marketing authorisation was granted the 2003 Act of Accession allows for derogations to the SPC Regulation¹⁴⁶ for products that were authorised in the new Member States before accession.¹⁴⁷ Following the amendment, an SPC had to be applied for within six months of the date of accession, i.e. before November 2004.¹⁴⁸

¹⁴⁴ N. 138 above, para. 1.

¹⁴⁵ See Council Regulation (EEC) 1768/92 concerning the creation of a supplementary protection certificate for medicinal products [1992] O.J. L182/01.

¹⁴⁶ *ibid.*

¹⁴⁷ Chapter 4 (Company law) of Annex II of the 2003 Act of Accession (n. 4 above), amends Article 19 of *ibid.*

¹⁴⁸ *ibid.* However, special rules apply to the Czech Republic (within six months of the date on which the first market authorisation was obtained), Estonia (within six months of the date on which the first market authorisation was obtained, or if the patent was granted before 1 January 2000 within a six month period), and Slovakia (within six months of the date on which the first market authorisation was obtained, or within six months of 1 July 2002 if the market authorisation was obtained before that date.). See C. van Nispen, 'The consequences of EU enlargement for the pharmaceutical sector,' De Brauw Blackstone & Westbroek publication (November 2003), (<<http://allens.com.au/pubs/bt/pharma.pdf>>), p. 4.

However, any guidance to what type of patent the SPC must be linked to - product, second medical use, or manufacturing process patent – is not made clear by the wording of the ‘specific mechanism.’ In the derogation included in the Act of Accession of Spain and Portugal the relevant provision is more precise and refers to a ‘product patent.’¹⁴⁹ The wording of the ‘specific mechanism’ can be interpreted as meaning that the particular type of patent protection (product, second medical use, or manufacturing process) must not have been obtainable in the new Member State at the time of filing the patent in the old Member State. This would mean that the holder of a manufacturing process patent, filed in an old Member State, will not be able to invoke the ‘specific mechanism’ for products imported from the Czech Republic or Slovakia as these countries made manufacturing process patents available as early as in 1957.¹⁵⁰ Conversely, the holder of a second medical use patent, filed in an old Member State before 2001, will be able to invoke the specific mechanism for parallel imports from the Slovak Republic for many years as ‘such’ protection (second medical use patent) was not obtainable until 2001 in this country.¹⁵¹ This simple interpretation, however, would not be in conformity with the ECJ ruling in *Merck v. Primecrown* where the ECJ held that any exceptions to the free movement of goods principle should be interpreted strictly, and the specific mechanism must be ‘interpreted in a way that the transitional [period] expires on the date which ensure the earliest application’ of the derogation.¹⁵² Therefore, as all new Member States introduced product patents before second medical use patents,¹⁵³ the relevant type of patents for the purpose of invoking the specific

¹⁴⁹ See n. 143 above.

¹⁵⁰ Czechoslovakian Law No. 34/1957.

¹⁵¹ Slovak Republic Act No. 435/2001.

¹⁵² Case C-267-268/95, n. 24 above, para. 23 and 25. See also Case C-191/90 *Generics Ltd. v. Smith Kline Ltd.* [1992] E.C.R. 5335, para. 41.

¹⁵³ See O. Lemaire, ‘Parallel trade of pharmaceutical products within the enlarged European Union,’ (2005) 27 E.I.P.R. 43, 45, for a list of dates. Product patents cover a product’s active ingredient or any other specified chemical composition, and also include so-called ‘formulation patents’ referring to a specific formulation; i.e. tablet, injection, extended release etc. On a strict interpretation of the mechanism, transitional legislation enacted in the new Member States before product patents became available, such as pipeline protection (allowing for patent protection in a non-Member State to be valid upon registration in the Member State in question), cannot be considered ‘such protection’ under the mechanism: (p. 50).

mechanism must be product patents.¹⁵⁴ In practice this is the only relevant date, as a product patent confers (at least) the same territorial rights upon the holder thereof as a second medical use patent. Secondly, all old Member States (except Spain and Finland) made product patents available before the new Member States.¹⁵⁵ Product patent protection could therefore have been obtained in the vast majority of old Member State before becoming available in the new Member States. Finally, as mentioned above, even if (theoretically) the holder of a manufacturing process patent, filed in an old Member State not providing for product patents at a time when manufacturing process patents were not available in the new Member State, could invoke the ‘specific mechanism,’ the temporal scope of the derogation will demote this to a purely academic question as a patent filed before 1957 will have expired a long time ago. It can therefore be concluded that the relevant type of patent protection is product patents with/and SPCs. Finally, in accordance with the ECJ ruling in *Merck v. Primecrown*, the relevant cut-off date for invoking the ‘specific mechanism’ is before the (exact) date product patent protection was made available in the new Member State, and not the last day of the relevant calendar year or any other elaborate interpretation.¹⁵⁶

A fundamental difference between the ‘specific mechanism’ and all previous derogation mechanisms is that the ‘specific mechanism’ provides for a dynamic transitional period, while all other mechanisms provided for a fixed period.¹⁵⁷ In order to ascertain whether a product will benefit from the derogation the parallel importer and the patent proprietor must determine when patent protection was filed

¹⁵⁴ Lemaire’s argument that ‘the ‘specific mechanism’ applies whenever there is an objective difference in the level of patent or supplementary protection, regardless of the form of the patent or SPC (product, second medicinal use, or process)’ therefore fails to fully consider the implications of *Merck v. Primecrown* (n. 24 above) by not restricting the product scope to product patents: Lemaire, n. 153 above, 50.

¹⁵⁵ See section 5.2.2, p. 175 below.

¹⁵⁶ Cases C-267-268/95, n. 24 above, para. 24; and Stamatoudi and Torremans, ‘Survives the test,’ n. 36 above, 255.

¹⁵⁷ For Spain and Portugal, the transitional provision was valid for three years after patent protection was extended to pharmaceutical products: n. 145 above. Similarly, Finland and Iceland benefited from a two-year transition period, whilst the transitional period for Sweden, Austria and Norway was limited to three years: Art. 65(2), and Art. 3(6) of Protocol 28 on Intellectual Property of the EEA Agreement, n. 101 above.

for in the old Member State and when patent protection was made available in the new Member State. Thus, as a relatively small and ever decreasing segment of products fit this description, a full list of the dates when product patent protection was made available in the new Member States must be compiled in order to analyse the extent of products covered by the ‘specific mechanism.’

Table 4¹⁵⁸

Date product patents were introduced in the new Member States

Member State	Date of introduction
The Czech Republic	January 1, 1991 ¹⁵⁹
The Slovak Republic	January 1, 1991 ¹⁶⁰
Slovenia	January 1, 1993 ¹⁶¹
Latvia	March 31, 1993 ¹⁶²
Poland	April 16, 1993 ¹⁶³
Lithuania	February 1, 1994 ¹⁶⁴
Estonia	May 23, 1994 ¹⁶⁵
Hungary	July 1, 1994 ¹⁶⁶

Thus, patent protection was made available in all the new Member States between 1991 and 1994. Pharmaceutical products for which a patent was filed for in an old Member State after 1994 will not under any circumstances benefit from the

¹⁵⁸ Gathered from C. Feddersen, ‘Parallel trade in pharmaceuticals in a Europe of 25: What the “specific mechanism” achieves and what it does not,’ (2003) 25 E.I.P.R. 545, 551; Brazell, n. 100 above, 156; Lemaire, n. 153 above, 45; and the author’s own research.

¹⁵⁹ S. 2 of the Law on Inventions, Industrial Designs and Rationalization Proposals, Law 527 of November 27, 1990. Entered into force on January 1, 1991.

¹⁶⁰ *ibid.*

¹⁶¹ The Law on Industrial Property, published in the Official Gazette RS 13/1992 of March 20, 1992. The provision providing for the granting of product patents did not enter into for until January 1, 1993.

¹⁶² Patent Law of March 2, 1993, Journal of Laws 1993, No. 12. Entered into force on March 31, 1993. Replaced by the Patent Law of March 30, 1995, Journal of Laws 1995, No.17.

¹⁶³ The Law on Inventive Activity (Journal of Laws No. 26 of April 8, 1993: Text No. 117). Entered into force on April 16, 1993. Subsequently replaced by The Industrial Property Law Act of June 30, 2000 (Journal of Laws No. 49 of May 2001: Text No. 508).

¹⁶⁴ Patent Law No. I-372 of January 18, 1994. Entered into force on February 1, 1994.

¹⁶⁵ Patent Act (RTI 1994, 25, 406) of March 16, 1994. Entered into force on May 23, 1994.

¹⁶⁶ Law No. VII of February 8, 1994, amendments to Law No. II of 1969 on the Protection of Inventions by Patents. Entered into force on July 1, 1994.

‘specific mechanism,’ whilst all products for which a patent was filed for in an old Member State before 1991 will automatically benefit from the derogation for the duration of the patent term and the SPC. Consequently, products for which a patent was filed for between 1991 and 1994 must be examined on a product-by-product basis for each new Member State. This is best illustrated by way of an example:

A patent application for a pharmaceutical product was filed in the UK in 1993. The patent was finally granted in 1997, and marketing authorisation was obtained through the centralised procedure in 2001. The ‘specific mechanism’ will be triggered as no patent protection was available in Lithuania in 1993. The UK patent will be valid until 2013, and the SPC expires in 2016.¹⁶⁷ The patented product may therefore not be exported from Lithuania to the UK before the end of 2016.

5.2.2 Geographical scope

The ‘specific mechanism’ purposely applies to products put on the market in eight new Member States. As Malta and Cyprus made patent protection available at approximately the same time as the old Member States, the two new Member States did not negotiate for the inclusion of a ‘specific mechanism’ in the Act of Accession.¹⁶⁸ Conversely, the ‘specific mechanism’ purposely applies to products imported into one of the old Member States. However, it should be noted that the new Member States acceded to the EEA simultaneously with their accession to the Community.¹⁶⁹ As a result of Annex B of the EEA Accession Agreement,¹⁷⁰ the

¹⁶⁷ Calculating the SPC period: $((2001 - 1993) - 5) + 2013 = 2016$: see p. 168 above.

¹⁶⁸ Pharmaceuticals have been subject to (product but not process) patent protection in Malta since the coming into force of the Industrial Property (Protection) Ordinance (Cap. 29) on 1 January 1900. A system whereby UK product patents can be registered in Cyprus has been in effect since the 1950’s. Cyprus joined the Convention on the Grant of European Patents (European Patent Convention) (1973) in 1998.

¹⁶⁹ Agreement on the participation of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic in the European Economic Area [2004] O.J. L130/1. Pursuant to Article 128 of the EEA Agreement, n. 101 above, accession to the European Community must be accompanied by accession to the EEA.

¹⁷⁰ *ibid.*, Annex B, sets out that the ‘specific mechanism’ shall apply between the contracting parties.

‘specific mechanism,’ in its own right, applies to products exported from the new Member States to Norway, Iceland and Lichtenstein.¹⁷¹

However, the ‘specific mechanism’ only refers to ‘new Member States’ and ‘Member States’ making it unclear whether patent proprietors in Malta and Cyprus can, in fact, invoke the ‘specific mechanism’ in order to prevent products imported from the eight new CEE Member States. Remembering that any derogations to the Community’s free movement provisions must be strictly interpreted, it can be argued that patent proprietors in the two island States can indeed invoke the ‘specific mechanism’ with regard to products imported from the (other) new Member States, as the ‘specific mechanism’ refers to the ‘abovementioned Member States,’¹⁷² of which Malta and Cyprus are not part, and not to ‘new Member States’ *de facto*. This interpretation can however be negated by an even stricter interpretation of the mechanism. The phrase ‘filed in a Member State at a time when such protection could not be obtained in one of the abovementioned new Member States’¹⁷³ can be interpreted so as to imply that the Member State in question must indeed have been a Member State at the time of filing the patent application. Needless to say, if the latter interpretation is correct patent proprietors in Malta and Cyprus may not under any circumstances invoke the ‘specific mechanism’ as neither Malta nor Cyprus were Members of the Community prior to 1994. Nevertheless, as the phrasing of the mechanism is ambiguous, and considering that the purpose of the ‘specific mechanism’ is to provide a transition period so as to allow for a smooth integration into the Community, the ECJ is not

¹⁷¹ Owing to Liechtenstein’s patent convention with Switzerland it has been argued that SPCs granted by the Swiss Patent Office only takes effect within Liechtenstein owing to the Swiss-Liechtenstein patent union so as to preclude patent proprietors from relying on the ‘specific mechanism’ for the duration of the SPC term: see Feddersen, n. 158 above, 549. However, this argument cannot be sustained following the ECJ ruling in Joined Cases C-207 and 252/03 *Novartis AG v. Comptroller-General, & Ministre de l’Economie v Millenium Pharmaceuticals Inc.* [2005] E.C.R. 3209, where the Court held that a marketing authorisation issued by the Swiss Patent Office constitutes the ‘first authorisation to place the product on the market’ within the meaning of Regulation 1768/92 (n. 145 above) for the purposes of the EEA Agreement (n. 101 above). As Liechtenstein adopted SPC legislation in 1997 the relevance of this legal question will eventually diminish.

¹⁷² ‘Specific mechanism,’ n. 138 above, para. 1.

¹⁷³ *ibid.*

likely to discriminate between the 15 old Member States and Malta and Cyprus, especially since Malta and Cyprus enacted patent legislation at a similar time as the 15 old Member States.

The same reasoning, albeit with a few modifications, can be applied to the interesting legal question of whether the ‘specific mechanism’ can be invoked by a patent proprietor in one of the eight new CEE Member States for products imported from another new CEE Member State.¹⁷⁴ From a strict interpretation of the derogation,¹⁷⁵ it is clear that the new CEE Member States are explicitly part of the ‘abovementioned new Member States’ listed in the ‘specific mechanism.’¹⁷⁶ From this, it can be argued that the ‘abovementioned new Member States’¹⁷⁷ are simultaneously ‘Member States’ for the purpose of the ‘specific mechanism.’¹⁷⁸ But again, this may be negated by interpreting the mechanism so as to imply that the importing State must have been a Member of the Community at the time of filing the patent application. However, the ECJ would be seen as discriminating between (new and old) Member States if not allowing the ‘specific mechanism’ to be invoked in one of the new CEE Member States for products imported from another of the ‘abovementioned new [CEE] Member States.’¹⁷⁹ Indeed, in *Merck v. Primecrown*, the ECJ stated that the derogation in the Spanish and Portuguese Act of Accession¹⁸⁰ ‘should apply in full to trade between Spain and Portugal, on the one hand, and the existing Member States, on the other,’ giving support to this reasoning.¹⁸¹ Following this reasoning, the ‘specific mechanism’ can potentially be invoked for products patented in the Czech and Slovak Republics destined for Poland or Hungary if the patent application was filed between 1991 and 1994.

¹⁷⁴ ‘Specific mechanism,’ n. 138 above, para. 1. See Feddersen, n. 158 above, 549, for a discussion.

¹⁷⁵ As required following the ruling in Cases C-267-268/95, n. 24 above, para. 23.

¹⁷⁶ ‘Specific mechanism,’ n. 138 above, para. 1.

¹⁷⁷ *ibid.*

¹⁷⁸ *ibid.*

¹⁷⁹ Lemaire, n. 153 above, 49.

¹⁸⁰ N. 143 above. The wording of the derogation, in respect of the geographical scope in relation to acceding and old Member States, is similar to that of the ‘specific mechanism’ (n. 139 above).

¹⁸¹ Cases C-267-268/95, n. 24 above, para. 38 (emphasis added).

This highlights the fact that the temporal scope affects the *de facto* geographical scope. Member States that made patent protection available after it became available in the eight new Member States are technically outside the scope of the ‘specific mechanism.’ Patent proprietors in Finland,¹⁸² Spain,¹⁸³ and the EEA Member States Iceland¹⁸⁴ and Norway¹⁸⁵ (albeit the latter as well as Spain only in relation to products originating from the Czech and Slovak Republics), will not under any circumstances be able to invoke the ‘specific mechanism’ owing to the (late) date(s) these Member States made patent protection available.

Interestingly, the ‘specific mechanism’ allows patent proprietors to prevent ‘the import and marketing’ of the product.¹⁸⁶ It can therefore be asked whether parallel importers are allowed to circumvent the ‘specific mechanism’ by using Member States where the mechanism cannot be invoked as a gateway before re-exporting the goods to a Member State coming within the scope of the mechanism. By way of illustration, owing to the temporal scope of the mechanism patent proprietors in Spain are unable to invoke the mechanism for products imported from the Czech Republic. Germany, however, made patent protection available long before such protection became available in the Czech Republic. The question is therefore whether a German patent proprietor may invoke the mechanism for products imported from the Czech Republic through Spain, assuming that the products were never marketed in Spain but merely repackaged, before marketed in Germany.

The answer must be positive for two reasons. First, following *Merck v. Primecrown* derogations to the free movement provisions must be interpreted strictly.¹⁸⁷ The

¹⁸² Förordningen om patent på läke- eller livsmedel (932/1987). Product patents for pharmaceutical products are available if the application was filed on or after January 1, 1995.

¹⁸³ Law No. 11/1986 of March 20, on Patents. Para.1(1) of the Transitional Provisions provide that inventions concerning chemical and pharmaceutical products shall not be patentable before October 7, 1992.

¹⁸⁴ Icelandic Patent Act No. 17 of 1991 (amended 1996). The Act allows for the granting of product patents for pharmaceuticals after June 1, 1996, based on applications filed after January 1, 1995.

¹⁸⁵ Norwegian Patent Act of 1991. Product patents for pharmaceuticals became available on January 1, 1992. Applications must have been filed on or after this date.

¹⁸⁶ N. 138 above, para. 1.

¹⁸⁷ Cases 267-268/95, n. 24 above, para. 23.

above discussed legal issue therefore concerns the interpretation of the ‘specific mechanism,’ and not the ECJ’s case-law on consent and the exhaustion doctrine. Consent can only be given under the ‘specific mechanism’ when the parallel importer has given adequate notice to the patent proprietor, which will be further discussed in the next section. Secondly, if derogating from the above argument, mere importation ‘without actually selling [the products]’ cannot be regarded as ‘having been put on the market’ for the purpose of the exhaustion doctrine.¹⁸⁸ The products cannot therefore be deemed to have been put ‘in free circulation within the EEA’ until the products are marketed in an EEA Member State falling outside the geographical scope of the mechanism, or until the proprietor has exhausted his rights under the ‘specific mechanism’ by consenting to such marketing in a Member State falling within the scope of the mechanism. In conclusion, considering that allowing parallel importers to circumvent the ‘specific mechanism’ by routing the transport of the goods through Member States where the ‘specific mechanism’ is not applicable would undermine the very purpose of the mechanism, the ECJ would be well advised to simply rule that the ‘specific mechanism’ can be invoked, at least, up until first marketing in a Member State falling outside the scope of the mechanism, or until the proprietor has consented to such marketing (having received adequate notice from the parallel importer) in a Member State falling within the scope of the mechanism. This will prevent the rights under the mechanism being exhausted after first importation.

5.2.3 *The notification requirement*

Products benefiting from the ‘specific mechanism’ can legally be imported if, following one month’s notice, the patent holder has no objections to such importation. Even if adequate notification is given by the ‘intending’ parallel importer, the patent holder ‘may’ exercise his rights so as to prevent such

¹⁸⁸ See Case C-16/03, n. 117 above, para. 43.

importation, thus conferring a discretionary power on the patent holder.¹⁸⁹ A patent holder is even free to invoke the ‘specific mechanism’ in one Member State, but not in another. It is foreseeable that patent holders may not object to parallel importation between low-price Member States such as the eight new CEE Member States,¹⁹⁰ but object to parallel importation from the new CEE Member States to high-price Member States such as Sweden and the UK. The patent holder may even approve of only a certain quantity of products to be imported so as to limit the risk of the products being re-exported post marketing into a high-price Member State. It must be remembered that the notification requirement is not an exemption to the ‘specific mechanism,’ but exists independently of the rights conferred on the patent proprietor by the ‘specific mechanism.’¹⁹¹ The only function of the notification requirement is therefore to allow the patent proprietor to consider whether to allow parallel importation by waiving the rights conferred on him by the ‘specific mechanism.’

As the notification requirement in the ‘specific mechanism’ clearly draws upon the ECJ’s case-law on repackaging, it is clear that the parallel importer and not a third party must notify the patent proprietor.¹⁹² The ‘specific mechanism’ does not explicitly require that the marketing authorisation holder be notified in addition to the patent holder.¹⁹³ This is, however, advisable in order to waive any liability on

¹⁸⁹ The ‘specific mechanism,’ n. 138 above, para. 1, states that the patent holder ‘may rely on the rights granted by that patent’ or SPC.

¹⁹⁰ Subject to the geographical scope of the ‘specific mechanism.’ See section 5.2.2 above.

¹⁹¹ See Feddersen, n. 158 above, 553, for a detailed discussion of the notification requirement.

¹⁹² The Court’s case-law on repackaging is an extension of the exhaustion of rights doctrine. In order not to infringe the intellectual property owners rights when repackaging trademarked products the parallel importer must give the intellectual property owner 15 days’ prior notice. See Case C-143/00 *Boehringer Ingelheim KG v. Swingward Ltd & Dowelhurst Ltd* [2002] E.C.R. 3759, para. 64. The period of one month (in the ‘specific mechanism,’ n. 138 above) appears to be an adoption of Advocate General Jacobs’s suggestion in his Opinion in the abovementioned case, where he suggested a notice period of 3-4 weeks for repackaged products (para. 34). The patent holder must be notified by the parallel import directly, as notification by the competent authority granting a parallel import licence (PIL) will not be sufficient. See chapter 6(8) below for further discussion.

¹⁹³ The Commission Communication on a stronger European-based pharmaceutical industry for the benefit of the patient [2003] COM/383/final., p. 22, states that the patent holder as well as the marketing authorisation holder shall be notified. As it is difficult to reconcile this statement with a strict interpretation of the ‘specific mechanism’ it is unclear whether the marketing authorisation holder must be notified. It is however clear that the marketing authorisation holder will, for other reasons, be notified by the competent authority in connection with the granting of a PIL (see chapter

behalf of the parallel importer. Presumably the notification must include the name of the product, as well as information on where, when and by whom the products were supplied to the parallel importer.

That adequate notice is given should be of utmost concern to the parallel importer, as the granting of a 'parallel import licence' (PIL) is dependant on the parallel importer demonstrating to the competent authority that one month's notification has been given.¹⁹⁴ Notification in writing, preferably by registered mail, is therefore advisable.¹⁹⁵ The definition of 'competent authority' is dependant on the patent proprietor's form of marketing authorisation for the product in question. If the product benefits from a Community marketing authorisation the parallel importer must prove that adequate notice has been given to the patent proprietor when notifying the European Medicines Agency (EMA) of its intention to carry out parallel importation.¹⁹⁶ Similarly, if the product benefits from a national marketing authorisation the parallel importer must prove that adequate notice has been given to the patent proprietor when obtaining a PIL from the relevant national Medicines Control Agency. The competent authority must also verify that the correct patent 'holder or beneficiary of such protection' has been notified. The only guidance is that the beneficiary must be able to 'rely on the rights granted by that patent'¹⁹⁷ or SPC. Thus, the national patent holder as well as a potential licensee must come within the notion 'holder or beneficiary.'¹⁹⁸ Failure to demonstrate that adequate notice has been given to the patent holder should result in the non-issuance of a PIL or, depending on the definition of 'competent authority,' negative clearance by the EMA. If the patent holder responds to the notification by mere silence the competent authority may give clearance or issue the PIL and the parallel importer

3(3.2) above), albeit not given one month's notice. It should also be noted that in the majority of cases the patent holder and the marketing authorisation holder is one and the same person.

¹⁹⁴ PILs are granted by national Medicines Control Agencies. See chapter 3(3.2) above for further discussion.

¹⁹⁵ Lemaire, n. 153 above, 52.

¹⁹⁶ See chapter 3(2.1.1) above.

¹⁹⁷ N. 138 above, para. 2.

¹⁹⁸ Whether a licensee has a right to enforce the patent against a third party is a matter of contract law. In most Member States the assignment of licensing of a patent must be recorded with the national patent office so as to be enforceable against third parties: Lemaire, n. 153 above, 51.

may commence importation. Should, subsequently, the patent holder object to the parallel importation, the importer should not be liable for damages, but sanctioned by the withdrawal of the PIL/clearance resulting in an end to the parallel importation.

6. *Conclusion*

The insertion of the 'specific mechanism' in the 2003 Act of Accession¹⁹⁹ can be seen as evidence of the Member States' disapproval of the principle of international exhaustion. If intellectual property proprietors are allowed to derogate from the exhaustion of rights doctrine in relation to products marketed within the Community, albeit only in the new Member States for a dynamic period, it would be paradoxical to apply the doctrine to goods imported from outside the Community. The 'specific mechanism' should therefore not only be welcomed by patent proprietors, but also by supporters of a competitive pharmaceutical industry within the Community. Opponents of the 'specific mechanism' can take comfort in the fact that the product scope of the derogation is very limited and ever decreasing. The Court can expect questions concerning the temporal and geographical scope of the 'specific mechanism' in the near future, as the derogation is not satisfactorily clear on this matter. As an identically-phrased derogation will be included in the Act of Accession of Romania and Bulgaria,²⁰⁰ it is not unlikely that the scope of the 'specific mechanism' will be subject to a referral to the ECJ even before the abovementioned Act comes into force in 2007. In such a situation, it is important that the ECJ rules that the rights under the 'specific mechanism' cannot be exhausted by mere importation through (but not marketing in) a Member State falling outside the scope of the mechanism.²⁰¹

¹⁹⁹ N. 138 above.

²⁰⁰ See Annex 3(1) of the Treaty of Accession of Bulgaria and Romania (signed by the EU Member States and Bulgaria and Romania in Luxembourg on 25 April 2005).

²⁰¹ See pp. 175-176 above.

By limiting the exhaustion of rights doctrine to products first put into circulation within the common market the ECJ in effect created a 'fortress Europe.'²⁰² Even if international exhaustion would have lowered pharmaceutical prices, it is likely that the profit from parallel imports originating in non-Member States would remain with the parallel importer while simultaneously weakening the Community's pharmaceutical industry.²⁰³ The aim of the EC Treaty is to enhance economical competitiveness within the Community by establishing a common market, not allow parallel imported goods from third countries to destabilise the European pharmaceutical industry. Nevertheless, the Court did not completely refute the concept of international exhaustion in its entirety, but left a glimmer of hope for parallel importers by allowing exhaustion of intellectual property rights if it can be proved that the proprietor consented to re-importation into the Community. The definition of 'consent' is therefore still a highly relevant question. The exhaustion of rights doctrine has nevertheless had a drastic impact on the trade in pharmaceutical products within the EEA. Parallel imports account for an increasingly large share of the European pharmaceutical sales market, while manufacturers find it increasingly difficult to prevent parallel importers from exporting not only their products but, in effect, the exporting Member State's pricing policy.²⁰⁴ Yet the exhaustion of rights doctrine, as accounted for in this chapter, is only the doctrine in its basic form. As will be discussed in the following chapter, the ECJ has applied a very pro-integration policy to the trade in intellectual property protected products, even allowing for repackaging and rebranding of parallel imported pharmaceutical products.

²⁰² See Cases C-414-416/99, n. 113 above.

²⁰³ See chapter 1(3.1) above.

²⁰⁴ See chapter 1(2.2) above.

REPACKAGING OF PHARMACEUTICAL PRODUCTS I: THE INTELLECTUAL PROPERTY ASPECT

Disparities in the regulatory harmonisation of pricing control have, together with the operation of the principle of exhaustion, produced vast opportunities for parallel trade in pharmaceutical products.¹ However, national marketing regulations governing marketing authorisations, commercial practices and customer preferences have presented obstacles to parallel importers' ability to fully exploit these opportunities.² By way of illustration, goods purchased in bulk originally packaged for sales to hospitals may require repackaging to accommodate smaller quantity consumer sales;³ packaging with instructions or warnings in one language may need to be translated for sale in another Member State, and fragile packaging could be covered by a more durable outer layer.⁴ More controversial is the claim that parallel importers actively seek to make packaging more attractive to consumers, notably by marketing products under an 'own-brand' label and package design, so as to increase the products' market share.⁵ The legal argument arises between parallel importers (repackagers) and manufacturers (trademark proprietors). The parallel importer argues that the trademark proprietor has lost the right to prevent repackaging when the products were first put into circulation within the

¹ See chapter 1(3) above.

² For example, a rule authorising packaging only of a certain size, or sickness insurance rules making reimbursement dependant on the size of the packaging, may entail repackaging. See chapter 3(2.1.1) above.

³ In the UK for example, medicines usually come in multiples of seven, whereas in other continental Member States medicines are usually packaged in multiples of five or ten. See Report from the Select Committee on Trade and Industry: Trade marks, fakes and consumers, (1999 HC 380); and P. Koutrakos, 'In search of a common vocabulary in free movement of goods: the example of repackaging pharmaceuticals,' (2003) 28 E.L.Rev. 53, 54.

⁴ T. Hays, *Parallel importation under European Union Law*, (London: Sweet & Maxwell, 2004) p. 94.

⁵ See section 4.2 below.

Community. Not to allow repackaging would amount to a conscious partitioning of the single market. The manufacturers/trademark owners take the opposite view, claiming that the right to prevent repackaging is part of the specific subject matter of the trademark, in itself a guarantee of origin.

1. *A proprietary right to oppose unauthorised use of trademarks*

It has already been established that a trademark proprietor may only rely upon the derogation under Article 30 EC Treaty if the unauthorised use of the trademark, or movement of the trademark goods, falls within the specific subject matter or essential function of the trademark.⁶ That essential function is to guarantee ‘the identity of the origin of the trademarked product to the consumer or ultimate user, including the guarantee that the product has not been subject to interference by a third party at a previous stage of marketing such as to affect the original condition of the product.’⁷ The ECJ in *Hoffman-La Roche v. Centrafarm* therefore concluded that a consumer was entitled to know that the original condition of a trademarked product had not been affected by the interference of a third party.⁸ The Court confirmed that the trademark proprietor was justified under Article 30 EC Treaty in preventing a parallel importer from re-affixing the trademark after repackaging.⁹ Similarly, in *Centrafarm v. American Home Products* the ECJ held that Centrafarm was not justified under Article 30 EC Treaty in affixing the trademark ‘Seresta’ on products marketed in the Netherlands, when the products had originally been marketed under the trademark ‘Serenid’ in the UK prior to repackaging by

⁶ Case 16/74 *Centrafarm BV v. Winthrop BV* [1974] E.C.R. 1183. See chapter 5(2) for discussion of the specific subject matter of intellectual property rights.

⁷ Case 102/77 *Hoffman-La Roche & Co AG v. Centrafarm mbH* [1978] E.C.R. 1139, paras. 8-11.

⁸ *ibid.* Hoffman-La Roche had marketed ‘Valium’ in Germany for individual patients in packages containing 20-50 tablets and for hospitals in batches of five packages containing 100-250 tablets. Its British subsidiary marketed the same product in the UK at a considerably lower price, in packages of 100 or 500 tablets per package. Centrafarm, a parallel importer, imported ‘Valium’ from the UK into Germany, affixing the trademark ‘Valium’ on the new packages following repackaging by Centrafarm in the Netherlands.

⁹ *ibid.*, para. 8.

Centrafarm.¹⁰ The Court however recognised that in some cases this may be allowed and would go beyond the trademark proprietor's right to oppose such activity.¹¹ When there is no threat to the guarantee of origin and the quality of goods, opposing trademark re-affixation can form a disguised restriction on intra-Community trade which cannot be justified by Article 30 EC Treaty. The ECJ formulated four conditions which would in effect exhaust the trademark proprietor's rights.¹² First, it must be showed that allowing the trademark proprietor to rely on his rights would amount to a partitioning of the market.¹³ Secondly, the repackaging must not affect the original condition of the goods.¹⁴ Thirdly, the parallel importer must give adequate prior notice to the trademark proprietor together with a specimen of the repackaged product,¹⁵ and finally, the repackaging must clearly indicate the identity of the repackager.¹⁶

An interesting legal question arose shortly after *Hoffman-La Roche v. Centrafarm*¹⁷ by the facts referred to the ECJ by the German Landesgericht in *Pfizer v. Eurim-Pharm*.¹⁸ The difference between these two cases was that the importer in *Pfizer v. Eurim-Pharm*¹⁹ did not reaffix the trademark. The original trademark, 'vibramycin Pfizer,' was still in place, and was visible through a 'window' on the new outer packaging. The Court, recalling the essential function of a trademark, which is part of the specific subject matter of the trademark, held on the facts that Eurim-Pharm's repackaging was not liable to impair the guarantee of origin. Repackaging so that the inner packaging is not breached or altered and the manufacturer's trademark is visible through a window on the outer packaging had not impaired the guarantee of

¹⁰ Case 3/78 *Centrafarm BV v. American Home Products Corp.* [1978] E.C.R. 1823. See section 3 below.

¹¹ See section 3 below.

¹² Case 102/77, n. 7 above, para. 10.

¹³ *ibid.*, para. 14.

¹⁴ *ibid.* See also Joined Cases C-427, C-429 and C-436/93 *Bristol-Myers Squibb v. Paranova A/S* [1996] E.C.R. 3457, para. 60

¹⁵ Case 102/77, *ibid.*, para. 14; Cases C-427/93 etc., *ibid.*, para. 78; and Case C-143/00 *Boehringer Ingelheim KG v. Swingward Ltd & Dowelhurst Ltd* [2002] E.C.R. 3759, paras. 66-68.

¹⁶ Case 102/77, *ibid.*, para. 14; and Cases C-427/93 etc., *ibid.*, para. 70.

¹⁷ Case 102/77, *ibid.*

¹⁸ Case 1/81 *Pfizer Inc. v. Eurim-Pharm GmbH* [1981] E.C.R. 763.

¹⁹ *ibid.*

origin and therefore not interfered with the essential function of the trademark.²⁰ Further, by clearly stating the identity of the repackager and the manufacturer, the packaging cannot be liable to mislead consumers as to the origin of the products.²¹ A trademark proprietor may not therefore rely on his rights to prevent a parallel importer from marketing a product repackaged in this way.²² The fact that the original trademark remained visible, allowed the ECJ to prohibit Pfizer from opposing Eurim-Pharm's repackaging without overruling *Hoffman-La Roche v. Centrafarm*.²³

The ECJ has therefore held that there is no need for a legal distinction between relabelling and repackaging.²⁴ The practical difference, however, is that relabelling is the least intrusive way of meeting national regulations and gaining market access. As a result, the trademark proprietor may find it difficult to show that the relabelling risks impairing the guarantee of origin. If, however, the *form* of relabelling risks impairing the guarantee of origin and so has not satisfied all the conditions outlined in *Hoffman-La Roche v. Centrafarm*, 'then by way of derogation from the free movement of goods, the trademark owner's rights may...prevail.'²⁵ In practice, a legal distinction is therefore unnecessary, and following *Loendersloot v. Ballantine*²⁶ re-labelling should be subject to the same conditions outlined in *Hoffman-La Roche v. Centrafarm*.²⁷

²⁰ Case 1/81, n. 18 above, para. 10.

²¹ *ibid.*, para. 11.

²² *ibid.*, para. 13.

²³ N. 7 above.

²⁴ Joined Cases C-71-73/94 *Eurim-Pharm GmbH v. Beiersdorf AG* [1996] E.C.R. 3603. However, Advocate General Sharpston is of the opinion that the Case 102/77 *Hoffman* (n. 7 above) and Cases C-427/93 etc. (n. 14 above) conditions 'do not apply where a parallel importer markets in one Member State a pharmaceutical product imported from another Member State in its original internal and external packaging to which the parallel importer has applied an additional external label:' see Opinion of Advocate General Sharpston in Case C-348/04 *Boehringer Ingelheim KG v. Swingward Ltd.* (delivered on 6 April 2006, not yet reported), para. 42. The ruling of the ECJ in this case is therefore eagerly awaited.

²⁵ Advocate General Sharpston, *ibid.*, para. 41.

²⁶ Case C-349/95 *Loendersloot v. George Ballantine & Son Ltd* [1997] E.C.R. 6227.

²⁷ N. 7 above.

The ECJ's decision in *Hoffman-La Roche v. Centrafarm*²⁸ provides the legal framework for the unauthorised use of trademarks in the course of repackaging. The decision has subsequently been amended, most notably by *Bristol-Myers Squibb v. Paranova*²⁹ and *Boehringer v. Swingward and Dowelhurst*.³⁰ These rulings have affected the balance struck between the trademark proprietors' right to oppose unauthorised use of their intellectual property rights, and the parallel importers' rights under the free movement provisions. Before the four conditions as outlined in *Hoffman-La Roche v. Centrafarm*³¹ can be discussed in detail, the effect of the Trade Mark Directive³² on repackaging must be discussed.

2. *The Trade Mark Directive and unauthorised use of trademarks*

The Trade Mark Directive, adopted after the decision in *Hoffman-La Roche v. Centrafarm*,³³ effectively enshrines the principle of Community-wide exhaustion of trademarks. Article 7(1) states that 'the trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent.'³⁴ Since repackaging involves placing the products in a new box with a new trademark, it can be argued that the exhaustion principle in Article 7(1) should not apply to repackaged goods which have not been put on the 'Community under that [particular] trade mark by the proprietor or with his consent.'³⁵ Naturally, this would affect the case-law established by the ECJ before the adoption of the Directive. The matter was complicated further by the exception to the exhaustion formula introduced in Article 7(2) 'where there exist legitimate reasons for the proprietor to oppose further commercialization of the goods, especially where the

²⁸ N. 7 above.

²⁹ N. 14 above.

³⁰ N. 15 above.

³¹ N. 7 above.

³² Council Directive 89/104 EEC to approximate the laws of the Member States relating to trade marks [1989] O.J. L40/1

³³ N. 7 above.

³⁴ Directive 89/104, n. 32 above, Art. 7(1).

³⁵ *ibid.* (emphasis added).

condition of the goods is changed or impaired after they have been put on the market.³⁶ This Article is perhaps even more important to parallel trade and repackaging than Article 7(1). Considering the nature of pharmaceutical products, it is not hard to find legitimate reasons to prevent repackaging, especially in the context of public health and safety, which threatened to restrict the ECJ's previous case-law.³⁷ The ECJ was faced with the compatibility of Article 7(1) and 7(2) of the Trade Mark Directive and repackaging in *Bristol-Myers Squibb v. Paranova*.³⁸ The Court found that Article 7(1) of the Trademark Directive does not exclude repackaged products from the exhaustion of rights principle. To do so would be to restrict Articles 28 and 30 EC Treaty and established case-law. The Court observed that 'to accept the argument that the principle of exhaustion under Article 7(1) cannot apply if the importer has repackaged the product and re-affixed the trade mark would...imply a major alteration to the principles flowing from [the free movement provisions] of the Treaty.'³⁹ Reaffirming its previous case-law, the Court held that 'the prohibition on quantitative restrictions and measures having equivalent effect applies not only to national measures but also to those emanating from Community institutions.'⁴⁰ In order to circumvent Article 7(2) the ECJ interpreted the word 'especially' so as to show that the 'case envisaged is given only as an example.'⁴¹ Article 30 EC Treaty and Article 7 of the Trade Mark Directive pursue the same result, namely to protect trademark rights, and must therefore be given the same interpretation. Article 7 must be read in conjunction with the Court's case-law establishing that derogation from the free movement of goods principle is only permissible in so far as it aims to protect the specific subject matter of intellectual property rights.⁴² The ECJ restated that intellectual property proprietors may oppose parallel importation of repackaged goods bearing a

³⁶ Directive 89/104, n. 32 above, Art. 7(2).

³⁷ See e.g. Koutrakos, n. 3 above, 54.

³⁸ N. 14 above. Paranova, a parallel importer, acquired pharmaceutical products manufactured and trademarked by Bristol-Myers Squibb in Member States with low-price regimes, repackaged the products and re-affixed Bristol-Myers Squibb's trademark on the new packaging before being sold by Paranova in higher-priced Member States, primarily Denmark and Sweden.

³⁹ *ibid.*, para. 35.

⁴⁰ *ibid.*, paras. 35-36.

⁴¹ *ibid.*, para. 39.

⁴² *ibid.*, paras. 47-48.

reaffixed trademark, unless the parallel importer has fulfilled the conditions set out in *Hoffman-La Roche v. Centrafarm*.⁴³ Before these conditions, applicable to repackaged, relabelled, and rebranded products alike, are discussed in detail, a comprehensive discussion on rebranding is necessary as a legal and practical distinction can be drawn between repackaging/relabelling and rebranding.

3. *Rebranding*

The difference between repackaging/relabelling and rebranding is that the parallel importer does not merely re-affix the trademark on the new packaging, but actually affixes a different trademark. Rebranding tends to occur when manufacturers market products using different brand names throughout the Community. It is important to remember that under a centralised Community marketing authorisation a single product name must be used throughout the Community.⁴⁴ It is therefore essential that only products benefiting from national marketing authorisations and marketing authorisations granted under the mutual recognition procedure are allowed to use different product names in different Member States.

Linguistic differences are inevitable due to the existence of 20 official languages in the EC, their respective subtleties and the different alphabets and script (Greek). AstraZeneca, for example, markets the stomach acid-lowering product “ Losec ” throughout the EU, but uses the brand name “ Mopral ” in France (because of the meaning of “ l’leau sec ”). Pfizer markets “ Norvasc ” in most Member States, but calls it “ Norvas ” in Spain because “ c ” cannot end a word in Spanish.⁴⁵ National health authorities may also have requested that a certain name may or may not be

⁴³ N. 7 above.

⁴⁴ However, the ECJ has held that in exceptional circumstances relating to the protection of health and human life, variations to the package layout and product name may be allowed. National laws precluding the use of a particular brand name, which may prevent market access, may be such an exception. See Case T-123/00 *Thomae GmbH v. Commission* [2002] ECR II-5193; and chapter 3(2.1) above.

⁴⁵ See European Federation of Pharmaceutical Industries and Associations (EFPIA), ‘The single trademark issue – the importance of trade mark rights for medicines,’ Position paper (June 2002), (<http://www.efpia.org/4_pos/legal/Trademarks0602.pdf>).

used. The name may be similar to the name of another pharmaceutical product (thus constituting a risk to public health and safety), or invoke associations that may lead to a risk to public health and safety. Trademark rights may also preclude the use of a single product name. If a similar or identical name is already registered in one Member State, the pharmaceutical company must decide whether to use a different name, available throughout the Community, or to simply use a slightly different name in the Member State concerned. Bayer, for example, markets “Ciproxin” throughout the Community, but use the brand name “Ciprobay” in Germany due to prior trademark rights. Speculative trademark owners are also a growing concern for pharmaceutical companies. A choice must be made between paying an excessive price for the trademark rights, or to use a different trademark in the Member State concerned.⁴⁶

Preventing parallel importers from marketing products under different brand names in the Member States of exportation and importation may obstruct intra-Community trade. The ECJ was given a chance to discuss this issue in *Centrafarm v. American Home Products*.⁴⁷ The Court recalled that the right granted to the trademark proprietor to prohibit the affixing of a trademark not originally affixed to the product is part of the specific subject matter of the trademark, and only the proprietor may confer an identity on the product. The proprietor is therefore justified, under Article 30 EC Treaty, in prohibiting such interference with its goods and trademark. However, the Court also held that prohibiting a third party from unauthorised usage of the trademark would constitute a restriction on Community trade under Article 28 EC Treaty, if the practice of using different trademarks in different Member States had been adopted to prevent parallel imports, and therefore to artificially partition the common market.

⁴⁶ EFPIA ‘Single trademark,’ n. 45 above, 8.

⁴⁷ N. 10 above. Centrafarm, a parallel importer, acquired products manufactured by AHP and marketed them using the trademark ‘Serenid’ in the UK. The products were subsequently repackaged, and the trademark ‘Seresta’ affixed to the new packaging before marketing in the Netherlands.

The issue of rebranding was finally resolved by the ECJ in *Pharmacia & UpJohn v. Paranova*.⁴⁸ UpJohn, a pharmaceutical manufacturer, claimed that Paranova, a parallel importer, was in breach of Danish intellectual property laws by affixing a different trademark to the repackaged products. The manufacturer also claimed that Community measures cannot justify such actions since there are objective grounds justifying the use of different trade names in different Member States where the product is to be marketed. Paranova claimed the different trademarks were in reality the same, and so the trademark proprietor had exhausted his trademark rights when the goods were first marketed. In the alternate - and this is the interesting claim - Paranova claimed that the system of using different trademarks throughout the Community amounts to artificial partitioning of the market, and therefore not compatible with Articles 28 and 30 EC Treaty.

The ECJ established that the national Court was proceeding on the assumption that UpJohn had used different trademarks in Denmark, France and Greece to market clindamycin. 'It is thus in the light of Article 36 [30] of the Treaty that the legality of the trademark proprietor's opposition to the replacement of the trade mark falls to be assessed.'⁴⁹ It is also established that Article 7 of the Trade Mark Directive⁵⁰ and Article 30 EC Treaty must be given the same interpretation in order to protect the fundamental interests of the free movement of goods provisions within the single market.

The ECJ confirmed *Centrafarm v. American Home Products*⁵¹ but stated that it cannot be justified if it amounts to an artificial partitioning of the market. More importantly, the ECJ continued by saying that 'that condition cannot be applied differently depending on whether the original trade mark is reaffixed after repackaging or replaced, unless separate rules are justified by objective differences

⁴⁸ Case C-379/97 *Pharmacia & UpJohn S/A v. Paranova A/S* [1999] E.C.R. 6927.

⁴⁹ *ibid.*, para. 29.

⁵⁰ N. 32 above.

⁵¹ N. 10 above.

between the two situations.’⁵² It can however be argued that there is a difference between the practice of reaffixing and replacing. The practice of using different trademarks was not adopted with the intention of partitioning the market. Moreover, the right to affix a trademark, and to place a new trademark on a product, thus changing its identity, is part of the specific subject matter of a trademark and is therefore a right only granted to the trademark proprietor. The ECJ, however, ruled that it does not matter whether the products are merely repackaged and the trademark re-affixed, or whether the trademark is replaced with another trademark, since in both cases the ‘parallel importer is interfering with a trademark that do not belong to him.’⁵³ The practice of using different trademarks throughout the Community will lead to a partitioning of the market regardless of the trademark proprietor’s intention. Rebranding is therefore necessary in order to enable intra-Community trade. ‘The condition of artificial partitioning of the markets between Member States, as defined by the Court in *Bristol-Myers Squibb v. Paranova*,⁵⁴ thus applies where a parallel importer replaces the original trade mark by that used by the proprietor in the Member State of import.’⁵⁵ However, this means that the condition of necessity as applied by the Court in *Bristol-Myers Squibb v. Paranova*⁵⁶ also applies in circumstances of rebranding. The condition of necessity will be satisfied if objecting to rebranding would effectively hinder access to the importing Member State market. This would be the case, for example, if national legislation prohibits the parallel importer from importing and marketing the goods in the importing Member State with the trademark used on the exporting Member State market. This could be for reasons of consumer safety if the trademark is liable to mislead consumers. It is for the national court to determine, in each specific case, whether replacing the trademark with the trademark used in the importing Member State is objectively necessary.⁵⁷ However, the ECJ made it clear that ‘the condition

⁵² Case C-379/97, n. 48 above, para. 32.

⁵³ *ibid.*, paras. 37-38. The view taken by the Court, that there is no objective difference between rebranding and mere trademark re-affixing, has been criticised: I. Forrester, ‘The Repackaging of Trade Marked Pharmaceuticals in Europe: Recent Developments,’ [2000] 22 E.I.P.R. 512, 516.

⁵⁴ Cases C-427/93 etc., n. 14 above.

⁵⁵ Case C-379/97, n. 48 above, para. 40.

⁵⁶ N. 14 above. Further discussed in section 4 below.

⁵⁷ Case C-379/97, n. 48 above, paras. 43 and 45.

of necessity will not be satisfied if replacement of the trademark is explicable solely by the parallel importer's attempt to secure a commercial advantage.'⁵⁸

This decision left many questions unanswered. Did it overrule *Centrafarm v. American Home Products*,⁵⁹ or merely expand it? In *Centrafarm v. American Home Products*⁶⁰ the Court said that rebranding is not allowed unless it would lead to a partitioning of the internal market. In *Pharmacia & UpJohn v. Paranova*⁶¹ the Court ruled that rebranding is only allowed if it fulfils a 'necessity' test, i.e. when the use of different trademarks on the importing and exporting market partitions the market to such an extent that rebranding is 'necessary.' The ECJ also gave clear guidance to the effect that rebranding is not allowed when done in order to secure a commercial advantage. The Court did not define 'necessity' any further. However, if the use of different trademarks throughout the Community partitions the market, and therefore hinders parallel importation, rebranding should be considered 'necessary.'

It is interesting that the ECJ took the view that the requirement of market partitioning as set out in *Bristol-Myers Squibb v. Paranova*⁶² 'has the practical advantage that it does not require national courts to assess evidence of intention, which is notoriously difficult to prove.'⁶³ For some reason the ECJ finds the notion of 'intention' harder to define than the concept of 'necessity.' Furthermore, the rule that purely commercial reasons are not sufficient as to necessitate rebranding sits badly with the ECJ's general case-law on the free movement of goods. If a product is marketed under trademark X in the exporting Member State and trademark Y in the importing Member State, this may require the parallel importer to spend considerably more funds on advertising and marketing for strictly commercial reasons. That can be considered an 'obstacle to trade' if the product in question is

⁵⁸ Case C-379/97, n. 48 above, para. 44.

⁵⁹ N. 10 above.

⁶⁰ *ibid.*

⁶¹ N. 48 above.

⁶² N. 14 above.

⁶³ Case C-379/97, n. 48 above, para. 41.

not a pharmaceutical product.⁶⁴ Further, if two identical products appear on the market under different trademarks, this may confuse consumers as to the origin and quality of the parallel imported product. Rebranding would therefore be necessary for commercial reasons. This shows that a much clearer definition of ‘necessity’ is needed. However, in paragraph 39 of its ruling the ECJ states that ‘...where the repackaging with reaffixing or the replacement of the trademark is necessary to enable the products to be marketed by the parallel importer in the importing Member State, there are obstacles to intra-Community trade...’⁶⁵ This seem to suggest that where repackaging is necessary, rebranding is allowed. As a result, rebranded, as well as repackaged/relabelled products, must fulfil the four conditions set out in *Hoffman-La Roche v. Centrafarm*⁶⁶ in order for the unauthorised use of the trademark to come within the exhaustive effect of Articles 28 and 30 EC Treaty. These conditions are discussed below, beginning with the ‘market partitioning’ (commonly referred to as the ‘necessity’) condition.

4. *Market partitioning, effective market access and the need to repackage*

Partitioning of the market occurs when the packaging of pharmaceutical products prevents effective access to the market. This could be the result of national laws in the importing Member State, the most obvious being laws only authorising pharmaceutical products sold in certain package sizes.⁶⁷ Sickness insurance rules on reimbursement of sickness expenses may depend on the size of the packaging.⁶⁸ Well-established practice, recommended by professional bodies such as pharmacists and doctors, may amount to partitioning of the market if they recommend dispensation in certain package sizes.⁶⁹ The ECJ used the phrase ‘in particular’

⁶⁴ It could be seen to be a measure equivalent to a quantitative restriction (see Case 8/74 *Procureur du Roi v. Dassonville* [1974] E.C.R. 837). The Cases C-267-268/91 *Criminal proceedings against Keck and Mithouard* [1993] E.C.R. 6097 ‘selling arrangement’ exception seems unlikely to apply since the measure is not non-discriminatory – it directly affects importers, and hence obstructs the free movement of goods.

⁶⁵ Case C-379/97, n. 48 above, para. 39.

⁶⁶ N. 7 above.

⁶⁷ Cases 427/93 etc., n. 14 above, para. 53.

⁶⁸ *ibid.*

⁶⁹ *ibid.*

when listing measures that would amount to market partitioning, suggesting that it is not an exhaustive list.⁷⁰ As a result of the diversity of such measures throughout the Community, the first condition for repackaging identified by the Court requires a parallel importer to establish ‘that the use of the trade mark right by the owner, having regard to the marketing system which he has adopted, will contribute to the artificial partitioning [of markets] between Member States.’⁷¹ This wording suggests that ‘artificial’ refers to some degree of intention on the part of the intellectual property owner.⁷² In *Bristol-Myers Squibb v. Paranova*,⁷³ the Court stressed that it is not necessary for the parallel importer to prove that the intellectual property owner deliberately sought to partition the market by using various forms of packaging. Hence, as discussed above in relation to rebranding, showing intention is not required.⁷⁴ ‘Artificial’ merely refers to the protection of the specific subject matter. If the repackaging does not interfere with the specific subject matter of the trademark, the resultant partitioning of the market is artificial, in the sense that it will not be justifiable under the EC Treaty.⁷⁵

This ‘objective’ test restricts the intellectual property owner to the extent that he can never lawfully exercise his intellectual property rights. If market partitioning can be showed, the trademark owner will be unable to exercise his trademark rights. However, it should also be emphasised that repackaging is not allowed for purely commercial reasons; as such reasons alone would not render the market partitioning ‘artificial.’⁷⁶ In consequence, the test is very straightforward, namely ‘if market

⁷⁰ Cases 427/93 etc., n. 14 above, para. 53.

⁷¹ *ibid.*, para. 49. See also Case 102/77, n. 7 above, para. 14. As noted by Koutrakos (n. 3 above, 66): ‘in rendering effective access to the market the key to the determination of whether repackaging is objectively justified, the Court introduces consistency in its overall free movement of goods case-law.’ The definition of the outer limit of measures having equivalent effect to quantitative restrictions under Article 28 EC Treaty is increasingly focusing on ‘market access.’

⁷² See F. Castillo de la Torre, ‘Trademarks and free movement of pharmaceuticals in the European Community: To partition or not to partition the market,’ (1997) 19 E.I.P.R. 304, 306.

⁷³ N. 14 above.

⁷⁴ In Case C-379/97, n. 48 above, para. 41, the Court stated that intention is ‘notoriously difficult’ to prove.

⁷⁵ *ibid.*, para. 57.

⁷⁶ This can be inferred from *ibid.*, para. 44. For example, if the parallel importer is seeking to use repackaging as a springboard for marketing generic products or to build up a ‘customer following’ for its products. See section 4.2 below.

partitioning can be showed.’ If this test is fulfilled, it can only be rebutted if proven necessary to preserve the guarantee of origin. However, if the intellectual property owner, due to national laws in the importing Member State, markets a product using many different package sizes in the importing Member State, and one of these sizes is also available on the exporting market, this does not render repackaging unnecessary. Partitioning of the market would still occur even if the importer has access to part of the market.⁷⁷ However, repackaging will not be allowed if other measures would be viable. This means that the need to repackage must comply with the Community principle of proportionality. Intellectual property owners may oppose repackaging in new external packaging if relabelling would suffice to market the product in the importing Member State. Similarly, repackaging in new external packaging when a new translated information leaflet inserted into the original packaging would have been sufficient under national regulations will not be considered proportional.⁷⁸

The Court has been very pro-integration and has prohibited intellectual property owners from opposing repackaging as long as the actions undertaken by the parallel importer have been proportionate to the need to repackage or otherwise alter the presentation of the product. National courts also take proportionality into consideration when applying the ECJ’s rulings in national litigation. In *Bristol-Myers Squibb v. Paranova*⁷⁹ the Danish Supreme Court, having received the preliminary ruling from the ECJ, ruled in favour of the claimant intellectual property owner. Paranova’s claim that ‘sealing’ of the packages by Boehringer Ingelheim made it necessary to repackage, since the boxes could not be sufficiently sealed after an information leaflet had been inserted, was rejected.⁸⁰ The Supreme

⁷⁷ Cases C-427/93 etc., n. 14 above, para. 54. However, see the special rules applicable to centrally authorised pharmaceutical products: Case C-433/00 *Aventis GmbH v. Kohlfarma GmbH & MTK GmbH* [2002] E.C.R. 7761. See also chapter 7(3.1) below.

⁷⁸ Cases C-427/93 etc., *ibid.*, para. 55. See D. Dryden and S. Midlemis, ‘Parallel importation of repackaged goods: Is ‘necessity’ really necessary,’ (2003) J.B.L. 82, for discussion of the limitations of the market partitioning condition.

⁷⁹ N. 14 above.

⁸⁰ *Bristol-Myers Squibb v. Paranova A/S* [2003] (Unreported) (HR(DK)), joined case (reference) with Case 272/2001 *Paranova A/S v. C.H. Boehringer GmbH & Others* [2004] E.T.M.R. 24. See K.

Court also rejected Paranova's claim that repackaging was necessary following the removal of an article from the original package, which allegedly rendered the box too big.⁸¹ Paranova had over-labelled certain products, only leaving Boehringer Ingelheims' trademark visible through a 'window.' The 'window labelling' was not prohibited in itself, in line with *Pfizer v. Eurim-Pharm*,⁸² but the extensive over-labelling was held disproportionate.

The 'market partitioning' test fails to consider one important factor, that of consumer preference. Following *Merck v. Paranova*,⁸³ where the ECJ ruled that repackaging is objectively necessary if without such repackaging effective access to the market would be hindered, this test, in essence relying on the preferences of a 'significant proportion of consumers,' has come to be known as the 'consumer preference test.' This test is an extension of the *Bristol-Myers Squibb v. Paranova*⁸⁴ 'market partitioning' condition.

4.1 *The customer preference test*

The ruling in *Merck v. Paranova*⁸⁵ heralded the Court's new approach to 'market access.' The Court failed to define the concept of a 'significant proportion of customers,' but nevertheless allowed repackaging when relabelling had been sufficient to satisfy national legislation, following recommendations by national authorities in the importing Member State to the effect that there was significant customer resistance to relabelled products.

Dyckjaer-Hansen, 'Denmark: Trade Marks –parallel imports – rebranding and repackaging' (2003) 25 E.I.P.R. N183.

⁸¹ Dyckjaer-Hansen, n. 80 above.

⁸² N. 18 above.

⁸³ Case C-443/99 *Merck, Sharp & Dohme GmbH v. Paranova GmbH* [2002] E.C.R. 3703: Paranova repackaged products after the Austrian authorities had recommended replacement packaging and not mere relabelling. Paranova did not rely on statistics or reports showing that there was resistance to relabelled products from a significant proportion of consumers. Even though the size of the packages was the same in the exporting Member State and Austria, the ECJ held that repackaging is objectively necessary if without such repackaging effective access to the market would be hindered. The fact that national authorities recommended repackaging was strong evidence in support of Paranova's claim that repackaging was necessary.

⁸⁴ N. 14 above.

⁸⁵ N. 83 above.

In *Boehringer Ingelheim v. Dowelhurst*, the defendant parallel importer claimed that repackaging was necessary in order to gain effective access to the market, but the claimant manufacturer argued that ‘the reluctance of consumers to accept over-stickered products is not a legitimate reason for repackaging.’⁸⁶ The Court repeated established case-law, stating that trademark proprietors cannot rely on their national trademark rights when repackaging is necessary in order to overcome market partitioning, and parallel importers are not allowed to repackage solely on grounds of gaining a commercial advantage.⁸⁷

‘However, there may exist on a market, or on a substantial part of it, such strong resistance from a significant proportion of consumers to relabelled pharmaceutical products that there must be held to be a hindrance to effective market access. In those circumstances, repackaging of the pharmaceutical products would not be explicable solely by the attempt to secure a commercial advantage. The purpose would be to achieve effective market access.’⁸⁸

This takes ‘necessity’ beyond national regulations and conscious partitioning of the market, and in essence creates a ‘customer preference’ test to be applied by national courts. This is a difficult test for national courts to apply because no clear guidelines exist as to what is a ‘significant proportion’ of customers. The term demands two separate definitions; a definition of ‘customer’ and a definition of a ‘significant proportion’ [of customers].

Mr Justice Laddie, in the first *Boehringer Ingelheim v. Swingward* UK High Court judgment, considered that both consumers and pharmacists come within the notion of ‘customer.’⁸⁹ However, the pharmaceutical industry, especially the pharmaceutical wholesale industry, is very price competitive. The prime factor for pharmacists is the price of the pharmaceutical product, not the box. It is more

⁸⁶ Case C-143/00, n. 15 above, para. 40.

⁸⁷ See C. Stothers, ‘Are parallel imports bad medicine? Repackaging of trade-marked pharmaceuticals within the EU,’ (2002) 23 E.C.L.R. 417, for discussion.

⁸⁸ Case C-143/00, n. 15 above, para. 52.

⁸⁹ *Glaxo Group Ltd v. Dowelhurst Ltd* [2000] 2 C.M.L.R. 571, para. 165.

plausible to see patients being concerned with the appearance of the pharmaceutical product than pharmacists. Even though it can be argued that pharmacists can actively inform patients about the safety of reboxed and relabelled pharmaceuticals, and thus overcome this barrier, ‘this is not the real world – poorly people want their pills, not explanations.’⁹⁰ Similarly, in *MPA Pharma v. Rhone Poulenc*⁹¹ the ECJ made a distinction between pharmaceutical products sold to hospitals and pharmaceutical products sold to consumers through pharmacies.⁹² The presentation of the product is of little importance to hospital patients since professionals administer the pharmaceutical products. The presentation of the product is of greater importance when they are sold to consumers through pharmacies, even though the fact that the pharmaceutical products are subject to a prescription by a doctor should give consumers some confidence.⁹³ Consumers/patients are therefore the ‘customers’ most concerned with the appearance of the products. However, this simple analysis fails to consider that pharmacists, acting in a market economy, are in theory representatives of their customers’ demands; and it is in their interest to satisfy that demand. Pharmacists, as representatives of their customers, are therefore the most competent group to assess ‘customer preference.’

As for the definition of a ‘significant proportion’ [of customers], the defendants in the first *Boehringer Ingelheim v. Swingward* High Court judgment relied on the results of a survey.⁹⁴ There are between 9000 – 9500 independent pharmacies in the UK. Questionnaires were sent out to between 3500 – 4000 pharmacies. 1,153 out of 1200 pharmacists [replies] stated that they preferred re-boxed, whilst 1,116 said that their patients preferred repackaged. Only 26 preferred relabelled, and 728 stated that they would sell more of the product if it were repackaged, whilst 386 stated that they would sell the same. The claimant manufacturers answered by relying on a similar report aimed at pharmacists:

⁹⁰ Per Lord Justice Jacobs in (the second UK case of) *Boehringer Ingelheim v. Swingward and Boehringer Ingelheim v. Dowelhurst* [2004] 3 C.M.L.R. 3, para. 50.

⁹¹ Case C-232/94 *MPA GmbH v. Rhone-Poulenc GmbH* [1996] E.C.R. 3671

⁹² *ibid.*, para. 48

⁹³ *ibid.* This paragraph concerned the ‘brand reputation’ condition (section 6 below) but nevertheless is good *obiter dicta* which can be applied to the ‘customer preference’ test.

⁹⁴ N. 89 above, para. 187.

‘Pharmacies buy based on price but they are very aware of the varying quality of product and availability. Many pharmacists spoke of changing suppliers because of out-of-stock problems or issues with the quality of the product. In some cases, the pharmacist refused to use [parallel importers] who did not repackage into English language packs, while in others, although they did not refuse foreign language packs, they were less happy about their use.’⁹⁵ Many pharmacists claimed that they could overcome consumer reluctance to relabelled (and parallel imported) products by carefully explaining that the products are identical to the original trademark owners’ products.⁹⁶

This shows the complexity, and lack of objectivity, of the ‘customer preference’ test. The UK Court of Appeal acknowledged that there is a ‘customer preference’ test, but failed to define the term ‘significant proportion’ [of customers] as the Court decided to refer questions regarding what *form* of relabelling and reboxing considered necessary, which is now pending before the ECJ.⁹⁷

The Danish Supreme Court faced similar facts when ruling in *Bristol-Myers Squibb v. Paranova*.⁹⁸ Before the Supreme Court could apply the ECJ ruling in *Bristol-Myers Squibb v. Paranova*,⁹⁹ the ECJ had amended the test so as to include the ‘customer preference test’ established in *Boehringer Ingelheim v. Dowelhurst*.¹⁰⁰ The defendant relied on an AIM survey; similar to the survey relied on in *Boehringer Ingelheim v. Dowelhurst*.¹⁰¹ The survey showed that pharmacists generally preferred repackaged and rebranded pharmaceutical products to relabelled.¹⁰² However, Paranova had successfully marketed repackaged and rebranded pharmaceutical products since 1999. The ‘customer preference test’

⁹⁵ N. 89 above, para. 179.

⁹⁶ *ibid.* The report, prepared by Taylor Nelson Ltd., was commissioned by GlaxoWellcome and the Association of the British Pharmaceutical Industry (ABPI).

⁹⁷ Case C-348/04 *Boehringer Ingelheim KG v. Swingward Ltd.* [2004] O.J. C273/11. See Opinion of Advocate General Sharpston, n. 24 above. See also section 4.2 below.

⁹⁸ Case 272/2001 (Denmark), n. 80 above. See Dyekjaer-Hansen, n. 80 above, N184.

⁹⁹ N. 14 above.

¹⁰⁰ N. 15 above.

¹⁰¹ N. 90 above, para. 187.

¹⁰² Case 272/2001, n. 80 above, para. 13-15.

could therefore not be applied, since the resistance to relabelled pharmaceutical products was a consequence of Paranova's own action by letting pharmacists become accustomed to repackaged and rebranded products. Indeed, it is likely that pharmacists would have grown accustomed to relabelled instead of repackaged pharmaceutical products if Paranova had decided to market relabelled products as early as in 1999.¹⁰³ In consequence, repackaging is not necessary where the resistance to relabelled products can, over time, be overcome.¹⁰⁴ A survey should therefore be carried out before first marketing, so as to be able to argue that repackaging is necessary in order to access the market for a first sale.

The 'customer preference test' means that repackaging is now allowed not only when it is necessary for legal reasons, but also when it is necessary for practical reasons. This will most likely lead to new and innovative claims by parallel importers, relying on expert advice and specialist reports. It can be claimed that the test is important for the establishment of a common market. However, if the parallel importer can lawfully market a product in its original packaging, or by using relabelling, repackaging may be disproportionate. In a market economy it should be for the parallel importer to overcome consumer tendencies, being able over time to influence customer preference. The 'customer preference test' may therefore be an important pro-integration policy in the short run, but unnecessary in the long run.¹⁰⁵

4.2 *'Necessity' of co-branding*

In order to create a following for their products, parallel importers frequently attach their own brand and logo to the repackaged or relabelled products, or simply reattach the original manufacturer's brand name in conjunction with the parallel importer's distinct 'get-up' (e.g. colours and lines arranged in a distinctive manner). This is often referred to as 'co-branding.' For example, the UK based parallel importer Dowelhurst has created its own brand called 'Concept Generics.'

¹⁰³ *ibid.*

¹⁰⁴ Dyekjaer-Hansen, n. 80 above, N184.

¹⁰⁵ This argument was raised by Merck in Case C-443/99, n. 83 above, para. 18.

Dowelhurst advertises this brand without reference to the manufacturer's trademark, and does not attach the trademark to the new packaging even though the packages contain the trademark owner's products.¹⁰⁶

The issue of co-branding can be divided into two parts. First, can co-branding ever be considered necessary in order to gain 'market access,' and secondly, does co-branding affect the specific subject matter of the trademark? It can be argued that co-branding is carried out for purely 'commercial reasons' if mere repackaging/relabelling or rebranding would have been sufficient in order to gain market access. Considering that repackaging/relabelling or rebranding is not allowed for purely 'commercial reasons,' the same rule must apply to co-branding. This can, hypothetically, be rebutted by proving that co-branding is 'necessary' in order to gain market access due to resistance from a significant proportion of customers to products that have not been co-branded. However, the 'customer preference test' concerns the right to repackage instead of relabel products, rendering it unlikely that the ECJ would consider it 'necessary' to co-brand if repackaging would have been sufficient, or, indeed, that the 'necessity' of co-branding would justify repackaging if relabelling would have been sufficient to gain market access.¹⁰⁷ The relevant question is instead whether co-branding is allowed after it has been established that repackaging is objectively necessary. The necessity to repackage and co-brand should therefore not be part of the same 'necessity' test, but two separate issues to be assessed individually.

This reasoning was adopted by the EFTA Court when delivering judgment in *Paranova v. Merck*.¹⁰⁸ Coloured stripes along the outer packaging, designed so as to

¹⁰⁶ See N. Gross and L. Harrold, 'Fighting for pharmaceutical profits – the decision in *Boehringer Ingelheim v Swingward*,' (2002) 24 E.I.P.R. 497, 499.

¹⁰⁷ In Case 272/2001 (Denmark), n. 80 above, para. 23, The Danish Supreme Court held that *Paranova*'s 'window-labelling,' relabelling the entire package in its own distinctive colour and design scheme, only leaving *Boehringer Ingelheim*'s trademark visible in order to make it look like a repackaged product, was unnecessary in order to market the products. It is not clear whether the Court only considered the extensive relabelling to be disproportional, or whether the 'window labelling' was considered co-branding, and therefore prohibited. See *Dyckjaer-Hansen*, n. 80 above, N184; and pp. 194-195 above.

¹⁰⁸ Case E-3/02 *Paranova AS v. Merck & Co Inc.* [2003] 40 C.M.L.R. 7

resemble the original packaging by the manufacturer, were used by Paranova on parallel imported pharmaceutical products in Norway. According to the Court, the parallel importer must be considered to be on ‘basically equal footing with the manufacturer and trade mark proprietor within the limits set by the [Trade Mark] Directive,’ after the products have been lawfully repackaged and the trademark re-affixed.¹⁰⁹ The ‘market partitioning/necessity’ condition is therefore only relevant when determining the parallel importer’s right to repackage as such, but not to the parallel importer’s particular packaging design. It follows from *Christian Dior v. Evora*¹¹⁰ that the trademark proprietor’s right to oppose use of the trademark in relation to advertising and/or package design is exhausted simultaneously with the right to oppose marketing of the products. The trademark proprietor will therefore have lost his right to prevent co-branding after it is established that repackaging is necessary in order to gain access to the importing market. However, in line with *Bristol-Myers Squibb v. Paranova*,¹¹¹ the repackaging/co-branding must not be done in such a way that it is liable to damage the reputation of the trademark.¹¹² Untidy packaging may damage the reputation of the trademark. A further basis of damage to the reputation of the trademark may occur if the repackaging is done in a way which may give the impression that there is a commercial connection between the repackager and the trademark proprietor, thus jeopardising the guarantee of origin.¹¹³ This could amount to a ‘legitimate’ interest for the purpose of Article 7(2) of the Trade Mark Directive.¹¹⁴ ‘In assessing whether the use of coloured stripes would in fact give rise to such an impression, the national court must take into account the level of knowledge and consciousness of doctors and pharmacists, since

¹⁰⁹ Case E-3/02, n. 108 above, para. 45.

¹¹⁰ Case C-337/95 *Parfums Christian Dior SA v. Evora BV* [1997] E.C.R. 6013

¹¹¹ N. 14 above.

¹¹² Case E-3/02, n. 108 above, para. 50. This is further discussed in section 6 below.

¹¹³ See Case C-63/97 *BMW AG v. Deenik* [1999] E.C.R. 905, para. 55, where the ECJ held that the use of the trademark gave rise to the impression that the reseller’s business was affiliated with the trademark proprietor’s distribution network. See also Opinion of Advocate General Sharpston in Case C-348/04, n. 24 above, para. 66, where the Advocate General suggests that an ‘incorrect suggestion of a commercial connection [is] capable in principle of damaging the trade mark’s reputation.’

¹¹⁴ N. 32 above, Art. 7(2).

the products at issue are prescription drugs.¹¹⁵ It is ‘immaterial,’ in this context, that the parallel importer takes advantage of a particular graphic design in order to create a ‘brand line.’¹¹⁶ The fact that parallel importers must state the name of the manufacturer on the new packaging will in any event prevent parallel importers from marketing the products as ‘their own.’¹¹⁷

The issue of co-branding therefore falls to be decided in the light of damage to the brand reputation in conjunction with public health and safety considerations, rather than a necessity test.¹¹⁸ However, like the ‘customer preference test,’ a final conclusion on the legitimacy of co-branding cannot be made until the ECJ has decided in the latest referral made by the UK Court of Appeal in the *Boehringer v. Swingward*¹¹⁹ saga. It is hoped that the Court will follow Advocate General Sharpston’s Opinion, in which the Advocate General states that ‘the requirement that repackaging be necessary...applies merely to the fact of reboxing and does not extend to the precise manner and style thereof,’¹²⁰ thus approving the EFTA Court’s judgment in *Paranova v. Merck*.¹²¹ Whether the damage caused to the trademark owner by co-branding is sufficiently serious to amount to a ‘legitimate reason’ for the trademark owner to oppose further marketing is a question of fact for the national court. In consequence, national courts may implement a wide definition of ‘legitimate reason’ for the purpose of prohibiting co-branding, as parallel traders will not be able to show that such (particular) co-branding is ‘necessary’ in order to gain market access.

¹¹⁵ Case E-3/02, n. 108 above, para. 53.

¹¹⁶ *ibid.*, para. 54.

¹¹⁷ Discussed in section 7 below.

¹¹⁸ The Danish Supreme Court, in *Orifarm A/S* (unreported), interpreted the judgment by the EFTA Court to mean that the necessity criterion is not applicable in matters that may involve certain elements of co-branding. Orifarm’s excessive co-branding was held to infringe the manufacturer’s trademark rights. See K. Dyekjaer-Hansen, ‘Denmark: Trade Marks – Parallel Imports,’ (2004) 26 E.I.P.R. N108

¹¹⁹ Case C-348/04, n. 97 above.

¹²⁰ Advocate General Sharpston in *ibid.*, n. 24 above, para. 100.

¹²¹ Case E-3/02, n. 108 above, para. 45; and *ibid.*, paras. 49-52.

5. *Not affect the original condition of the product*

The ECJ has repeatedly held that a trademark proprietor may oppose repackaging on grounds of it having an adverse effect on the original condition of the pharmaceutical product, as this would infringe the specific subject matter of the trademark. If the quality of the product is affected, due to interference by the parallel importer or repackager, this will affect the guarantee of origin.¹²² This was one of the original conditions in *Hoffman-La Roche v. Centrafarm*,¹²³ most recently discussed and clarified by the ECJ in *Bristol-Myers Squibb v. Paranova*.¹²⁴

*'As regards pharmaceutical products, it follows from the same paragraph in Hoffman-La Roche that repackaging must be regarded as having been carried out in circumstances not capable of affecting the original condition of the product where, for example, the trade mark owner has placed the product on the market in double packaging and the repackaging affects only the external layer, leaving the inner packaging intact, or where the repackaging is carried out under the supervision of a public authority in order to ensure that the product remains intact.'*¹²⁵

As long as the product is not removed from its 'inner packaging' and directly exposed, the repackaging will not be such as to affect the original condition of the product.¹²⁶ Removing the products from their original outer packaging into a new container, inserting a new information leaflet and applying self-stick labels, or the

¹²² The Court has ruled that, if the inner packaging is not affected, 'the essential function of a trade mark as a guarantee of origin is safeguarded. The consumer or end user is not misled as to the origin of the products, and does in fact receive products manufactured under the sole supervision of the trade mark owner.' Case C-232/94, n. 91 above, para. 39.

¹²³ N. 7 above.

¹²⁴ N. 14 above. The ECJ has consistently rejected a number of claims from trademark owners and manufacturers concerning the risks involved with repackaging of pharmaceutical products due to their toxic and potentially hazardous nature. For a discussion on this topic, see Forrester, n. 53 above, 514-515.

¹²⁵ *ibid.*, para. 60.

¹²⁶ Case 102/77, n. 7 above, para. 14. In Case C-232/94, n. 91 above, para. 30, the Court made it clear that 'the concept of adverse effects on the original condition of the product refers to the condition of the product inside the packaging.'

inclusion and substitution of an extra article without interfering with the inner packaging was not held to affect the original quality of the products in *Bristol-Myers Squibb v. Paranova*.¹²⁷ As such, the mere over-labelling of inhalers, flasks, phials, or ampoules, by its very nature, is unlikely to affect the original quality of the products. Relabelling, leaving the inner packaging intact, only affecting the outer packaging, cannot affect the quality of the product since it has not been interfered with.

However, it is not only the risk of direct interference with the actual chemical product that may pose a threat to public health and safety. Mixing pharmaceutical products from batches with different use-by dates may have severe consequences.¹²⁸ All pharmaceutical products have use-by dates, and can pose a threat to health if administered past these dates. The storage of the pharmaceutical products may also affect quality. Over-lengthy storage or excessive lighting may have detrimental effects. The Court does not recognise this: ‘those arguments cannot be accepted. It is not possible for each hypothetical risk of isolated error to suffice to confer on the trade mark owner the right to oppose any repackaging of pharmaceutical products in new external packaging.’¹²⁹ The Court however recognises that omitting certain important information relating to the usage instructions, composition, ingredients, or information regarding the storage of the product, may have an effect on its original condition. An additional article not complying with the user instructions or dosage instructions may have the same consequences.¹³⁰ It is for the national court to assess whether repackaging has affected the original condition of the repackaged product.¹³¹

The pharmaceutical industry is characterised by strict regulations, with the majority concerning quality control. The low safety threshold set by the ECJ is therefore

¹²⁷ Cases C-427/93 etc., n. 14 above, paras. 61 and 64.

¹²⁸ See chapter 7(3.2.1-2) for a thorough discussion of batch codes and expiry dates within the context of public health and safety.

¹²⁹ Cases C-427/93 etc., n. 14 above, para. 63.

¹³⁰ *ibid.*, para. 65.

¹³¹ *ibid.*, para. 65.

surprising. The presumption that repackaging does not alter the original condition of the product is a standpoint that contradicts most national regulations governing the repackaging process. The ECJ said that the ‘hypothetical risk of [an] isolated error’ is not enough to oppose repackaging.¹³² Quality flaws in the repackaging of ‘normal’ consumer goods may have minor consequences, and can be overlooked if relevant to the integration of the common market. However, quality flaws (isolated errors) in repackaging of pharmaceutical products may have fatal consequences, and the common market objective cannot justify taking this risk. It should however be remembered that this condition only concerns the conformity of the trademark proprietors’ right to exercise their intellectual property rights with the Community’s free movement of goods provisions. Public health and safety should therefore not be affected since the Community’s and Member States’ quality controls, in conjunction with the labelling and package leaflet regulations, discussed in chapter 7 below, do not consider intellectual property aspects.¹³³

6. *Not affect ‘brand reputation’*

In *Bristol-Myers Squibb v. Paranova*¹³⁴ the ECJ recognised that poor quality or defective repackaging can damage the reputation of the trademark. A trademark forms part of the identity of a product, and serves to distinguish it from other products. As such, the goodwill invested in the trademark serves to give the product and brand a reputation and following which may prove a valuable asset both before and after patent expiration.¹³⁵ Repackaged products must therefore not be presented in such a way as to affect the reputation of the manufacturer’s brand.¹³⁶ Pharmaceutical manufacturers will have spent much time and funds on creating a strong brand reputation. ‘In the case of pharmaceutical products, that is certainly a

¹³² Cases C-427/93 etc., n. 14 above, para. 63.

¹³³ The Court had already (in Case 102/77, n. 7 above, para. 10) concluded that in the event the inner packaging is not left intact, repackaging would have to be made under the supervision of a public authority to satisfy this condition. See Case C-232/94, n. 91 above, para. 32; and chapter 7 below.

¹³⁴ N. 14 above.

¹³⁵ See J. Nazerali, S. Hocking and U. Ranasinghe, ‘Parallel imports of pharmaceuticals – a prescription for success or a free market overdose?’, (1998) 19 E.C.L.R. 332, 334.

¹³⁶ See Hays, n. 4 above, 103, for a general discussion of this condition.

sensitive area in which the public is particularly demanding as to the quality and integrity of the product, and the presentation of the product may indeed be capable of inspiring public confidence in that regard.’¹³⁷

It can be argued that this condition is especially important in relation to relabelled products, since relabelled products can often appear untidy, which contradicts manufacturers’ response to repackaged products seen in the discussion on whether repackaging is necessary in order to gain access to the market.¹³⁸ In fact, manufacturers prefer relabelled products to repackaged products even though repackaged products often look tidier and as such are less likely to affect the reputation of the brand.¹³⁹ The Court, however, states that the ‘requirements to be met by the presentation of a repackaged pharmaceutical product vary according to whether the product is sold to hospitals or, through pharmacies, to consumers.’¹⁴⁰ The discussion of the definition of ‘customer’ carried out in the section concerning the ‘customer preference test’ can therefore be applied to this condition. For the purpose of the ‘customer preference test,’ pharmacists were held to come within the notion of ‘customer’ by Mr Justice Laddie.¹⁴¹ Pharmacists, acting in a market economy, are in theory representatives of their customers’ demands; and it is in their interest to satisfy that demand.¹⁴² Nevertheless, it is likely that consumers/patients are more concerned with the packaging and appearance of the product than the brand of the product. Consumers/patients generally prefer repackaged to relabelled because such products look tidier, not because they are relying on the reputation of that particular brand. Pharmacists and doctors in hospitals, on the other hand, are the customers who take brand reputation into account when prescribing or buying pharmaceutical products, not least because they frequently have many years of experience with different brands. However, it is also true that doctors and pharmacists should be experienced enough to know that the

¹³⁷ Cases C-427/93 etc., n. 14 above, para. 76.

¹³⁸ See section 4.1 above. See also section 1 above regarding relabelling, in particular Advocate General Sharpston in Case C-348/04, n. 24 above, para. 100.

¹³⁹ See Case C-143/00, n. 15 above, para. 52.

¹⁴⁰ Case C-232/94, n. 91 above, para. 48

¹⁴¹ *per* Mr Justice Laddie in *Glaxo v. Dowelhurst*, n. 89 above, para. 165.

¹⁴² See pp. 196-197 above.

particular product in question has been repackaged. Nevertheless, pharmacists are the most competent group (of customers) to assess harm to the reputation of the brand. Not only as professionals with many years of experience with different brands, but also as actors in a market economy eager to satisfy their customers demands of tidily packaged products.

The condition, however, should not be limited to untidy and poor quality packaging. According to Advocate General Sharpston's Opinion in *Boehringer v. Swingward* (currently pending before the ECJ), both inappropriate presentation of the trademark and the incorrect suggestion of a commercial link between the parallel importer and the manufacturer may damage the trademark.¹⁴³ There may also be other factors affecting the reputation of the brand which are only visible and noticeable to pharmacists and doctors. For example, removing the batch codes from repackaged products may harm the reputation of the brand.¹⁴⁴ Even if product recalls are still possible in the absence of batch codes, they will include a larger number of products being recalled from a wider geographic area. This is likely to harm the manufacturer's brand image due to the extensive information campaign it would entail.¹⁴⁵ In the event of a product recall, the parallel trader (who removed the batch codes) will not be burdened, whilst the manufacturer will suffer injury to his 'brand reputation' as a result of the parallel importer's action.

The manufacturer should bear the burden of proving interference with his trademark rights, as the manufacturer is in the best position to 'assess whether the repackaging

¹⁴³ Advocate General Sharpston in Case C-348/04, n. 24 above, para. 66. See also section 4.2 above re: co-branding; and Case C-63/97, n. 113 above, para. 55.

¹⁴⁴ Whether or not removing batch codes is compatible with the Community's free movement provisions and the Community's labelling and package leaflet regulations will be discussed in chapter 7(3.2.2) below; this section will only discuss its impact on 'brand reputation.'

¹⁴⁵ For a wider discussion see P. Sheppard, 'Batch codes used in Davidoff: The brand owners' view,' (2000) 22 E.I.P.R. 147. In a comment on Joined Cases C-414-416/99 *Zino Davidoff SA v. A&G Imports Ltd, & Levi Strauss & Co v. Tesco Stores Ltd* [2001] E.C.R. 8691, Jeetun commented that 'it may be in the interest of the reputation of the trade mark proprietor if he is able to remove defective or sub-standard products through use of batch code numbers. It is for the national court to determine whether the removal causes sufficiently serious damage to the reputation of the trade mark.' See P. Jeetun, 'Parallel victories,' *Ent.L.R.* 12 (2001) 210, 215-216.

presents no risk, or a possible risk, of damaging the trademark's reputation.¹⁴⁶ This may be more difficult to prove than to prove that the original condition of the product has been affected, or indeed to prove that any of the other conditions have not been fulfilled. Nevertheless, the 'brand reputation' condition, at least, gives the trademark proprietor an opportunity to demand that the repackaged product does not affect the reputation of the brand; and so may prevent parallel importers from abusing their rights by diminishing the goodwill created by the trademark proprietor.

7. *Clearly indicate the identity of the repackager*

'Since it is in the trade mark owner's interest that the consumer or end user should not be led to believe that the owner is responsible for the repackaging, an indication must be given on the packaging of who repackaged the product.'¹⁴⁷ This requirement was established in *Hoffman-La Roche v. Centrafarm*,¹⁴⁸ and confirmed in *Bristol-Myers Squibb v. Paranova*.¹⁴⁹ It is for the national court to assess whether the indication is proper, and 'printed in such a way as to be understood by a person with normal eyesight, exercising a normal degree of attentiveness.'¹⁵⁰ The ECJ states that 'it may indeed be in the manufacturer's interest that the consumer or end user should not be led to believe that the importer is the owner of the trade mark and that the product was manufactured under his supervision.'¹⁵¹ The product should therefore clearly state the name of the manufacturer on the outer packaging. It is, however, equally important for liability reasons. If the repackaged products are defective, and it is proved that it is not the result of negligent repackaging, the

¹⁴⁶ Advocate General Sharpston in Case C-348/04, n. 24 above, para. 98.

¹⁴⁷ Cases C-427/93 etc., n. 14 above, para. 70. This is 'in the interest of the owner as proprietor of the trade mark, and to protect him against any misuse:' (para. 69). The ECJ followed the same line of reasoning as in Case 102/77, n. 7 above, para. 11, referring to the need to protect the trademark owner from 'abuse.' See also chapter 7(3.2) below for a discussion of the requirements under the Community's labelling and package leaflet regulations, relating to indicating the name of the repackager and parallel importer on the new (so-called) 'blue box.'

¹⁴⁸ N. 7 above.

¹⁴⁹ N. 14 above.

¹⁵⁰ Cases C-427/93 etc., n. 14 above, para. 71; and Case C-232/94, n. 91 above, para. 44.

¹⁵¹ Cases C-427/93 etc., *ibid.*, para. 74, referring to Case 1/81, n. 18 above, para. 11; and Case C-232/94, *ibid.*, para. 45.

manufacturer will be liable for any damage caused. If the identity of the manufacturer is not clearly indicated the products may (hypothetically) be considered 'own-brand' products under Council Directive 85/374/EEC¹⁵² on liability of defective products, transferring any liability from the manufacturer to the parallel importer.

Further, the repackaged product need not indicate whether or not the product was repackaged with the consent of the trademark owner. According to the ECJ, stating that the parallel imported product is not repackaged with the authorisation of the trademark owner may lead consumers to believe that the products are illegitimate.¹⁵³ However, stating that repackaging has been authorised by the trademark owner could serve as a distinction between parallel imports and counterfeit products, since counterfeit pharmaceutical products are often repackaged into boxes similar or identical to the original packaging.

The same requirements will apply if the trader includes additional articles in the new box. The parallel importer must clearly indicate the origin of the additional article on the box in order to rebut any liability on behalf of the trademark owner, and avoid applying the manufacturer's trademark to the additional article as this would amount to an infringement of the manufacturer's trademark.¹⁵⁴ The ECJ's reasoning in *Bristol-Myers Squibb v. Paranova* has since been applied by national courts. In *Sony Entertainments v. Tesco*,¹⁵⁵ Tesco was seen as infringing Sony's trademark by not clearly indicating that additional adaptors added to Playstation boxes manufactured by Sony were not approved and manufactured by Sony.

¹⁵² Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products [1985] O.J. L210/29.

¹⁵³ Cases C-427/93 etc., n. 14 above, para. 72; and Case C-232/94, n. 91 above, para. 44.

¹⁵⁴ Cases C-427/93 etc., *ibid.*, paras. 65 and 73: 'he must ensure that the origin of the extra article is indicated in such a way as to dispel any impression that the trade mark owner is responsible for it.' Such additions of new articles may adversely affect the original condition of the product, depending on how the national court views the addition: Hays, n. 4 above, 102.

¹⁵⁵ *Sony Computer Entertainments Inc. v. Tesco Stores Ltd* [2000] E.T.M.R 102 (Ch.D).

8. *The requirement to give prior notice*

When a product has been repackaged the repackager must give notice to the trademark owner prior to marketing of the product. This is in order to give the manufacturer a chance to examine the product, and check that the repackaging process has not affected its original condition.¹⁵⁶ The accompaniment of a specimen of the repackaged product with the notice will also allow the manufacturer to inspect 'that the presentation after repackaging is not likely to damage the reputation of the trademark. Similarly, such a requirement affords the trademark owner a better possibility of protecting himself against counterfeiting.'¹⁵⁷

Mr Justice Laddie, in the first *Boehringer Ingelheim v. Swingward* High Court judgment, thought that the notification given by the UK Medicines and Healthcare products Regulatory Agency (MHRA) when granting a parallel import licence (PIL), published in the London Gazette, would suffice.¹⁵⁸ The ECJ did not agree, stating that prior notification must be given by the parallel importer himself.¹⁵⁹ If the notification given by a PIL licensing authority had been sufficient, the notice requirement as such would have been unnecessary, since licensing authorities always notify the original marketing authorisation holder when a PIL is granted. Instead, the ECJ ruled that fifteen working days would constitute a reasonable notification period for the parallel importer.¹⁶⁰ It is however possible for the parallel importer to allow for a shorter period of notice, and for the trademark proprietor to ask for a longer time to react to the notice.¹⁶¹ The trademark proprietor should be given a reasonable period of notice to respond to the repackaging, but consideration should also be given to the parallel importer's interest in proceeding to marketing the product as soon as possible after obtaining a PIL.¹⁶² It is for the national court to

¹⁵⁶ Cases C- 427/93 etc., n. 14 above, para. 78.

¹⁵⁷ *ibid.*, para. 78. See also Case C-143/00, n. 15 above, para. 67; and *Gross and Harrold*, n. 106 above, 503.

¹⁵⁸ N. 89 above, para. 155. See chapter 3(3.2) above.

¹⁵⁹ Case C-143/00, n. 15 above, para. 64.

¹⁶⁰ *ibid.*, para. 67.

¹⁶¹ *ibid.*

¹⁶² *ibid.*, para. 66.

determine in the light of the facts of the particular case whether the manufacturer was given a reasonable time to react to the intended repackaging.¹⁶³ This is now embodied in the 2003 Commission Communication¹⁶⁴ which also notes that the notification requirement imposed by the derogation from the ‘exhaustion of rights’ doctrine in the 2003 Act of Accession¹⁶⁵ (which should not be confused with the notification requirement relating to repackaging) requires parallel importers to give manufacturers one month’s prior notification.¹⁶⁶ There is no logical explanation as to why the notification period is longer under the Act of Accession, since the inspection procedures carried out by manufacturers are the same for both notification systems.¹⁶⁷

The notification requirement allows the trademark proprietor to verify whether there is an actual infringement of the specific subject matter.¹⁶⁸ The contention is that a failure to notify would turn a non-infringement of the specific subject matter into an infringement.¹⁶⁹ Mr Justice Laddie, in the *Boehringer Ingelheim v. Swingward* UK High Court judgment, rightly observed that such a requirement

¹⁶³ Case C-143/00, n. 15 above, para. 68. It is likely that the definition of ‘a reasonable time’ will vary from Member State to Member State. The difficulty in defining this term is highlighted by the fact that Mr Justice Laddie in the UK High Court decision, Advocate-General Jacobs in his Opinion, and the ECJ could not agree upon the length of a ‘reasonable time:’ varying from 2 days (Mr Justice Laddie, n. 89 above, para. 155); 3-4 weeks (Opinion of Advocate General Jacobs in Case C-143/00, n. 15 above, para. 134); to 15 days (ECJ in Case C- 143/00, n. 15 above, para. 67). In Ystad County Court (Sweden) a case is currently being brought by Merck against the parallel trader Parallell Pharma for not waiting the required time (which, according to Merck, is three weeks in Sweden) after notification before marketing the product. Merck demands that the Court orders Parallell Pharma to stop marketing the repackaged and rebranded products, as well as holding Parallell Pharma liable for damages amounting to one million SEK if not complying with the Court’s judgment: see J. Hyden, ‘Anklagas för varumärkes intrång,’ *Skånska Dagbladet*, 11 September 2005, p. 8.

¹⁶⁴ Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted [2003] Com/839/final.

¹⁶⁵ Chapter 2 (Company Law) of Annex IV of the Act of Accession [2003] O.J. L236/33; see Introduction, p. 4, n. 15 above for a full reference. See chapter 5(5.2) above for discussion of the derogation (‘specific mechanism’).

¹⁶⁶ See Commission Communication (2003), n. 164 above, para. 5.5. See also chapter 5(5.2.3) above.

¹⁶⁷ See *ibid.* for further discussion of the differences and similarities of the two notification requirements.

¹⁶⁸ See Gross and Harrold, n. 106 above; and Dryden and Middlemiss, n. 78 above for further discussion of the notification requirement.

¹⁶⁹ Case C-143/00, n. 15 above, para. 63. However, the ECJ noted that ‘adequate functioning of the notice system presupposes that the interested parties make sincere efforts to respect each other’s legitimate interests:’ (para. 62).

would introduce ‘a wide ranging and powerful instrument for preventing or dislocating the free movement of goods...under the guise of protection of trademarks which is decoupled from the need to preserve the specific subject matter of those rights.’¹⁷⁰ It can therefore be an unnecessary obstacle to the free movement of goods within the Community. However, it is also arguable that the requirement is little more than yet another formality which the parallel importer must comply with, and ‘satisfying the [notice requirement] scarcely poses any real practical problems for parallel importers.’¹⁷¹ Failure to give notice will therefore, in the vast majority of cases, be deliberate. It should therefore result in a dissuasive, but proportionate, sanction being imposed on the parallel importer.¹⁷² The appropriate sanction should be determined by the national court, regarding every subsequent importation as an infringement.¹⁷³

From a public health and safety standpoint, the notice requirement will enable manufacturers of pharmaceutical products to assess the quality and authenticity¹⁷⁴ of the repackaged product as well as the adequacy of the new box, thus preventing repackaging that is likely to affect the quality and safety of pharmaceutical products. The notice requirement also, to a certain extent, prevents parallel importers from infringing the specific subject matter of the trademark, as well as providing a mechanism to monitor the quality (and quantity) of repackaged pharmaceutical products.

¹⁷⁰ N. 89 above, para. 119.

¹⁷¹ Case C-143/00, n. 15 above, para. 62.

¹⁷² See Advocate General Sharpston in Case C-348/04, n. 24 above, para. 100.

¹⁷³ *ibid.*, para. 80.

¹⁷⁴ However, see A. Worsdall and A. Clarke, *Anti-counterfeiting: A practical guide*, (Bristol: Jordan Publishing, 1998), p. 10: where it is argued that product testing is an inefficient way of detecting counterfeit products in the market place ‘due to the time consuming and expensive procedure of testing products, which often render the products unsaleable.’ Nevertheless, the notice is only accompanied by one product sample, and notice is only required once. It may therefore, in comparison with, for example, a system of ‘random-product tests’ of products already in the market place, prove to be an efficient and inexpensive way of detecting counterfeits.

9. Conclusion

In order to prevent the European pharmaceutical market from being partitioned along national borders the ECJ has repeatedly ruled that trademark proprietors are precluded from ‘exercising’ their intellectual property rights so as to prevent repackaging of pharmaceutical products as long as the parallel importer fulfils a set of conditions. If satisfied, these conditions effectively afford the parallel trader a licence for the unauthorised use of the relevant trademark. The conditions, at first being concerned only with the ‘necessity’ of repackaging in order to comply with national legislation and the protection of the specific subject matter of the trademark, have with the ‘customer preference test’ and the practice of ‘co-branding’ developed into a grey-zone between enabling parallel trade and satisfying parallel importers’ commercial aspirations. Being beneficial for the integration of the Member State markets, the ECJ nevertheless may have taken the pro-integration aspect a step too far by allowing parallel importers to adjust to the different Member State market conditions, instead of delegating the responsibility of letting customers and commercial forces in the Community grow accustomed to repackaged products to the parallel importers themselves.¹⁷⁵ The latest additions by the ECJ illustrates that the doctrine of exhaustion still generates difficult and highly controversial case-law, often leading to discrepancy in Member States’ subsequent employment of the guidance in national judgements.¹⁷⁶

It should be remembered that the case-law on repackaging concerns the right to exercise intellectual property rights against another private undertaking. The integration aspect therefore takes priority over the public health and safety aspect. However, even though the trademark proprietor may be precluded from exercising his intellectual property rights so as to prevent repackaging, the repackaged product

¹⁷⁵ See the Danish Court’s argument in Case 272/2001 (Denmark), n. 80 above, paras. 13-15.

¹⁷⁶ For example: Case C-143/00, n. 15 above, together with Case 272/2001 (Denmark), n. 80 above, and the UK Court of Appeal in *Boehringer v. Swingward*, n. 90 above. However, Advocate General Sharpston in Case C-348/04, n. 24 above, para. 3, expressed the view that: ‘every judge knows that ingenious lawyers can always find a reason why a given proposition does or does not apply to their client’s situation. It should not however in my view be for the Court of Justice to adjudicate on such detail for evermore.’

may not fulfil the Community's labelling and package leaflet regulations. These regulations, discussed in the following chapter, do not consider intellectual property aspects but are only concerned with public health and safety. Fulfilling the conditions established by the ECJ so as to 'exhaust' the trademark proprietor's right to exercise his trademark rights may therefore not be sufficient to subsequently market the repackaged products.

REPACKAGING OF PHARMACEUTICAL PRODUCTS II: THE COMMUNITY'S LABELLING AND PACKAGE LEAFLET REGULATIONS

Following the establishment of the exhaustion of rights principle parallel traders are free to repackage and rebrand pharmaceutical products so as to comply with national legislation and customer preference.¹ However, intellectual property rights and the free movement of goods provisions are not the only Community measures to take into consideration when repackaging pharmaceutical products. There are Community measures governing the packaging of pharmaceutical products, equally applicable to manufacturers and parallel importers. The trader will be in breach of these Community measures if the new packaging does not meet the standard required by the Community. This chapter will therefore discuss the impact of these measures on parallel trade in pharmaceutical products, taking into account public health and safety issues as well as Community integration aspects.

1. *Repackaging in practice*

A parallel importer who decides to repackage products intended for importation generally has three concerns. First, will the repackaging amount to an infringement of the manufacturer's trademark? As discussed in chapter 6, repackaging will amount to an infringement, but the trademark proprietor has lost the right as to exercise the trademark rights once the product was first put into circulation within the Community. Secondly, is the repackager authorised to carry out the repackaging process? Finally, does the new packaging satisfy Community measures regulating

¹ Subject to conditions discussed in chapter 6 above.

the packaging of pharmaceutical products? The two latter issues are discussed below.

2. *Manufacturer's (assemble) licences (MAL)*

Directive 2001/83/EC states that 'Member States shall take all appropriate measures to ensure that the manufacture of the medicinal products within their territory is subject to the holding of an authorization.'² This applies to manufacturers in relation to both the production of the product itself and the subsequent packaging thereof. However, Article 40(2) of Directive 2001/83/EC clarifies that authorisation 'shall be required for both total and partial manufacture and for the various processes of dividing up, packaging or presentation.'³ Thus, parallel importers require a manufacturer's licence before carrying out any form of repackaging. Since parallel importers only intend to tamper with the packaging, not affecting the actual pharmaceutical products, they can apply for a 'manufacturer's (assemble) licence' (MAL)⁴ which only gives them the right to 'assemble' pharmaceutical products. 'Assemble' is defined as 'enclosing the products (with or without other medicinal products of the same description) in a container which is labelled before the product is sold or supplied, or, where the product is already enclosed in the container in which it is to be sold or supplied, labelling the container before the product is sold or supplied in it, and 'assemble' has a corresponding meaning.'⁵ The UK Medicines and Healthcare products Regulatory Agency (MHRA) also makes it clear that the over-labelling of medicinal products is an 'assemble' activity and therefore licensable.⁶

² Article 40(1) of Council Directive 2001/83/EC on the Community code relating to medicinal products for human use [2001] O.J. L311/67.

³ *ibid.*, Art. 40(2).

⁴ Section 132 of the UK Medicines Act 1968.

⁵ *ibid.*

⁶ See MHRA, 'Notes for applicants and holders of a manufacturer's licence,' Guidance Note No. 5, p. 3.

A MAL holder in the Member State of importation does not require a ‘wholesale dealer’s licence’ (WDL).⁷ It is therefore reasonable that the requirements under a MAL are similar to, if not stricter than, those relating to a WDL.⁸ The licence holder must provide and maintain suitable staff, premises and equipment. However, in *Gyselinx* the ECJ held that it would restrict intra-Community trade under Article 28 EC Treaty to require a WDL holder, wishing to supply pharmacists directly, to maintain suitable premises for the storage of products in the Member State where the licence is granted, if the applicant already has access to such premises in the Member State where its headquarters is situated.⁹ ‘Cooperation and exchange of information between the authorities of the two Member States will make it possible to ensure that the products at issue are in a good condition before their importation.’¹⁰ WDL holders are therefore allowed to store their products in another Member State. MAL holders, on the other hand, are only allowed to carry out the repackaging in the Member State where the licence is granted, which does not necessarily have to be the Member State of importation. It should also be remembered that traders who have access to adequate premises and equipment for storage and repackaging of pharmaceutical products in the Member State of importation only require a MAL in this Member State (i.e. do not have to apply for a WDL).¹¹ In contrast, a trader who decides to carry out the repackaging process and store the products in the Member State where the trader’s headquarters is situated, having access to suitable premises and equipment for repackaging and storage in that Member State for the purpose of applying for a MAL, must either apply for a WDL in the Member State of importation (which is an additional cost) or, alternatively; get access to adequate premises and equipment for repackaging in

⁷ Directive 2001/83, n. 2 above, Art. 77(3); Medicines Act, n. 4 above, s. 8(3)(c). See MHRA, ‘Notes for applicants and holders of a wholesale dealer’s licence,’ Guidance Note No. 6, Appendix 2(7). WDLs are discussed in detail in chapter 3(3) above.

⁸ Directive 2001/83, *ibid.*, Title VII; and Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use [2003] O.J. L262/22. See chapter 3, pp. 100-101 above, for further discussion of the requirements applying to the granting of WDLs.

⁹ Joined Cases 87-88/85 *Legia & Gyselinx v. Minister for Health* [1986] E.C.R. 1707, para. 22. See chapter 3, pp. 101-102 above, for further discussion of this case and WDLs.

¹⁰ *ibid.*, para. 20.

¹¹ See n. 7 above.

the Member State of importation in order to apply for a MAL (also an additional cost) so as to avoid the extra costs of having to apply for a WDL in this Member State. This is illustrated in Table 5 below:

Table 5.

Attributes of PI ¹	Licence in MS ² of importation	Licences in another MS	Need to obtain additional premises
PI in MS of importation - need to repackage	MAL	No.	No.
PI in MS of importation - no need to repackage	WDL	No.	No.
PI in another MS - need to repackage	<u>WDL</u>	MAL	No.
PI in another MS - need to repackage	MAL	No. (But have access to adequate premises for the purpose of a MAL in this MS)	<u>Yes. In MS of Importation</u>
PI in another MS - no need to repackage	WDL	No.	No.

¹ Parallel importer.

² Member State.

As the requirements under a MAL are, at least, as strict as those applying to WDL holders, it can be argued that national legislation prohibiting MAL holders in other Member States from importing pharmaceutical products in the absence of holding a WDL in the Member State of importation is not compatible with Article 28 EC Treaty. This is because it penalises against traders that need to repackage the products before importation, and already have at their disposal suitable premises for this purpose in another Member State, by rendering them liable for the extra costs of having to apply for a WDL. MAL holders in the Member State of importation, however, do not require WDLs.¹² Similarly; traders who do not need to repackage their products only need to be in possession of a WDL in the Member State of importation even if the products are stored in another Member State.¹³ However, in the absence of a sufficient degree of harmonisation at Community level, every Member State is entitled to adopt appropriate measures in order to protect public

¹² See n. 7 above.

¹³ Cases 87-88/85, n. 9 above.

health and safety in accordance with Article 30 EC Treaty. ‘Cooperation and exchange of information between the authorities in the two Member States’ may be enough to ensure public health and safety if the licence holder is merely allowed to store the products in another Member State.¹⁴ However, it is likely that national legislation requiring traders to, at least, be in possession of one licence (MAL or WDL) in the Member State of importation can be justified under Article 30 EC Treaty, as it will be very difficult for the importing Member State to ensure public health and safety if the trader is neither licensed nor store the products in this Member State.

The alternative, taking into account that the trader must be in possession of a licence (WDL or MAL) in the Member State of importation for public health and safety reasons, would be to allow MAL holders in the Member State of importation to carry out the repackaging process in a Member State other than the one issuing the licence. The question is therefore whether national legislation prohibiting MAL holders from carrying out the repackaging process in another Member State is in conformity with Articles 28 and 30 EC Treaty. Such legislation penalise against traders who already have at their disposal suitable premises and equipment for repackaging in another Member State by rendering them liable for the extra costs of either obtaining suitable premises for repackaging in the Member State of importation, or, as discussed above, the extra costs of applying for a WDL in this Member State. However, allowing MAL holders to carry out the repackaging process in another Member State than the one issuing the licence may have a negative impact on public health and safety. It is therefore possible that legislation to this effect can be justified under Article 30 EC Treaty. It is true that adequate safety checks can potentially still be carried out by the authority granting a parallel import licence (PIL) for the product in question.¹⁵ The problem, however, is whether cooperation between the national Medicines Control Agency granting the MAL and the national Medicines Control Agency in the Member State where the

¹⁴ See Cases 87-88/85, n. 9 above, para. 20.

¹⁵ See Case C-347/89 *Freistaat Bayern v. Eurim-Pharm GmbH* [1991] 1747, para 20. Further discussed below. See chapters 3(3.2) and 4 above for discussion of the granting of PILs.

products are *de facto* repackaged will be sufficient to protect public health and safety. Even if the individual inspections and control tests carried out by the two national Medicines Control Agencies are sufficient, a lack of adequate cooperation may still lead to a larger amount of products being refused a PIL due to inadequate packaging. In the ‘worst-case scenario,’ it could have fatal consequences for public health and safety if the inspections and control tests, carried out by the national Medicines Control Agency granting the PIL and MAL, are not sufficient to notice inadequacies in the packaging of the products due to insufficient cooperation with the national Medicines Control Agency in the Member State where the products were *de facto* repackaged.

Consideration of whether national legislation prohibiting MAL holders from carrying out the repackaging in another Member State is compatible with Articles 28 and 30 EC Treaty should be contrasted with consideration of national legislation prohibiting the importation of pharmaceutical products because they are not already repackaged so as to comply with national legislation in this Member State. These were the facts in *Freistaat Bayern v. Eurim-Pharm*.¹⁶ Eurim-Pharm, a parallel importer, was refused a PIL because the products were already packaged and provided with a leaflet which only complied with the laws of the exporting Member State. Eurim-Pharm claimed that it intended to repack the products so as to conform to German law once they were imported into Germany. For this purpose, Eurim-Pharm successfully applied for a MAL in Germany.¹⁷ The ECJ held that this constitutes a restriction to intra-Community trade, precluded by Articles 28 and 30 EC Treaty, as it forces parallel traders to move their repackaging process to each of the exporting Member States in order to satisfy German legislation prior to importation.¹⁸ The measure could not be justified under Article 30 EC Treaty as a PIL enables authorities to make sure that the product is ‘essentially identical’ to a product already benefiting from a marketing authorisation in Germany, and a MAL enables the same authority to make sure that the packaging is safe and in

¹⁶ Case C-347/89, n. 15 above, para 20.

¹⁷ *ibid.*, para. 18.

¹⁸ *ibid.*, paras. 22 and 36.

conformity with German legislation.¹⁹ Thus, public health and safety can be satisfactorily maintained even if the products are repackaged in Germany.

First, it should be said that this ruling is difficult to criticise from a public health and safety perspective. The products are inspected at the border (when applying for a PIL) and inspected and controlled following repackaging. In fact, carrying out the repackaging in Germany may well minimise the risk to public health and safety as the products are subject to two inspection checks, at the border and following repackaging, instead of only at the time of applying for a PIL. Secondly, the decision cannot be criticised for being too pro-integration, as the national legislation completely barred importation of products not yet repackaged so as to comply with German law, rendering MALs practically useless for importers.

Despite the legal questions yet to be resolved, and the health and safety issues highlighted by the ECJ's rulings, the law can be summarised as follows. A MAL is only required in the Member State where the repackaging process is carried out, which may also be the Member State of importation.²⁰ Further, a MAL also functions as a WDL, and WDL holders are allowed to store products in the Member State of exportation prior to being directly supplied in the Member State of importation. Taking this into consideration, it can be argued that national legislation prohibiting MAL holders in other Member States from importing pharmaceutical products in the absence of holding a WDL in the Member State of importation is not compatible with Article 28 EC Treaty. The same argument can be applied to national legislation in the importing Member State prohibiting the issuance of a MAL unless the repackaging process is carried out in this Member State. This is because it penalises against traders who already have access to suitable premises for repackaging in another Member State. However, strong cooperation between the national Medicines Control Agency granting the MAL and the national Medicines Control Agency in the Member State where the products are *de facto* repackaged

¹⁹ Case C-347/89, n. 15 above, para. 33.

²⁰ *ibid.*

will be needed in order to protect public health and safety in the absence of such legislation. It is therefore possible that legislation to this effect can be justified on the basis of the protection of public health and safety in accordance with Article 30 EC Treaty.

3. *The Community packaging regulations*

Title V of Directive 2001/83/EC²¹ regulates the labelling and package leaflets of pharmaceutical products. All products marketed within the Community must comply with these regulations. Manufacturers may, in theory, prevent the marketing or importation of repackaged products using trademark laws, even though the packaging is in conformity with these regulations.²² Conversely, trademark owners may not, in theory, be allowed to exercise their trademark rights in order to prevent the products from being repackaged, even though the repackaging fails to conform to the requirements of Directive 2001/83/EC.²³ It is therefore important not to confuse the intellectual property aspect of repackaging with the Community's packaging regulations.

A successful marketing authorisation application is dependant on the conformity of the packaging and package leaflet with the labelling and package leaflet section of Directive 2001/83/EC.²⁴ All pharmaceutical products supplied by the original marketing authorisation holder are therefore, in theory, correctly labelled. The fact that the national Medicines Control Agency does not refuse a marketing authorisation even though the labelling and package leaflet is not in conformity with Directive 2001/83/EC²⁵ does not alter the legal liability of the marketing authorisation holder.²⁶ The relevance of Directive 2001/83/EC²⁷ for parallel

²¹ N. 2 above.

²² For example by not fulfilling the conditions established in Joined Cases C-427, C-429 and C-436/93 *Bristol-Myers Squibb v. Paranova A/S* [1996] E.C.R. 3457. See chapter 6 above.

²³ N. 2 above.

²⁴ *ibid.*, Art. 61(1). See chapter 3(2) above on marketing authorisations.

²⁵ *ibid.*

²⁶ *ibid.*, Art. 61(4).

²⁷ *ibid.*

importers is therefore two-fold. First, the parallel importer must follow the labelling and package leaflet regulations in order to be granted a PIL. Secondly, even though a parallel importer is not refused a PIL, it will not waive the parallel importer's legal liability if the packaging is subsequently found to be non-compliant with Directive 2001/83/EC.²⁸ However, as the packaging and package leaflet must have, in theory, been in conformity with Directive 2001/83/EC²⁹ when the manufacturer was granted marketing authorisation, the parallel importer can be reasonably confident that the subsequent repackaging will be in conformity with the Directive if the only changes carried out to the packaging are necessary in order to comply with national legislation in the Member State of importation. Nevertheless, a distinction must be made between repackaging of products benefiting from a PIL and repackaging of products benefiting from a Community marketing authorisation,³⁰ discussed below in section 3.2 and 3.1 respectively. The reason for discussing these two classes of imported pharmaceutical products separately is the special measures applying to the packaging of pharmaceutical products benefiting from a Community marketing authorisation, which measures will first be discussed below.

3.1 *Products benefiting from a Community marketing authorisation*

Parallel traded pharmaceutical products benefiting from a centrally authorised Community marketing authorisation are usually referred to as parallel distributed products, and the trader as a parallel distributor.³¹ Since a PIL is not needed for products distributed in parallel, the legal liability will remain with the original marketing authorisation holder.³² However, the parallel distributor still has responsibilities in situations where defect products are discovered, particularly in

²⁸ N. 2 above.

²⁹ *ibid.*

³⁰ See chapter 3(2.1) on Community marketing authorisations.

³¹ See *ibid.* See also Commission Notice to Applicants - The Rules governing Medicinal Products in the European Community, (Volume 2C: Regulatory Guidelines) (F2/BL D(2005) Rev 8, for further information on the Community packaging regulations of parallel distributed pharmaceutical products.

³² See chapter 3(3.1-3.2) above for discussion of the centralised Community procedure.

cases where the packaging and package leaflet have been changed.³³ Parallel distributors can only change the packaging and package leaflet if they hold a MAL issued by the relevant authority. As such, they are bound by the principles and guidance on ‘Good Manufacturing Practice’ (GMP).³⁴ Under these guidelines a parallel distributor is required to notify the relevant authority, as well as the relevant Community marketing authorisation holder, of any defect it has become aware of. Following such a notification, the relevant authority will assist the distributor in the recall process.

The modifications allowed to the packaging of pharmaceutical products benefiting from Community marketing authorisations are strictly regulated. The parallel distributor is required to translate the packaging and package leaflet into the prevailing language in the Member State of importation. Proposed changes to the packaging of the product and changes to the package leaflet must be included in the ‘notification of parallel distribution of a centrally authorised medicinal product,’³⁵ which the parallel distributor must submit to the European Medicines Agency (EMA).³⁶ The notification enables the EMA to verify that the packaging and package leaflet complies with the Community marketing authorisation. If not, the notification will be ‘refused,’ and parallel distribution denied.

However, in order to comply with the customary practice of pharmacists in the Member State of importation, or simply in order to maximise profits, parallel distributors have created larger pack sizes by bundling together smaller product packages. This is technically possible, since manufacturers often market a product using a variety of different pack sizes. In *Aventis v. Kohlpharma*³⁷ this practice was criticised by the ECJ. Aventis marketed ‘Insuman’ in packs of ten cartridges in

³³ See EMA, ‘Post-authorisation guidance on parallel distribution,’ (EMA/Ho/2368/04/Rev 2), s. 28.

³⁴ Directive 2003/94, n. 8 above.

³⁵ See EMA, ‘Post-authorisation,’ n. 33 above. A specimen is no longer required to be supplied with the notification. Mock-ups of the proposed packaging and package leaflet are, however, still required: see chapter 3(2.1.1) above.

³⁶ See chapter 3, pp. 89-90 below for the functions of the EMA.

³⁷ Case C-433/00 *Aventis Pharma GmbH v. Kohlpharma GmbH & MTK GmbH* [2002] E.C.R. 7761.

Germany. In other Member States the drug was marketed in packs of five cartridges. Kohlpharma, a parallel distributor, purchased packs of five cartridges in other Member States, and repackaged them so as to contain ten cartridges in every package before distributing the packs in Germany. Aventis claimed that this was an unnecessary practice, and in any event, infringed Aventis's trademark rights.³⁸ Aventis considered that, for the purpose of marketing the products in Germany, Kohlpharma could bundle two packs of five cartridges together and relabel them so as to become a single pack of ten cartridges instead of repackaging the products completely.³⁹ The ECJ noted that 'Insuman' was subject to two separate Community marketing authorisations, one for packs of five cartridges and one for packs of ten cartridges.⁴⁰ Every Community marketing authorisation relates to the specific presentation and packaging of the product, and is given a number which must appear on the packaging. These detailed and specific requirements are intended to prevent patients from being misled and thereby to protect public health and safety. As a result, Regulation 2309/93⁴¹ precludes a product subject to two separate Community marketing authorisations, one for packs of five cartridges and one for packs of ten cartridges, 'to be marketed in a package consisting of two packs of five items which have been joined together and relabelled.'⁴²

Bundling and labelling involves far less risk to the quality of the product than repackaging. By precluding the bundling together of two smaller packs into one pack, thus avoiding repackaging, the Court did not find in favour of public health and safety. Neither did the Court act upon overriding pro-integration policies. Bundling and relabelling would have been as efficient as repackaging in terms of market access. Linguistic differences and customary practices by pharmacists could

³⁸ Case C-433/00, n. 37 above, para. 11.

³⁹ *ibid.*

⁴⁰ *ibid.*, para. 25.

⁴¹ Council Regulation (EEC) 2309/93 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [2003] O.J. L214/1, subsequently repealed and replaced by Council Regulation (EC) 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] O.J. L136/1.

⁴² Case C-433/00, n. 37 above, para. 27.

be as effectively addressed by bundling together and relabelling as by repackaging. The Court's ruling must therefore be seen as a disguised attempt to achieve legal certainty in relation to the centralised procedure, instead of focusing on the underlying problem of discrepancy in Community harmonisation. The centralised procedure allows for a single Community marketing authorisation, for which products a PIL is not needed. But without complete harmonisation of national legislation concerning dispensation sizes and customary practice by pharmacists, repackaging is nevertheless necessary.

The fact that a PIL is not needed when importing products benefiting from a Community marketing authorisation means that any changes to the design, layout and name of the product are not in conformity with Community regulations.⁴³ The only amendments allowed to the packaging of parallel distributed products, except for linguistic differences and the inclusion of the name of the distributor, repackager and manufacturer on the outer and inner labelling, is the inclusion of a 'blue-box.'⁴⁴

The 'blue-box' is a box-shaped frame on the packaging in which the marketing authorisation holder is allowed to include Member State-specific information, such as the local representative, whether driving is recommended in conjunction with taking the product, and so on.⁴⁵ As these requirements differ from Member State to Member State, parallel distributors must change the information in the 'blue-box' so as to comply with the requirements in the Member State of importation. If the original marketing authorisation holder have not already completed a 'blue-box' for products destined for the Member State of importation chosen by the parallel distributor, a 'blue-box' must be created from scratch by the parallel distributor so

⁴³ See case T-123/00 *Thomae GmbH v. Commission* [2002] ECR II-5193; and chapter 3(2.1.1) above.

⁴⁴ See EMEA, 'Post-authorisation,' n. 33 above, 15-16. The name of the parallel distributor as well as the repackager and manufacturer must appear on the outer packaging of the product, whilst it is optional on the inner packaging. This is in line with established ECJ case-law in relation to the intellectual property aspect of repackaging, most notably Cases C-427/93 etc., n. 22 above. See chapter 6(7) above.

⁴⁵ See Commission Notice, n. 31 above. This document describes the functions and limitations of the 'blue-box.' Included in the guidelines is also a list of different Member States' requirements in relation to the 'blue-box.'

as to comply with national legislation. The name of the ‘local representative,’ which must be included in the ‘blue-box,’ has to be a representative of the parallel distributor if the marketing authorisation holder does not already have representation in the particular Member State.⁴⁶ This is an issue specific to parallel distribution of centrally authorised products, as nationally authorised products cannot be parallel imported unless a marketing authorisation for an ‘essentially identical’ product is already in force in the Member State of importation, and thus, the original marketing authorisation holder would automatically have a presence in the importing Member State.⁴⁷

Lastly, the parallel distributor is obliged to ensure that the product information remains in conformity with the current version of the Community marketing authorisation as authorised by the EMEA. Should the product information (labelling and/or package leaflet) be amended, the parallel distributor must submit a ‘notification of change’ to the EMEA.⁴⁸ This does not only relate to the package and package leaflet layout, but also amendments to the package leaflet in respect of the discovery of additional adverse side effects or urgent safety restrictions warranting updating. In consequence, the parallel distributor and repackager must regularly check the European Public Assessment Reports (EPAR) relating to the relevant product in question.⁴⁹ The content of the EPAR is derived from the various

⁴⁶ The inclusion of the contact details of a local representative is useful as it helps to increase consumer protection. It enables consumers to contact that representative and ask for advice in their mother tongue. It has been argued that the inclusion of a logotype alongside the name of the local representative gives rise to a risk of confusion when consumers distinguish between the marketing authorisation holder and the local representative. However, the ECJ has held that the inclusion of the local representative’s logotype in the ‘blue-box’ helps to increase consumer protection and is useful for health education. The local representative can subsequently refer the consumer to the marketing authorisation holder if necessary. The ECJ has also ruled that it is necessary to distinguish between the general information appearing on the packaging of the pharmaceutical products, and the information specific to every Member State appearing in the ‘blue-box.’ The risk of confusion is therefore not sufficient to warrant the exclusion of the local representative’s logotype in the ‘blue-box:’ see Case T-179/00 *A. Menarini Srl v. Commission* [2002] E.C.R. II-2879.

⁴⁷ See chapter 3(3.2) above.

⁴⁸ EMEA, ‘Notification of a change for parallel distribution of a centrally authorised medicinal product,’ (Rev. 5).

⁴⁹ See F. Braun, ‘The legal framework for parallel trade in pharmaceuticals for human use in the European Economic Area,’ Master of Drug Regulatory Affairs Thesis, Friedrich-Wilhelms-Universität Bonn (2004), pp. 10-11, for a good introduction to the relationship between EPAR’s and parallel distribution.

reports produced during the market authorisation evaluation procedure, resulting from the review of the documentation submitted by the applicant. The EPAR will be updated regularly throughout the marketing authorisation period to reflect changes to the terms and conditions of the marketing authorisation.⁵⁰ The EPAR also provides authorised versions of the labelling and packaging leaflet in all official languages.

Parallel distributors have free access to EPARs as they are published on the EMEA's website, and as such are public information. The responsibility of regularly updating the packaging and package layout can therefore not be classified as a barrier to trade. The parallel distributor is not dependant on the cooperation of the marketing authorisation holder to supply him with the information. As a result, this requirement cannot be compared to the facts in *de Peijper*⁵¹ where the ECJ held that the dependency of the parallel trader on the marketing authorisation holder when obtaining the relevant information necessary to apply for a marketing authorisation is not compatible with Articles 28 and 30 EC Treaty.⁵² The EMEA is empowered to inform the Member State where the parallel distributed product is marketed if the distributor has not complied with the post-notification responsibilities.⁵³ This may result in a recall process being instigated by national Medicines Control Agencies in order to prevent a risk to public health arising from the parallel distributor's non-compliance, or a review of the parallel distributor's WDL.

3.2 *Products benefiting from a parallel import licence (PIL)*

Most parallel imported pharmaceutical products benefit from a PIL. The difference between repackaging products benefiting from a (national) PIL and repackaging of products benefiting from a Community marketing authorisation concerns the lack of

⁵⁰ See EMEA website on EPARs: <<http://www.emea.eu.int/hums/human/epar/epar.htm>>.

⁵¹ Case 104/75 *Officier van Justitie v. de Peijper*. [1976] E.C.R. 613.

⁵² See chapter 3(3.2) above.

⁵³ See EMEA, 'Post-authorisation,' n. 33 above; and Braun, n. 49 above, 10-11.

a uniform packaging throughout the Community. The absence of a requirement not to mix products benefiting from different marketing authorisations (same products but different packaging sizes) and not make any amendments (except for the insertion of a 'blue-box' and necessary translations), gives a parallel importer more freedom than a parallel distributor. On the other hand, this only compensates for the fact that parallel importation, compared to parallel distribution, frequently demands repackaging of the products before marketing. A distinction, however, is not made between the two practices in relation to the right to repackage. An MAL is required and the intellectual property rights aspect is equally applicable to repackaging of parallel imported and parallel distributed pharmaceutical products.⁵⁴

The repackaging must be in conformity with Title V of Directive 2001/83/EC.⁵⁵ The labelling and package leaflet section of the Directive can be divided into three main areas; the outer packaging, the inner packaging, and the package leaflet. The PIL number and the name and address of the parallel importer must be stated on the outer packaging.⁵⁶ In line with the ECJ's case-law on repackaging, the outer packaging should also bear the name and address of the manufacturer.⁵⁷ If the parallel importer has not repackaged the product, i.e. the actual repackaging process is carried out by a contractor; it is advisable that this name also be printed on the outer packaging.⁵⁸ Similarly, the name of the PIL holder, in addition to the name of the product, should be printed on the inner packaging.⁵⁹ Furthermore, 'the original condition of the product inside the packaging might be indirectly affected' if the

⁵⁴ See chapter 6 on the intellectual property aspect of repackaging.

⁵⁵ N. 2 above.

⁵⁶ Directive 2001/83, n. 2 above, Arts. 54(k) and 54(l); and Cases C-427/93 etc., n. 22 above, paras. 70-71.

⁵⁷ It may be in the manufacturer's interest that the consumer or end user should not be led to believe that the importer is the owner of the trademark, and that the product was manufactured under his supervision. See Cases C-71-73/94 *Eurim-Pharm GmbH v. Beirersdorf AG* [1996] E.C.R. 3603, para. 64. See also chapter 6(7) above.

⁵⁸ Cases C-427/93 etc., n. 22 above, para. 70.

⁵⁹ Directive 2001/83, n. 2 above, Art. 55(2). However, following advice from the European Commission, the MHRA no longer requires the name of the parallel importer to be printed on blister strips, as long as it appears on the outer packaging and the package leaflet. The MHRA will therefore not refuse the granting of a PIL solely on the basis of a failure to include the parallel importer's name on the blister strip: *per* Keith Jones (Director and Chief Executive of the MHRA's predecessor; 'the Medicines Control Agency') in K. Jones, 'Parallel imports: Labelling of blister strips,' (2000) 264 P.J. 293.

requirements under Directive 2001/83/EC relating to the outer and inner packaging are not adhered to.⁶⁰ If this is shown, the trademark proprietor (in addition to the national Medicines Control Agency) will have a legitimate reason to prevent the products from being marketed.

Directive 2001/83/EC also states that all pharmaceutical products must carry a batch code and an expiry-date as well as a package leaflet in the language of the Member State of importation. These issues must be discussed in the context of Directive 2001/83/EC's aim of protecting public health and safety as well as intellectual property rights. Even though the intellectual property aspect was discussed in chapter 6, the specific and detailed nature of these three issues warrant separate discussions in this chapter.

3.2.1 *Re-attaching the expiry-date*

According to Directive 2001/83/EC all inner and outer packaging must state the expiry-date of the pharmaceutical products.⁶¹ The expiry-date is there to inform the consumer when and for how long it is advisable to consume/use the pharmaceutical product.

The inclusion of an expiry-date is particularly important in relation to parallel imports. Direct-imported pharmaceutical products (i.e. by the manufacturer) are usually transferred straight from the factory to the pharmacist. However, parallel imported products are often repackaged, which may mean that the period between reaching the pharmacist and the expiry-date is shorter than when supplied by the original manufacturer. Secondly, repackaging pharmaceutical products from

⁶⁰ In particular, where for example the outer or inner packaging of the repackaged product 'omits certain important or gives inaccurate information concerning the nature, composition, effect, use or storage of the product.' Cases C-71-73/94, n. 57 above, para. 56. Since these requirements are part of Articles 54 and 55 of Directive 2001/83 (n. 2 above) it is likely that the ECJ would consider that a failure to conform to these articles would affect the original condition of the product. See chapter 6(5) above.

⁶¹ N. 2 above, Arts. 54(h) and 55(3).

different batches may lead to products with different expiry-dates being packaged into one box.

In *Bristol-Myers Squibb* the plaintiffs claimed that ‘blister packs coming originally from different packs and grouped together in single external packaging might have come from different production batches with different use-by-dates,’⁶² and as such entail the risk of adversely affecting the original condition of the product. The ECJ stated that those arguments cannot be accepted.⁶³ According to case-law concerning the intellectual property aspect of repackaging, this practice is therefore accepted. It is not mentioned in other Community measures, nor in UK guidelines. However, one solution to this problem is to only allow repackaging of one batch at a time, and only allow one particular batch into the repackaging room at any given time.⁶⁴ This would prevent products with different expiry-dates and batch codes, further discussed below, from being grouped together into a new pack.

3.2.2 *Failure to re-affix the batch code*

Directive 2001/83/EC states that the ‘manufacturer’s batch number’ must appear on the outer packaging of the pharmaceutical product.⁶⁵ The inner packaging, including blister packs as well as immediate smaller packaging, must also bear a ‘batch number.’⁶⁶ Whether a distinction can be made between ‘manufacturer’s batch number’ and ‘batch number’ is not clear. For now, it suffice to note that the

⁶² N. 22 above, para. 62.

⁶³ *ibid.*

⁶⁴ This has been the practice of the leading Swedish parallel importer Cross-Pharma since 1998: see Läkemedelsvärlden (ed.), ‘Klagomål avsevärt vanligare för parallellimporterade läkemedel,’ Läkemedelsvärlden, 1 October 1998, (<<http://www.lakemedelsvarlden.nu/article.asp?articleID=1379&articleCategoryID=2&issueID=50>>). Also recommended by the European Association of Euro-Pharmaceutical Companies (EAEPc) in, ‘Good parallel distribution practice guidelines for medicinal products,’ (September 2005), (<http://www.eaepc.org/admin/files/eaepc_good_parallel_distribution_practice_guidelines.pdf>), p. 4.

⁶⁵ N. 2 above, Art. 54(m).

⁶⁶ *ibid.*, Art. 55(2) and 55(3).

‘manufacturer’s batch number’ (also known as ‘batch code’) must appear on the outer packaging according to Directive 2001/83/EC.⁶⁷

Batch codes⁶⁸ serve two important purposes - allowing the manufacturer to trace the goods in the event of a recall of defective products, and to detect counterfeit products. When relabelling or repackaging a product it is important that the batch code is left intact or re-affixed to the new packaging. In relation to the intellectual property aspect of repackaging, the ECJ has recognised that new external or internal packaging which omits certain important information regarding the nature or storage of the product may affect the original condition of the product.⁶⁹ However, it is not clear whether batch codes are considered ‘important information.’

*Loendersloot v. Ballantine*⁷⁰ concerned the removal of batch codes from whisky bottles. Loendersloot, a parallel importer, relabelled the whisky bottles omitting to re-affix the batch codes. Ballantine claimed that this was an infringement of its trademark rights, since it was not objectively necessary to remove the batch codes in order to obtain market access. Loendersloot, on the other hand, claimed that the batch codes enabled Ballantine to trace the goods back to Loendersloot’s supplier, effectively putting Ballantine in a position to prevent Loendersloot from obtaining products in the future. Removing the batch codes is therefore an effective way of hiding the parallel importer’s source of supply.

The ECJ agreed with Ballantine’s argument but observed that batch codes nevertheless enable manufacturers to trace their products back to the parallel importer’s supplier.⁷¹ If batch codes have been applied for purposes of complying with a legal requirement, or for a legitimate purpose such as recalling defective

⁶⁷ N. 2 above, Art. 54(m). It is possible that a distinction can be made between the two terms, and that this was done deliberately in order to allow for a ‘re-pack batch code’ on the inner packaging. This is further discussed in pp. 235-236 below.

⁶⁸ The term ‘batch code’ is, for the purpose of this chapter, interchangeable with the terms ‘batch number’ and ‘product identification code.’

⁶⁹ Cases C-427/93 etc., n. 22 above. See chapter 6(5) above.

⁷⁰ Case C-349/95 *Loendersloot v. George Ballantine & Son Ltd* [1997] E.C.R. 6227.

⁷¹ *ibid.*, para. 27.

products, manufacturers do not contribute to market partitioning by asserting their trademark rights to oppose marketing of products with removed batch codes.⁷² However, where it is established that the batch codes have also been applied to ‘combat parallel trade in [the manufacturer’s] products, it is under the Treaty provisions on competition that those engaged in parallel trade should seek protection against action of the latter type.’⁷³ The Court did not clarify how the manufacturer will be able to prove that the batch codes were not applied to combat parallel trade.⁷⁴ However, following *Van Doren*⁷⁵ it is likely that the burden of proof will be transferred to the trademark owner in situations where the parallel importer fears that his source of supply will be penalised by the manufacturer upon discovery. If such proof is given, the burden of proof will revert back to the parallel importer.⁷⁶

Batch codes were also at issue in the landmark case of *Davidoff v. A & G Imports*⁷⁷ concerning international exhaustion. The facts were as follows. The defendant parallel importer removed the batch codes from Davidoff’s cosmetic products before marketing. Davidoff unsuccessfully claimed trademark infringement under Article 7(2) of the Trade Mark Directive.⁷⁸ The Cosmetic Directive,⁷⁹ which had been implemented in the UK, required that all cosmetic products carry a batch code. However, the goods had not been affected by the removal of the batch codes. Mr Justice Laddie, in the UK High Court decision, did not accept product safety arguments since product recalls would still be possible, albeit in a wider scale,

⁷² Case C-349/95, n. 70 above, paras. 41-42.

⁷³ *ibid.*, para. 43.

⁷⁴ See Clark A, ‘Trade marks and the relabelling of goods in the single market: Anti-counterfeiting implications of *Loendersloot v. Ballantine*,’ (1998) 20 E.I.P.R. 328, for a wider discussion of this case and batch codes in general.

⁷⁵ Case C-244/00 *Van Doren + Q GmbH v. Lifestyle Sports mbH* [2003] E.C.R. 3051.

⁷⁶ *ibid.*, para. 41. See T. Hays, *Parallel Importation under European Union Law*, (London: Sweet & Maxwell, 2004) pp. 91-92; and T. Hays, ‘The burden of proof in parallel-importation cases,’ [2000] 22 E.I.P.R. 353, for a wider discussion. The ‘burden of proof’ is discussed in chapter 5(4.1) above.

⁷⁷ Joined Cases C-414-416/99 *Zino Davidoff SA v. A&G Imports Ltd, & Levi Strauss & Co v. Tesco Stores Ltd* [2001] E.C.R. 8691. See chapter 5(4) above for further discussion of this case.

⁷⁸ Council Directive 89/104/EEC to approximate the laws of the Member States relating to trade marks [1989] O.J. L40/1.

⁷⁹ Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products [1976] O.J. L262/69.

without the batch codes.⁸⁰ An Article 234 EC Treaty reference was made to the ECJ by the High Court, but unfortunately the issue was not discussed in the ECJ ruling. However, the Advocate General's Opinion provides some guidance. The Advocate General noted that the case concerned the interpretation of the Trade Mark Directive,⁸¹ and that, following *Loendersloot*,⁸² complying with a legal requirement would not amount to market partitioning. However, the Advocate General was of the opinion that 'the removal or obliteration of batch code numbers affixed in compliance with a statutory obligation may be of relevance for purposes of trade mark rights only if it would have a disproportionately adverse effect on the specific subject-matter of the trade mark right.'⁸³

The ECJ has not yet been asked to rule in a case concerning the removal of batch codes from pharmaceutical products. The ECJ has only briefly discussed the conformity of re-attaching batch codes with the Trademark Directive⁸⁴ and Article 28 EC Treaty.⁸⁵ The *Loendersloot*⁸⁶ ruling and Advocate General Stix-Hackl's Opinion in *Davidoff*⁸⁷ are therefore still relevant to parallel importers and repackagers. Just as in the UK High Court judgment in *Davidoff*,⁸⁸ batch codes must be affixed to pharmaceutical products in order to comply with a legal requirement (Directive 2001/83/EC).⁸⁹ However, the parallel trader may not be liable under Directive 2001/83/EC,⁹⁰ and the trademark owner may not have a legitimate reason to prevent marketing under the Trade Mark Directive,⁹¹ if it can be shown that the batch codes were attached for the purpose of combating parallel trade. In order for the parallel trader not to reveal his source of supply, the burden of proof rests with

⁸⁰ *Zino Davidoff S.A. v. A. & G. Imports Limited* [1999] C.M.L.R. 1056, para. 58. See P. Sheppard, 'Batch codes used in Davidoff: The brand owners' view,' [2000] 22 E.I.P.R. 147, for a wider discussion.

⁸¹ N. 78 above.

⁸² N. 70 above.

⁸³ Advocate General Stix-Hackl in Cases C-414-416/99, n. 77 above, para. 120.

⁸⁴ Directive 89/104, n. 78 above.

⁸⁵ See Cases C-71-73/94, n. 57 above.

⁸⁶ N. 70 above.

⁸⁷ N. 83 above.

⁸⁸ N. 80 above.

⁸⁹ N. 2 above.

⁹⁰ *ibid.*

⁹¹ N. 78 above.

the trademark owner. Following *Loendersloot*⁹² and Advocate General Stix-Hackl's Opinion in *Davidoff*,⁹³ it is likely that the trademark proprietor must show, first, that the batch codes were not attached in order to combat parallel trade, and, secondly, that the subsequent removal of the codes affects the specific-subject matter of the trademark. This is for national courts to decide. Looking at national court decisions, where for example removing batch codes from Reebok footwear has been held to affect the specific subject matter since the batch codes had several important functions (such as monitoring production efficiency, distribution routes, and preventing the circulation of counterfeit products), it is likely that national courts would interpret the ECJ's case-law in favour of the manufacturer.⁹⁴ Especially since pharmaceutical products are susceptible to counterfeiting, and defective pharmaceutical products can have fatal effects.

Nevertheless, the absence of legal certainty surrounding the removal of batch codes has led to the advancement of several theories on how to prevent this practice.⁹⁵ Perhaps the most plausible solution to the problems associated with this practice is to establish an alternative system of batch codes. By substituting the original codes by new codes that can be translated into the original code by the parallel importer,

⁹² N. 70 above.

⁹³ N. 83 above.

⁹⁴ *Reebok International Ltd. v. S.A. Cora, S.A. & Others* (Court of Appeal, Brussels) [1999] E.T.M.R. 649.

⁹⁵ A theory advanced in T. Hays, 'The Copyright Directive, rights management and the end of parallel trade,' [2002] 7 *IP & IT Law* 2, concerns the relationship between copyright and batch codes. By relying on Art. 7(2) of Council Directive 2001/29/EEC on the harmonisation of certain aspects of copyright and related rights in the information society [2001] O.J. L167/10, the manufacturer could prevent the removal of the batch codes by claiming that the codes are copyright protected. The manufacturer would have to overcome the hurdle of proving that the batch codes come within the notion of 'electronic rights-management information.' 'Rights-management information' is defined as 'any information provided by right holders which identifies the work...and any numbers or codes that represents such information' (Hays, 6). These codes, and information about the products bearing them, could be stored electronically on a computer. This would prevent parallel importers from removing the codes under Article 4(1) of the Copyright Directive. It is an interesting theory, but has not yet been tested in practice (although the Court did consider copyright rights in the context of batch codes in the Belgian Court of Appeal case of *Lancome Parfums v. Kruidvat Retail B.V.* [2005] E.T.M.R. 26). Considering how the ECJ has interpreted the Trade Mark Directive (n. 78 above), it seems unlikely that the ECJ would be more generous to manufacturers when interpreting the Copyright Directive given the ECJ's pro-integration policy: see chapter 6(2) above. In any event, the theory fails to reconcile the need to prevent the removal of batch codes with the need to protect the parallel importer's source of supply.

the manufacturer will be able to trace the goods in the event of a product recall from the information given by the parallel importer, thus only revealing the source of supply under such circumstances. This would allow the ECJ to maintain its pro-integration policy without affecting public health and safety. In a sense, this method is already applied in practice, since all WDL holders must keep a record of all products sold.⁹⁶ However, it is imperative that the new 're-pack batch code' be attached not only to the outer packaging, but also to the inner packaging, as there is a risk that one package might contain products originating from different batches.⁹⁷ The EMEA, in a recent Reflection Paper, states that parallel distributors of products benefiting from a Community marketing authorisation shall not replace the original batch code.⁹⁸ However, the mentioning of a 're-pack batch code' or the addition of a prefix or suffix to the original batch code is allowed, though the original batch code must always be retained.⁹⁹ As parallel distributed products benefit from the manufacturer's Community marketing authorisation it is understandable that the original batch code must be retained. However, substituting the original batch code for a 're-pack batch code' on products marketed under a PIL could be in line with the ruling in *Loendersloot*.¹⁰⁰ Parallel importers would not have to reveal their source of supply unless an emergency situation calls for a recall process, in which case the parallel importer would be able to translate the 're-pack batch code' into the 'original' batch code.

Whether introducing such a system would benefit public health and safety is debatable. Retaining the original batch code is most likely the best solution from a

⁹⁶ Directive 2001/83, n. 2 above, Art. 80(e). This must include at least: the date, name of the medicinal product, quantity received or supplied, name and address of the supplier. See also chapter 3, pp. 100-101 above.

⁹⁷ This is a concern voiced by manufacturers. See Report from the Select Committee on Trade and Industry: Trade marks, fakes and consumers, (1999 HC 380), questions 307-308, where evidence is given of a lipid lowering agent by Dr. Brickwood (Managing Director of Janssen Cilag Ltd). Out of 7 parts (containing 2 tablets each) only two parts had a batch code, which rendered a product recall impossible for the remaining 5 parts, as they clearly did not originate from the same original large block of tablets (otherwise it would have been unnecessary to cut it into pieces).

⁹⁸ See EMEA, 'PERF II Acquis Working Group: Reflection paper on parallel imports,' (EMEA-PERF-Acq-1367-02-Final).

⁹⁹ EMEA, 'Post-authorisation,' n. 33 above, s. 25.

¹⁰⁰ N. 70 above.

public health and safety perspective, as the lack of traceability of parallel imported products is (even) addressed by the Commission in a paper on Rapid Alerts and product recalls.¹⁰¹ However, an organised system for 're-pack batch codes' could be equally effective if embedded in legal certainty. The EMEA guidelines and reflection papers are not legally binding and the ECJ's case-law is not sufficiently clear on the matter. The issue of batch codes and parallel imports must therefore be included in a future amendment to Directive 2001/83/EC¹⁰² if the ECJ is not presented with these facts in the interim.

Finally, recording of batch codes could be centralised and standardised throughout the Community. This system could be established in addition to a system of 're-pack batch codes.' Manufacturers would be required to submit all batch codes to the EMEA before the products are supplied to the wholesalers. When a parallel importer subsequently acquires the products the batch codes would have to be compared to the batch codes already supplied to the EMEA by the manufacturer, so as to confirm authenticity.¹⁰³ The new 're-pack batch codes' could also be submitted to the EMEA in order to facilitate an effective product recall process. This would be possible, although unnecessary for product recall purposes, in the case of centrally authorised pharmaceutical products as the batch codes must be retained on such products. However, it would be impractical in respect of nationally authorised products as the recall process should be carried out by the national Medicines Control Agency responsible for the granting of the PIL, for reasons of

¹⁰¹ EMEA (published on behalf of the Commission), 'Compilation of Community Procedures on Inspection and Exchange of Information – Revised Procedure for Handling Rapid Alerts and Recalls arising from Quality Defects' (EMEA/INS/GMP/ 3351/03/rev1/corr), p. 18: 'In case of parallel imports, where there is difficulty in establishing the traceability of batches, consideration should be given to notifying all Member States by the Rapid Alert System.' See Braun, n. 49 above, 24 for a wider discussion. On the issue of traceability, it should be mentioned that some manufacturers, notably Pfizer, are experimenting with 'radio frequency identification technology.' With this technology manufacturers can ascertain 'how much, where it is, how it is being stored and whether it is in the correct place at the right time:' *per* Julian Mount (Senior European Director of Pfizer) in S. Shallar, 'Spaghetti junction,' European Pharmaceutical Executive, 1 March 2005, p. 12, 14. Parallel importers are likely to protest against the use of such technology, due to its potential parallel import-restrictive effect.

¹⁰² N. 2 above.

¹⁰³ See B. Irvine (ed.), P. Kanavos and P. Holmes, 'Pharmaceutical parallel trade in the UK,' Report, The Institute for the Study of Civil Society (2005), (<<http://www.civitas.org.uk/pdf/ParallelTradeUK.pdf>>), p. 74.

geographical efficiency. Secondly, Member States may object to such centralisation as the supervision of the pharmaceutical market falls under the retained national competence over the protection of public health and safety in accordance with Article 30 EC Treaty.

3.2.3 *The insertion of a translated package leaflet*

Article 58 of Directive 2001/83/EC states that ‘the inclusion in the packaging of all medicinal products of a package leaflet shall be obligatory...’¹⁰⁴

The new leaflet must, just like the outer packaging, include the name and address of the parallel importer and the name and address of the manufacturer.¹⁰⁵ Furthermore, the instruction leaflet must be translated into the language of the importing Member State.¹⁰⁶ This requires a good translator, as any mistakes may indirectly have fatal consequences.¹⁰⁷ Translating a package leaflet does not usually form the subject of an independent infringement action by the intellectual property holder, but is generally included in the infringement action by the trademark proprietor for repackaging or rebranding. However, it can be argued that package leaflets are copyright protected. As a direct consequence the translation of the leaflet will constitute an infringement of the copyright rights. Indeed, it is likely that copyright will be granted for leaflets under common law. However, most civil law jurisdictions would not afford copyright to works of low creativity, which is likely to include leaflets. Nevertheless, a company would be able to claim copyright in the leaflets when the products are being imported or exported to and from a common law jurisdiction.¹⁰⁸ Other factors must also be taken into consideration. A package

¹⁰⁴ N. 2 above, Art. 58.

¹⁰⁵ *ibid.*, Art. 59(1)(a).

¹⁰⁶ *ibid.*, Art. 63(2). The leaflet may be printed in several languages, provided that the same information is given in all the languages.

¹⁰⁷ For example, a parallel importer when translating the Spanish word for prostate cancer into English wrote ‘pre-menstrual pains.’ Select Committee, n. 97 above, question 306.

¹⁰⁸ In 1986 Glaxo successfully prevented the importation of Salbutamol by Europharm on the basis of copyright infringement in the patient leaflet. Copyright was granted to the leaflets by virtue of the Copyright Act 1956. Glaxo was granted an injunction against Europharm to prevent importation of products accompanied with patient leaflets: see *Glaxo v. Europharm*, (unreported) (1986) 1078 Scrip

leaflet is not the main 'work' in itself, its only function is to accompany the pharmaceutical products to which the leaflet refers.¹⁰⁹ If the copyright had been the main work, for example the copyright of a book, the proprietor would most likely be able to prevent the translation as this would have infringed the specific subject matter of the copyright, just as the manufacturing of patent protected pharmaceutical products would have infringed the specific subject matter of the patent.¹¹⁰ Exercising the copyright rights, when the reproduction and/or translation of the leaflet is necessary to enable the parallel importer to import the product into another Member State, would most likely infringe Article 28 EC Treaty. Preventing translation, whenever translation is as necessary as repackaging, would not be done to protect the specific subject matter of the copyright in the package leaflet, but to prevent parallel trade in the pharmaceutical product itself. Regardless of the 'exhaustion principle' such prevention is not compatible with Articles 28 and 30 EC Treaty.¹¹¹

10. It should be noted that this is an old case, and it was not referred to the ECJ. See L. Hancher, 'The European pharmaceutical market: Problems of partial harmonisation,' (1990) 15 E.L.Rev. 9, 25.

¹⁰⁹ See I. Stamatoudi, 'From drugs to spirits and from boxes to publicity (decided and undecided issues in relation to trade marks and copyright exhaustion),' [1999] I.P.Q. 95, 106-113, for an extended discussion of this topic (and the following paragraph).

¹¹⁰ A copyright right can be divided into two functions; the production and sale right, and the performance right. The performance right cannot be exhausted, as this would mean that the performance right would lose all its substance. The question is therefore whether the translation can be classified as 'performance' or 'reproduction.' Regardless of this, there is the third possibility, that translation is necessary in order to enable intra-Community trade. If so, the translation of the leaflet may not infringe the specific subject matter of the copyright right, as the package leaflet is only there to support the sale of the pharmaceutical product, and can therefore not be 'performed.' The only right that would be exhausted in such a scenario would be the sale right which is not part of the specific subject matter of the copyright right: see Case 158/86 *Warner Bros and Metronome Video ApS v. Christiansen* [1988] E.C.R. 2605; and Case 262/81 *Coditel v. Cine Vog Films SA* [1982] E.C.R. 3381. See I. Stamatoudi and P. Torremans, 'Merck is back to stay: The Court of Justice's judgment in *Merck v Primecrown*,' (1997) 19 E.I.P.R. 545, 548, for further discussion.

¹¹¹ In Case E-1/98 *Norwegian Government v. Autra Norge A/S* [1999] 36 C.M.L.R. 860, the EFTA Court had to consider whether copyright protection could be extended to 'summaries of product characteristics,' which include the specific information on the labels of packaging for pharmaceutical products as required by Articles 13 and 14 of Directive 65/65/EEC (replaced by Directive 2001/83, n. 2 above). The Court held that the exercise of the (potential) copyright so as to prevent parallel imports would be the equivalent of a prohibited quantitative restriction on imports. Further, the EFTA Court found the case to be concerned with the trade in the actual pharmaceutical products, and not the 'summary of product characteristics.' This could not be justified by Article 13 of the EEA Treaty (equivalent to Article 30 EC Treaty), and was a disguised restriction on trade between the parallel importer and the owner of the 'summary of product characteristics;' (paras. 24-26). See Hays, 'Parallel Importation,' n. 76 above, 67-68, for discussion.

Following the amendment of Directive 2001/83/EC¹¹² by Directive 2004/27/EC all package leaflets must ‘reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use.’¹¹³ This applies to both manufacturers and parallel importers. A group of 20 participants must undertake a 45-minute interview comprising 12 to 15 questions designed to determine whether the participants understand the leaflet.¹¹⁴ Evaluating all package leaflets will lead to manufacturers working even harder to meet consumer needs, which is the main aim of this final quality checkpoint for leaflets before marketing to the public. It will also insure that leaflets accompanying parallel imported products are correctly translated and contain all the information necessary to satisfy consumer needs.

Considering that a PIL cannot be granted in the absence of a reference marketing authorisation, the national Medicines Control Agency must already have carried out a ‘user test’ on the product leaflet at time of first marketing. The results of this test, which is estimated to cost £12,000 to £15,000, must therefore already be in the agency’s possession at time of applying for a PIL. Applying the ‘first marketing principle’ from *de Peijper*¹¹⁵ (establishing the simplified procedure for parallel imported products in relation to marketing authorisations), this test may not be necessary for parallel imported products, as it would obstruct trade under Article 28 EC and cannot be justified on grounds of public health and safety. The leaflet has already been tested once, and the national Medicines Control Agency already has the results. The MHRA states that ‘as knowledge and experience grows, it is likely that not all [patient information leaflets] will need to be user tested. Products may be exempt if the leaflet for a similar product has already been successfully

¹¹² N. 2 above.

¹¹³ *ibid.*, Art. 59(3), as amended by Council Directive 2004/27/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use [2004] O.J. L136/34. ‘The introduction of mandatory readability testing of leaflets’ was embodied in recommendation 11 of the Commission Communication on a Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action [2003] COM/383/final., p. 38.

¹¹⁴ See D. Connelly, ‘User testing of PILs now mandatory,’ (2005) 275 P.J. 12, for a discussion and explanation of ‘patient-testing’ of leaflets.

¹¹⁵ N. 51 above. See also chapter 3(3.2) above.

tested.¹¹⁶ This supports the argument that the ‘first marketing principle’ in *de Peijper*¹¹⁷ should be applied to the testing of patient information leaflets, something which the ECJ will have to rule on when presented with these facts in the future.

4. *Is public health and safety adequately observed?*

The debate over the safety of repackaging of pharmaceutical products seems to be never-ending. Pharmaceutical manufacturers claim that repackaging poses a significant risk to public health and safety, whilst parallel importers claim that repackaging is monitored by national authorities and does not jeopardise patient safety. Repackaging may present a risk to public health and safety in two different ways. First, the pharmaceutical products in question may have been affected during the repackaging process so as to have a non-existent, or in the ‘worst-case scenario,’ a negative therapeutic effect. Secondly, the packaging or package leaflet may be out of date or give inaccurate information which may indirectly have a negative effect on public health and safety. Before discussing the seriousness of these claims, and the various proposals to make repackaging safer, a summary of actual complaints made and defects discovered within a 12 month period will provide a good introduction.

Table 6¹¹⁸

24 March 2003 – 24 March 2004

Total number of complaints to the MHRA re: packaging of parallel imports	84
- concerning (actual) defective labelling/packaging	18
- concerning updating of patient leaflets	47
- concerning other aspect of the labelling/packaging or leaflet	19

¹¹⁶ MHRA, ‘Guidance on the user testing of patient information leaflets,’ (MHRA/usertesting/June/05)

¹¹⁷ N. 51 above.

¹¹⁸ Figures given by the Secretary of State for Health in *Hansard*, HC, Vol 419, Column 930-931W, 24 March 2004.

18 reports received by the MHRA Defective Medicines Report Centre¹¹⁹ concerned actual quality defects in the labelling or leaflets of repackaged parallel imports. These reports represent 6% of quality defects reported on all products, which is a relatively low number considering that parallel imports accounted for more than 17% of the UK pharmaceutical market in 2003.¹²⁰ The remaining complaints and reports were not grave enough to warrant a referral to the Defective Medicines Report Centre. The vast majority of complaints received by the MHRA were made by marketing authorisation holders.¹²¹

The statistics do not support the claims made by manufacturers. Naturally, the objectivity of the Government can be questioned, but so can the views of manufacturers and parallel importers. Pfizer, a large manufacturer of pharmaceutical products, conducted an audit of parallel traded pharmaceutical products in 2004.¹²² Pfizer claims that, of 300 pharmaceutical products surveyed, 80% failed for legal and trademark reasons, 50% failed because of poor quality and 25% failed for safety reasons. Boots Pharmacy, the pharmacy chain with the largest NHS dispensing business in the UK, takes the opposite view.¹²³ Although supplying approximately 600 000 packs of parallel imported pharmaceutical products per month, Boots can only report five instances since the start of 2004 where there have been difficulties. According to Boots, 'these were all relatively minor issues involving either labelling errors or wrong pack sizes and none of them posed a significant risk to patient safety.'¹²⁴ There is also a growing body of opinion and reports suggesting a link between parallel trade and the penetration of counterfeit pharmaceutical products into the Community. Again, there are no statistics to

¹¹⁹ The Centre receives and assesses reports of actual or suspected defective medicines and coordinates the necessary actions.

¹²⁰ See chapter 1, p. 26, n. 83 above.

¹²¹ *Hansard*, n. 118 above. 14 out of the total of 66 complaints not concerning actual defective labelling/packaging were from patients, patient groups and health professionals. The remaining 52 were from marketing authorisation holders.

¹²² Shallar, n. 101 above, 13.

¹²³ See David Loudon (Manager, Dispensing Buyer for Boots The Chemist) in Irvine (ed.) et al., n. 103 above, 60.

¹²⁴ *ibid.*

demonstrate this, even though the debate has been fuelled by the discovery of counterfeit Cialis on the UK market in 2004.¹²⁵

The above section highlights the absence of objectivity surrounding evidence to suggest that repackaging is a risk to public health and safety. A different approach is therefore necessary. Evidence from patient organisations, and examination of the potential risks from a practical perspective, will provide a better and more objective overview of the impact of repackaging on public health and safety.

A survey carried out by Epilepsy Action, a non-profit organisation, showed most of its members were not pleased with repackaged/relabelled pharmaceutical products.¹²⁶ Patients claimed that they experienced different side-effects, and in some cases no therapeutic effect at all when taking the substituted parallel imported product instead of the regular product. This opens up the interesting question of the occurrence of a 'reverse' placebo effect. Since parallel imported products must have the same therapeutic effect as the reference product, patients should not notice a difference between the two products. However, the absence of uniform packaging, and a different country of manufacture printed on the box, creates a reverse placebo effect. So, even if the product and packaging in itself do not constitute a risk to public health and safety the psychological impact must be considered. 'The placebo effect is well known and very powerful, and some have asked whether a similar 'reverse' placebo effect could be the cause of problems being blamed on parallel imports. Epilepsy Action acknowledges that this could play some part for some people. However, if the end result is a seizure, the underlying cause still needs to be addressed.'¹²⁷ The effect is strengthened by the fact that the packaging is different.

¹²⁵ See The Pharmaceutical Journal (ed.), 'Advice on counterfeit medicines,' (2004) 273 P.J. 361. The tablets had been supplied in the Netherlands, entering the UK through parallel imports. An extended discussion on the link between parallel imports and counterfeit pharmaceutical products does not belong in a chapter dealing with the direct safety risks associated with repackaging of genuine pharmaceutical products.

¹²⁶ Epilepsy Action, 'Epilepsy Action Survey,' (2004), (<<http://www.epilepsy.org.uk/research/reports/packaging.html>>).

¹²⁷ See Irvine (ed.) et al., n. 103 above, 59. When parallel imports started many of the complaints forwarded to national Medicines Control Agencies were a result of patient scepticism. A typical scenario would be when a patient has for a long time been using a certain medicine. When the

The absence of tamper-proof packaging gives rise to suspicion, adding more fuel to the 'reverse' placebo effect. Considering that most consumer products, from CD discs to soft drinks, are packaged in tamper-proof packaging, it is remarkable that pharmaceutical products on which people's lives depend are not. Allowing mixing of products from different batches and even cutting of blister packs may be statistically safe, but it nevertheless undermines patients' trust in parallel imported pharmaceutical products. The same principle applies to patient leaflets. The inclusion of a leaflet with correct and updated instructions is vital to public health and safety, and yet there are reports of more than 18% of epilepsy patients not receiving a package leaflet with their substituted parallel imported medicine.¹²⁸

Analysis of the various statistics in this section suggests that repackaging does not *per se* present a risk to public health and safety. However, repackaging is still an irrational practice if put into context. The pharmaceutical industry is one of the most regulated and supervised industries, and yet importers are allowed to open the original box, even cut blister packs into smaller pieces, subsequently putting the products in a new box. This practice in itself may be safe under optimal conditions when great care and attention is given to the process. Yet if packaging of pharmaceutical products is highly regulated and supervised so as to ensure safety by eliminating the chances of any mistakes in the packaging process, logical reasoning holds that repackaging must exponentially increase the chances of any mistakes in the repackaging process as it involves products being packaged for a second time.¹²⁹

In conclusion, it can be said that the current case-law and Community measures

pharmacy subsequently started to supply the parallel imported equivalent, the patient complained to the Medicines Control Agency and the parallel importer, claiming that the parallel imported version has not had any effect on the patient. Following testing by the Medicines Control Agency, comparing the two products, they are almost always found to be identical. In Sweden, for example, Astra always printed the name of the country of distribution on the packaging. When, post-1998, Astra wrote the name of the manufacturing country (Sweden) instead, complaints by Swedish patients concerning the parallel imported version decreased. This is an example of a reverse placebo effect: see *Läkemedelsvärlden*, n. 64 above.

¹²⁸ Epilepsy Action, n. 126 above (referred to in Irvine (ed.) et al., n. 103 above, 58): as much as 53% of patients receiving their medicine in plain white boxes (packaged by the pharmacists) complained of not receiving a package leaflet.

¹²⁹ Not unexpectedly, parallel importers claim that the repackaging process actually contributes to public health and safety by acting as a second safety check before marketing: see R. Freudenberg, 'An excuse to smear parallel trade, with no evidence,' (2004) 276 P.J. 560.

governing repackaging of pharmaceutical products adequately ensure public health and safety from a strictly theoretical perspective. However, the complexity of these measures and rulings, as well as the nature of the parallel system for directly and parallel imported pharmaceutical products, demands an effective enforcement and supervision of the established laws and regulations governing repackaging.¹³⁰ Being effective in theory, it is debatable whether cooperation between authorities in different Member States is sufficient to guarantee effective control of WDL and MAL holders and the eventual safety of repackaged products offered to patients.

The simplest proposal to remedy these concerns and risks would be to introduce a single Community pack and name for all pharmaceutical products by making the centralised procedure for the granting of Community marketing authorisations gradually compulsory. Although attractive from a public health and safety perspective, such reform would, most likely, not be welcomed by manufacturers and unacceptable to many governments.¹³¹ Instead, a proposal which satisfies public health and safety needs - as well as the demands of manufacturers and parallel importers - is 'over-packaging'.¹³² This would involve the original package being inserted into a new box together with a new package leaflet, and if required, blister labelling for patients to stick on over-packaged blister packs. The system has the advantage of avoiding opening of tamper-proof packaging, thus not subjecting the actual products to the risk of being adversely affected, making cutting of blister

¹³⁰ This could mean shorter intervals between inspections of MAL and WDL holders' premises. Currently, premises are only inspected once an application is made, and thereafter only sporadic – the maximum interval being 4 years (for overseas premises). See the MHRA website: <http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=613>.

¹³¹ As proposed in chapter 3(4) above, making the centralised procedure compulsory for all pharmaceutical products would enhance safety and stimulate cross-border trade. However, it will be difficult to introduce a single Community pack and name until national regulations and trademark laws have been further harmonised. Meanwhile, repackaging of centrally authorised products must, to an extent, be allowed: see section 3.1 and chapter 3(2.1.1) above for discussion of brand names and package sizes in relation to the Community marketing authorisation. Member States may object to such centralisation as the national pharmaceutical market falls under the retained national competence in accordance with Article 30 EC Treaty, and manufacturers may oppose such a reform as it would prevent them from using separate trademarks and names throughout the Community. See chapter 3(4) for further discussion of the possible objections to such centralisation.

¹³² See Shallar, n. 101 above, 14; and Irvine (ed.) et al., n. 103 above, 73.

packs a practice of the past.¹³³ The disadvantage is that patients, or the pharmacists, will have to stick the blister labels on the blister packs themselves.

The statistics concerning the risks to patient health and safety brought about by repackaging are not conclusive as it is hard to find scientifically objective statistics. This is particularly true considering that a normal patient – ‘the man on the Clapham omnibus’ - may not know that the trade exists let alone how to complain about it. The laws and regulations governing repackaging seem to be adequate and effective, but safety is largely dependent on the enforcement of these regulations. Making the centrally authorised marketing authorisation procedure compulsory for more pharmaceutical categories would make the system more manageable and safer, as parallel distribution does not involve a name change, pack size change, or a change in package layout.¹³⁴ Until such centralisation has been achieved, over-boxing coupled with tamper-proof packaging would be a step in the right direction.

5. *Conclusion*

The case-law concerning repackaging of pharmaceutical products can in many aspects be viewed as the pinnacle of pro-integration. Manufacturers, the intellectual property owners, are not only prohibited from exercising their trademark and patent rights so as to prevent trade in intellectual property protected products, but are also precluded from preventing the re-attachment of trademarks as a consequence of repackaging where this is necessary to comply with national legislation and in some cases consumer preference.¹³⁵ This has resulted in a fierce debate between parallel importers and manufacturers over the trade’s legitimacy. However, perhaps more important than the intellectual property aspect of repackaging are the Community’s labelling and package leaflet regulations, and ultimately public health and safety.

¹³³ Pfizer, being in favour of over-packaging, is introducing tamper-evident packaging which will make it evident if the package has been opened by using colour-shifting ink. The ink enables pharmacists and patients to determine the authenticity of products by using a special filter, similar to the system used for banknotes: see Shallar, n. 101 above, 15.

¹³⁴ See n. 131 above.

¹³⁵ See chapter 6 above.

The first step for a parallel importer wanting to engage in repackaging is to obtain a MAL, which also works as a WDL. Following *Gyselinx*,¹³⁶ it can be argued that national legislation prohibiting MAL holders in other Member States from importing pharmaceutical products in the absence of holding a WDL in the Member State of importation is not compatible with Article 28 EC Treaty. Nevertheless, it is likely that such legislation can be justified under Article 30 EC Treaty, as it will be very difficult for the importing Member State to ensure public health and safety if the trader is neither licensed nor store the products in this Member State. Similarly, as discussed in section 2 above, national legislation prohibiting the issuance of a MAL unless the repackaging process is carried out in this Member State may not be compatible with Article 28 EC Treaty. Such legislation penalises against traders who already have access to suitable premises for the purpose of a MAL in a Member State other than the importing Member State. However, it is likely that legislation to this effect can be justified with reference to Article 30 EC Treaty, as the abolishment of such legislation would require strong cooperation between the two national Medicines Control Agencies in order to protect public health and safety.

The requirement of a MAL is equally applicable to repackaging of parallel distributed and parallel imported products. However, as opposed to parallel distributed pharmaceutical products, parallel imported products can be repackaged into a larger or smaller pack size. As a result, the batch code and expiry-date may not be re-attached on the new blister pack after having been cut into smaller pieces. Due to the traceability which a batch code affords the manufacturer, this practice may be compatible with Articles 28 and 30 EC Treaty. Although the re-attachment of the original batch code is preferred in order to protect public health and safety in the event a product recall is necessary, a translatable 're-pack batch code' may be equally effective without allowing the manufacturer to trace the products in order to prevent parallel imports. Concerns have also been raised over the implications for public health and safety of the absence of expiry-dates on repackaged parallel

¹³⁶ N. 9 above.

imports. Following Directive 2001/83/EC¹³⁷ the expiry-date must be printed on at least the outer and inner packaging, but if the blister packs have been cut and mixed, there is a real risk that packages may contain products with different expiry-dates. This is a real concern. The insertion of a translated package leaflet, on the other hand, should be straightforward. Manufacturers will find it hard to claim copyright infringement by the parallel importer's translation, and the *de Peijper*¹³⁸ 'first marketing principle' will most likely prevent national authorities from demanding that package leaflets - having already been 'patient tested' once - be tested again following the granting of a PIL.

Overall, the case-law and Directive 2001/83/EC¹³⁹ adequately ensure public health and safety, although legal certainty is needed in the area of batch codes. Statistics do not point towards repackaging constituting a risk to public health and safety, but in such a disputed practice as repackaging it is difficult to verify the objectivity of statistics. Nevertheless, the ultimate effectiveness of these measures is dependent on their enforcement, which demands strong and close cooperation between Member State authorities and the EMEA. The Community should draw up clear guidelines and/or (preferably) include these in a future amendment to Directive 2001/83/EC¹⁴⁰ in order to clarify the responsibility of national Medicines Control Agencies, setting up clear channels of cooperation, and providing legal certainty in the areas of batch codes and expiry-dates. This will hopefully lead to an effective enforcement of the Community's labelling and package leaflet regulations. Finally, it is obvious that parallel importers have much to gain from complying with these measures, not least to build up patients' confidence in the safety of the trade.

¹³⁷ N. 2 above.

¹³⁸ N. 51 above.

¹³⁹ N. 2 above.

¹⁴⁰ *ibid.*

PART III

CONCLUSION AND RECOMMENDATIONS

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The elimination of cross-border barriers to trade can generally be expected to encourage intra-brand competition and widen customer choice. This will lead to increased production efficiency and harmonisation of product prices throughout the Community. Given these benefits, it is natural that the Commission actively encourages the facilitation of parallel trade.

These benefits, however, do not apply to parallel trade in the pharmaceutical sector. National laws still regulate the pharmaceutical industry on the basis of the retained national competence over the protection of public health and safety in accordance with Article 30 EC Treaty. National regulations decide when/if and at what price a pharmaceutical product can be marketed on the national market. The resultant disparity in pharmaceutical prices throughout the Community has resulted in large scale parallel trade in pharmaceutical products (*see recommendation 1* below). Some Member States value the importance of future R&D by allowing the imposition of high pharmaceutical prices; whilst other Member States have adopted a pricing policy aimed at generating savings for the national health budget.

Parallel trade in pharmaceutical products will not lead to price convergence, but merely result in the importation of the exporting Member State's pricing policy. The legal framework governing parallel trade therefore only facilitates parallel trade without having any long-term effect on the EC Treaty objective of establishing a common market. It reduces the funds available for future R&D and is therefore 'a key factor in Europe's declining attractiveness for pharmaceutical R&D.'¹ In addition, logic cannot deny that the extra transportation, repackaging, and

¹ Humer F, 'A tainted trade – parallel trade medicines are a clear symptom of the failure of Europe's pharmaceutical policy,' European Pharmaceutical Executive, 1 November 2005, p. 44.

simplified fast-track marketing authorisation application procedure entailed by parallel trade carries a potential risk to public health and safety. Parallel trade exponentially increases the chance of errors in the distribution chain.

The main beneficiaries of parallel trade are the parallel importers, and in the short term, Member States.² Parallel traders make a handsome profit, although having to rely on larger volumes due to increased sector competition. Parallel trade also generates savings for national health budgets. This, however, can be a misconception as Member States could simply amend their pricing regulations so as to lower prices instead of indirectly encouraging parallel trade.³

This thesis has discussed the need to balance the common market objective with various public health and safety concerns. The Commission and the Community courts have not yet fully considered these aspects of the trade when interpreting and/or applying the EC Treaty. However, the recent *Bayer*⁴ judgment heralded a change in the Court's approach to parallel imports. Mere unilateral decisions are not prohibited by Article 81 EC Treaty, and such prohibitions cannot be justified by the Treaty objective of market integration, as restricting parallel imports is not a *per se* violation of Article 81 EC Treaty. Manufacturers should, however, apply the *Bayer*⁵ judgment with care. In particular:

- Manufacturers should be aware that the principle in *Bayer*⁶ may not apply to a relationship between a manufacturer and a selective distributor. The ECJ did not rely on *Ford*⁷ and *AEG v. Commission*⁸ since these cases concerned selective distribution agreements.⁹

² Most price differences remain with the parallel importer, with only a small fraction accruing to the national health budget; see chapter 1(3.1) above.

³ See chapter 1(3.1) above.

⁴ Joined Cases C-2-3/01 P *Bundesverband der Arzneimittel-Importeure & Commission v. Bayer AG* [2004] E.C.R. 23.

⁵ *ibid.*

⁶ *ibid.*

⁷ See Cases 25-26/84 *Ford Inc. v. Commission* [1985] E.C.R. 2725.

⁸ Case 107/82 *AEG-Telefunken AG v. Commission* [1983] E.C.R. 3151

⁹ Cases C-2-3/01, n. 4 above, paras. 143-144.

- The manufacturer must not make its intentions, as to the refusal to supply, known to the distributor or any other party.
- Manufacturers must refrain from monitoring and tracing parallel exported goods back through the distribution chain, as this can be seen as enforcing the ‘export ban’ from which an agreement can be inferred if the distributors adhere to the manufacturer’s policy.¹⁰
- Finally, a manufacturer may potentially benefit from a dishonest relationship with its distributors. If the distributor ‘agrees’ to the unilateral policy the Commission may regard this as an agreement.

The *Bayer*¹¹ judgment may prompt the Commission to more actively consider the application of Article 82 EC Treaty to parallel import-restrictive measures. However, as chapter 2 showed, the Commission will have difficulties in establishing the manufacturer’s dominance, as the relevant market must be defined using the ‘arbitrage approach’ method giving rise to a very wide market definition. This will be further complicated considering the market position of pharmaceutical manufacturers versus national health authorities; a monopolist facing a monopsonist.¹² Should the Commission be able to establish a dominant position on the part of the undertaking, Advocate General Jacobs argued, in *Syfait*,¹³ that the special characteristics of the European pharmaceutical market coupled with the need to promote public health and safety provides an objective justification for parallel import-restrictive measures by dominant undertakings (see *recommendation 2* below). Indeed, it is likely that the CFI was influenced by Advocate General Jacobs’s Opinion in *Syfait*¹⁴ when giving judgment in *GlaxoWellcome*,¹⁵ where the

¹⁰ Commission Decision 80/1283/EEC *Johnson & Johnson* [1980] O.J. L377/16, recitals 15-17.

¹¹ N. 4 above.

¹² See chapter 2(2.3) above.

¹³ Opinion of Advocate General Jacobs in Case C-53/03 *Syfait & Others v. GlaxoSmithKline AEVE* [2005] E.C.R. 4609.

¹⁴ *ibid.*

Court held that certain dual-pricing agreements may be capable of benefiting from an Article 81(3) EC Treaty exemption despite having a parallel import-restrictive effect (see *recommendation 2* below). The Commission may therefore find it increasingly difficult to apply Articles 81 and 82 EC Treaty to parallel import-restrictive agreements following *GlaxoWellcome*¹⁵ and Advocate General Jacobs's Opinion in *Syfait*.¹⁷ Coincidentally, the European Association of Euro-Pharmaceutical Companies (EAEPC) has filed a complaint with the Commission alleging that Pfizer's recently implemented dual-pricing system in Spain is incompatible with Articles 81 and/or 82 EC Treaty.¹⁸ The outcome of the Commission's re-examination of GlaxoWellcome's request for an exemption, or, if appealed, the ECJ's judgment, is therefore eagerly waited for by commentators.

Similarly, the Commission and the Community courts have failed to fully consider the need to protect public health and safety when interpreting the conformity of the legal framework governing the granting of marketing authorisations with the EC Treaty. Following *de Peijper*¹⁹ and the ECJ's subsequent case-law concerning the 'simplified procedure' there are no real obstacles remaining for parallel importers in relation to marketing authorisations. The question is instead whether the ECJ has in fact adopted a stronger pro-integration policy than is necessary in order to protect the concept of a common market, and whether this can be justified despite the ensuing risks to public health and safety.

National Medicines Control Agencies will grant a parallel import licence (PIL) if the parallel imported product can be considered 'essentially identical' and share a 'common origin' with the reference product already benefiting from a marketing authorisation. The ECJ's interpretation of the conformity of these conditions with

¹⁵ Case T-168/01 *GlaxoWellcome plc v. Commission* [2006] E.C.R. (unreported: delivered on September 27 2006). See also Commission Decision 2001/791/EC *GlaxoWellcome* [2001] O.J. L302/1.

¹⁶ *ibid.*

¹⁷ N. 13 above.

¹⁸ EAEPC, 'Pfizer breaking EU competition rules,' (October 2005), (<http://www.eaepc.org/news_and_press/current_articles.php?n=3&id=274>). See also chapter 2, p. 42, n. 53 above.

¹⁹ Case 104/75 *Officier van Justitie v. de Peijper*. [1976] E.C.R. 613.

the EC Treaty has led to a very wide definition of ‘a common origin’ and ‘essentially identical.’

Following *Kohlpharma*, a PIL cannot be precluded solely on the ground that there is no ‘common origin’ between the product for which an application is sought and the reference medicinal product, where:²⁰

- a) the application is submitted with reference to a medicinal product which already benefits from a marketing authorisation in this Member State;
- b) the medicinal product for which a licence is sought is imported from a Member State in which it benefits from a marketing authorisation, and;
- c) the safety and efficacy assessment carried out for the reference marketing authorisation can be used in the application for a PIL without any risk to public health and safety.²¹

The requirement of a ‘common origin’ is secondary to ‘essentially identical’ and cannot play a decisive role in deciding whether or not to grant a PIL.²² However, it should be noted that the ECJ has not yet ruled on facts where no common origin, however remote, exists.

The ECJ has applied a similarly wide interpretation of the ‘essentially identical’ condition. The parallel imported and the reference product will be considered ‘essentially identical’ if they possess the same therapeutic effects. In order to have the same therapeutic effects, the products must possess the same active ingredients, and in particular the same active moiety. The excipients and the ‘pharmaceutical form’ need not be identical if it can be showed that the difference in excipients does not affect quality and safety assurance.

²⁰ Case C-112/02 *Kohlpharma GmbH v. Germany* [2004] E.C.R. 3369, para. 21.

²¹ *ibid.*, para. 21.

²² *ibid.*, para. 15.

Furthermore, the automatic revocation of the PIL upon the voluntarily withdrawal of the reference marketing authorisation is not compatible with Articles 28 and 30 EC Treaty. As a result, when the reference marketing authorisation is withdrawn for reasons other than the protection of public health, the automatic cessation and/or revocation of the linked PIL cannot be justified.²³ This may have a positive side-effect on integration. By leaving the PIL valid following the withdrawal of the reference marketing authorisation, the ECJ forces national Medicines Control Agencies to rely solely on information provided by other Member State Medicines Control Agencies. In consequence, this encourages Member States into stronger co-operation, as well as indicating that licences based on separate national procedures are no longer sufficient to satisfy Community integration and public health. Nevertheless, the previous marketing authorisation holder would not be under an obligation to submit the information necessary to carry out effective pharmacovigilance. Maintaining public health and safety is further complicated by the fact that most withdrawn marketing authorisations are replaced by a new marketing authorisation for a similar, albeit, improved version of the original product. Due to the potential differences between the new and 'old' (still parallel imported) version of the product, it becomes even more important to monitor the safety of the products; individually, as well as the consequences which may result from allowing the two products to be sold side-by-side.

To summarise, it now seems as if differences in the pharmaceutical formulation and a lack of a common origin are not only allowed in order to protect the common market, but have been relaxed so as to become an authorisation procedure for imported products in general, sharing some similarities with a product already benefiting from a marketing authorisation, instead of being a licence system strictly for the benefit of products imported in parallel. In addition, leaving the PIL valid following the withdrawal of the reference marketing authorisation may have serious consequences to public health and safety as it requires strong cooperation between

²³ Case C-172/00 *Ferring GmbH v. Eurim-Pharm GmbH* [2002] E.C.R. 6891, para 33; and Case C-15/01 *Paranova AB v. Läkemedelsverket* [2003] E.C.R. I-4175, and Case C-113/01 *Paranova Oy* [2003] E.C.R. 4243. See chapter 4(3) above.

Member States, and thus increases the risk of mistakes or omissions of information. A solution to this problem would be to go back to the ruling in *de Peijper*.²⁴ However, in order not to affect legal certainty, the best solution is to gradually make the centralised Community marketing authorisation procedure compulsory for more categories of pharmaceutical products (see *recommendation 3* below).

Part 2 of the thesis focused on the intellectual property and repackaging aspect of parallel trade. The absence of international exhaustion in conjunction with the exhaustion of rights doctrine for goods first marketed within the EEA has given rise to the expression ‘Fortress Europe.’ This is a very accurate description of the common market in terms of the bottleneck effect it applies to imports from third countries – the difficulties in gaining entry into the Community are compensated for by the Community’s free movement provisions giving rise to ample opportunities for traders to capitalise on price differences.

The ‘exhaustion of rights’ doctrine in its basic form, allowing for Community exhaustion, cannot be criticised from a pro-integration nor a public health and safety perspective. The doctrine’s significance to the fulfilment of the common market objective outweighs any risks it may pose to the promotion of public health and safety. Even though the doctrine may have an effect on the funds made available for future R&D, and thus the need to promote public health and safety, this can be compensated for by a less stringent application of Articles 81 and 82 EC Treaty to parallel import-restrictive measures (see *recommendation 2* below).

The derogation in the 2003 Act of Accession,²⁵ commonly referred to as the ‘specific mechanism,’ provides for the suspension of the ‘exhaustion of rights doctrine’ for a dynamic transition period in terms of pharmaceutical products imported from the new Member States (except Cyprus and Malta).²⁶ This means

²⁴ N. 19 above.

²⁵ Chapter 2 (Company Law) of Annex IV of the Act of Accession [2003] O.J. L236/33 (see introduction, p. 4, n. 15 above for a full reference).

²⁶ See chapter 5(5.2) above.

that the principle in *Merck v. Stephar*²⁷ is temporarily suspended for all products within the scope of the derogation. By suspending the exhaustion of rights doctrine, the pharmaceutical market and pharmaceutical traders will be given extra time to adjust pharmaceutical prices, distribution networks and patent protection. A patent proprietor which, fully aware of the consequences in terms of the exhaustion of rights doctrine, markets a product in a Member State where patent protection is not available can be said to have consented to the marketing and the aforementioned consequences. However, a patent proprietor which decided to market a product in one of the new Member States before patent protection became available cannot be said to have consented to the subsequent consequences of that decision, being unable to predict that the country in question would one day join the European Community. In fact, the 'specific mechanism' can be justified with reference to the judgment in *Pharmon v. Hoechst*.²⁸ Just as a patent proprietor cannot be said to have consented to the granting of a compulsory licence, a patent proprietor marketing a product in one of the new Member States before it joined the Community cannot be said to have consented to the future consequences of having marketed the products, compared to *Merck v. Stephar*²⁹ where the patent proprietor must necessarily have been aware of the consequences of such marketing.

The product, temporal and geographical scope of the mechanism is insufficiently clear (see *recommendation 4* below). However, it is most likely that the relevant form of patent protection in relation to the 'specific mechanism' is product or second medical use patents, whichever was introduced earliest.³⁰ As all Member States introduced product patents before second medical use patents, the relevant date must be the date product patents were introduced in the new Member States. As the mechanism expressly includes supplementary protection certificates (SPCs), the derogation refers to product patents with additional SPCs.

²⁷ Case 187/80 *Merck & Co. v. Stephar BV* [1981] E.C.R. 2063.

²⁸ Case 19/84 *Pharmon BV v. Hoechst AG* [1985] E.C.R. 2281.

²⁹ N. 27 above. See also chapter 5(5.2); and Joined Cases C-267-268/95 *Merck & Co. Inc. v. Primecrown Ltd* [1996] E.C.R. 6285.

³⁰ See O. Lemaire, 'Parallel trade of pharmaceutical products within the enlarged European Union,' (2005) 27 E.I.P.R. 43, 45 and 50. See also chapter 5(5.2.1) above.

Patent protection was made available in all the new Member States between 1991 and 1994.³¹ Pharmaceutical products for which a patent was filed for after 1994 will not under any circumstances benefit from the 'specific mechanism,' whilst all products for which a patent was filed for before 1991 will automatically benefit from the derogation for the duration of the patent term and the SPC. Consequently, opponents to the 'specific mechanism' can take comfort in the fact that the product scope of the derogation is very limited and ever decreasing. The geographical scope of the mechanism should extend not only to parallel imports from the new CEE Member States to the 15 old Member States. As the phrasing of the mechanism is ambiguous, and considering that the purpose of the 'specific mechanism' is to provide a transition period so as to allow for a smooth integration into the Community, the ECJ is not likely to discriminate between the 15 old Member States and Malta and Cyprus, especially not since Malta and Cyprus enacted patent legislation at a similar time as the 15 old Member States.³² Patent proprietors in these two island States should therefore be able to invoke the mechanism.

The same reasoning, albeit with a few modifications, can be applied to the interesting legal question of whether the 'specific mechanism' can be invoked by a patent proprietor in one of the eight new CEE Member States for products imported from another CEE Member State. Admittedly, the derogation explicitly refers to the (listed) 'abovementioned [new] Member States' and 'Member States,' as well as implying that the importing State must have been a Member State at the time of filing the patent application.³³ However, in *Merck v. Primecrown* the ECJ stated that the derogation in the Spanish and Portuguese Act of Accession³⁴ 'should apply in full to trade between Spain and Portugal, on the one hand, and the existing Member States, on the other.'³⁵ It is therefore likely that the 'specific mechanism'

³¹ See chapter 5(5.2.1) above.

³² See chapter 5(5.2.2) above.

³³ 'Specific mechanism,' n. 25 above, para. 1. See also chapter 5(5.2.2) above.

³⁴ Art 47 and 209 of the Act Concerning the Conditions of Accession of the Kingdom of Spain and the Portuguese Republic to the European Communities and Adjustments to the Treaties [1985] O.J. L302/23. The wording of the derogation, in respect of the geographical scope in relation to acceding and old Member States, is similar to that of the 'specific mechanism' (*ibid.*).

³⁵ Cases C-267-268/95, n. 29 above, para. 38 (emphasis added).

can be invoked in one of the new CEE Member States for products imported from another of the new CEE Member States,³⁶ as otherwise the ECJ would be seen as discriminating between (new and old) Member States.

An interesting observation is that the 'specific mechanism' allows patent proprietors to prevent 'the import *and* marketing'³⁷ of the product. It can therefore be debated whether parallel importers are allowed to circumvent the 'specific mechanism' by using Member States where the mechanism cannot be invoked (due to the temporal scope) as a gateway before re-exporting the goods to a Member State coming within the scope of the mechanism (see *recommendation 4* below).

The scope of the mechanism will likely be the subject of many rulings by the ECJ and subsequent comments by academic scholars. This, of course, is dependent on the effectiveness and enforcement of the derogation. Further research is therefore needed when enough time have lapsed so as to be able to assess the impact of the 'specific mechanism' in hindsight.

In contrast to the 'specific mechanism' and Community exhaustion of patents, it is clear that the ECJ considers the right to exercise trademark rights to be subordinate to the common market objective. Repackaging, rebranding and relabelling of parallel imported products are practices particular to pharmaceutical products. The linguistic, regulatory and customary barriers to intra-Community trade have prompted the ECJ to extend the boundaries of the 'exhaustion of rights' doctrine to allow unauthorised re-affixation of trademarks and alteration to the packaging where this is considered necessary to gain market access (see *recommendation 5* below). The ECJ case-law interpreting the Trade Mark Directive³⁸ and the EC Treaty in relation to repackaging is complex and substantial. The *Bristol-Myers*

³⁶ Lemaire, n. 30 above, 49.

³⁷ N. 25 above, para. 2.

³⁸ Council Directive 89/104 EEC to approximate the laws of the Member States relating to trade marks [1989] O.J. L40/1.

*Squibb v. Paranova*³⁹ and *Boehringer v. Swingward and Dowelhurst*⁴⁰ conditions, at first only concerned with the ‘necessity’ to repackage in order to comply with national legislation and the protection of the specific subject matter of the trademark, have been extended to include a ‘customer preference test’ in order to assess whether repackaging is considered necessary. Perhaps the most controversial issue, however, is the practice of ‘co-branding,’ involving not only the re-affixation of the manufacturer’s trademark, but the affixation of a parallel trader-specific brand mark to the new packaging (see *recommendation 5* below). Like the ‘customer preference test,’ a final conclusion on the legitimacy of ‘co-branding’ cannot be made until the ECJ has decided upon the latest referral made by the UK Court of Appeal in the *Boehringer v. Swingward*⁴¹ saga.

However, the intellectual property aspect of repackaging is secondary and unconnected to the Community’s labelling and package leaflet regulations. Contrary to the purpose of the ‘exhaustion of rights’ doctrine, which mainly concerns the common market objective, the objective of these regulations is to protect public health and safety. This can potentially have a negative effect on the common market objective. For example, following *Gyselinx*,⁴² it can be argued that national legislation prohibiting ‘manufacturer’s (assemble) licence’ (MAL) holders in other Member States from importing pharmaceutical products in the absence of holding a ‘wholesale dealer’s licence’ (WDL) in the Member State of importation is not compatible with Article 28 EC Treaty. Similarly, it is reasonable to question the validity of national legislation requiring MAL holders to repackage the products in the Member State where the licence is granted. This is so because a MAL holder does not need to be in possession of a WDL, but not vice versa. Such legislation penalise nationals from other Member States who have access to suitable premises

³⁹ Joined Cases C-427, C-429 and C-436/93 *Bristol-Myers Squibb v. Paranova A/S* [1996] E.C.R. 3457.

⁴⁰ Case C-143/00 *Boehringer Ingelheim KG v. Swingward Ltd & Dowelhurst Ltd* [2002] E.C.R. 3759.

⁴¹ Case C-348/04 *Boehringer Ingelheim KG v. Swingward Ltd*. [2004] O.J. C273/11 (currently pending before the ECJ).

⁴² Joined Cases 87-88/85 *Legia & Gyselinx v. Minister for Health* [1986] E.C.R. 1707. See also chapters 3(3) and 7(2) above.

and technology for repackaging in the Member State where the trader's headquarters are located, and may not be compatible with Article 28 EC Treaty as it renders the trader liable to the additional costs of either obtaining suitable premises or a WDL in the Member State of importation. However, as discussed in chapter 7(2) above, it is possible that legislation to this effect can be justified under Article 30 EC Treaty as the protection of public health and safety would demand strong cooperation in the absence of such legislation (see *recommendation 6* below).

Similarly, demanding the re-attachment of batch codes on repackaged products may not be compatible with Article 28 EC Treaty due to the traceability batch codes affords manufacturers⁴³ (see *recommendation 6* below). Concerns have also been raised over the potential implications for public health and safety of the possible mixing of products with different expiry-dates.⁴⁴ Following Directive 2001/83/EC⁴⁵ the expiry-date must be printed on the outer and inner packaging, but if the blister packs have been cut and mixed, there is a real risk that packages may contain products with different expiry-dates. The insertion of a translated package leaflet, on the other hand, should be straightforward. Manufacturers will find it hard to claim copyright infringement by the parallel importer's translation, and the *de Peijper*⁴⁶ principle will most likely prevent national authorities from demanding that package leaflets - having already been 'patient tested' once - be tested again following the granting of a PIL.⁴⁷

Statistics do not point towards repackaging constituting a risk to public health and safety, but in such a disputed practice as repackaging it is difficult to verify the objectivity of statistics.⁴⁸ It must be stressed, however, that unlike other product groups, one quality flaw in the chemical product or a wrongly or inadequately labelled pharmaceutical product can have fatal consequences. In this respect, the

⁴³ See chapter 7(3.2.2) above.

⁴⁴ See chapter 7(3.2.1) above.

⁴⁵ Articles 54(h) and 55(3) of Council Directive 2001/83/EC on the Community code relating to medicinal products for human use [2001] O.J. L311/67.

⁴⁶ N. 19 above.

⁴⁷ See chapter 7(3.2.3) above.

⁴⁸ See chapter 7(4) above.

common market objective must be secondary to the need to protect public health and safety.

The focus on primary and secondary resources has allowed for a thorough analysis of the Commission's and the Community courts' interpretation of the conformity of parallel import-restrictive measures with the EC Treaty. This doctrinal study has therefore clarified the legal framework governing parallel trade in pharmaceutical products, bringing to light the Community courts' and institutions' approach to the concept of balancing the common market objective with the need to promote and protect public health and safety. The originality of the contribution of this thesis to the academic and professional knowledge-base is two-fold. First, the laws and regulations governing the 'simplified procedure' for parallel imported products,⁴⁹ and the Community's labelling and package leaflet regulations are largely neglected by academic scholars.⁵⁰ In addition, recent events involving the interpretation of Articles 81 and 82 EC Treaty⁵¹ and the inclusion of a 'specific mechanism' in the 2003 Act of Accession⁵² demand novel and original research. Secondly, the thesis provides a novel exploration of the interrelationship between the different laws and regulations governing the various separate stages in the distribution chain of parallel imported pharmaceutical products. These laws and regulations must complement each other in order to facilitate the establishment of a common market without compromising public health and safety. To this end, the following recommendations seek to strengthen the balance between the common market objective and the need to protect and promote public health and safety.

⁴⁹ See chapter 4 above.

⁵⁰ See chapter 7 above.

⁵¹ See Cases C-2-3/01, n. 4 above; Case C-53/03, n. 13 above; and Case T-168/01, n. 15 above.

⁵² N. 25 above. See chapter 5(5) above.

2. **Recommendations**

2.1. *Harmonising national pricing regulations*

The underlying reason for the existence of parallel trade in pharmaceutical products is the disparity in pricing regulations as a consequence of the retained national competence over the protection of public health and safety in accordance with Article 30 EC Treaty. In this context, parallel importation of pharmaceutical products does not lead to price convergence, but merely results in the importation of the exporting Member State's pricing policy. A solution to this problem would be to harmonise national pharmaceutical pricing regulations throughout the Community so as to make parallel trade commercially unviable. This would be the best option for the European pharmaceutical industry as well as society as a whole. The current legal framework governing parallel trade is disparate and complex. Even if the need to promote future R&D could be achieved by allowing manufacturers more freedom under the EC Treaty, and the protection of public health and safety can be maintained by implementing recommendation 3 below, this could jeopardise legal certainty and add to the complexity of the law. Indeed, parallel trade may only prove to be a temporary practice in a transition period between partial- and full integration of Member State markets if pharmaceutical pricing regulations were harmonised throughout the Community. Further research is needed in this area, but as a preliminary remark it can be said that, albeit theoretically ideal, this recommendation is not likely to be implemented by the Member States for several reasons. First, pharmaceutical pricing is, as mentioned, part of the retained national competence over the protection of public health and safety. Secondly, currency fluctuations and variations in Member States purchasing power parity (PPP) will make such harmonisation difficult. Even if the harmonised regulations would allow for PPP and currency adjustments, this would lead to a disparity in prices which is the very reason for harmonising the pricing regulations in the first place. Finally, there is the possibility, however insignificant, that such harmonisation will be considered 'price-fixing,' and thus not in conformity with Article 81 EC Treaty, if it

is the result of a mere agreement between Member States as opposed to being the result of a Council or Commission measure.

2.2 *Providing an objective justification or exemption for certain parallel import-restrictive abuses/agreements*

If failing to implement recommendation 1 above, manufacturers must be given a certain amount of freedom to restrict parallel trade. As argued by Advocate General Jacobs in *Syfait*,⁵³ competition on the pharmaceutical market is already distorted due to Member State pricing regulations. To allow parallel trade, despite the fact that competition is already distorted, can have severe consequences for the promotion of public health and safety by reducing the funds made available for future R&D.⁵⁴ The special characteristics of the pharmaceutical market should therefore provide an objective justification for certain parallel import-restrictive measures by dominant undertakings. Alternatively, it is hoped that the proposed 'meeting competition defence' in the recent Commission discussion paper on the application of Article 82 of the Treaty to exclusionary abuses will provide such a justification for parallel import-restrictive measures.⁵⁵ The measure must be non-discriminatory and proportionate, for example, refusing to supply only in instances when the orders are out of proportion to the prevalent demand in the relevant Member State, or setting the price according to the reimbursement level in the relevant Member State. Similarly, the Commission must take into consideration, when applying Article 81(3) EC Treaty, the fact that certain dual-pricing agreements may remedy a loss in efficiency, and provide a gain in efficiency by allowing for an increase in funds made available by the pharmaceutical company for future R&D.⁵⁶

⁵³ N. 13 above.

⁵⁴ See chapter 1(3.1) above. This is a controversial issue, but the pharmaceutical industry definitely tends to favour the US to Europe as a location for carrying out R&D and introducing new products. According to the pharmaceutical industry, this is partly a result of the industry's inability to restrict the practice of parallel trade: see chapter 1(2) above.

⁵⁵ DG Competition discussion paper on the application of Article 82 of the Treaty to exclusionary abuses – public consultation, DG Competition (December 2005), (<<http://ec.europa.eu/comm/competition/antitrust/others/discpaper2005.pdf>>), para. 81. See also chapter 2(2.5) above.

⁵⁶ See Case T-168/01, n. 15 above.

By providing an objective justification or declaring such measures to be exempt under Article 81(3) EC Treaty, the common market objective would be proportional to the need to promote public health and safety. Advocate General Jacobs's Opinion in *Syfait*⁵⁷ and the CFI's *GlaxoWellcome*⁵⁸ judgment should therefore be endorsed. This would compensate for the effects of the 'exhaustion of rights' doctrine on the need to promote R&D.

2.3 *Gradually making the Community marketing authorisation procedure compulsory*

The Community market for pharmaceutical products consists of pharmaceutical products benefiting from a range of different marketing authorisations and licences granted using different procedures. This complicated system threatens the free movement of pharmaceutical products and, to an extent, the safety and efficacy of the pharmaceutical trade. The safety and efficacy is weakened due to the fact that there is no centralisation. Member States have to rely on the European Medicines Agency (EMA) and other Member State Medicines Control Agencies.

This can be remedied without affecting legal certainty by gradually making the centralised Community marketing authorisation procedure compulsory for more categories of pharmaceutical products.⁵⁹ This would solve many problems for all the three involved parties; the marketing authorisation holder, the parallel importer, and society at large, not to mention further Community integration. Since parallel imported products which benefit from a Community marketing authorisation do not need to apply for a PIL, the 'simplified procedure' would be abolished altogether. Further, once the marketing authorisation is withdrawn, parallel importation will not be possible. However, since most withdrawn marketing authorisations are replaced by new marketing authorisations for similar products, parallel importation of the replacing product can commence instantly. Repackaging of pharmaceutical

⁵⁷ N. 13 above.

⁵⁸ Case T-168/01, n. 15 above.

⁵⁹ See chapter 3(2.1-2.2) on the centralised procedure.

products would not be necessary, at least not to the same extent as it is with products which benefit from PILs. This would increase public health and safety, not least since bundling together of different packs with different expiration dates and the removal of batch codes from centrally authorised products is not allowed.

As discussed in chapter 3(4), the wording of Regulation 726/2004 indeed suggests that the Community marketing authorisation procedure may gradually become compulsory for more product groups.⁶⁰ This is supported by the fact that, as of 20 May 2008, the procedure will be made compulsory for products to treat auto-immune diseases, immune dysfunctions and viral diseases.⁶¹ However, objections to such reform are likely to come from national Medicines Control Agencies, and indirectly Member States, since it would lead to a decrease in responsibilities and possible down-sizing of such agencies, and the regulation of the national pharmaceutical industry and market falls under the retained national competence over the protection of public health and safety in accordance with Article 30 EC Treaty. Manufacturers may also oppose this recommendation as it potentially affects the ability to foreclose national markets even though that ability should be non-existent following the *Paranova* cases⁶² and the *AstraZeneca* Decision.⁶³ However, the benefit of only having to apply for one marketing authorisation is likely to outweigh this disadvantage. Similarly, parallel importers may object to the proposal due to its centralisation. If the Community marketing authorisation is withdrawn, it will be withdrawn throughout the Community. However, this argument should be outweighed by the benefit of not having to apply for a PIL in the first place.

⁶⁰ See Annex to Council Regulation (EC) 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] O.J. L136/01.

⁶¹ *ibid.*

⁶² Case C-15/01, n. 23 above; and Case C-113/01, n. 23 above.

⁶³ In Commission Decision COMP/A.37.507/F3-AstraZeneca of 15 July 2005 (not yet reported, but non-confidential version available on DG Competition's website: <http://ec.europa.eu/comm/competition/index_en.html>), the Commission held that the practice of withdrawing marketing authorisations, with the intention of blocking parallel imports, is an infringement of Article 82 EC Treaty if the undertaking holds a dominant position. See chapter 2(2.4.2) above.

Applying the mutual recognition principle to national marketing authorisations⁶⁴ (in effect making the ‘mutual recognition’ procedure compulsory for all pharmaceutical products)⁶⁵ would perhaps be more welcomed by Member States than eventually making the centralised procedure compulsory. It would potentially increase safety, but would still require certain cooperation and exchange of information between Member States, while not solving the issue of PILs: a PIL would still be needed in order to guarantee safety in the absence of a centralised procedure only allowing for the marketing of a single version in terms of origin, pack size, and brand name of the authorised product.⁶⁶

2.4 *Applying a strict interpretation of the 2003 ‘specific mechanism’*

Allowing parallel importers to circumvent the ‘specific mechanism’ by routing the transport of the goods through, and carrying out the repackaging process, in Member States where the ‘specific mechanism’ is not applicable would undermine the very purpose of the mechanism, and have an effect on the need to promote future R&D, thus indirectly affecting public health and safety. As the ‘specific mechanism’ allows patent proprietors to prevent the ‘import *and* marketing’⁶⁷ of the product, the ECJ would be well advised to simply rule that the ‘specific mechanism’ can be invoked, at least, up until the proprietor has consented to such marketing in a Member State within the scope of the mechanism, or until first marketing in a Member State outside the scope of the mechanism. This will prevent the rights under the mechanism being exhausted after first importation.⁶⁸

⁶⁴ See Case 120/78 *Rewe-Zentrale AG v. Bundesmonopolverwaltung für Branntwein* (Cassis de Dijon) [1979] E.C.R. 649.

⁶⁵ See chapter 3(2.2) above on the mutual recognition procedure.

⁶⁶ See chapter 3(2.1.1) above.

⁶⁷ N. 25 above, para 2.

⁶⁸ See chapter 5(5.2.2) above.

2.5 *Limiting the exhaustion of rights doctrine to strictly necessary repackaging and rebranding*

The exhaustion of rights doctrine cannot be criticised from a public health and safety perspective, as this falls upon the Community's labelling and package leaflet regulations to safeguard. Since the doctrine is an important aspect of the common market objective, it must be equally applicable to all product groups in order to preserve legal certainty.

However, the doctrine should be limited to strictly 'necessary' repackaging and rebranding. The ECJ may have taken the pro-integration aspect a step too far by introducing the 'customer preference test,' allowing parallel importers to adjust to the different Member State market conditions, instead of delegating the responsibility of letting customers and commercial forces in the Community grow accustomed to repackaged products to the parallel importers themselves.⁶⁹ The 'exhaustion of rights' doctrine, in relation to parallel imported pharmaceutical products, has with the introduction of the 'customer preference test' and the practice of 'co-branding'⁷⁰ developed into a grey-zone between enabling parallel trade and satisfying parallel importers' commercial aspirations.

It is therefore hoped that the Court will follow Advocate General Sharpston's Opinion in Case C-348/04, in which the Advocate General states that 'the requirement that repackaging be necessary...applies merely to the fact of reboxing and does not extend to the precise manner and style thereof.'⁷¹ This will allow national courts to implement a wide definition of 'legitimate reason' for the purpose of prohibiting co-branding, as parallel traders will not be able to show that such (particular) co-branding is 'necessary' in order to gain market access. Allowing co-branding if deemed 'necessary' in order to fulfil the common market objective, as a separate and additional 'necessity/market partitioning' test, would have an

⁶⁹ See chapter 6(4.2) above.

⁷⁰ See Case chapter 6(4.2) above.

⁷¹ Advocate General Sharpston in Case C-348/04, n. 41 above, para. 100 (delivered on 6 April 2006, not yet reported).

unnecessarily negative impact on the trademark owner's rights to the benefit of the parallel importers' commercial aspirations. The ECJ must limit the doctrine to strictly 'necessary' repackaging and rebranding, sending a clear signal to national courts that further rulings should not be necessary within this area of the law.

2.6 *Drawing up clear guidelines for the repackaging of parallel imported pharmaceutical products*

Failing to implement recommendation 3,⁷² the Community should draw up clear guidelines and/or (preferably) include these in a future amendment to Directive 2001/83/EC.⁷³ This should;

- Clarify the responsibility of national Medicines Control Agencies, setting up clear channels of cooperation. Particularly concerning the granting and enforcement of MALs and WDLs, as the current requirement that MAL holders must carry out the repackaging process in the Member State issuing the licence may not be compatible with Article 28 EC Treaty.⁷⁴ The same argument can be applied to national legislation prohibiting MAL holders in other Member States from importing pharmaceutical products in the absence of holding a WDL in the Member State of importation.⁷⁵ Strong and structured cooperation will be needed in order to guarantee public health and safety should the ECJ consider such legislation to be incompatible with Articles 28 *and* 30 EC Treaty in a future ruling.
- Introduce clear guidelines on the re-attachment of batch codes.⁷⁶ Perhaps the most plausible solution to the problems associated with this practice is to establish an alternative system of 're-pack batch codes.' By substituting the original codes by new codes that can be translated into the original code by

⁷² Gradually making the Community marketing authorisation procedure compulsory: see pp. 264-266 above.

⁷³ N. 45 above.

⁷⁴ See chapter 7(2) above.

⁷⁵ *ibid.*

⁷⁶ See chapter 7(3.2.2) above.

the parallel importer, the manufacturer will be able to trace the goods in the event of a product recall from the information given by the parallel importer, thus only revealing the source of supply under such circumstances. This would allow the ECJ to maintain its pro-integration policy without affecting public health and safety.

Even though statistics do not suggest that repackaging constitutes a risk to public health and safety,⁷⁷ the implementation of this recommendation will strengthen the Community regulatory framework so as to minimise the *potential* risk to public health and safety. Parallel importers have much to gain from the implementation of, and their subsequent compliance, with this recommendation - not least to increase patients' confidence in the safety of the trade.

⁷⁷ See chapter 7(4) above.

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EMA website

<<http://www.emea.eu.int>>

EMA (website on EPAR)

<<http://www.emea.eu.int/htms/human/epar/epar.htm>>

ESRC

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The European Association of Euro-pharmaceutical Companies (EAEPIC)

<<http://www.eaepc.org>>

The European Commission

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The European Commission: DG Enterprise and Industry – Unit F2 Pharmaceuticals

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European Generics Medicine Association

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