



Master of European Affairs, Business Section - Thesis

**Pharmaceutical Manufacturer Strategies to Parallel
Importation in the EU: A Strategic Update in Light of
European Court of Justice Rulings**

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Abstract

Title: Pharmaceutical Manufacturer Strategies to Parallel Importation in the EU: A Strategic Update in Light of European Court of Justice Rulings

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Problem:

Parallel trade occurs when a product is released on one market, and an importer purchases the product in question on a lower priced market, and subsequently imports the product to a higher priced market, and sells it there. Parallel trade of pharmaceuticals in the European Union is prevalent since the legal, business and political environment makes the trade relatively easy and legal. This is largely because of differing price containment methods employed by European Member States to control health care costs. This creates an environment where the pharmaceutical manufacturers are not free to set the prices of pharmaceuticals as they wish, and different prices across Member States is the norm. This eats into the profits of the manufacturers, and creates a need for effective, and legal strategies to prevent the gray market.

Objective:

Stated concisely, the goal of this paper is to:

Consider a wide spectrum of strategic options found in academic literature to combat parallel trade, assess strategic options available to pharmaceutical companies in light of the current legal framework in the EU, and evaluate whether current strategies employed have resulted in lessening competitive pressure from parallel importers.

Working Structure:

This paper uses both primary (interviews, numerical analysis), and secondary resources to come to its conclusions. After the introduction, a theoretical background is presented which shows that the market for pharmaceutical parallel trade in Europe is ripe. Effects on the manufacturer follow to show when and why a firm may want to prevent the gray market. The political section of the paper shows that the market for pharmaceuticals is only partially harmonized, and is likely to remain so, and also presents the special mechanism for newly acceding countries. The legal analysis looks mainly at the relevant case law, and the strategic implications of the cases is then looked at. A brief numerical analysis then tests three hypotheses to see if strategies have been successful, and if parallel trade competition causes more pressure on prices. Finally, strategies that were considered earlier in the paper are re-assessed in light of the legal and political environment.

Preface

Dear Reader:

This piece of work should be the final submission required for completion of the Master of European Affairs Program's Business Section. This work is to bridge both the areas of European Business and European Law.

The focus of this paper is parallel trade, more specifically assessing strategies available to pharmaceutical manufacturers to prevent parallel trade after looking the current EU legal framework. The topic area I chose in part because it naturally bridges these two areas of study. The focus of this report is more specifically upon Corporate/Business Strategy, Competition Law, and Intellectual Property law.

This paper is the result of much effort on the part of the author, however, would not have been possible without the help of some key individuals that should be mentioned. I would like to thank for Cecile Brokelind for meeting with me and allowing me to direct myself to make the tough decision to change topics relatively late in the year. I would also like to thank my advisors; Jens Forssbaeck, who helped me through both topic areas I explored while conducting research; as well as Anneli Carlsson and Henrik Norinder whose advice in the last months, has been greatly appreciated.

I would also like to thank those who agreed to help me by performing interviews with me. Markos Montmar Stavroulakis of Kommerskollegium found the time to answer some questions, which was appreciated. Kim Jensen should be especially thanked, as he went above and beyond the call of duty by granting me a thorough interview on a holiday afternoon, which proved to be highly beneficial to the quality of this paper.

I would also like to thank the Lund University for providing the opportunity for international students such as myself who came to this reputable institution from across the globe to study European Affairs.

I would like to finally thank my family and friends who have supported me through the year.

Andrew Ryan

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Abbreviations Used

CFI: Court of First Instance

DP: Dominant Position

EC: European Community

ECJ: European Court of Justice

ECLR: European Common Law Review

EEA: European Economic Area

EEC: European Economic Community

EFPIA: European Federation of Pharmaceutical Industries and Associations

EFTA: European Free Trade Area

EIPR: European Journal of Intellectual Property Rights

EU: European Union

GDP: Gross Domestic Product

IP: Intellectual Property

MIP: Managing Intellectual Property

MS: Member States

NHS: National Health Service

OJ: Official Journal of the European Community

OECD: Organisation for Economic Co-operation and Development

PI: Parallel Import/ation

PT: Parallel trade/ing

TM: Trademark

TMD: Trademark Directive

1.0 Introduction

This first chapter will introduce the reader to the area of parallel trade, and the problem that will be analyzed. The purpose of the thesis is presented along with research questions. Furthermore the target audience will be hypothesized and delimitations will be presented. The intended structure of the paper will be presented in the final section.

1.1 Background

Parallel trade (PT) can be defined as: 'the legal movement of identical products between nation states without the explicit consent of the original manufacturer'.¹ They are genuine goods that are bought by the parallel importer in one country or region where the product is released by the manufacturer and sold in another country or region, usually for profit in a 'parallel' distribution network to the 'official' network distributors authorized by the intellectual property (IP) right holder. Figure 1.1 will aid in understanding how pharmaceutical parallel distribution works. The matter of concern in the EU PI is not the authenticity of the products, but rather the means of distributing the products. Other terms used for parallel trade include parallel importation (PI), gray markets² and re-importation in cases where the goods find their way back into the manufacturers country of origin after being 'officially' exported elsewhere.³

The issue of parallel trade is certainly not new. In 1871 a case appeared in the Belgian courts considering international exhaustion when the arms of French regiments were put on sale in Liege. The patent holder, Monsieur Chassepot contended a breach of patent rights since he had patents in both France and Belgium. Interestingly, the word 'epuise' (exhausted) was used, perhaps for the first time in regarding intellectual property.⁴ Likewise, a case appeared well over a hundred years ago involving a European company that saw its exclusive distribution rights limited in the USA due to an entrepreneurial parallel trader who under cut their prices in USA from importing the product from Germany.⁵ The gray trade in pharmaceuticals in the EU is likewise an old problem, having a history dating 'back to the 1970s when a number of entrepreneurial pharmacists ascertained that drug prices varied significantly between Member States of the EEC.'⁶

Parallel trade occurs in many industries in the European Union. A non-exhaustive list of industries where PT is prevalent includes: footwear, leather goods, musical recordings, motor vehicles, consumer electronics, consumer appliances, cosmetics, perfume, clothing, soft drinks, confectionary and alcoholic beverages.⁷ One area where

¹ West, Peter, Mahon, James, *Benefits to Payers and Patients From Parallel Trade*, York Health Economics Consortium, May, 2003

² Casvugil, Tamer, S., and Sikora, Ed, *How Multinationals can Counter Gray Market Imports*, Columbia Journal of World Business, Winter 1998, pg. 75, pages 75-85

³ Weigland, Robert E. *Parallel Import Channels: Options for Preserving Territorial Integrity*, Columbia Journal of World Business, Spring 1991, pg. 2

⁴ (1871) Pasicrisie belge 208. (as cited in: Forrester, Ian, S., *The Repackaging of Trade Marked Pharmaceuticals in Europe: Recent Developments*, EIPR, Issue 11, 2000.)

⁵ Appollinaris Co., V. Scherer, (1886) 27 F. 18, SDNY

⁶ The British Association of European Pharmaceutical Distributors, www.baepd.co.uk April 6, 2004

⁷ NERA, SJ Berwin & Co. *The Economic consequences of the choice of regime of exhaustion in the area of trademarks*, London, 8th February 1999

special consideration needs to be given because of its unique nature is in the pharmaceutical industry.

There are many pre-conditions that contribute to the emergence of parallel trade in a given country or region. Brought down to its basics, an opportunity for profit in parallel importation needs to exist, barriers to trade must be sufficiently low to allow for movement of the goods, and there needs to be supply source for the PI goods. Further prerequisites and catalysts include: demand for the goods, easy transportation, exchange rate fluctuations, price transparency, easy import authorization, pricing/reimbursement regulations, national support of PI, and a supportive legal environment.

The pharmaceutical sector is somewhat unique because most countries in the EU have cost containment measures in place in order to keep health service costs in check. Cost containment is performed in two broad manners, directly via price control, and indirectly through reimbursement schemes. These price and reimbursement controls keep prices for medicinal products artificially low in most Member States (MS), and price divergence still exists in the EU, in no small part because of such measures. This creates an ideal breeding ground for parallel imports (PI).

A problem arises between intellectual property rights and competition. Intellectual property rights reward and promote innovation and in so doing it decreases competition by granting monopolistic rights over a trademark, patent or copyright. Conversely, competition laws seek to promote competition by limiting the power of monopolistic actors. The conflict between these two streams of law is obvious, and is central to the study of parallel importation.⁸ To summarize, one observer calls exhaustion a contradiction, explaining that 'While patents provide incentives for innovation, they stifle competition. Competition, in turn, improves affordability, but may stifle innovation.'⁹ Unfortunately for the pharmaceutical sector, which is so heavily dependent on IP rights¹⁰, the European Court of Justice (ECJ), while recognizing the conflict, decides in generally favour of competition and the free movement of goods.

As mentioned, the legal environment can support PI in some circumstances. In combination with political objectives, such is the case in the EU. Despite these pricing and reimbursement controls, the pharmaceutical sector is not exempted from PT competition. One of the Community's fundamental objectives is to promote the free movement of goods between Member States (MS).¹¹ In strict adherence to this competitive objective, the Community Courts have noted that it is a matter of no significance that such cost containment measures exist.¹² Such cost control measures cannot stand in the way of the free movement of goods. The 'Commission has always insisted on the freedom of intermediaries to respond to price differences between Member States and engage in parallel trade as central to its policy of ensuring that distribution arrangements have a market integration and not a market partitioning

⁸ Ibid. Paragraph 10

⁹ Gonzalez Perini, Federico, *Patent vs. Trade?: The Issue of Patent Right Exhaustion, Legal Issues of Economic Integration* 30(2): pg. 133, 133–156, 2003.

¹⁰ Mansfeld, E. *Patents and Innovation: An Empirical Study, Management Science*, February 1986 – Attests that the pharmaceutical industry is at least twice as reliant on intellectual property rights as the next sector, chemicals.

¹¹ Treaty Establishing the European Community, Article 3a), and Articles 28-30

¹² Case 15/74 Centrafarm v. Sterling (1974), paragraph 2.

effect.’¹³ This goal has stood in the way of intellectual property law, although there is an exception to the free movement of goods in Article 30 for protection of commercial property. According to many of the European courts this exemption has been defined very narrowly and has seen limited successful usage. In general the ECJ has favoured parallel importers in their rulings.¹⁴ They have held onto the principle of free movement very tightly, however, the ECJ seems to be lightening their strict adherence to free movement of goods, and has let IP law serve its purpose. In addition, national courts do not seem to rule in favour of competition and free movement over IP rights with the same gusto as their big brother in Luxembourg.

The principle of exhaustion makes parallel trade possible in the EU. According to the First Sale Doctrine (exhaustion principle), the Intellectual Property (IP) owner receives the benefit of IP ownership upon release of the product onto the market when monopoly profits are reaped by the initial sale of the good/service/method.¹⁵ After that benefit is reaped, the IPR holder loses the right of control subsequent distribution since the IP right has been 'exhausted'. This allows purchasers of these goods to resell, destroy, give away, lend the goods as they see fit. The Courts in 1998 ruled that the principle of exhaustion within the EU is EEC-wide. Thus any goods released in this area have seen their IP rights 'exhausted', and parallel trade is allowed to subsequently occur anywhere in the European Economic Community (European Union in addition to Norway, Liechtenstein and Iceland).

Another area that should be understood to comprehend the environment that both the pharmaceutical and importation industries operate in is European harmonization in the area. The EU has to its credit come forward significantly in harmonizing the pharmaceutical market in the EU. However, some key areas remain to be harmonized before the gray market loses strength. Most notably, the pricing, reimbursement and pharmaceutical tax policies need to be brought in line, which is an unlikely scenario because due to the subsidiarity principle. This legal principle predominantly leaves policy areas such as health under Member State (MS) control, and pharmaceutical price harmonization would require the Council adopting an agreement on the matter. Considering the EU has not even been able to adopt a directive on parallel trade, a regulation or adoption of price harmonization in the area is even less likely.

The debate surrounding parallel trade is fierce, and there are two distinct sides to the argument. In one corner there are the gray marketers themselves who claim they are providing a market integrating, and competition promoting service to their customers. They cite advantages of parallel trade as being lower costs to consumers and health authorities. The traders use Article 28 Treaty of the European Community as their principle legal defense. The other corner finds the pharmaceutical intellectual property right holders. They state that the parallel traders are not providing any benefit to society, and indeed are surviving simply because of benevolent legislation and price controls. According to the IP holders, the importers are having a free ride on their

¹³ Green Paper on vertical restraints in EC competition policy, Executive Summary, p. Iii, <http://europa.eu.int/en/record/green/gp9701/vrsumen.htm>

¹⁴ Chaudhry, Peggy E. and Walsh, Michael, G., *Managing the Gray Market in the European Union: The Case of the Pharmaceutical Industry*, Journal of International Marketing, Vol. 3, No. 3, 1995, pg 13, pages 11-33

¹⁵ Kanavos, Panos, Costa-i-Font, Joan, Merkur, Sherry, Gemmill, Marin, *The Economic Impact of Parallel Trade in European Union Member States: a Stakeholder Analysis*

R&D, trademarks, patents, marketing and reputation. The IP holders mainly use their IP rights as a defense from parallel trade, although other legal tools are being developed in view that IP law is not proving very effective.

Parallel trade does not only affect these two groups. Other stakeholders to the argument should also be acknowledged, as they are both affected by PI, and have contributed much to research not to mention policy in the area. These other stakeholders are the Member States themselves, the Community institutions, consumer groups, health insurers (private and public), as well as the public at large. These stakeholders take differing views on the issue. The heated debate surrounding the practice makes it difficult to remain objective at times. However, it also makes the parallel trade area a particularly interesting study area.

The study of parallel trade provides an ideal research area for another reason. Research by interested parties spans an impressive spectrum of disciplines. As one observer notes: 'The causes of parallel trade are both of *legal* and *economic* nature: without the achieved integration, the possibility for trade in pharmaceuticals would not exist – and without the price differences among nationally regulated markets, no economic incentive to trade would exist.'¹⁶ It is not only legal and economic interests that are presented in academic work. Research has been undertaken looking at PI in the EU from a wide array of perspectives including: micro/macro economics, pharmacoeconomics, marketing, management, human resources, corporate strategy, health policy, political policy, competition law, licensing law, intellectual property law, and from an international trade perspective. To put the interdisciplinary problem bluntly: the problem is largely created because of political reasons (cost containment), is kept in check via the law (ECJ and national courts), and the effects are largely felt by business (drug manufacturers and importers). The fact that the topic bridges so many areas of research makes for diverse reading.

Given that most necessary pre-requisites for parallel trade are met in the EU's pharmaceutical industry, the industry has grown rapidly over since it began in the 1970s. In an interview with Kim Jensen, legal advisor of Paranova A/S, he mentioned that company founder, Erik Pfeiffer did not expect the company to grow so quickly adding '*He also thought that only a few products could be attractive for parallel imports. But the development has been somewhat different. There are a lot of products that are attractive for parallel importers. The market share is 10-12%*'.¹⁷ Every sale that the importer makes, the IP right holder loses the chance to sell the product at a higher price in the importation market, and forgoes that sale in exchange for a sale to the importer in the lower priced market. This equates to lost profits and sales revenue. In response to this, pharmaceutical manufacturers have developed strategic weapons to counter the effects of parallel trade. Some of the weapons are dulled from the existing legal framework, but some possible tools remain for use. The future of parallel importation depends in part on the success of the implementation of the pharmaceutical companies' reactionary strategies, in part on the jurisprudence of the Community Courts, and in part on the backs of political leaders.

¹⁶ Kotzian, Peter, Stuck in the Middle: Welfare Effects of the European Pharmaceutical Markets' Incomplete Integration and a Possible Remedy, Mannheimer Zentrum für Europäische Sozialforschung, 2002 page 4

¹⁷ Interview with Kim Jensen, Advokat, Paranova A/S, May, 6, 2004

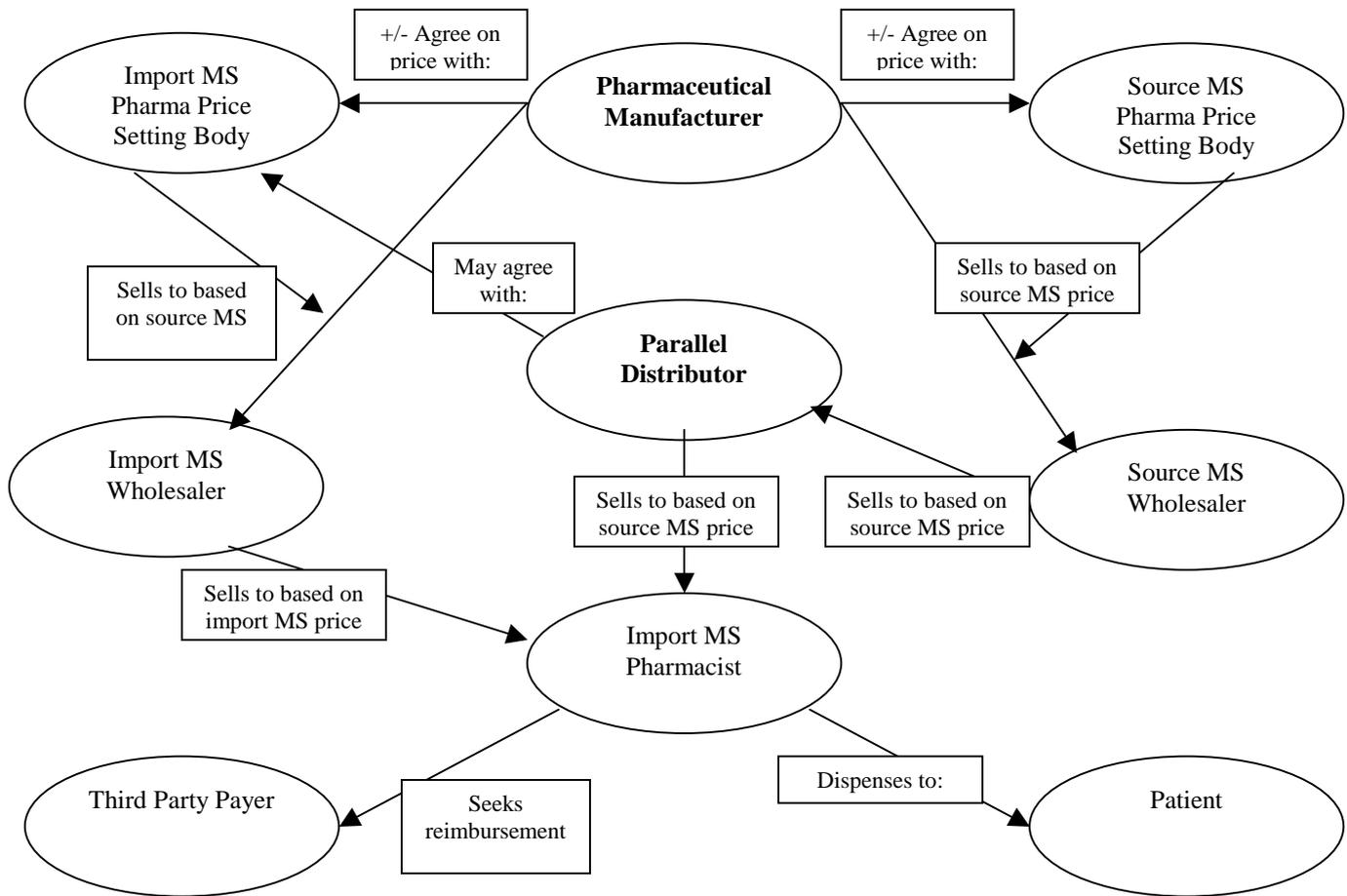


Figure 1: Reimbursed Parallel Pharmaceutical Distribution Chain¹⁸

1.2 Problem Discussion

As has been mentioned, there has been good deal of controversy regarding parallel trade of pharmaceuticals in the European Union. The simple fact remains that until Member States of the EU harmonize their pricing and reimbursement policies of medicinal goods, the gray market is likely to continue in full force. A major legal issue discussed above regarding the contradiction between competition and IP protection will leave the European courts with ample case law to work with regarding PI issues.

The jurisprudence of the European Court of Justice is constantly evolving, and it changes the parameters in which traders and IP holders operate. Furthermore, pricing and reimbursement practices change with equivalent speed. Changing practices of various stakeholders including importers, Community institutions, and pharmaceutical companies further make confusion a likely outcome of a brief look into the area. Created also, is the need for timely research in the area.

¹⁸ Adapted from diagram in: West, Peter, Mahon, James, *Benefits to Payers and Patients From Parallel Trade*, York Health Economics Consortium, May, 2003, pg. 3.

There is a wealth of academic literature in the area surrounding parallel trade that will be discussed in more detail below. Research on the pharmaceutical PI market has focused primarily on intellectual property issues, benefits/detriments to parallel trade, pharmacoeconomics, pre-conditions for parallel trade and some economic analysis of PI. There is much written on strategies employable to prevent the gray market, although it is of a general nature, and much of it is outdated. Only one piece of academic work seemed to assess strategies employable by pharmaceutical manufacturers in the EU to respond to parallel trade.¹⁹ This work considered only the strategic recommendations of Casvugil, who seemingly holds the credit for authoring the capstone work on countering gray trade in 1988.²⁰ The research area of parallel importation has seen significant changes because of ECJ jurisprudence, political changes with EU expansion, pharmaceutical market harmonization (albeit uncompleted), a wealth of academic literature advances and rapid growth of the importation of medicinal products in the EU. For this reason combined with the fact that many strategic options for IP holders have not previously been considered in light of the situation faced by pharmaceutical industry in the EU, it was felt that further research could fill a current hole in academic research. In addition to this, much of the research in the area is biased depending on who financed the research. An attempt was made as far as possible to remain objective, which is made easier by not having financial backing or pressure to slant my views in a certain manner.

This paper raises an array of issues that are discussed and analyzed to varying degrees. These primary areas include:

- ™ What are the pre-requisites for a flourishing gray market in pharmaceuticals?
- ™ What are the effects of PI on the manufacturer?
- ™ When should IP holding firms react to parallel trade?
- ™ In general, what are the possible strategies available to IP holders to respond to gray trade?
- ™ What is the legal situation of the gray market of medicinal goods in the EU?
- ™ What is the EU legislation on exhaustion?
- ™ Can IP rights prevent PI?
- ™ Can importers repackage, co-brand or re-brand pharmaceutical products?
- ™ How have national courts judged PI cases?
- ™ Can Member States enact measures preventing parallel imports?
- ™ Can IP holding firms interfere and limit supply as they deem fit?
- ™ What are the most recent developments in the ECJ's jurisprudence?
- ™ Did the Bayer case have any effects on the market for PI?
- ™ What work has been done and remains to be done to harmonize the European pharmaceutical market?
- ™ In light of Court rulings, what strategies remain as possible tools for pharmaceutical companies?
- ™ Have the strategies employed in the last five years enabled pharmaceutical companies to charge higher prices? (economic analysis)

¹⁹ Chaudhry, Peggy and Michael G. Walsh, *Managing the Gray Market in the European Union, the Case of the Pharmaceutical Industry*, Journal of International Marketing, March 1994.

²⁰ Tamer, Cavusgil, S. and Sikora, Ed, *How Multinationals Can Counter Gray Market Imports*, Columbia Journal of World Business, Winter, 1998, pg. 77, pages 75-85

TM Does PI competition cause competitive pressure resulting in slower price increases than if they had no competition? (economic analysis)

1.3 Problem Definition

The research gap that exists lies in the fact that no single piece of work has considered a thorough array of possible strategies available to prevent pharmaceutical PI in the EU, and a focused strategic assessment for pharmaceutical manufacturing IP holding firms in the EU has not seen an update for nearly ten years. Stated concisely:

The purpose of this thesis is to consider a wide spectrum of strategic options found in academic literature to combat parallel trade, assess strategic options available to pharmaceutical companies in light of the current legal framework in the EU, and evaluate whether current strategies employed have resulted in lessening competitive pressure from parallel importers.

The theoretical value of the thesis lies in the fact that the constantly changing environment surrounding PI in Europe requires updated research in order to keep abreast with these changes. Strategies that could have worked ten years ago may not still be effective, and new strategies that may not have worked previously may be employed today.

1.4 Target Audience

The target audience for this work is the faculty and staff studying parallel importation in universities in Europe, and European studies programs elsewhere. It is also possible that pharmaceutical manufacturing firms and parallel importers could find the text useful given its updated legal and strategic analysis of the environment surrounding them and presentation of some original thoughts. However, it is felt that these parties are peripheral to the primary academic audience.

1.5 Delimitations

The focus of this thesis is on the environment surrounding parallel importation of pharmaceutical in the European Union. Due to the size and complexity of the area in question, not every point of discussion is touched on. The effects on other stakeholders would not affect their strategic choice to nearly the same extent as the effects on their operations. For this reason, the effect of parallel trade of pharmaceuticals was limited by and large to the effects on the manufacturers. This was in cognizance because the focus of the paper concerns the manufacturers. Thus the effects on the manufacturers were considered in primary concern in order to lead to conclusions on what strategies they need to circumvent the negative effects that they themselves see. Likewise the debate surrounding who the beneficiaries of parallel trade are was on the whole left out of discussion. These concerns are likewise of secondary concern when assessing strategic options. In addition, the starkly conflicting literature makes it difficult to determine who in fact the main beneficiaries actually are.

Seeing as the focus of this paper concentrates on pharmaceuticals, parallel trade in other areas is on the whole ignored. However, due to the lack of literature specifically on how European pharmaceutical manufacturers can face parallel trade, it was necessary to

consider strategic options presented in academic literature that generically consider how firms should counter parallel trade. This also gave the author a chance to consider a wealth of strategic options.

No internal environmental or competitive analysis of the pharmaceutical industry took place in this paper. Seeing as the focus of the paper was on competition between generally parallel traded goods and 'official' stream goods, it was felt this would not add to the thesis.

Although there is beginning to be a burgeoning parallel market for markets for pharmaceuticals, most notably between Canada and the United States, the focus for this paper remains on Europe, more specifically the European Union. This was done in order to remain within the set parameters of the program requirements, as well as a lack of knowledge on the part of the author of the legal framework regarding re-importation of pharmaceutical products in North America. The time frame studies remained on the large part after 1974 when the parallel trade market for pharmaceuticals began. Focus was placed on cases in the last decade as these are the cases that currently define the boundaries in which parallel traders and pharmaceutical manufacturers can act. An attempt was made to have a logical flow of the paper. Thus an extensive theoretical background is done in order to prepare the reader for the analytical section of the paper.

1.6 Structure of Thesis

This thesis attempts to present itself in a logical manner. The introduction section of the thesis provides a brief background to parallel trade of pharmaceuticals in the EU, a discussion of the problem at hand, a problem statement, delimitations and statement on the intended audience. A theoretical/empirical framework section follows that gives the frame of reference of the author, a discussion of the theoretical framework, approach taken, literature review/criticism, data collection, methods used and analytical methods employed.

The paper then presents a theoretical section in order to accustom the reader with parallel trade. General discussion regarding the conditions that foster parallel trade is looked at first. The related section that follows considers the pricing and reimbursement schemes employed in the EU that is necessary in order to understand the opportunity presented to parallel traders.

The following analytical section of the paper focuses on the potential effects of parallel trade on the pharmaceutical manufacturer. Broad presentations of possible strategies that are presented in academic literature to combat parallel trade are then looked at. A section that looks at the political arena surrounding PI in the EU precedes the legal section. The legal analysis follows this section that discusses the historical and current case law surrounding PI in the EU after a brief background. Strategic implications of the case law presented are then given. The next section of the paper seeks to determine from looking at pharmaceutical pricing data whether IP holding firms have been successful in countering parallel trade over the last five years. In light of the legal/political and considering the success of strategic countering to parallel importation, the possible strategies that remain for parallel importers will be assessed. Several appendices and a bibliography then follow a brief conclusion.

2.0 Empirical and Theoretical Frameworks

This section of the thesis explains how the information was gathered, selected, organized, and handled in order to be provide the author with fuel for coming to a conclusion. The empirical framework, theoretical framework, data collection techniques, use of primary and secondary data, literature review and criticism and the author's frame of reference is all presented in this section of the paper.

2.1 Empirical Framework

This report, as far as remains possible, attempts to keep an objective view on parallel importation of pharmaceuticals in the EU. The bulk of this report uses a fusion of existing research and case law to come to its conclusions. This method was in part because of time constraints, and in part because of the wealth of information on the EU PI situation. Furthermore, this method was deemed to be acceptable because collectively, the literature gave a broad selection of strategies to choose from, a solid base for the theoretical section of the paper, and support for the conclusions of the paper. A deductive approach for the paper was taken in so far that the background and analysis are largely based from existing literature in the field. Some of the findings of this literature were extrapolated upon and incorporated into the analytical section of the thesis. The paper greatly relied on qualitative data and assumptions. It is not supported from case analysis because of the limiting nature of such work.

Secondary data is fortified with a selected primary source interview with actors that are knowledgeable of the subject matter of the thesis. The primary source used does not provide the main information source of the thesis, but rather supports its findings. Some primary empirical research was also conducted in order to prove certain points. The empirical section of the paper attempts to remain unbiased by its reliance on numbers. The section only takes into account pricing in one country, and conclusions should not be drawn far beyond this. A deductive technique is used in drawing conclusion from empirical results. Other considerations would need to be accounted for factual findings. Conclusions drawn from the empirical section of the paper provided mixed support. Some hypotheses did not prove to be true, while one did prove to be true.

2.2 Theoretical Framework

The pharmaceutical industry is one of the most heavily regulated industries in Europe. The interdisciplinary ground in which parallel trade operates, balancing political, legal, economics and business issues is likewise complex. The constantly evolving reimbursement and pricing policies and ECJ jurisprudence in the area certainly do not detract from the complexity of the issue at hand.

For this reason, a theoretical section precedes the analytical section of the paper. This section provides the reader with the understanding of environment that needs to exist for parallel trade to exist. A specific section is provided on pharmaceutical reimbursement and pricing operations by EU Member States in order to accustom the reader with such practices and realize that this is the primary reason why parallel trading of pharmaceuticals is so prevalent in the European Union.

2.3 Data Collection Techniques, Use of Primary and Secondary Sources

2.3.1 Business Data Collection

For the *business* section of this report, the bulk of the information used for this thesis involved secondary source usage. To gain a comprehensive view of the parallel trade industry, as many information sources as possible were used in locating information. However, some secondary data sources are also used to fortify the findings of the secondary research. Primary interviews and numerical analyses were performed to strengthen the secondary analysis

2.3.2 Law Data Collection

For the *legal* section of the report, case law, and case opinions formed the back bone of the material used. Cases from the European Court of Justice were found on the curia.eu.int website. EFTA cases were found on that court's website. National cases were found on the national court web sites when the cases in English, and case commentary was referred to when cases were only available in other languages. Case commentary in academic journals was used to help the author locate important passages in the case law, and is some times directly used.

2.3.3 Literature Search

I conducted my literature search in an effort to gather information on parallel trade, and its effect on Europé. I looked for empirical and non-empirical research, and admittedly poached the reference lists of core research papers to find out common literature strains to reports on parallel trade. Starting off, I started by using key words and typing them into search engines (notably google.com) to get me started. The key words included:

- Parallel import/export
- Parallel trade
- Parallel trade Europe
- Gre(a)y goods
- Gre(a)y trade
- Gre(a)y import/export
- Re-import
- Re-importation
- Pharmaceutical trade
- Pharmaceutical export/import
- Pharmaceutical parallel
- Drug import/export
- ECJ parallel trade
- ECJ parallel import/export
- ECJ repackaging
- Journal article parallel trade/import/export
- Thesis parallel trade/import/export
- Working paper parallel trade/import/export

Lund University's ELIN database was used heavily in all cases. Heavier use of Kluwer, ABI Inform, EconLit, World Bank Documents and Reports, Eur-lex, Index to foreign Legal Periodicals, Business Source Premier, Blackwell Synergy, Thomson Research and Economist/EIU should be mentioned. In addition to this, use of Copenhagen Business School and Göteborg Business Schools on line and bricks-and-mortar libraries aided in the search for information. Access to certain articles that were not available through ELIN were often found using these other resources.

On line tools were also used extensively. Websites used heavily include europa.eu.int, curia.eu.int, pharmacos.eudra.eu.int, kluwerlawonline.com and euractiv.com.

Throughout when research became more specific, additional searches were performed in relation to certain concepts, or cases as they arose. For example:

- ‘Directive 65/65’
- ‘C-16/74 Centrafarm commentary’
- ‘Business strategy parallel trade’
- ‘Parallel trade pharmaceutical protective measure’

Some information has been attained from the Swedish government, trade organizations, and independent research entities.

In some cases, especially in searching for information of business strategies to counter the gray market, it was necessary to visit traditional libraries and photocopy the original journal articles. Libraries visited include: Lund University’s Juridicum, Economics and Main libraries, Copenhagen Business School’s Solbjerg Plads library, and Göteborg University’s Economics library. Additionally, an attempt was made to gain free access to Visiongain’s ‘Parallel Trade in Global Pharma 2003’ report by contacting Visiongain directly. The attempt remained that as access was denied.

2.3.4 Primary Data Usage

In order to strengthen the conclusions drawn from the secondary research, it was felt that some primary research would help matters. After asking several pharmaceutical companies, government departments and parallel trading companies via email, two interview subjects agreed to perform an in-depth interview with me, and one responded briefly to questions posed via e-mail.

The first interview subject was Kim Jensen who is a legal advisor for Danish parallel importation firm Paranova A/S. It is felt that few people in Europe that would have a whole view of the legal situation facing parallel importers and pharmaceutical companies in regards to parallel trade. It is a fact that Paranova has battling for their right to operate Community and national courts for much of its existence, including central references to the ECJ regarding parallel importation. Mr. Jensen is the only full time ‘Advokat’ employed at Paranova A/S, is in charge of legal operations in Sweden, Austria, Finland, and Norway for the company, and has personally represented Paranova in Court. Furthermore, since Paranova is the largest pharmaceutical parallel importer in Nordic countries, Mr. Jensen has first hand knowledge of the strategic tactics employed by the pharmaceutical industry to stifle their operations.

The second respondent was Markos Montmar Stavroulakis. He is employee of the Swedish Board of Trade, Kommerskollegium, however, made it clear he was answering in his capacity as a lawyer, and not an employee of Kommerskollegium. He wrote his Masters thesis on the subject of PI in 1998, and currently handles all matters parallel trade related for the Kommerskollegium.

In addition to interviews, some empirical analysis was performed. The information source was the Danish Medicines Authority, which publishes bi-weekly pricing information of every pharmaceutical sold in the country over the last five years. This data set includes information on whether the product was sold by a parallel trader or through 'official' streams.

The drugs selected in the analysis were taken from the top 25 drugs by volume and sales in Denmark in 2002, the top 25 drugs of 2001 in Denmark, as well as drugs from Dr. Kanavos' LSE study of 2003. Where comparisons are made between drugs with and without parallel importation competition, a total of 21 drugs with around 100 variations are looked at. When comparing parallel imported drugs with official stream goods, 7 drugs are looked in 48 variations.

An index was created that set the 1999 price at 100, and tracked movements from that base level. One of the graphs calculated the average index price over the five-year period, and another tracked the indexed prices over the five-year period. It was found that the average index price over the five-year period was significantly higher for the pharmaceuticals that did not have any consistent parallel trade competition over the five-year period. Tracking the index prices over time found that the prices of pharmaceuticals with and without parallel competition went up and down with a high degree of correlation.

A third analysis looked at average bi-weekly percentage price movements on a year-to-year basis. It was hypothesized that if pharmaceutical manufacturers were successful in employing counteractive strategies, they would have seen less price competition from parallel traders, and thus should have been able to increase prices to a greater extent in recent years than earlier years. This hypothesis was not supported from the graph.

The empirical analysis should be seen for what it is; a one-country study concentrating on a small basket of drugs. Implications are found from such analysis, not hard proof of the hypotheses presented.

2.5 Literature Review and Criticism

The literature found came from two divergently thinking schools. The first school of thought was that which supported the parallel importers. This group included on the importers themselves, and organizations that represent them, many of the Member State governments, and consumer groups. The opposing view was taken the IP holding pharmaceutical manufacturers and MS who support them, notably, France. When looking at the benefits and costs of parallel importation, there seemed to be two answers to the same questions depending on whose point of view was being presented. An example will suffice to prove the point, in 2003; two pivotal reports were released regarding the beneficiaries of pharmaceutical PI. They both had conflicting findings. When one looked a bit further into why this might be the case, one found out that the London School of Economics report was financed by pharmaceutical monolith Johnson & Johnson, while the York Health Economics Consortium study was financed by an association of parallel importers.²¹

²¹ West, Peter, Mahon, James, *Benefits to Payers and Patients From Parallel Trade*, York Health Economics Consortium, May, 2003. Found that total direct savings of € 631,000,000. Kanavos, Panos, Costa-i-Font, Joan, Merkur, Sherry, Gemmill, Marin, *The Economic Impact of Parallel Trade in*

The literature found that delved into the strategic responses of IP holders was largely of American origin in the late 1980s and early 1990s. It is hypothesized that the wealth of literature at the time was due to the USA Supreme Court K-Mart ruling²² which confirmed that American trademark owners 'generally cannot prevent unauthorized importation or products bearing their own marks or names.'²³ There seemed to be surprisingly little written on the subject recently, and it seems that the capstone piece of academic literature on the subject is Cavusgil and Sikora's work in 1988,²⁴ which was used by Chaudhry in 1995²⁵ to look at the European pharmaceutical industry. Cavusgil and Sikora²⁶ cited fourteen possibilities wrote the most thorough evaluation of various strategic maneuvers. Fourteen possible strategic possibilities are presented in two categories, seven categorized as reactive, and seven categorized as proactive. Some of their possibilities are mentioned above.

2.6 Frame of Reference

My background is mainly in Business Administration, though I also have some experience with law, politics and history in an academic environment. Given that the parallel trade of pharmaceuticals covers such a wide spectrum of areas, my diverse background should benefit the analysis. Specifically, my background in European law has provided me with a good overall view of the European legal framework, and analytical skills in regards to ECJ case law. I have taken several courses in business strategy and research skills, which have provided me with a background to assess the strategic approaches suggested. It is admitted that my background in statistics is not strong, so the reader should keep this in mind when looking at the empirical analysis presented.

European Union Member States: a Stakeholder Analysis, London School of Economics, 2003. Found that total direct savings of € 44,151,000 for the same five countries (€ 99,508,000 with claw back). It is hypothesized that the difference in findings stems at least in part from who commissioned the studies.

²² 486 US176, K Mart vs. Cartier, Inc, 1988

²³ Cespedes, Frank, V., Corey, Raymond, E., Kasturi, Rangan, V., Gray Markets: Causes and Cures, Harvard Business Review, July-August, 1988, pg. 76, pages 75-82

²⁴ Cavusgil, Tamer, S., Sikora, Ed., *How Multinationals can Counter Gray Market Imports*, Columbia Journal of World Business, Winter, 1988, page 75-85

²⁵ Chaudhry, Peggy E. and Walsh, Michael, G., *Managing the Gray Market in the European Union: The Case of the Pharmaceutical Industry*, Journal of International Marketing, Vol. 3, No. 3, 1995, pg 22, pages 11-33

²⁶ Cavusgil, Tamer, S., Sikora, Ed., *How Multinationals can Counter Gray Market Imports*, Columbia Journal of World Business, Winter, 1988, pg. 77, page 75-85

3.0 Theoretical Background

This section of the report will give the reader a background in parallel importation by firstly outlining the necessary pre-conditions for parallel trade to exist including cost control mechanisms used by Member States. After it is shown that the EU provides an ideal area for parallel trade to function, the effects on the manufacturer to come to an idea as to when reactionary strategies may become necessary to employ.

3.1 Pre-conditions for Parallel Trade

As has been looked at in some detail above, a supportive legal and political environment for parallel trade creates a breeding ground for parallel traders to thrive. Certainly, in the EU, such a legal environment exists. Many of the other pre-conditions are commercial in nature.

3.1.1 Price Differences and Elasticity

The first, and primary pre-condition for parallel trade to exist is that there needs to be a difference in prices between the source state and the import state. In the following section, the pricing and reimbursement schemes, which are a primary cause of European price differentials is explored in greater detail. It has been stated that parallel traders need a price difference of 15-20% to make parallel trading of pharmaceuticals profitable.²⁷ In fact, some countries use generic/parallel import substitution rules that oblige pharmacists to choose PI pharmaceuticals if the price is cheaper. International price differences can occur for many reasons such as taxes, insurance systems, purchasing power, national price discrimination, historical and cultural differences, and the IP holders marketing strategy. Some argue that price discrimination by the IP holding monopolist according to national price elasticities is the main reason for PT.²⁸ In the EU pharmaceutical market it is more likely that the main reason for price differences in the EU is pharmaceutical cost containment measures by Member States. With price differences between the highest and lowest priced Member States in the EU averaging around 18%,²⁹ and the government price controls ranging between relatively free pricing nations such as Denmark and Germany³⁰ to Member States such as Greece which attempt to remain well below the European average pharmaceutical price³¹, this prerequisite is met.

3.1.2 Patient Population

²⁷ Multiple Authors, *The Pharmaceutical Parallel Trade Outlook: Challenges to Pharmaceutical Companies Across Europe and the US*, Reuters Business Insight, Reuters Business Insight, 2003, pg. 24, A conflicting price difference requirement of 35-30% is found by the Swedish Competition Authority: *Parallel Imports – Effects of the Silhouette Ruling*, Konkurrentsverket, 1999, page 28

²⁸ West, Peter, Mahon, James, *Benefits to Payers and Patients From Parallel Trade*, York Health Economics Consortium, May, 2003, pg. 1. and Cespedes, Frank; Corey, Raymond E. and Kasturi Rangan, V. *Gray Markets: Causes and Cures*, Harvard Business Review, July-August 1998, pg. 76, pages 75-82

²⁹ *Pharmaceutical Pricing Strategies: Optimizing Returns throughout R&D and Marketing*, Reuters Business Insight, 2003, page 34

³⁰ West, Peter, Mahon, James, *Benefits to Payers and Patients From Parallel Trade*, York Health Economics Consortium, May, 2003, pg. 7, 47

³¹ Multiple Authors, *The Pharmaceutical Parallel Trade Outlook: Challenges to Pharmaceutical Companies Across Europe and the US*, Reuters Business Insight, Reuters Business Insight, 2003, pg. 22. Greece uses the lowest price in the EU as a comparison when utilizing reference pricing.

However, not all drugs with high price differences are equally attractive to parallel importers. A catalyst for parallel trade to exist in a drug category is a high patient population. Drugs with not only a high patient population but that also treat a chronic disease with consistent demand makes a drug especially attractive to import. According to a recent report by Reuters on parallel trade, drugs that treat the following conditions are particularly attractive to parallel traders: anti-hypertension, rhinitis, asthma, diabetes, and depression.³²

3.1.3 Supply Source

Parallel importers need to have access to surplus drugs in the exporting state. The availability of drugs in the exporting country is necessary for pharmaceutical gray trade to exist. It is often wholesalers in the source states that are the suppliers of parallel importers. It is sometimes exclusive distributors of pharmaceuticals in a region that are suppliers of parallel trade. The rogue trader can often easily rationalize the decision to supply parallel traders. Since the parallel importer is often willing to pay more than the governmental body or pharmacist in charge of buying drugs in a particular MS, it often makes sense for wholesalers to supply traders. On the demand side, the demand for the drugs in the importing state needs to be sufficiently high to warrant the trade. If there is an existing supply of drugs that are set at a low enough price in the importing state, PI will be deterred.

3.1.4 Exchange Rates

Fluctuating exchange rates are also another reason why parallel trade sometimes flourishes. In the EU, much has changed since the introduction of the Euro introduction because exchange rate movements have no value to parallel traders within the Euro-zone. However, three of the main importers of pharmaceutical parallel imports (Denmark, Sweden, and the United Kingdom) still operate their own currencies, and parallel traders can still optimize benefits by taking advantage of exchange rate movements. For example, after the South East Asian markets busted in the late 1990s, the devalued currencies, and the dead construction market prompted parallel traders to re-import construction equipment to America. The result was a tidal wave of construction equipment to America at deeply discounted prices.³³ Another scenario could be if the Swedish Kroner is expected to rise in the coming months against the Euro. A smart parallel trader would purchase a swath of pharmaceutical supply now in a country such as Greece or Spain that uses the Euro, and subsequently sell the drugs in Sweden when the Kroner has appreciated. The profit margins for the parallel trader are thus widened if the expected rise comes to fruition. A fast change in exchange rates (rise in importing country) is advantageous to parallel traders because often the manufacturer takes time to re-adjust prices, or has to negotiate a price change with the government while the importer can take advantage of this by offering lower prices or widening profit margins the movement the exchange rate fluctuation takes place.³⁴

³² Multiple Authors, *The Pharmaceutical Parallel Trade Outlook: Challenges to Pharmaceutical Companies Across Europe and the US*, Reuters Business Insight, Reuters Business Insight, 2003.

³³ Yang, Rachel, B., Ahmaci, Reza, H., Monroe, Kent, B., *Pricing in Separable Channels: The Case of Parallel Imports*, Journal of Product and Brand Management, Vol. 7, Issue 5, pg. 2

³⁴ Weigland, Robert E. *Parallel Import Channels: Options for Preserving Territorial Integrity*, Columbia Journal of World Business, Spring 1991, pg. 4

3.1.5 Transportation and Product Differentiation

The ease of transport and level of product adaptation also determines the level of parallel trade.³⁵ Pharmaceuticals are often notoriously easy to transport, and have a high price to volume ratio. As such, pharmaceuticals are prime candidates for parallel importing. Traditionally parallel traded drugs come in pill or capsule form since repackaging is usually the only adaptation needed to sell these drugs in the importing MS. Some drugs such as insulin need to be cooled, even during transportation, in order to be safe to use. There are indications that even insulin is being parallel traded,³⁶ indicating the higher sophistication of the PI industry in recent years. Yet another prerequisite of parallel imports is met by pharmaceuticals.

3.1.6 Transparency

Internationally, within the EU, in private companies, NGOs and governments there is a move seen towards greater transparency. Transparency in markets is another precondition of parallel importing that is met by pharmaceuticals. The European Union's adoption of the Euro made drug prices, and price differences across the Euro-zone more transparent. The risk associated with exchange rate fluctuations has been reduced for parallel traders, and potential profit-making drugs for parallel importers are easier to pin-point with the use of a single currency. Such risks still exist when importing into MS that opted out of the adoption of the Euro. Transparency of prices is also seen in MS such as Denmark, which publish their pharmaceutical prices. An EU pharmaceutical price database, EudraMat is planned but is as of yet incomplete.³⁷

3.1.7 Marketing Authorization

Parallel importers of pharmaceuticals have to apply for an authorization to import pharmaceuticals in to Member States. The ease of attaining these authorizations determines to some extent the level of pharmaceutical imports. In the EU, importers are allowed to use the original marketing authorization received by the IP holder if the drug has the same active ingredient, and use it as a 'piggy back' in receiving approval to import the drug, thus making it easier to attain authorization for importation.³⁸ The ease of attaining importing licenses is indicated in the growth in license numbers in the late 1990s,³⁹ and the number of licenses handed out in the UK in 2002.⁴⁰

3.1.8 Free-Ride

³⁵ Tamer, Cavusgil, S. and Sikora, Ed, *How Multinationals Can Counter Gray Market Imports*, Columbia Journal of World Business, Winter, 1998, pg. 77, pages 75-85

³⁶ *Novo Nordisk hit by Parallel Import*, Perspective, The Newsletter from Novo Nordisk, August 1998

³⁷ European Federation of Pharmaceutical Industries and Associations (EFPIA), *Position Paper, Medicine Information Network for Europe*, pg. 2

³⁸ Commission communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted, OJ No C 115/5, May 6, 1982, page 127-130

³⁹ Select Committee on Trade and Industry, Minutes of Evidence, Memorandum submitted by the Association of the British Pharmaceutical Industry, pg. 4. Indicates that there was a growth in the number of licenses issued of 18% between 1997-1998

⁴⁰ Multiple Authors, *The Pharmaceutical Parallel Trade Outlook: Challenges to Pharmaceutical Companies Across Europe and the US*, Reuters Business Insight, Reuters Business Insight, 2003, pg. 27. 193 PI licenses were handed out for active ingredients in 2002

Generally, parallel traders prefer to have a 'free ride' on some aspect of the product. Possible 'piggy-backing' opportunities found for parallel importers include, but are not limited to: promotion/marketing of IP holder; inventory control of IP holder; sales work done by IP holder; reputation of IP holder; research and development expenditure by IP holder; brand name of IP holder; service attributes of IP holder; sales/marketing authorization/ testing done by IP holder; and manufacturing techniques used by the IP holder. Different industries see gray marketers riding the coat tails of different costs borne by the manufacturing company. Car dealerships and manufacturers would more concerned about service issues, while a luxury good such as a Rolex watch would be more concerned with brand and reputation issues. The primary concern of pharmaceutical companies is the free ride that parallel importers are receiving from their extensive R&D costs.

3.1.9 Generic Competition

In markets where generics do not exist, and the IP holder still has exclusive first right to release a certain drug onto the European market, parallel trading is more likely to be found.⁴¹ Kim Jensen pointed out that the market for parallel importers more or less disappears when generic competition is allowed.⁴² Where generics compete on price in the importing state, parallel trade is less likely to be profitable because of the lower margins existing when a drug reaches the post patent protection period.

3.1.10 Member State Initiatives

Though not a pre-condition for PI in most trade areas, many European MS have policies in place that encourage parallel imports. These policies act as catalysts promoting the gray market for pharmaceuticals. Member States in the EU such as Sweden, Denmark, Ireland, Finland the Netherlands, Germany, and the UK all support parallel trade by providing incentives to pharmacists to use PI drugs, or obliging pharmacists to use cheaper drugs.⁴³

An obvious catalyst for parallel trade to exist is pricing and reimbursement controls that create divergent prices across markets and artificially low prices in some countries. Also a PI supportive legal environment is another catalyst. These areas are explored in more detail directly below.

⁴¹ Chaudhry, Peggy E. and Walsh, Michael, G., *Managing the Gray Market in the European Union: The Case of the Pharmaceutical Industry*, Journal of International Marketing, Vol. 3, No. 3, 1995, pg 22, pages 11-33

⁴² Interview with Kim Jensen, Advokat, Paranova A/S, May 6, 2004

⁴³ Multiple Authors, *The Pharmaceutical Parallel Trade Outlook: Challenges to Pharmaceutical Companies Across Europe and the US*, Reuters Business Insight, Reuters Business Insight, 2003 pg. 2. The UK's NHS uses the 'claw-back' method where pharmacists are charged according to the estimated savings PI purchasing has given them. In Ireland PI drugs must offer state savings before they are added to the reimbursement list. In the Netherlands the savings are split between the pharmacist and the payor. In Finland the savings are split between the patient and the insurer. In Sweden, Denmark and Finland, pharmacists are obliged to prescribe the most cost-effective drug. In Germany, pharmacies must dispense 7% PI drugs.

3.2 Pharmaceutical Cost Control Mechanisms in the EU

The major pre-requisite for parallel trade to exist is that there needs to be a profit motive created by different prices between areas. This pre-condition is looked at separately because of its importance on the PI and pharmaceutical industries. Pharmaceutical pricing is unique in that in most countries in the world have pricing control mechanisms set up that disallow pharmaceutical companies from setting prices at the optimum level that the market will bear. The EU is a case in point of such an area where prices are regulated by the Member States. Each country has their own method of cost containment measures in place to control the costs to national health care services. Pharmaceutical price controls are an anomaly in Europe in that they are in direct conflict with the internal market implication and goal of price convergence.

3.2.1 Rising Healthcare and Pharmaceutical Costs

Cost containment is becoming increasingly important as the cost of healthcare and pharmaceuticals rises year to year. Not only are health costs rising as a percentage of GDP, but pharmaceutical expenditure is rising as a percentage of health care costs. **Appendix A** is a graph summarizing the change in pharmaceutical prices in regards to GDP in from 1990-2002. It should be noted from **Appendix A** that the costs of medicinal products are generally rising over time.

The OECD concluded from its 'Health Data 2003, that 'the increase in public and private spending on pharmaceuticals has been one of the main drivers of rising health expenditure in many OECD countries in recent years, reflecting the introduction of new and more expensive drugs. Pharmaceutical spending rose by more than 70%, in real terms, between 1990 and 2001 in Australia, Canada, Finland, Ireland, Sweden and the United States'.⁴⁴ With spiraling prices such as this seen in most European countries, cost containment measures by payors is imperative to keep costs in check. The variety of methods in use in some of the more important pharmaceutical markets is summarized in the charts below.

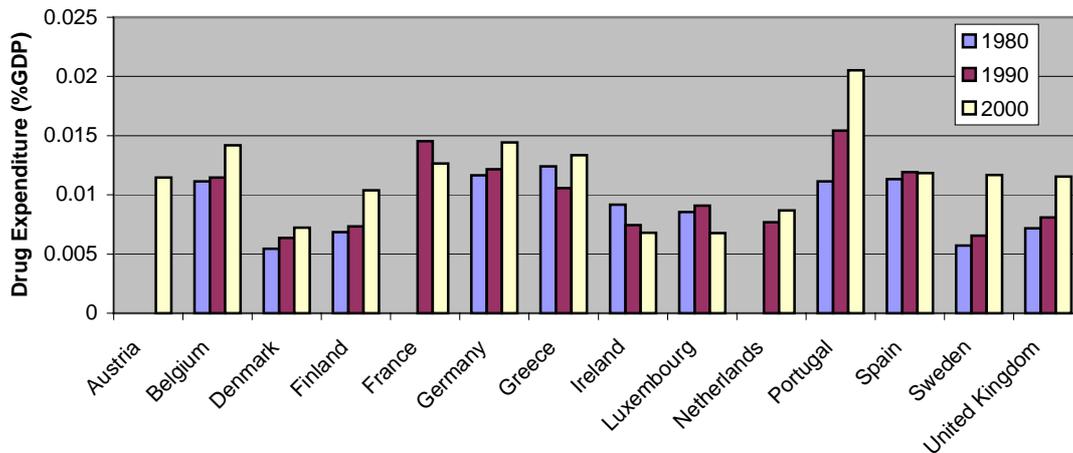
The graph immediately below looks at pharmaceutical cost as a percentage of GDP at the beginning of each of the last three decades. The growing costs for pharmaceuticals in most EU countries are clear from even a brief look at the graph. For this reason, pharmaceutical pricing mechanisms are important to study. Cost containment measures such as parallel trade of pharmaceuticals are likewise an important consideration for research.

Figure 2: Pharmaceutical Expenditure as Percentage of GDP⁴⁵

⁴⁴ OECD Health Data Show Health Expenditure at all time high, Press Release, June 23, 2003, http://www.who.dk/pharmaceuticals/Topics/20020226_1

⁴⁵ Data from OECD Health Data 2003, calculations made by author

Pharmaceutical Expenditure as % of GDP



3.2.3 Substitution Rules

Factors such re-imburement, and pharmaceutical cost containment allow pharmaceutical parallel traders to exist. Parallel importation is a cost containment measure used by EU Member States with more expensive drug prices. Member States in the EU with strict cost containment and low costs provide the purchasing grounds for parallel traders. The drugs are subsequently imported to countries with higher pharmaceutical costs. Traditional exporting Member States of parallel traded pharmaceuticals include: Greece, Spain, Italy, France. Traditional importing countries of parallel traded pharmaceuticals include: Germany, Sweden, Denmark, the Netherlands and the United Kingdom.

A trend that is occurring in the European Union is substitution rules for generic and parallel traded products. Currently, countries such as Denmark, Sweden, Germany and Finland practice this. Under advanced substitution regimes, a generic or parallel traded product is to be automatically dispensed to the patient by the pharmacist if it is cheaper than the brand name item unless the brand name item is specifically requested in the doctor's prescription. Mr. Jensen sees substitution rules as being extremely important for the parallel importation business: *'The penetration of parallel imports, if you could say that changed dramatically because of these substitution rules. And you must understand that the market in that that the market is very dependent on how the regulation is. This was the most important regulation introduced.'*

3.2.4 Pricing and Reimbursement Measures

The area of pharmaceutical pricing, re-imburement and national cost containment is an area that is the subject of a number of reports⁴⁶, but is not the focus of this one. Since

⁴⁶ See the following for full reports in pharmaceutical pricing and reimbursal schemes in the EU: Martikainen J, Rajaniemi S., Drug reimbursement systems in EU member states, Iceland and Norway. Helsinki: The Social Insurance Institution, Finland, Social security and health reports 54, 2002.; *Pharmaceutical Pricing Strategies: Optimizing Returns throughout R&D and Marketing*, Reuters Business Insight, 2003;

the containment measures are essential to appreciate in order to understand the business environment in which parallel traders and pharmaceutical companies function in the EU, a summary of measures taken in various EU Member States is provided in the tables below.

Some definitions that are found immediately below will aid the reader in understanding the charts below and cost containment measures⁴⁷:

Cost Containment: Pharmaceutical payers attempting to limit the costs incurred from buying pharmaceuticals by exerting buyer pressure to limit their exposure to pharmaceutical costs.

Reimbursement: Payment of part or all of pharmaceuticals by a third party, usually a governmental or private health insurance entity.

Reference Pricing: Sets price levels above which patients have to pay the difference for prescribed products. The price is set by referring to either a basket of international pharmaceutical prices, or by referring regionally (internal) within one's own MS.

Pharmacoeconomics: Applying economic principles to the use of various drug therapies by applying a monetary value or qualitative measure to differing treatments and their outcomes to achieve an efficient use of health care budgets.

Negative or Black Lists: These are lists of pharmaceuticals that are not covered by insurers because of the existence of a more efficient treatment method. Black lists (used in the UK) list drugs that public employees are not entitled to prescribe.

Positive lists: A list of pharmaceuticals that are covered by national health insurance schemes.

Budgets: Annual national healthcare budgets are usually made in order to contain costs. Some countries also have regional budgets for pharmaceutical spending (Spain, Italy), while others have budgets set for each hospital or Doctor. There needs to be direct consequences for over spending for effectiveness.

Price Control: Sets the price at which pharmaceuticals are sold.

Profit Control: Sets a maximum profit level for pharmaceutical manufacturers. This is used widely in the United Kingdom with a general profit limit of 21%

Negotiations: Prices are set after extensive price negotiations between various stakeholders, most importantly, the national health insurers and the pharmaceutical companies. This method is used predominantly in France

⁴⁷ Definitions are taken from Seget, Steven, *Pharmaceutical Pricing Strategies: Optimizing Returns throughout R&D and Marketing*, Reuters Business Insight, 2003, Yang, B. Rache., Atmadi, Reze H., Monroe, Kent, B., *Pricing in separable channels: the case of parallel imports*, The Journal of Product and Brand Management, 1998, Vol. 7, 5, pg. 443 and Maskus KE, Chen Y. Vertical Price Control and Parallel imports: Theory and Evidence. *Review of International Economics* 2003

N.B. On the chart below, an **X** indicates that this cost containment measure is used to a full degree, while an **x** indicates that the cost containment measure is used in some cases or with a set of limitations. Please also note that that a chart developed by leading a leading European observer, Panos Kanavos in 2001 is included as **Appendix B** to provide a more complete listing of cost containment and control mechanisms in use within the EU.

Figure 3: EU Member State Cost Containment Strategy Chart

N.B. X = Use of technique x = Minor use of technique

	Country	FR	GER	IT	SP	UK	DK	SW	NL	POR	GRE	AUS	BEL	FI	IRE	LUX
Cost Containment Strategy																
Positive List		X	X	X	X		X	X	X	X	X	X	X	X	X	X
Negative List			X		X	X	x	x								
Reference Based Pricing		x	x	X	X		X	X	X	X	X				X	
Budgets (doctors, pharmacists, global, regional)		X	X	X	X	x									X	
Negotiations		X		x	X		X	X		X		X			X	
Price Control				X	X			X		X	X		X			
Profit Control						X										
Free Price Setting			X	x		x	X							x	x	
Substitute Drugs?		x	X	X		X	X	X	X				x	X	X	X
Generic Usage		x	X	X		X	X	X	X	x			x	X	X	
PI Promotion						X		X	X							
Price Cuts/Freeze		x		X		X							X		X	
Price level takes into consideration:																
Sales Forecast		X		X												
Usefulness		X					X			X						
Production Cost		X														
R&D spending in home MS		X														
Treats Disease covered under MS Health Insurance?			X													
Other Treatment?			X	X												
Cost Effectiveness		X	X	X		X	X	X	X	X				X	X	
Degree of Innovation				X									X			
Pharmacoeconomics		X		X		X		x	X	X				X	X	

It is clear from the chart above, and the one presented in **Appendix B** that it is not only the lower priced lower priced MS that have an array of cost control mechanisms. Indeed, the way PI is currently working in the EU, importation is happening from North to South as well as South to North. As Kim Jensen pointed out in our interview *‘in the early days of parallel imports the cheaper countries were the selling countries, and the*

more expensive countries were buying countries. That is not the fact anymore. For some products, the prices can be more expensive in the Southern countries than the Nordic countries.’ In any case, it is clear that these cost control mechanisms create artificially low prices that are maintained by most MS, which in turn creates an ideal environment for parallel trade.

International price referencing is used extensively as is showed in the chart below. An X indicates which countries the MS in the left column refer to in national price setting. It is clear that the pricing mechanism within Europe is highly integrated in that only five countries set their pharmaceutical prices independently.

Figure 4: International Reference Based Pricing – Chart Summary

Country	AU	GER	DK	SW	FI	IT	GR	FR	SP	PG	LUX	BEL	NL	UK	IRE
Austria															
Germany															
Denmark	X	X		X	X	X	X	X	X	X	X	X	X	X	X
Sweden		X	X		X								X		
Finland															
Italy	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Greece	X	X	X	X	X	X		X	X	X	X	X	X	X	X
France									X						
Spain															
Portugal						X		X	X						
Luxembourg		X						X				X			
Belgium															
Netherlands		X						X				X		X	
United Kingdom															
Ireland		X	X										X	X	

The situation that is created with so many countries within Europe referencing the prices in other EU Member States is that there is a particular national order that drugs must be released in order for pharmaceutical companies to maximize their profits that is presented in figure 5.

The results of this pricing and re-imbursement control at the national level are that prices in the EU are very different from country to country. According to a price index published in *Pharmacoeconomics*, the prices in the EU vary slightly over 50% from the highest priced Belgium, to the lowest priced country, Greece.⁴⁸

Legally speaking, all Member States can autonomously choose cost containment measures that suit their needs provided that the regime does not discriminate *de facto* or *de jure* against imported products and provided that the prices set are remunerative to the suppliers.⁴⁹ The ECJ has further noted that it is not a matter of significance that

⁴⁸ Ess, Silvia, M., Schneeweiss, Sebastian, and Szucs, thomas, D., European Healthcare Policies for Controlling Drug Expenditure, *Pharmacoeconomics*, 21 (2): pg. 97

⁴⁹ Case 181/82 Roussel Laboratoria (1983) and Case 249/88 Commission v. Belgium (1991)

national measures cause price variance within the European market place leading to parallel trade.⁵⁰ This cannot be used to defend illegal retaliatory measures taken by pharmaceutical companies.

⁵⁰ Case 15/74 Centrafarm v. Sterling (1974), C-267/95 and C-268/95, Merck v Primecrown, (1996), paragraph 47; see also case C-436/93 Bristol-Myers Squibb v. Paranova, (1996)

3.3 The Effects of Parallel Trade

N.B. This section of the paper more or less uses the same categorization as Chapter 3.4 'General Strategies for Parallel Import Prevention' and Chapter 7.2 'Recommended Strategies' in order to provide for easy reference and comparison when reading this paper.

Volumes have been written about the benefits and detriments of parallel trade.⁵¹ There is a strong contrast taken in the points of view presented, and sometimes, the difference in research findings depends to a large extent on who commissions and pays for the study. In 2003, two reports were released regarding the beneficiaries of pharmaceutical PI. They both had conflicting findings. When one looked a bit further into why this might be the case, one found out that the London School of Economics report was financed by pharmaceutical monolith Johnson & Johnson, while the York Health Economics Consortium study was financed by an association of parallel importers.⁵² For the purposes of this paper, the debate regarding the beneficiaries of parallel trade will not be assessed in full. Suffice it to say that there are benefits and costs to having parallel trade in a given region. Benefits noted are a lowering of prices and savings to the insurers, the Member States and the public in addition to the market integrating effect of PI. Negative effects noted are that the importers are by and large the main beneficiaries of parallel importation. A diagram from a recent Reuters report summarizes the arguments for and against parallel trade.⁵³

⁵¹ A non-exhaustive list includes: Anderson, S.P. and V. Ginsburgh, *International Pricing with Costly Consumer Arbitrage*, Review of International Economics, vol. 7, issue 1, 126-139, 1999

Danzon, P.M. *The economics of Parallel Trade*, PharmacoEconomics 13(3), pages 293-304, 1998

Danzon P. M., *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents*

WP, The Wharton School, University of Pennsylvania, December, 2001.

Ganslandt M. and K. E. Maskus, *Parallel Imports of Pharmaceutical Products in the European Union* IUI, The Research Institute of Industrial Economics Working Paper n° 546 2001

Ganslandt M. and K. E. Maskus, *The Price Impact of Parallel Trade in Pharmaceutical Products: Evidence from the European Union*, IUI, The Research Institute of Industrial Economics January, 2001.

Hewitt G., *Synthesis Report on Parallel Imports Joint Group on Trade and Competition*, OECD, 2002

[http://www.oilis.oecd.org/olis/2002doc.nsf/43bb6130e5e86e5fc12569fa005d004c9dc5047a2329c883c1256be400510e2f/\\$FILE/JT00128903.DOC](http://www.oilis.oecd.org/olis/2002doc.nsf/43bb6130e5e86e5fc12569fa005d004c9dc5047a2329c883c1256be400510e2f/$FILE/JT00128903.DOC)

Kanavos, Panos, Costa-i-Font, Joan, Merkur, Sherry, Gemmill, Marin, *The Economic Impact of Parallel Trade in European Union Member States: a Stakeholder Analysis*, London School of Economics, 2003

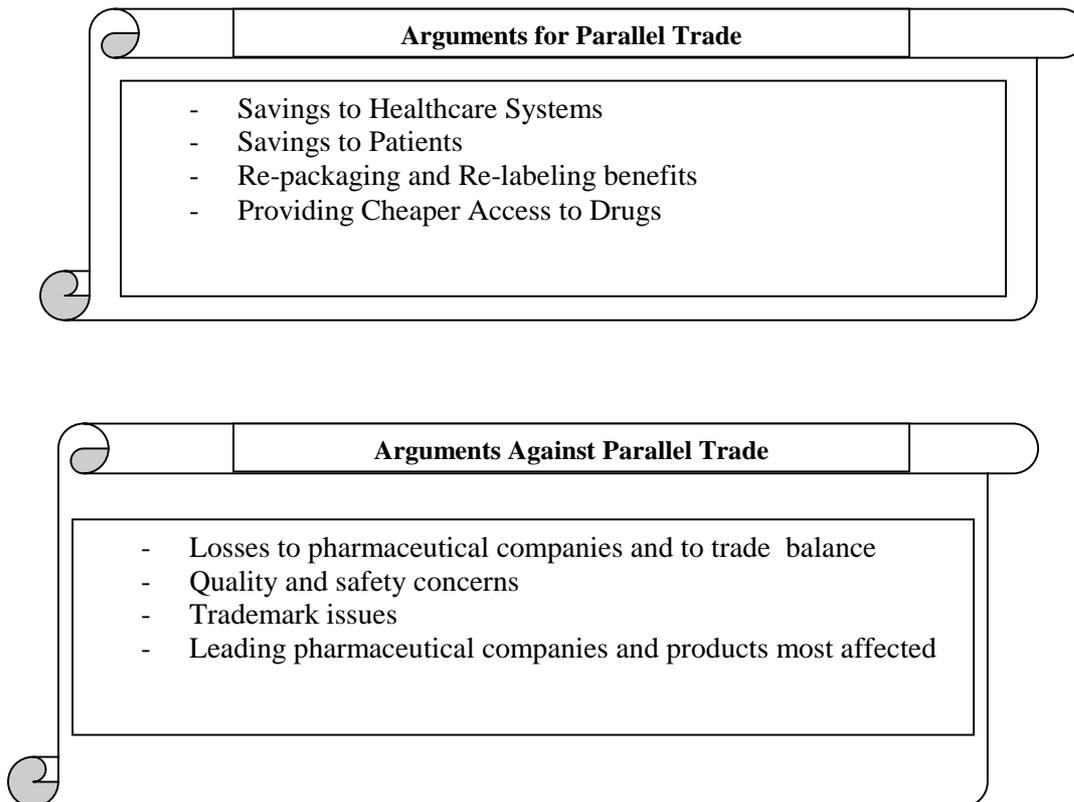
West, Peter, Mahon, James, *Benefits to Payers and Patients From Parallel Trade*, York Health Economics Consortium, May, 2003

NERA, SJ Berwin & Co. *The Economic consequences of the choice of regime of exhaustion in the area of trademarks*, London, 8th February 1999

⁵² West, Peter, Mahon, James, *Benefits to Payers and Patients From Parallel Trade*, York Health Economics Consortium, May, 2003. Found that total direct savings of € 631,000,000. Kanavos, Panos, Costa-i-Font, Joan, Merkur, Sherry, Gemmill, Marin, *The Economic Impact of Parallel Trade in European Union Member States: a Stakeholder Analysis*, London School of Economics, 2003. Found that total direct savings of € 44,151,000 for the same five countries (€ 99,508,000 with claw back). It is hypothesized that the difference in findings stems at least in part from who commissioned the studies.

⁵³ Multiple Authors, *The Pharmaceutical Parallel Trade Outlook: Challenges to Pharmaceutical Companies Across Europe and the US*, Reuters Business Insight, Reuters Business Insight, 2003, pg. 185

Figure 5: Arguments for and Against Parallel Trade



Concentration will be placed on the effects of parallel trade on the manufacturer and IP holder of pharmaceuticals in order to come to some kind of idea as to when reactive strategies should be undertaken. Effects seen on other stakeholders are peripheral to the effects on the manufacturer in determining their strategic plan, so will not be assessed here. Even for the manufacturer of pharmaceuticals, there are positive as well as negative effects of having parallel trade, albeit true that the negative effects far outweigh the positive effects for the manufacturer. We will firstly look at the parallel trade's negative effects on the manufacturer.

It has been noted by some observers that PI can 'reduce a manufacturer's ability to control vital aspects of international marketing. This lack of control can seriously affect the company's global performance outcomes.'⁵⁴ This is true for all Ps of the marketing mix. As will be seen: *pricing* becomes more difficult with PI, problems are created in *promotion* of products, especially on sales forces, *place*, or distribution is highly distorted when PI exists, and finally, the form of the *product* and packaging needs change in efforts to make PI more difficult

3.3.1 Negative Effects on Pricing

In general, pricing decisions are made more difficult when parallel trade is allowed to exist. One of the primary purposes of a trademark is to provide the opportunity to reap monopolistic returns on products having IP protection. In the United States for example, in-patent drugs are priced at the highest level at which the market will bear with no competition. This makes for large returns for the IP holder. The cost-

⁵⁴ Myers, Matthew B., Griffith, David A., *Strategies for Combating Gray Market Activity*, Business Horizons, November-December 1999. pg. 3, pages 2-8

containment measures in the EU create an environment where prices are artificially lower than what the market would bear. Some countries such as Germany and Denmark allow free pricing of first release, in-patent drugs making for higher in-patent drug prices. This fact combined with the free movement of goods principle, breeds parallel trade which in effect moves in-patent drugs from low price areas such as Greece, where monopolistic profits are not allowed, to areas where free pricing is allowed that in turn creates price competition that otherwise would not have existed. To summarize, the ability to reap monopolistic benefits from in-patent drugs is taken away from the patent holder when parallel trade is allowed. The obvious result of all this is that profits erode for the intellectual property holder, and the ability to price differentially is reduced as well.

Some observers state that there are further effects on the manufacturers. Erosion of overall sales is seen as one possibility.⁵⁵ Because the higher prices that could have been garnered in higher priced countries go in differing proportions to the parallel traders, sales revenue erodes. The sales that would be registered in higher priced MS are transferred to countries with lower prices and profit levels.⁵⁶ The level of revenue erosion depends on several factors including:

- The volume of sales lost to the parallel trader in the higher priced countries (V_a),
- The purchase price of the products by the trader in the lower price countries (P_b)
- The sale price of the product in the higher priced country if parallel trade did not exist, *ceteris paribus* (P_a)
- Price competition in the higher priced country (C_a).
- A simple model assessing the lost sales revenue would be $= V_a * (P_a - P_b) + C_a$

In other words, if the competition effect is excluded, the loss in sales revenue is equal to the benefits accrued by the parallel traders, sick funds⁵⁷, and to patients.

The growth of parallel trade has created some large companies that are poised to continue to grow. As the PI industry matures, further consolidation is expected to occur. This will put further pressure on pricing strategies of manufacturers. As parallel importing companies grow, economies of scale/scope in purchasing and will allow them to find the cheapest sources thus reducing the price differential necessary for them to make a profit. This will further limit the pharmaceutical companies to price differentially in various MS. A result of growth is also that these importers will be able to supply a consistent, complete range of products to the buyers and build better relationships as the manufacturers have done for many years. This competition will create further downward price pressure in the import market as an element of trust enters the relationship between the importers and their customers.⁵⁸

⁵⁵ Cespedes, Frank V., Corey, Raymone, E., and Rangan, and Kasturi Rangan, V., *Gray Markets: Causes and Cures*, Harvard Business Review, July-August 1988, pg. 76, pages 75-82. Lowe, Larry, S. and McCrohan, Kevin F., *Minimize the Impact of the Gray Market*, Journal of Business Strategy, November – December, 1989, pg. 49, pages 47-51

⁵⁶ Kanavos, Panos, Costa-i-Font, Joan, Merkur, Sherry, Gemmill, Marin, *The Economic Impact of Parallel Trade in European Union Member States: a Stakeholder Analysis*, LSE Health and Social Care, January 2004, pg. 109

⁵⁷ Kanavos, Panos, Costa-i-Font, Joan, Merkur, Sherry, Gemmill, Marin, *The Economic Impact of Parallel Trade in European Union Member States: a Stakeholder Analysis*, LSE Health and Social Care, January 2004, pg. 96

⁵⁸ *Pharmaceutical Pricing Strategies: Optimizing Returns throughout R&D and Marketing*, Reuters Business Insight, 2003, pg. 42-43

3.3.2 Negative Effects on Product, Brand and R&D

Limiting the right of differential pricing in a region, such as is done in the EU effects the incentive provided to invest in Research and Development (R&D). R&D is a huge cost in the pharmaceutical industry. Developing new drugs is a primary cost for pharmaceutical manufacturers. According to PhRMA, pharmaceutical companies in the USA spend 13-20% of sales on research and development compared to a 4% average for all industries. Pharmaceutical observer, Patricia Danzon adds that the opportunity cost of using the money on R&D in contrast to investing it in the market over the 8-12 year drug development time forces the ratio up closer to 30%.⁵⁹ The argument goes that the incentive to spend money on R&D is diminished when parallel trade is allowed to exist because of revenue erosion when PI exists. Some observers believe that the existence of PI contributes significantly to Europe's struggle against pharmaceutical R&D spending being re-located to the USA where free pricing is allowed and PI of pharmaceutical products is only partially illegal.⁶⁰

Trademark erosion is another effect on the product.⁶¹ During the UK Parliament's investigation into extension of the exhaustion principle, several examples of faulty products and packaging were cited to be the fault of PI.⁶² An example is a sample of Zoladex, a prostate cancer drug that was shown to the Committee where the parallel importer incorrectly indicated that the needle should be injected into the chest, when the proper injection should be in the abdomen. Other examples were shown where drugs had French instructions, no instructions, or no batch numbers. This not only affects the brand image and trademark reputation of the product, but also could be potentially dangerous to the patient. Another possible effect of parallel trade is customer confusion from the different forms drugs imported through PI. In a five-year period, for one drug Risperdal, seven suppliers were listed as supplying seven package sizes, in twelve medicinal amounts in five different drug formats.⁶³ This confusion could manifest itself in erosion of customer loyalty, loss of good will, customer dissatisfaction and image diffusion.⁶⁴

3.3.3 Negative Effects on Promotion/ Sales

Difficulties are created in forecasting demand for certain markets when PI exists. Also, costs are raised in determining which wholesalers are providing goods to the PI network. The difficulties created in sales forecasting could have side effects on the sales force as well as they will become de-motivated if they do not reach sales quotas

⁵⁹ Danzon, Patricia, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents*, Commission on Macroeconomics and Health (CMH) Working Paper Series, WG2:10, pg. 5

⁶⁰ See in particular: Gambardella, Alfonso, Orsenigo, Luigi, and Pammolli, Fabio, *Global Perspective of Pharmaceuticals, a European Perspective*, Enterprise Directorate General of the European Commission, November 2000. Concludes that: g) The above findings are consistent with other features of the European environment, linked to the "institutional shock" created by *cost containment* policies in a context of *fragmented institutions and rules*. pg. 85

⁶¹ Casvugil, Tamer, S., and Sikora, Ed, *How Multinationals can Counter Gray Market Imports*, Columbia Journal of World Business, Winter 1998, pg. 76, pages 75-85

⁶² United Kingdom Parliament, Select Committee on Trade and Industry, Minutes of Evidence, Examination of Witnesses Dr. J. Patterson, Dr. A. Hesketh, and Dr. D. Brickwood, Questions, 300-321, April, 27, 1999, pg. 2

⁶³ Authors observations from Danish Medicines Agency pharmaceutical pricing data.

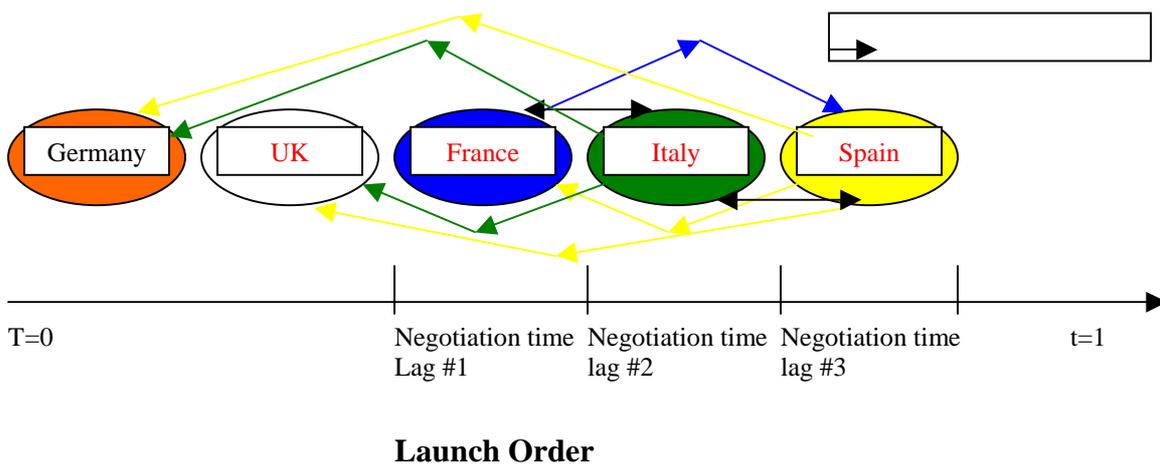
⁶⁴ Lowe, Larry, S. and McCrohan, Kevin F., *Minimize the Impact of the Gray Market*, Journal of Business Strategy, November – December, 1989, pg. 50, pages 47-51

that were determined using incorrect sales predictions due to PI. Since profits could fall as a result of PI, there could be diminished motivation to support a product with promotion as well. Furthermore, any expense on promotion to decision makers is benefiting not only your firm, but also parallel traders acting on the market. The manufacturer may not see the point in contributing to promotion if the beneficiaries of their efforts are the traders as much as themselves.

3.3.4 Negative Effects on Place/Distribution

It is a side effect of parallel trade that the manufacturer loses full control over their distribution system. If national IP monopolies were allowed to exist in the EU, the manufacturer could determine what goods are supplied to whom and at which price. The IP holder must maintain discrimination, and perform research to minimize the parallel distribution of their products. This entails an additional cost. Reimbursement schemes, reference pricing and parallel trade also make it unattractive to release a pharmaceutical product on the European market at the same time. This means that after all the research costs have been endured by the firm, they must release products in a profit maximizing order country by country and negotiate with many countries whilst doing so in order to reap the highest benefits from international reference pricing. The opportunity cost of this time lag not being able to reap sales benefits from the EU as a whole after a marketing authorization is granted. The profit maximizing launch dates in the five major pharmaceutical markets is shown below with due regard to reference pricing. With eight current Member States currently using price negotiations, and nine Member States using international price comparisons, the time passed between the first launch in Germany, and the last launch in a country such as Greece can be significant. This results in a loss of revenue compared to being able to release new products instantaneously EU-wide upon marketing authorization approval from EMEA.

Figure 6: Launching order and time lags in major EU pharmaceutical markets⁶⁵



3.3.5 Positive Effects for the Manufacturer

As has been mentioned, there are some positive effects of parallel trade for the manufacturer. For some drugs that are not heavily reimbursed, PI can aid a manufacturing drug company serve price-sensitive customers and other buyers who lye

⁶⁵ Author's own diagram, original source *Pharmaceutical Pricing Strategies: Optimizing Returns throughout R&D and Marketing*, Reuters Business Insight, 2003, pg. 183

outside of their traditional channels. In this case, it seems reasonable to assume that if a patient were not willing to pay the portion that is not reimbursed, and does buy the drug, but would be willing to do so at a lower parallel imported price, it is better for the manufacturer to have made one sale to the parallel trader in the exporting state than not to have made a sale at all.⁶⁶ Another possible positive effect of PI for the IP holder lies in the fact that some patients may only be able to take one form of a medication, or may prefer one form to another such as liquid over a pill. Sometimes, PI can bring in different forms of the same medication into a MS, thus resulting in a possible increase in sales, albeit to the parallel importer in the source MS.⁶⁷

As reported in the Harvard Business Review, parallel trade can in fact be beneficial in cases when there are sharp differences in consumer price sensitivity, and when a large number of consumers are price insensitive.⁶⁸ Brought to a Member State level, there appears to be a large difference in price sensitivity between a country like Greece, which sets its prices the lowest in the EU, and Germany which allows free pricing for new products. Allowing free pricing in some MS indicates that some countries are in fact price insensitive as well. Although the study in question looked at retail, it may still be relevant. In the study, the benefit on the high end retailers was being allowed to focus on service while allowing discounters to have their take of low priced sales supplied through parallel networks. Could it be possible to draw a parallel between service and R&D, and say that having high prices allows countries like Germany to concentrate on R&D and the benefits that provides, while allowing Greece to enjoy their low prices? No research was found answering this possibility.

3.3.6 Assessing Effects of Parallel Imports

In light of all of these effects on the manufacturer, all of this brings us to assessing when it becomes necessary to take reactive actions against the parallel trader. The manufacturer needs to determine exactly what effect parallel trade is having on their operations in what areas, and make an attempt to quantify what is being lost. Assigning numerical values for each individual effect of PI would be a good starting point to later weigh against the cost of reactive strategies. In the absence of the ability to do this, the different effects should be categorized according to level of effect PI has on the firm in question, ranging from 'Very High' to 'Very Low', and then placed into a prioritization categorization ranging from 'Must Prevent' to 'Must Promote'. There are generally two streams of strategies used to prevent parallel trade, namely, those that you use before it becomes a major problem, and more antagonistic methods used after PI has become a major quandary. It is therefore important to determine effects early, and if possible to begin developing a PI stratagem when the roots of a problem are detected.

⁶⁶ Champion, David, *The Bright Side of Gray Markets*, Harvard Business Review, September-October, 1998, pg. 22, pages 21-22.

⁶⁷ Myers, Matthew B., Griffith, David A., *Strategies for Combating Gray Market Activity*, Business Horizons, November-December 1999, pg. 3, pages 2-8

⁶⁸ Champion, David, Harvard Business Review, September-October, 1998, pg. 22, pages 21-22

4.0 General Strategies for Parallel Import Prevention

This section of the thesis explores to what extent was possible, all of the strategies that have been proposed to prevent parallel trade in academic literature. The section is divided into the four P's of marketing: Place, Price, Product, Promotion, as well as section covering technological options. Legal strategies are discussed chapter 6.

N.B. This section of the paper more or less uses the same categorization as Chapter 3.3 'The Effects of Parallel Trade', and Chapter 3. 'Recommended Strategies' in order to provide for easy reference and comparison when reading this paper.

After determining the effects that PI is having on the IP holder, the next step is to assess various strategies to deter, prevent, or even work with PI. For our purposes, an attempt is made to list and describe as far as possible the strategies available to prevent parallel imports in general. After examining the business and legal situation that pharmaceutical companies are currently facing in the EU, we will assess these strategies according to the manufacturer's needs, and their ability to utilize the strategic tools.

Now that we have seen the pre-conditions and effects of gray markets, we will now look at the various strategies that have been proposed in academic literature to counter the effects of PI and will give a brief description of each. Peggy Chaudhry⁶⁹, using the strategic choices presented by Casuvgil⁷⁰, analyzed the PI market for pharmaceuticals in the EU, and came to conclusions on which strategies were available to the pharmaceutical companies to prevent PI after considering the business and legal situation in the EU in 1995. This paper will in part attempt to update Chaudhry's analysis in light of more recent ECJ, national rulings and political efforts within the Union. Furthermore, a number of strategic options that were not considered by Chaudhry will be considered. The strategies have been divided into: Distribution/Supply, Price, Product, Promotion, Technological and Legal categories for simplification.

4.1 Place (Distribution and Supply Strategies)

Because of the wealth of distribution strategies available to the importer to prevent PI, the strongest maneuvers were considered first, followed by less aggressive tactics. Farquharson's presentation of general distribution strategies and their effects on PI follows.

A strategic option presented by but not necessarily endorsed by multiple authors⁷¹ is the strong move of disenfranchisement of dealers. This involves cutting off supply to

⁶⁹ Chaudhry, Peggy E. and Walsh, Michael, G., *Managing the Gray Market in the European Union: The Case of the Pharmaceutical Industry*, Journal of International Marketing, Vol. 3, No. 3, 1995, pg 22, pages 11-33

⁷⁰ Casuvgil, Tamer, S., Sikora, Ed., *How Multinationals can Counter Gray Market Imports*, Columbia Journal of World Business, Winter, 1988, page 75-85

⁷¹ Cespedes, Frank, V., Corey, Raymond, E., Kasturi, Rangan, V., Geay Markets: Causes and Cures, Harvard Business Review, July-August, 1988, pages 75-82, Bergen, Mark, Heide, Jan, B., and Dutta, Shantanu, *Managing Gray Markets Through Tolerance of Violations: A Transaction Cost Perspective*, Managerial and Decision Economics, May, 1998, pg. 158, pages, 157-165, Weigland, Robert, E., *Parallel*

dealers that sell into the parallel channels. Cespedes states that this 'emotionally satisfying' response sends 'loud signal of commitment to distributors who abide by the terms of the franchise agreement.'⁷² Legal regimes in some areas prevent companies from using this tactic, but it has been employed by Glaxo Smith Kline in Canada and is currently being investigated.⁷³ When setting up contracts with distributors, a clause can be included in some areas restricting sales to the parallel network.⁷⁴ This may give a possibility of termination or of supply limitation upon breach of the contract.

One way that will aid in PI prevention is entirely cutting supply to source countries.⁷⁵ Small, low priced markets may not contribute very much to the profits/revenues of companies while the extent of PI supply from such countries may make it seem sensible to cut off national supply. If PI is biting into sales revenue to a great extent, this may prove to be a wise option. It is also recommended in cases where the manufacturer is particularly powerful financially, they bid up the price for parallel traded goods to a point where the gray marketer cannot endure the revenue strain and has to bow out of competition.⁷⁶

A strong signal of commitment is sent of authorized dealers who remain loyal to the official network when a manufacturer conducts a product buy-back of parallel goods. Weigland and Casvugil recommend doing so in some circumstances.⁷⁷ It is a costly reactive technique that may not have the required effect in other circumstances. A similarly expensive move that would enforce the image of a manufacturer's commitment against gray markets would be to compensate official dealers for lost sales to PI.⁷⁸

In order to find which wholesalers are supplying the gray market, some research needs to be undertaken. Product tracking, as seen below is one possibility. Another tack that some firms take is to limit PI is to undertake investigations. Hiring private investigators can help in pin pointing detractors from the official supply chain. The usual method

Import Channels – Options for Preserving Territorial Integrity, Columbia Journal of World Business, Spring 1991, pages 53-61

⁷² Cespedes, Frank, V., Corey, Raymond, E., Kasturi, Rangan, V., Geay Markets: Causes and Cures, Harvard Business Review, July-August, 1988, pg. 79, pages 75-82

⁷³ http://www.ag.state.mn.us/consumer/PR/PR_PharmaceuticalReport_093003.htm, May 3, 2004, GSK refused to supply Canadian pharmacies re-importing drugs into the USA and is currently being investigated by the Minnesota Attorney General's office for anti trust breach.

⁷⁴ Multiple Authors, *The Pharmaceutical Parallel Trade Outlook: Challenges to Pharmaceutical Companies Across Europe and the US*, Reuters Business Insight, Reuters Business Insight, 2003, pg. 73, Lee, Khae, S., Lim, Guan, H., Tan, Soo, J., *Strategic Management of Grey Marketing*, Journal of Strategic Marketing, issue 8, 2000, pg 69, pages 67-88

⁷⁵ Kanavos, Panos, *The Single Market for Pharmaceuticals in the European Union in Light of European Court of Justice Rulings*, *Pharmacoeconomice*, vol. 18, issue 6, 2000, pg. 525, pages 523-532, and Lee, Khae, S., Lim, Guan, H., Tan, Soo, J., *Strategic Management of Grey Marketing*, Journal of Strategic Marketing, issue 8, 2000, pg 69, pages 67-88

⁷⁶ Cavusgil, Tamer, S., Sikora, Ed., *How Multinationals can Counter Gray Market Imports*, Columbia Journal of World Business, Winter, 1988, pg. 80 age 75-85

⁷⁷ Cavusgil, Tamer, S., Sikora, Ed., *How Multinationals can Counter Gray Market Imports*, Columbia Journal of World Business, Winter, 1988, pg. 79, page 75-85 and Weigland, Robert, E., *Parallel Import Channels – Options for Preserving Territorial Integrity*, Columbia Journal of World Business, Spring 1991, pg. 60, pages 53-61

⁷⁸ Palia, Aspy, F., and Keown, Charles, F., *Combating Parallel Importing: Views of US Exporters to the Asia Pacific Region*, International Marketing Review, vol. 8, issue 1, 1991, pg. 52

used is to set up a faux company that builds a buying relationship with the wholesaler in order to see if they will sell into the parallel network.⁷⁹

It was also mentioned in the UK Parliament's investigation into international exhaustion that manufacturers can and do supply pharmacy outlets directly, especially in the hospital sector at reduced prices while guaranteeing supply. After the patient leaves the hospital, it is likely that he/she will continue medicinal usage at higher prices, allowing for a pay back period. Furthermore, limitations on supply, agency use, and dual pricing are also used to varying degrees in the industry.

Another possibility may be to limit supply strictly to what is needed within a nation, and any goods that are picked up by parallel traders will not be replaced in the source nation. This was the subject of the recent Bayer Adalat ruling which is discussed below. According to Kim Jensen of Paranova (Appendix C), the most common strategy employed by manufacturers to prevent parallel importations is to enact one of these supply quota (SQ) systems.

Exclusive agency distributorship is a supply chain management strategy that could be used to counteract PI.⁸⁰ In a study by Palia and Keown, it was rated as the best way to strategize against the gray market. By not selling to any dealers who sell into gray markets, the supply of parallel goods is effectively cut off.

Cespedes hypothesizes that an examination of a company's distribution chain should be done in order to reward dealers who have been contributing value-adding functions to your product. For those that are adding value, higher levels of support in promotion, merchandising or even financial incentives could be possible rewards.⁸¹ Palia and Cavusgil also include dealer development as an option, adding that improving service, marketing, finance and HR capabilities will aid in asphyxiating PI. Two things that firms seeing PI competition should do is to reassess marketing plans and change employee evaluation schemes in light of the competitive pressures.⁸²

Dealer education is seen as one possibility. In order to reduce dealer anxiety, education of dealers on gray markets could be helpful. Assessing the strengths and weaknesses of dealers, and in turn promoting the strengths to buyers and aiding the dealers to minimize their weaknesses may also help.

Bergen assessed the level of PI tolerance and evaluated what influences it. The lesser the ability to detect parallel traders and the greater the need to minimize 'free-riding' led

⁷⁹ Interview with George J. Arnold, president of Arnold, Mills and Associates Inc., *Defenders of the Mark*, Business Without Borders, December 1999, pg. 28, pages 24-29

⁸⁰ Palia, Aspy, F., and Keown, Charles, F., *Combating Parallel Importing: Views of US Exporters to the Asia Pacific Region*, International Marketing Review, vol. 8, issue 1, 1991, pg. 52, pages 47-56 and Eighth Report of the United Kingdom Parliament, Select Committee on Trade and Industry, Minutes of Evidence, Memorandum Submitted by the Association of Pharmaceutical Importers, 1999 pg. 7

⁸¹ Cespedes, Frank, V., Corey, Raymond, E., Kasturi, Rangan, V., Geay Markets: Causes and Cures, Harvard Business Review, July-August, 1988, pg. 80, pages 75-82

⁸² Cespedes, Frank, V., Corey, Raymond, E., Kasturi, Rangan, V., Geay Markets: Causes and Cures, Harvard Business Review, July-August, 1988, pg. 81, pages 75-82

to lower PI tolerance levels. It was then proposed that in many circumstances tolerance of PI should be used in order to create new markets for the firms products.⁸³

Two authors mention the possibility of including parallel imports into your distribution chain.⁸⁴ Cespedes declares that this move will decrease the exclusivity of your product and will subsequently lessen parallel opportunities.

In her book on trade in Europe, Melanie Farquharson broaches a number of possibilities that firms may use to oppose parallel trade.⁸⁵ Five distribution options are looked at including (from most control by manufacturer to least: In house distribution, local agents, franchising, solus, exclusive distribution and selective distribution.

In house distribution is allowed provided the firm is not in a dominant position and refuses to supply. Competition laws regulate distribution techniques employed when the firm is in a dominant position. In cases where a dominant position does not exist, this could prove to be a wise distribution option. Solus is an option also known as tied reselling. It does not give an exclusive territory, but the reseller is required to buy goods from one manufacturer. It is stated that protection from PI in other MS is not provided. The agreements are subject to the competition exemption, Regulation 1984/83, which applies to bi-lateral agreements. Exclusive distributorship agreements, likewise, cannot effectively prevent parallel trade since dealers are allowed to supply customer requests from outside their territory and the Regulation 1983/83 exemption does not apply where 'one or more of the parties makes it difficult for intermediaries or users to obtain the contract goods from other dealers inside the common market of in so far as no alternative source of supply is available there from outside the common market.'⁸⁶ Selective distribution arrangements leave the supplier with the least amount of control of the options explored so far. It can be an effective tool for firms that are not in dominant positions. However, a firm cannot refuse supply/re-entry into a supply network-dealers that meet certain minimum standards. The chart below shows the exceptions available by agreement type.

⁸³ Bergen, Mark, Heide, Jan, B., and Dutta, Shantanu, *Managing Gray Markets Through Tolerance of Violations: A Transaction Cost Perspective*, Managerial and Decision Economics, May, 1998, pg. 164 pages, 157-165

⁸⁴ Cavusgil, Tamer, S., Sikora, Ed., *How Multinationals can Counter Gray Market Imports*, Columbia Journal of World Business, Winter, 1988, pg. 80, page 75-85 and Cespedes, Frank, V., Corey, Raymond, E., Kasturi, Rangan, V., *Gray Markets: Causes and Cures*, Harvard Business Review, July-August, 1988, pg. 80, pages 75-82,

⁸⁵ Farquharson, Melanie and Smith, Vincent, *Parallel Trade in Europe*, Sweet and Maxwell, 1998.

⁸⁶ Regulation 1983/83, Article 3 d)

Figure 7: Exceptions for Distribution Agreements⁸⁷

	Tie for supply of goods?	Control Over Brand	Active Sales Allowed Outside Territory?	Passive (Parallel trade) Sales Allowed?	No Time Limits on Agreements
Type of Agreement					
Agency	//	//	//	/	//
Franchise	/	//	//	x	/
Exclusive Purchasing	//	/	x	xx	xx
Exclusive Distribution	//	/	/	x	/
Selective Distribution	x	//	x	xx	/

N.B. // = allowed, xx = not allowed, / = allowed with some exceptions, x =not allowed with some exceptions

4.2 Pricing

Lowering prices in the importing country was a method mentioned often in academic literature.⁸⁸ This logically will negate the market for PI products if the price differential is low enough that the importer could not make a profit. This strategy requires deep enough pockets to out last the importer. The two dangers of this are if the importer survives long enough to make buyers perceive the low prices are the norm, and if legal actions are taken by the parallel importer.

A pricing method proposed by Yang and Simon is ‘friction pricing’.⁸⁹ This involves setting the price differentials between the source and importing state at the level equal to the transaction costs incurred by the importer, in so doing taking away any profit opportunity for gray marketers. Alternatively frequent pricing change with the goal of making supply of PI goods inconsistent was another related strategy mentioned by two authors.⁹⁰ It has also been stated that goods sold internationally should be priced in a stable currency.⁹¹

Rebates are mentioned in the literature reviewed as a method for tracking goods. They could prove to be more useful than the academic literature gives them credit for. Rebate agreements could also be used with national health service providers to encourage them to switch to ‘official’ products. In exchange for contractually agreeing to purchase from

⁸⁷ Farquharson, Melanie and Smith, Vincent, *Parallel Trade in Europe*, Sweet and Maxwell, 1998 pg. 59.

⁸⁸ Yang, Rachel, B., Ahmadi, Reza, H., Monroe, Kent, B., *Pricing in Separable Channels: The Case of Parallel Imports*, Journal of Product and Brand Management, vol. 7, issue 5., pg. 446, pages 433-440, Cavusgil, Tamer, S., Sikora, Ed., *How Multinationals can Counter Gray Market Imports*, Columbia Journal of World Business, Winter, 1988, pg. 79, page 75-85.

⁸⁹ Simon, Hermann, and Kucher, Erckhard, *The European Pricing Time Bomb: And How to Cope with it*, European Management Journal, vol. 10, issue 2, 1992, pages 136-146, Yang, Rachel, B., Ahmadi, Reza, H., Monroe, Kent, B., *Pricing in Separable Channels: The Case of Parallel Imports*, Journal of Product and Brand Management, vol. 7, issue 5., pg. 446, pages 433-440

⁹⁰ Weigland, Robert, E., *Parallel Import Channels – Options for Preserving Territorial Integrity*, Columbia Journal of World Business, Spring 1991, pg. 57 pages 53-61 and Lee, Khae, S., Lim, Guan, H., Tan, Soo, J., *Strategic Management of Grey Marketing*, Journal of Strategic Marketing, issue 8, 2000, pg. 69, pages 67-88.

⁹¹ Weigland, Robert, E., *Parallel Import Channels – Options for Preserving Territorial Integrity*, Columbia Journal of World Business, Spring 1991, pg. 56, pages 53-61

the official network, a rebate equal to, or slightly more than the savings provided by the parallel traders could be offered as an enticement to buy from the official network in an effort to squeeze parallel trader profits.

Another option takes away the profitability of parallel trade and was first proposed by Howell,⁹² and later mentioned by several other authors⁹³ as a possible countering tack to PI. This move involves setting a uniform price across all markets, thus taking away any stimulus for parallel trade. The strategy of charging one price is raised and deemed to be ineffective by Farquharson because the ability to profit maximize is lost in higher priced countries.⁹⁴

The dual price strategy involves charging a lower price for pharmaceuticals used within an exporting state, while charging more for goods that are expected to be exported. In actuality this pricing strategy sees a surprising amount of practice considering its potential problems in relation to Article 82.

4.3 Product

Mentioned in most articles was the need to collect tracking information on a firm's products by including necessary tracking tools as part of your product offering.⁹⁵ This strategy involves having numbered warranty cards, serial/batch numbers, as well as factory rebates to track leakages in the authorized distribution chain and subsequently take corrective action. It has been mentioned that this information is not only useful for parallel importing purposes, but also helps in other marketing functions.

Changing the product across national lines is seen as another strategy to oppose parallel imports.⁹⁶ This involves changing the product to suit local tastes,

⁹² Howell, R.D., R.R. Kuzdrall, P.J., and Wilcox, J.B., *Unauthorized Channels of Distribution: Gray Markets*, Industrial Marketing Management, vol. 15, November, 1986, pages 257-263

⁹³ Cespedes, Frank, V., Corey, Raymond, E., Kasturi, Rangan, V., Geay Markets: Causes and Cures, Harvard Business Review, July-August, 1988, pg. 79, pages 75-82, Palia, Aspy, F., and Keown, Charles, F., *Combating Parallel Importing: Views of US Exporters to the Asia Pacific Region*, International Marketing Review, vol. 8, issue 1, 1991, pages 47-56, Yang, Rachel, B., Ahmadi, Reza, H., Monroe, Kent, B., *Pricing in Separable Channels: The Case of Parallel Imports*, Journal of Product and Brand Management, vol. 7, issue 5., pages 433-440

⁹⁴ Farquharson, Melanie and Smith, Vincent, *Parallel Trade in Europe*, Sweet and Maxwell, 1998, pg. 39

⁹⁵ Cavusgil, Tamer, S., Sikora, Ed., *How Multinationals can Counter Gray Market Imports*, Columbia Journal of World Business, Winter, 1988, pg. 80, page 75-85, Cespedes, Frank, V., Corey, Raymond, E., Kasturi, Rangan, V., Gray Markets: Causes and Cures, Harvard Business Review, July-August, 1988, pg. 80, pages 75-82, Lowe, Larry, S., and McCrohan, Kevin, F., *Minimize the Impact of the Gray Market*, The Journal of Business Strategy, November-December, 1989, pages 47-51, Palia, Aspy, F., and Keown, Charles, F., *Combating Parallel Importing: Views of US Exporters to the Asia Pacific Region*, International Marketing Review, vol. 8, issue 1, 1991, pages 47-56 and Lee, Khae, S., Lim, Guan, H., Tan, Soo, J., *Strategic Management of Grey Marketing*, Journal of Strategic Marketing, issue 8, 2000, pages 67-88.

⁹⁶ Palia, Aspy, F., and Keown, Charles, F., *Combating Parallel Importing: Views of US Exporters to the Asia Pacific Region*, International Marketing Review, vol. 8, issue 1, 1991, pages 47-56, Lee, Khae, S., Lim, Guan, H., Tan, Soo, J., *Strategic Management of Grey Marketing*, Journal of Strategic Marketing, issue 8, 2000, pages 67-88, Weigland, Robert, E., *Parallel Import Channels – Options for Preserving Territorial Integrity*, Columbia Journal of World Business, Spring 1991, pg. 60, pages 53-61, Cavusgil, Tamer, S., Sikora, Ed., *How Multinationals can Counter Gray Market Imports*, Columbia Journal of World Business, Winter, 1988, pg. 81, page 75-85 and Eighth Report of the United Kingdom Parliament, Select Committee on Trade and Industry, Minutes of Evidence, Memorandum Submitted by the Association of Pharmaceutical Importers, 1999 pg. 6

health/safety/technical standards and income levels. Changing product attributes including size, shape, dosage sizes, color, service levels, warranties and functionality can cause consumer confusion and resistance in the importing country, as well as complicating marketing authorizations. Changing the packaging of a product across national lines also makes the resale of the product in the importing state more difficult, while raising the costs to the parallel importers.⁹⁷ It is also not a highly expensive alternative, and may be supported by various national requirements. For example, in the UK, pack sizes of pharmaceuticals come in seven, whereas on the continent, the sizes are five and ten.

Using small batch sizes was also presented as an option. Since importers need to keep samples from each batch for safety reasons, having batch sizes that are a dozen or two increases their cost of doing business.

4.4 Promotion

Cavusgil and Sikora state that an effective method of battling parallel trade is to promote the product limitations of gray market goods.⁹⁸ Promotional bursts that flood the media (directed at your target audience: Doctors, Pharmacists, and national health authorities) with the dangers of PI goods could curtail demand.

In her book on gray trade in Europe, Melanie Farquharson broaches a number of possibilities that firms may use to oppose parallel trade.⁹⁹ It is stated that creating brand value is important in stifling imports. A company such as Johnson & Johnson has a very strong brand name and reputation. If they were to present a legitimate safety concern to decision makers regarding parallel trade, they would be more inclined to listen than the to promotional efforts of a less reputable company. The possibility of having different brands in various member states, and creating differing brand images can be successful if it is not deemed to be contributing to the partitioning of the single market. Another idea of hers was to have primary (premium) and secondary brands in order to stifle PI.

Cavusgil presents acquisition as a maneuver that is potentially dangerous and expensive. This strategy should only be considered where importers operate in a high opportunity area and where authorized streams are limited. A manufacturer must ensure that there is little chance of the importer re-opening the business under a different name. This strategy involves going into a new business area for the manufacturer where they do not necessarily possess the required skill sets necessary to compete, and thus this option must be considered carefully.

Furthermore, given the size and clout of the pharmaceutical industry, another strategy could be to start a collective industry effort to decrease the influence of PI. Exchange of

⁹⁷ Palia, Aspy, F., and Keown, Charles, F., *Combating Parallel Importing: Views of US Exporters to the Asia Pacific Region*, International Marketing Review, vol. 8, issue 1, 1991, pg. 52, pages 47-56 and Eighth Report of the United Kingdom Parliament, Select Committee on Trade and Industry, Minutes of Evidence, Memorandum Submitted by the Association of Pharmaceutical Importers, 1999 pg. 8

⁹⁸ Cavusgil, Tamer, S., Sikora, Ed., *How Multinationals can Counter Gray Market Imports*, Columbia Journal of World Business, Winter, 1988, pg. 80, page 75-85

⁹⁹ Farquharson, Melanie and Smith, Vincent, *Parallel Trade in Europe*, Sweet and Maxwell, 1998.

best practices, distribution techniques, and mutual support could work to effectively minimize any threat from the gray market.

Lobbying is can be seen as a form of political advertising in an attempt to promote a company's viewpoints. The manufacturer can attempt influence parallel trade policy within the EU.

4.5 Technological

Matthew Myers and David A. Griffith make the one broad recommendation to use a web-accessible database that offers the manufacturer, and reliable distributors 'input and review of information that may be critical to monitoring and forecasting gray market activities.'¹⁰⁰ Myers states that a management information system (MIS) network will help in the co-ordination of the distribution channel horizontally in that having an MIS system gives timely information to the manufacturer when sales anomalies occur, enabling 'flagging' PI suppliers as well as stimulating communication. Lee supports such channel co-ordination by: 'Carefully restructuring reseller channels, prohibiting re-sales outside specified territories, adjusting prices, providing special promotional allowances, terminating dealer agreements and buying back gray market goods.'¹⁰¹ He goes on to argue that MIS will aid in staying apprised of changing regulations, paying attention to the product portfolio across markets as well as aiding in disseminating and gathering pricing information. Communication between dealers and the manufacturer should also be increased with an effective MIS system.

¹⁰⁰ Myers, Matthew B. and Griffith, David A., *Strategies for Combating Gray Market Activity*, Business Horizons, November-December, 1999, page 6, pages 2-8

¹⁰¹ Lee, Khae, S., Lim, Guan, H., Tan, Soo, J., *Strategic Management of Grey Marketing*, Journal of Strategic Marketing, issue 8, 2000, pg 69, pages 67-88

5.0 Political Environment for PI and Pharmaceuticals

The existence of parallel importation is in no small part because of political motivations. While the semi-political area of pricing and re-imburement is discussed above, the wholly political areas of harmonization and EU expansion are discussed in this section.

5.1 Harmonization of the European Market for Pharmaceuticals

The common market for pharmaceuticals is not complete, and the currently existing patchwork of harmonization is not likely to ever be completed with the existing subsidiarity principle. The first European Directive for pharmaceuticals was released during the EC's youth in 1965 (Directive 65/65)¹⁰². It came about to protect human health after the thalidomide tragedy in the early 60s when thousands of children were born with limb deformities after the drug thalidomide during pregnancy.¹⁰³ One area where harmonization is complete is in the area of mutual recognition of drug marketing authorizations, which makes not only the legal leg work easier for pharmaceutical companies but essentially created a major impetus for the parallel importation industry. Directives 75/318, and 75/319¹⁰⁴ sought to introduce mutual recognition of national marketing authorizations within the EC, and had to goal of ensuring the free movement of medicines through the Community. This was really the first step towards a common market for pharmaceuticals. The Directives also made parallel trade of pharmaceuticals within the European Union a whole lot easier for traders.

5.1.1 First Commission Communication

Following the *Centrafarm* and *DePeijper* rulings, the European Commission issued the 'Commission communication regarding parallel imports of proprietary medicinal products for which marketing authorizations have already been granted'.¹⁰⁵ The Communication left it to member states to decide the level of stringency national checks on imported drugs from within the EU (above a minimum standard), but stated that national rules restricting pharmaceutical imports that breach the Treaty are only allowed insofar as they are necessary for the protection of health and life of humans. It also sets up minimum information requirements that parallel traders have to provide to the national health services in the importing country. Many countries have opted to take a more stringent approach to checking parallel imports than the minimum standard set.¹⁰⁶ This Communication has been recently updated, and will be assessed below.

¹⁰² Directive 65/65, OJ L 022, 09/02/1965, p. 0369

¹⁰³ European Commission, Directorate General for Enterprise, *Pharmaceuticals in the European Union*

¹⁰⁴ Directive 75/318 and 75/319, OJ L 147, 09/06/1975, p. 1

¹⁰⁵ Commission communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted, OJ No C 115/5, May 6, 1982, page 127-130

¹⁰⁶ According to a memorandum submitted to the UK Select Committee on Trade and Industry by the Association of Pharmaceutical Importers, page 3 <http://www.parliament.the-stationery-office.co.uk/pa/cm199899/cmselect/cmtrdind/380/9051113.htm> : The UK for example requires a) Each product must be checked against predetermined and agreed quality standards as well as being subject to documentation establishing an audit trail back to the manufacturer. b) The Inspection & Enforcement Division of the MCA undertakes regular visits to the premises of all the licensed importers to ensure compliance not only with the terms of each and every Parallel Import license issued but also to undertake random checks on: quality, the audit trail for specific products and health and safety aspects. c) The MCA (regulatory authority of Medicines in the UK) undertakes the monitoring of medicinal products once they have been placed upon the market d) The importer must comply with pharmacovigilance and product

5.1.2 The Trademark Directive

In between the times of the *Stephar* and *Primecrown* rulings, the Commission released its Trademark Directive. Embedded in the Directive (TMD)¹⁰⁷ was the legal tool that was used by the ECJ to endorse regional exhaustion is the much discussed Article 7 (1) of the trademark directive explicitly states in support of the Articles above: "a trademark owner cannot prohibit use of its mark on goods once these goods have been put on the market in the EEA by the trademark owner or with his consent."¹⁰⁸ The Directive also states however, that the goods should not be impaired. The TMD was adopted in 1989, but was not enforced until 1996. Its primary purpose 'was to approximate the main provisions of trademark law in all Member States so as to facilitate the functioning of the Internal Market'.¹⁰⁹

The development of the Trademark Directive (TMD) did not happen over night however. In the early 1980, the Commission first proposed a Trademark Directive, in order to harmonize the TM laws of Member States, but much was debated regarding the issue.¹¹⁰ Originally, the proposed directive opted for international exhaustion¹¹¹, however the Economic and Social Committee lobbied to get regional exhaustion put instead, and accordingly the words three words 'in the Community' were added to "The trade mark shall not entitle the proprietor thereof to prohibit its use in relation to goods which have been put on the market under that trade mark by the proprietor or with his consent".¹¹² The debate was later noted in Advocate General Jacobs' Opinion of the *Silhouette* ruling.¹¹³ The changed directive was adopted in 1989, and was amended to cover the EEA. The Directive was another harmonization effort by the Council that affected the environment in which parallel traders and pharmaceutical companies have to deal with.

The effects of the TMD and the *Silhouette* ruling affected different countries differently. Sweden, for example, had an EEA exhaustion for some time for pharmaceuticals. Other countries did have trade of pharmaceuticals from outside the EEA, as is implied in one research paper.¹¹⁴ Countries that opted for international exhaustion of pharmaceuticals should be aware however, for as the UK Parliament concluded in its extensive research into international exhaustion: '*We accept that the nature of the pharmaceutical market means that any move towards international exhaustion of intellectual property rights*

recall obligations, and monitor variations on licenses. And e) Have a Qualified Person hired by the Medicines Control Agency to monitor operations

¹⁰⁷ First Directive 89/104/EEC of the Council, of 21 December 1988, to Approximate the Laws of the Member States Relating to Trade Marks, OJ EC No L 40 of 11.2.1989

¹⁰⁸ First Directive 89/104/EEC of the Council, of 21 December 1988, to Approximate the Laws of the Member States Relating to Trade Marks, OJ EC No L 40 of 11.2.1989

¹⁰⁹ O'toole and Treanor, Colm, *The European Union's Trade Mark Exhaustion Regime*, World Competition 25(3) page 286, pages 279-302, 2002

¹¹⁰ Eighth Report of the United Kingdom Parliament, Select Committee on Trade and Industry, <http://www.parliament.the-stationery-office.co.uk/pa/cm199899/cmselect/cmtrdind/380/38008.htm>

¹¹¹ O'toole and Treanor, Colm, *The European Union's Trade Mark Exhaustion Regime*, World Competition 25(3) page 287, pages 279-302, 2002

¹¹² Trogh, Ramses, *The International Exhaustion of Trade Mark Rights after Silhouette: the End of Parallel Imports?* Lunds Universitet, May 2002, page 18

¹¹³ Jacobs, Advocate General, Opinion, European Court of Justice, Case C-355/96, *Silhouette vs. Hartlauer*, ECR I 676, paragraph 43, 1998

¹¹⁴ Parallel Imports – Effects of the *Silhouette* Ruling, Konkurrentsverket, 1999, page 36

could have severe consequences'.¹¹⁵ The Directive still did lay the groundwork for the most substantial ruling in regards to exhaustion, the *Silhouette* ruling. It stated that in the EEA, even for pharmaceuticals, that regional exhaustion would be the law of the land.

Sixteen years after the proposal, the TMD came into force in 1996. At this time, the wording of Article 7(1) was still a bit ambiguous. Before the TMD was transposed into national law, Member States differed significantly in their approach to exhaustion. Denmark, Austria, Belgium, Finland, UK, Sweden, Ireland, Luxembourg, Netherlands and Germany all had regimes of international exhaustion.¹¹⁶ It was interpreted by many Member States that international exhaustion was still acceptable, and that Community exhaustion was a minimum standard. Sweden for example steadfastly supported International Exhaustion as was seen by their support of Hartlauer, the parallel importer in the *Silhouette* case, and did not transpose regional exhaustion until it was forced to. Other Member States were using national exhaustion including: Spain; Portugal; Italy; France and Greece.¹¹⁷ It appeared that for some time, since the *Consten vs. Grundig*¹¹⁸ ruling, and even after the TMD came into force, that Community exhaustion had been co-existing side by side with national and international exhaustion with out much fanfare. It is now clear that the only exhaustion regime that can exist is within the EEA.

5.1.3 Harmonization during 1990-2004

The 1990s saw a wealth of integrative steps in the pharmaceutical field. 1992 saw further harmonization in packaging,¹¹⁹ leaflets and advertising¹²⁰ of pharmaceuticals. The European Agency for the Evaluation of Medicinal Products was created in 1995, which created a 'one stop shop' for pharmaceutical companies seeking marketing authorizations across the entire EU either through centralized authorizations or via mutual recognition.¹²¹ The transparency directive¹²² was the first move of the EU institutions into the national realm of pharmaceutical pricing and reimbursement. One observer put it thus, 'Its main function was to establish a "foot in the door" for the Commission in the question of national price regulations.'¹²³ Directive 93/39 further implemented this mutual recognition of pharmaceuticals principle and stated that as of January 1, 1998, mutual recognition of pharmaceuticals is compulsory for all medicines marketed in a Member State other than that in which they were first authorized.¹²⁴

¹¹⁵ Summary of Conclusions and Recommendations, Eighth Report of the United Kingdom Parliament, Select Committee on Trade and Industry, <http://www.parliament.the-stationery-office.co.uk/pa/cm199899/cmselect/cmtrdind/380/38014.htm>

¹¹⁶ O'toole and Treanor, Colm, *The European Union's Trade Mark Exhaustion Regime*, World Competition 25(3) page 286, pages 279-302, 2002

¹¹⁷ Ibid.

¹¹⁸ C-56/64, and C-58/64, Judgment of the Court of 13 July 1966. *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community*

¹¹⁹ Directive 92/27 EEC

¹²⁰ Directive 92/28 EEC

¹²¹ Ninth Annual Report on the Activities of the European Agency for Evaluation of Medicinal Products, 11 March, 2004, page 5

¹²² Directive 89/105 EEC

¹²³ Kotzian, Peter, *Stuck in the Middle: Welfare Effects of the European Pharmaceutical Markets' Incomplete Integration and a Possible Remedy*, Mannheimer Zentrum für Europäische Sozialforschung, 2002

¹²⁴ Directive 93/39/EEC, Official Journal L 214 , 24/08/1993 P. 0022, Article 7(1)

In between *Hoffman LaRoche* and the *Paranova* cases, Directive 92/27 was written as a step in harmonizing packaging requirements in the Community. It requires that all information identifying the product be stated on the outer packaging,¹²⁵ that the language must be that of the Member State in which it is sold, is legible, and it requires that a leaflet must be included if all information is not on the outer package. The Directive gave a tool to parallel traders to modify packaging since it required that the language must be native on the packaging in order for a pharmaceutical product to be saleable in that state.

In 1998, the Commission released a Communication on the single market in pharmaceuticals¹²⁶ in consideration of the 'Bangemann Round Table' discussions between pharmaceutical players, Member States and the European Commission. The initiative was started largely because of the EUs slipping attractiveness as a pharmaceutical R&D location for investment.¹²⁷ The Communication highlighted three future alternatives of harmonization of pharmaceutical policies in the EU: the status quo approach, the fully integrated approach, and the middle way approach. It appears that the middle approach has been opted for. The EU institutions can only harmonize the pharmaceutical market in the EU as far as they do not breach the subsidiarity principle, which leaves health policy to Member States.¹²⁸

As mentioned above, a recent political development seen in the PI realm is the recent update to the 1982 Communication on parallel imports of medicinal products with the Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted, which highlights the right to parallel import in light of previous ECJ decisions.¹²⁹ The Communication emphasizes the simplified marketing authorization of goods that are granted first authorizations to the IP holder in the MS of origin as was outlined in the 1982 Communication. It states that this is even the case when the marketing authorization has been withdrawn. In light of the *Hoffman LaRoche* and *Paranova* cases, the Communication outlines the situations where repackaging is permissible. It goes on to recognize the developments made in the ECJs jurisprudence in light of a number of cases.¹³⁰ The Communication concludes with a FAQ section where within the last answer effectively summarizes the current situation regarding parallel trade in the European Union:

¹²⁵ Such information includes: product name; pharmaceutical form; composition, excipients and method of administration; contents; name and address of authorisation holder as well as authorisation number and batch number

¹²⁶ Commission Communication on the Single Market in Pharmaceuticals, European Commission, November 25, 1998

¹²⁷ Chevrouvri, Anna, *The Initiative of a Single Market for Pharmaceuticals in the EU, Impact on the Industry*, May, 2002, pg. 21

¹²⁸ Treaty Establishing the European Community, Article 152

¹²⁹ Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted, COM(2003) 839, December 30, 2003

¹³⁰ In parallel import licensing: Case 247/81 Commission v Germany (1984); C-201/94 Smith & Nephew (1996); C-94/98 Rhône-Poulenc (1999); C-172/00 Ferring (2002), In national patent rights: Case 434/85 Allen & Hansburys (1988), C-191/90 Generics (1992), joined cases C-267 and 268/95 Merck v Primecrown (1996), In trademarks and repackaging: Joined cases C-427, 429 & 436/93 Bristol-Myers Squibb (1996) ECR I-3457, case C-232/94 Rhône-Poulenc (1996) ECR I-3671, C-379/97 Pharmacia & Upjohn (1999) ECR I-6927, C-143/00 Boehringer etc (2002) ECR I-3759, C-443/99 Merck, Sharp and Dohme vs Paranova (2002) ECR I-3703, and others

Even though the Court has addressed a great number of issues and despite the Community legislation that deals with general issues regarding the marketing of medicinal products, there can by no means be any "definitive" guide to parallel imports. New questions keep emerging and old answers need more clarification. Respect of what has already been achieved and continuous cooperation among Community institutions, national authorities and economic operators has been and still is a solid basis for the resolution of all remaining problems.¹³¹

The Communication recognizes the lack of co-ordination in some areas including: ‘improving access to risk capital, especially for start up companies; providing better links between basic and applied research; monitoring the trend for large companies to link up or merge; eliminating the remaining barriers to entry in the main third country markets.’¹³² It goes on to recognize the market distortions caused by pricing policies, but passes the responsibility of harmonization onto the Member States. It currently stands in Europe that some areas of pharmaceutical policy are harmonized, while others; including some of the most important areas such as pricing and reimbursement remain under the scope of Member State responsibility. This patchwork of Directives, Communions, Regulations and Agencies currently acts to the benefit of parallel traders. Harmonizing in areas such as packaging and mutual recognition of authorizations reduce the cost of doing PI while leaving pricing up to Member States promotes it.

The G10 Medicines Group, with the objective to reconcile ‘the twin goals of both encouraging innovation and competitiveness and ensuring satisfactory delivery of public health’¹³³, is a collective initiative by the pharmaceutical industry and Brussels. The high level group makes recommendations such as disallowing MS to control the price of medicines not purchased or reimbursed by the State, and that neoclassical competition should be allowed for other medicines.¹³⁴ It is clear that an attempt was made to recommend a more competitive environment be endorsed in Europe. Apart from the ‘Special Mechanism’ for accession countries, it seems that the pro-competitive advice of the high group has not come to fruition.

The legislation regarding pharmaceutical use is constantly evolving, and creating greater harmony in the area within the EU. A chart below summarizes some of the more important areas where harmonization has occurred, is partially completed, and where there is currently no harmonization on a pan-European level.

Figure 8: The EU Pharmaceutical Harmonization Patchwork

Harmonized	Partially Harmonized	Not Harmonized
Transparency Directive for IP Rights 89/105	Agreements on Directives on Product Classification (Directive 92/26)	Pricing Policies for new, off patent and generics - MS control via principle of subsidiarity

¹³¹ Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted, COM(2003) 839, December 30, 2003, pg. 20

¹³² Commission Communication on the Single Market in Pharmaceuticals, European Commission, November 25, 1998, pg. 7

¹³³ Nazzini, Renato, *Parallel Trade in the Pharmaceutical Market: Current Trends and Future Solutions*, World Competition, 26 (1), 2003 pg. 56

¹³⁴ Ibid. pg. 57

Extension of Patent Protection with Supplementary Patent Certificate (SPC), (Regulation 1768/1992)	Working on an EU level with third countries such as the Good Manufacturing Practice Agreements with Canada and USA	Re-imbusement of pharmaceuticals - MS control via principle of subsidiarity, Article 152 Treaty of Amsterdam
Agreement on Directives on Product Classification (Directive 92/26)	Mutual Recognition of Marketing Authorizations of other MS	Taxes of pharmaceuticals such as Value Added Tax (VAT)
Patents on biotechnology, Directive (98/44)	Good Manufacturing Practices (Directive 89/341)	Parallel Trade incentivization and deterrence: Council invited Commission to address in patent PT (Council of Ministers Conclusions on Single Market for Pharmaceuticals, 1998)
Centralized Marketing Approvals through Creation of EMEA (Regulation 2309/1993)	Labeling, packaging and inserts (Directive 92/27): but packaging standardization, pill formats etc. Does not exist within the EU	Incetivizing and Deterrence of Pharmaceutical R&D
Advertising and Promotion (Directive 92/28)	Wholesale Distribution (Directive 92/25)	Generic Prescribing, Promotion, Substitutions, and Dispensing
	Community Trademarks (Regulation 40/94)	Use of pharmacoeconomics
	Community Patents (In Discussion, Possible Completion in Near Future)	
	Mutual Recognition of Health Services (ECJ Decker C-120/95 Ruling)	
	Clinical Trials (Directive 2001/120)	
	Promotion of Orphan Drugs Research (Regulation 141/2000)	

5.2 European Union Expansion

As is well known, the European Union expanded its horizon to include ten new Member States on May 1, 2004, during the time of writing. Seeing as the expansion is both timely and has an effect on parallel importation, an explanation and some commentary regarding the accession countries is included.

Article 2 and Article 10 of the Act of Accession¹³⁵ includes a ‘Specific Mechanism’, which targets and helps to prevent parallel imports of some pharmaceuticals for a period of time. This derogation for Community exhaustion holds that:

‘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 (all accession countries hold Cyprus and Malta) for that product, may rely on the rights granted by that patent or supplementary protection certificate in order to prevent the import and

¹³⁵ 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) OJ L 236/33

marketing of that 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'

This means products that filed for patent or SPC protection in an EU 15 MS at a time when no such protection was available in the accession country in question, the patent-holding firm can use their IP protection in the MS of importation to prevent PI from countries that did not have such IP protection at time of filing. This covers a relatively narrow and gradually decreasing product segment. It has been observed that 'the Specific Mechanism raises a plethora of questions which will likely result in numerous legal proceedings before national and Community courts.'¹³⁶ It is noted that because of differences in health care spending, GDP per head, and pharmaceutical prices, there is expected to be considerable scope for arbitrage both into and from acceding countries, which made the Specific Mechanism necessary.

Sufficient IP protection was offered in accession countries as follows:¹³⁷

Czech and Slovak Republics	January 1, 1991
Slovenia	April 4, 1992
Latvia	March 31, 1993
Poland	April 16, 1993
Lithuania	February 1, 1994
Estonia	May 23, 1994
Hungary	July 1, 1994

Thus products that filed after these dates are fair game for parallel importers. However, products that filed for protection before these dates can be protected from PI via the IP filings in the MS of importation. The Specific Mechanism will last a long time for some products, ranging from 2016 for Czech and Slovak Republics, and 2019 for Hungary.

In effect, what this Specific Mechanism acknowledges is that the *Stephar* and *Primecrown* rulings will not be allowed to happen with this accession round. Considering the flack that the ECJ received for the above rulings, it is understandable that the Community would not want to place ECJ in such a precarious position again. It has been mentioned that this Specific Mechanism was due to the aggressive lobbying of the pharmaceutical industry to protect their IP rights.

The implications of the expansion on parallel importation and the subsequent effects on the pharmaceutical industry are not clear-cut. With a quick glance at the situation, one would assume, as did the author did, that the accession countries will provide a fresh and cheap sourcing pool for importers, making the trade much more easy and profitable. However when asked: '*This (expansion) should give Paranova a huge opportunity for sourcing, would that be a correct assumption?*' Kim Jensen responded in saying that: '*Huge, I don't know... many of these countries have more expensive drugs than in western countries.*'¹³⁸ (Appendix C) Another observer notes that because a lack of

¹³⁶ Feddersen, Christoph, T., Parallel Trade in Pharmaceuticals in a Europe of 25: What the 'Specific Mechanism' Achieves, and What it Does Not, EIPR, Issue 12, pg. 545, pages 545-555, 2003

¹³⁷ Feddersen, Christoph, T., Parallel Trade in Pharmaceuticals in a Europe of 25: What the 'Specific Mechanism' Achieves, and What it Does Not, EIPR, Issue 12, pg. 551, 2003

¹³⁸ Interview with Kim Jensen, Advokat, Paranova A/S, May 6, 2004

effective protection along with other economic reasons within Central and Eastern Europe, the prices are likely to be lower than in the rest of the EU, and likely to be a source of cheap parallel imports.¹³⁹ A simple statement will suffice to summarize the situation in either case: The expanded internal market will provide further opportunities for parallel trade be it using accession countries as source states, or states of importation.

¹³⁹ Brerton, Graham, *Crucial Questions About EU Expansion*, July/August, 1998, Issue 81,

6.0 Legal Environment of PI and Pharmaceuticals

This section does not specifically look at legal strategies employed to prevent PI, but are presented along with a broader picture of the current EU legal framework regarding pharmaceuticals and parallel importation. After a background section, the relevant case law is explored from ECJ and National Courts. A brief analysis of the strategic implications of ECJ and national cases for the pharmaceutical manufacturer follows.

6.1 Legal Background

A strategy employed regularly in the EU is one that is revealed in three sources,¹⁴⁰ namely using available laws in an attempt to slow down or stop PI by creating legal precedence. Even if use of litigation is unsuccessful, it may be worth the cost, because during an action sometimes, an injunction may be obtained preventing the importer from dealing in the subject product thus limiting effective PI competition from that importer for the duration of the case. If such actions are successful, a precedent has been created that could be relied upon in the future. After considering the legal situation for PI in the EU below, this paper will discuss legal alternatives that are still available for pharmaceutical companies.

The complexity of the legal framework surrounding PI in Europe, particularly in regards to exhaustion and IP rights, means that the jurisprudence is constantly evolving. The stance taken by the ECJ in favour of the free movement of goods over IP rights has seemingly softened over time. Parallel importers use the Treaty of Rome as the primary tool to defend from attacks regarding IP infringement by pharmaceutical IP right holders. Efforts to eliminate PT in other industry sectors have primarily focused on price harmonization between European markets. The pharmaceutical industry cannot readily employ this tactic since prices and re-imburement schemes are controlled by the Member States. The evolution is discussed via interpreting relevant case law and Community measures.

The EU and the ECJ have been notoriously supportive of Parallel Trade. The support has been necessary primarily because of some fundamental Articles in The Treaty Establishing The European Community (TEC), which is the backbone of Europe's legislative framework. Recently, their decisions are indicating that they are beginning to roll back on their blind adherence to the free-movement of goods and subsequent support for parallel traders. Looking briefly at three Articles of the TEC should help us to understand the relevant free movement principles:

Article 3 states as a primary objective to establish: 'an internal market characterized by the abolition, as between Member States, of obstacles to the free movement of goods, persons, services and capital'

¹⁴⁰ Weigland, Robert, E., *Parallel Import Channels – Options for Preserving Territorial Integrity*, Columbia Journal of World Business, Spring 1991, pg. 57, pages 53-61, Cavusgil, Tamer, S., Sikora, Ed., *How Multinationals can Counter Gray Market Imports*, Columbia Journal of World Business, Winter, 1988, pg. 83, page 75-85 and Eighth Report of the United Kingdom Parliament, Select Committee on Trade and Industry, Minutes of Evidence, Memorandum Submitted by the Association of Pharmaceutical Importers, 1999 pg. 6.

Article 28 states that: 'Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.'

Article 29 prohibits the same actions in exports,

*And Article 30 states that: 'The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; 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.'*¹⁴¹

The free movement of goods is a 'central plank of the integration process of the economies of Europe'.¹⁴² Indeed, Kim Jensen, the legal advisor of Paranova A/S, regarded Article 28 as the legal basis of the parallel trade business in a recent interview shown in Appendix C. It is generally accepted to be the most important of the four fundamental freedoms. EU competition law and the fundamental free movement of goods principle seeks to promote movement of goods across borders. IP Law protects industrial property that 'is the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time.'¹⁴³ There is a definite conflict between these two sets of laws, one observer calls exhaustion a contradiction, explaining that 'While patents provide incentives for innovation, they stifle competition. Competition, in turn, improves affordability, but may stifle innovation.'¹⁴⁴ Another observer notes that the exclusivity that IP rights provide are: 'anti-competitive since they restrain other people from taking advantage of innovation or reputation without the consent of the holder: they constitute barriers to entry.'¹⁴⁵ On the other hand, they encourage investment in innovation, particularly in pharmaceutical products 'that are costly to develop and take time through their clinical trials, but can be cheaply copied from the specification required for the marketing authorization.'¹⁴⁶ Unfortunately for the pharmaceutical sector, which is so heavily dependent on IP rights¹⁴⁷, the ECJ, while recognizing the conflict decides generally in favour of the free movement of goods. The national courts have been somewhat supportive of IP rights however.

The conflict is at least addressed by Article 30's recognition of industrial and commercial property protection as being a possible derogation from Article 28 and 29.

¹⁴¹ Treaty Establishing the European Community

¹⁴² Farquharson, Melanie and Smith, Vincent, *Parallel Trade in Europe*, Sweet and Maxwell, 1998, page 6

¹⁴³ Judgment of 31/10/1974, C-15-74 Centrafarm BV and others / Sterling Drug, paragraph 9

¹⁴⁴ Gonzalez Perini, Frederico, *Patent vs. Trade?: The Issue of Patent Right Exhaustion*, *Legal Issues of Economic Integration* 30(2): pg. 133, 133-156, 2003.

¹⁴⁵ Korah, Valentine, *An Introductory Guide to EC Competition Law and Practice*, 2000, pg. 257

¹⁴⁶ Korah, Valentine, *An Introductory Guide to EC Competition Law and Practice*, 2000, pg. 278

¹⁴⁷ Mansfeld, E. *Patents and Innovation: An Empirical Study*, *Management Science*, February 1986 – Attests that the pharmaceutical industry is at least twice as reliant on intellectual property rights as the next sector, chemicals.

The ECJ, acting as interpreter of the Treaty, has only allowed national IP right holders to use Article 30 in matters involving inter-Community trade,¹⁴⁸ and use of Article 30 to prevent parallel trade within the EU of pharmaceuticals is almost never allowed by the ECJ.

6.2 Case Law

Due to the lack of clear, politically created regulations and directives on the European level, it has been largely through the case law of the European Court of Justice (ECJ) from which one should analyze the current legal environment for pharmaceuticals in the European Union. To understand the ECJ's reasoning, an overview of several decisions and important opinions will be examined. It is worth noting that the pharmaceutical IP right holders initiated most cases. Historically, most of the decisions have gone the way of the parallel trader at the European level; however, decisions are more mixed at the National level. Several other cases surrounding exhaustion and the free movement of goods do not deal directly with pharmaceuticals, but helped create the legal environment in which traders and IP right holders have to deal with. As it stands now, there are still many holes in the case law, which is why there is an abundance of EJC level cases.¹⁴⁹

In looking at the relevant case law, we will separate the discussion into several groups of cases including the following: Exhaustion Principle, International Agreements regarding Exhaustion, Re-Packaging, Re-branding, Co-branding, Supply Restriction, Licensing, National Rulings, National Measures.

6.2.1 Exhaustion Principle

At the core of Parallel Trade is the Principle of Exhaustion (or First Sale Doctrine). According the Exhaustion Principle, the IP owner receives the benefit of IP ownership upon release of the product onto the market when monopoly profits are reaped by the initial sale of the good/service/method.¹⁵⁰ After that benefit is reaped, the IP right holder loses the right of control over the patent/trademark since the IP right is 'exhausted'. This allows the subsequent purchasers of these goods to resell, destroy, give away, lend the goods as they see fit. Three exhaustion regimes are currently used:

- 1) International Exhaustion: In the case of international exhaustion, rights become exhausted upon first sale anywhere, and the IP right holder has no legal power to prevent the introduction of the patented product in his national market once the product was legally put onto market anywhere else.¹⁵¹
- 2) In regional exhaustion, rights become exhausted upon first sale within the territory of a specific group of countries. Even though the right holder cannot prevent the introduction of the patented product in his national territory, or when it comes

¹⁴⁸ Trogh, Ramses, *The International Exhaustion of Trade Mark Rights after Silhouette: the End of Parallel Imports?* Lunds Universitet, May 2002

¹⁴⁹ Interview with Kim Jensen, legal advisor of Paranova A/S, May 6, 2004

¹⁵⁰ Kanavos, Panos, Costa-i-Font, Joan, Merkur, Sherry, Gemmill, Marin, *The Economic Impact of Parallel Trade in European Union Member States: a Stakeholder Analysis*

¹⁵¹ Kanavos, Panos, Costa-i-Font, Joan, Merkur, Sherry, Gemmill, Marin, *The Economic Impact of Parallel Trade in European Union Member States: a Stakeholder Analysis*, LSE Health and Social Care, January 2004, page 18

from one of the countries belonging to the 'region', he retains legal power to prevent the introduction of patented products when they come from outside the region. This is the regime imposed in the ECJ opted for in 1998¹⁵².

- 3) In the case of national exhaustion, patent/TM rights become 'exhausted' upon first sale in a nation state, but the IP right holder retains legal power to prevent the introduction of the patented product into the national territory, in situations when the good/service comes from outside that country.

Since the time of the *Consten and Grundig* ruling¹⁵³, it appeared that the ECJ had adopted some kind of Community level exhaustion. The Trademark Directive of 1989¹⁵⁴, which is discussed in some detail below, was the legal tool that was used by the ECJ to endorse regional exhaustion, and the much discussed Article 7 (1) of the trademark directive states simply that: "a trademark owner cannot prohibit use of its mark on goods once these goods have been put on the market in the EEA by the trademark owner or with his consent."¹⁵⁵ It was still unclear to some parties whether Member States were allowed to adopt international exhaustion, since it was argued that it could be seen that EEA exhaustion could be seen as a minimum standard.

The chance for the ECJ to clarify the vision of exhaustion for the EU came in the form of an Austrian case between a sunglass manufacturer, Silhouette and a parallel importer, Hartlauer.¹⁵⁶ The ruling is a cornerstone of European IP law. The facts surrounding the case are as follow: Silhouette, a manufacturer of high-end sunglasses that it sold via selective distribution, had in its possession a batch of sunglasses that were deemed to be outdated. It arranged to sell the sunglasses to a firm with the instructions only to sell the glasses in Bulgaria or the Newly Independent States. Hartlauer, an Austrian retailer attained the batch, and proceeded to sell them in Austria through their retail stores.

Silhouette brought an action for interim relief in April 1996 before an Austrian local Court that was denied, and lost again on appeal before the regional Court. Silhouette then appealed on a point of law to the Austrian Supreme Court. This court was unsure as to what the answer should be regarding exhaustion. Indeed, Austria applied the principle of international exhaustion for trademark rights previous to this time.¹⁵⁷

Advocate General Jacobs' Opinion stated that having more expansive exhaustion than EEA wide would require reading an implied derogation into Article 7 (1) of the TMD. He reasoned that in light of the debate surrounding TMD, case law, and his own views on the aims and scope of the Directive stated that: '*if the Directive is seen as establishing the essential terms and effects of trademark protection it is difficult to*

¹⁵² ECJ Ruling, C-355/96, *Silhouette International Schmied GmbH & Co. KG v. Hartlauer Handelsgesellschaft mbH*, 1998

¹⁵³ C-56/64, and C-58/64, Judgment of the Court of 13 July 1966. *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community*

¹⁵⁴ First Directive 89/104/EEC of the Council, of 21 December 1988, to Approximate the Laws of the Member States Relating to Trade Marks, OJ EC No L 40 of 11.2.1989

¹⁵⁵ First Directive 89/104/EEC of the Council, of 21 December 1988, to Approximate the Laws of the Member States Relating to Trade Marks, OJ EC No L 40 of 11.2.1989

¹⁵⁶ Case C355/ 96 *Silhouette International Schmied GmbH & Co. KG v. Hartlauer Handelsgesellschaft mbH*, Judgment of 16 July 1998. 1998

¹⁵⁷ Case Law, Court of Justice, *Silhouette International Schmied GmbH & Co. KG v. Hartlauer Handelsgesellschaft mbH*, Judgment of 16 July 1998. 1998, C.M.L.R. 306 pages, pg. 809

*argue that it leaves Member States free to opt for international exhaustion.*¹⁵⁸ He went on to point out that the level of exhaustion is one of the matters that most directly affects the functioning of the internal market. He firmly concluded that: ‘Article 7 (1) of the Directive precludes Member States from adopting the principle of international exhaustion.’¹⁵⁹

The Court was posed a complex question, and Member States were divided in their opinion of how it should rule. Sweden supported international exhaustion rights,¹⁶⁰ while the Austrian, French, Italian and British were in favour harmonization in the area. After hearing the arguments presented, the Court decided to follow the opinion of AG Jacobs, and decided: ‘in the light of [the first and ninth recitals in the preamble to the Directive], Articles 5 to 7 of the Directive must be construed as embodying a complete harmonization of the rules relating to the rights conferred by a trademark’¹⁶¹.

The ECJ made clear what it had been deciding since *Consten and Grundig*¹⁶² in trademarks, *Merck vs. Stephar*¹⁶³ in patents, and *Deutsche Grammophon vs. Metro*¹⁶⁴ in copyrights, that in the EU community exhaustion is the only regime that can ensure the common market goals. The Court erased the previous ambiguity of Article 7(1) of TMD, and made it clear to all Member States to harmonize their laws in accordance with the regional exhaustion regime.

This was a blow to those who partook in parallel trade, especially those who sourced with an inter-community element. Mr. Montmar-Stavroulakis of the Swedish Board Trade regarded this ruling as one of the three most important rulings of the last decade regarding parallel importation.¹⁶⁵ IP right holders, while not totally satisfied with the ruling, perhaps saw it as a minor victory, while importers had their source grounds limited from a world of opportunity to the EEC region. An interesting side note to the case was the ECJ left it open for the community to conduct mutual agreement with third states in order to expand the exhaustion area as deemed necessary.¹⁶⁶

A number of cases fortified the Silhouette ruling as well in case there was any doubt as to where the ECJ stood. In *Sebago vs. G.B. Unic-S.A.*¹⁶⁷, the ECJ was asked whether in a case where there was no explicit agreement not to bring in a batch of goods from

¹⁵⁸ Jacobs, Advocate General, Opinion, European Court of Justice, Case C-355/96, *Silhouette vs. Hartlauer*, , paragraph 43, 1998, paragraph 40

¹⁵⁹ Jacobs, Advocate General, Opinion, European Court of Justice, Case C-355/96, *Silhouette vs. Hartlauer*, , paragraph 43, 1998, paragraph 43

¹⁶⁰ In explaining why Sweden advocates for global exhaustion, Markos Montmar Stavroulakis of Kommerskollegium responded: ‘The reason why Sweden would favour parallel trade is that Sweden is a small country and small countries generally benefit from a high degree of free trade. In contrast to other European countries we don't have any strong trade marks of our own to protect. Further, historically Sweden has always been in favour of the principle of global exhaustion.’

¹⁶¹ Case C355/ 96 *Silhouette International Schmied GmbH & Co. KG vs. Hartlauer Handelsgesellschaft mbH*, Judgment of 16 July 1998. 1998, paragraph 25

¹⁶² C-56/64, and C-58/64, Judgment of the Court of 13 July 1966. *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community*

¹⁶³ C-Judgment of 14/07/1981, *Merck vs. Stephar* and

¹⁶⁴ C-187/80, *Deutsche Grammophon Gesellschaft mbH vs. Metro-SB-Großmärkte GmbH & Co. KG.*

¹⁶⁵ Correspondence with Markos Montmar Stavroulakis, Kommerskollegium, May 17, 2004

¹⁶⁶ Case C355/ 96 *Silhouette International Schmied GmbH & Co. KG v. Hartlauer Handelsgesellschaft mbH*, Judgment of 16 July 1998. 1998, paragraph 28

¹⁶⁷ C-173/98, *Sebago and Ancienne Maison Dubois et Fils SA vs. GB Unic SA*

outside the EU for sale in the EU, an implied consent exists to do so existed. The ECJ bluntly stated that: *'the rights conferred by the trade mark are exhausted only if the products have been put on the market in the Community and that provision does not leave it open to the Member States to provide in their domestic law for exhaustion of the rights conferred by the trade mark in respect of products put on the market in non-member countries.'*¹⁶⁸

The court clarified the issue of consent in the *Zino Davidoff and Levi Strauss* case.¹⁶⁹ The ECJ concluded that consent, whether it is implied or contractual must: *'unequivocally demonstrate that the proprietor has renounced his right to oppose placing of the goods on the market within the European Economic Area.'*¹⁷⁰ It is also interesting to note in the EFTA case of *Maglite*,¹⁷¹ the EFTA court decided that since the EEA agreement is not a customs union nor has any common trade policy vis-à-vis a third countries, that EFTA states were free to choose the exhaustion regime that suited their needs.

The *Zino Davidoff* case¹⁷² placed the onus on parallel traders to show from where the imported products came. The ruling allows IP right holders to file an allegation of a TM/patent infringement to find out where the products were sourced. This subsequently allows the IP right holders to distribute selectively assuming they are not in a position of market power. This combined with the fact that batch codes used by manufacturers to locate where goods came from are often illegal to take off packages¹⁷³ gives the pharmaceutical companies the information necessary to find out which wholesalers are supplying parallel traders, and subsequently can limit their supply. This combined with the recent *Bayer Adalat* appeal completion gives pharmaceutical companies a significant strategic defense maneuver against parallel traders.

In 1999 the European Commission looked into the consequences of adopting an international exhaustion regime, and commissioned National Economic Research Associates (NERA) to study the economic consequences of adopting an international exhaustion regime in the EU. The report recommended that the EU keep its existing exhaustion regime citing eight arguments.¹⁷⁴ The Commission followed up with a Working Paper on possible abuses of TM rights in the EU.¹⁷⁵

¹⁶⁸ Ibid, paragraph 24

¹⁶⁹ C-414/99, C-415/99 and C-416/99 *Zino Davidoff SA v A&G Imports Ltd; Levi Strauss & Co, Levi Strauss (UK) Ltd v Tesco Stores Ltd, Tesco plc*

¹⁷⁰ C-414/99, C-415/99 and C-416/99 *Zino Davidoff SA v A&G Imports Ltd; Levi Strauss & Co, Levi Strauss (UK) Ltd v Tesco Stores Ltd, Tesco plc*, paragraph 70

¹⁷¹ E-2/1997,

¹⁷² C-414/99, C-415/99 and C-416/99 *Zino Davidoff SA v A&G Imports Ltd; Levi Strauss & Co, Levi Strauss (UK) Ltd v Tesco Stores Ltd, Tesco plc*

¹⁷³ Possible Abuses of Trademark Rights within the EU in the Context of Community Exhaustion, Commission Working Paper, May 21, 2003 pg. 8

¹⁷⁴ NERA, SJ Berwin & Co. *The Economic consequences of the choice of regime of exhaustion in the area of trademarks*, London, 8th February 1999. Arguments are as follows: 1. Parallel Trade is not efficient way to reduce costs; 2. Counterfeit Risk; 3. Quality Reduction; 4. Product Recall Difficulties 5. Parallel Traders don't pay for promotion; 6. Buyer access in low price countries; 7. Parallel traders are main beneficiaries; 8. R&D Threat

¹⁷⁵ Possible Abuses of Trademark Rights within the EU in the Context of Community Exhaustion, Commission Working Paper, May 21, 2003

6.2.2 International Agreements - Exhaustion

Internationally, exhaustion regimes are left for nation states/customs unions to decide. The Trade Related Aspects of Intellectual Property Rights (TRIPS), which was signed in Marrakesh in 1994,¹⁷⁶ is decidedly ambiguous on the issue of exhaustion. According to Frederick Abbott, during the Uruguay Round discussion of the WTO, it was largely favoured to adopt WTO rules forcing international exhaustion on all members. Consensus was not reached with the USA and the EU both wanting to maintain their existing exhaustion regimes.¹⁷⁷ The result was a decision not to decide. Article 6 of TRIPS states '*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 exhaustion of intellectual property rights.*'¹⁷⁸

6.2.3 Patent Rights

A balance between the principles of free movement of goods and IP laws was first addressed in the *Consten v. Grundig* decision in 1966,¹⁷⁹ where the ECJ ruled that a national law prohibiting parallel trade because of existence of a national IP right went against the free movement principle and separated the existence of IP rights, guaranteed under Article 295 of the EC Treaty from the exercise of them, thus creating a very flexible instrument to enforce common market principles.¹⁸⁰

The balance between IP and Competition law was acknowledged and first examined for pharmaceuticals¹⁸¹ in the *Centrafarm* decisions of 1974.¹⁸² The case concerned a drug marketed by Sterling under the name Negran, which Centrafarm imported into the Netherlands from the UK. Winthrop (Sterling's Dutch Subsidiary) sued for patent infringement. The ECJ concluded that: '*the exercise, by the patentee, of the right he enjoys under the legislation of a Member State to prohibit the sale, in that state of a product protected by the patent which has been marketed in another Member State by the patentee or with his consent is incompatible with the rules of the EEC Treaty concerning the Free Movement of Goods*'.¹⁸³

¹⁷⁶ http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm February 19th, 2004

¹⁷⁷ Abbott FM. First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation, *Journal of International Economic Law* 1998;1: pg. 608, pages 607-636.

¹⁷⁸ Agreement on Trade Related Aspects of Intellectual Property Rights, http://www.wto.org/english/docs_e/legal_e/27-trips.doc February 19th, 2004

¹⁷⁹ C-56/64, and C-58/64, Judgment of the Court of 13 July 1966. *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community*

¹⁸⁰ Korah, Valentine, *An Introductory Guide to EC Competition Law and Practice*, 2000, pg. 259

¹⁸¹ Snell, Jukka, Free Movement of Pharmaceutical Products: An Overdose of Cheap Drugs? *European Business Law Review*, 14 (5), pg 513, pgs 507-521, 2003

¹⁸² C-15/74, *Centrafarm BV and others vs. Sterling Drug* and C-16/74, *Centrafarm BV vs. Winthrop BV*

¹⁸³ Judgment of C-15/74, *Centrafarm BV and others vs. Sterling Drug*, and C-16/74, *Centrafarm BV vs. Winthrop BV*

It should be noted that *Centrafarm v. Winthrop* C-16/74 concluded likewise that: "The owner of a trade mark cannot exercise his rights to prohibit the importation of products with the same trade mark and marketed in another Member State provided that the goods are marketed by the trade mark owner, or by a third party with the trade mark owner's consent. To do so would be incompatible with the free movement of goods provisions in the EEC Treaty."

The ECJ also saw as a moot point that the market for pharmaceuticals in the Community was subject to Member State price and reimbursement cost-containing schemes. They simply left the matter for the Community authorities to deal with.¹⁸⁴ To this day, it is largely an issue that is left un-addressed due to the subsidiarity principle, which leaves Member States to control pharmaceutical pricing and reimbursement.

In addition to this the ECJ ruled in this case that the '*specific subject matter of the industrial property is the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view of to manufacturing industrial products and putting them into circulation for the first time.*'¹⁸⁵ In saying this, the Court ruled that the *raison d'être* of a patent right is to allow the inventor first placement on the market. The other reasons such as allowing for monopolistic conditions and distribution control were not deemed to be of primary concern and could not prevent free movement of goods. It was thus decided that the Article 30 exception was valid insofar as to the limited extent necessary to protect the specific subject matter of the mark (ie. the owner of the TM has the exclusive right of first placement on the market). This was a major victory for parallel traders in Europe, and set the tone of much of what was to come for three decades in advance.

In 1980 came a ruling that was the 'high water mark'¹⁸⁶ of the exhaustion doctrine and parallel trade tolerance in the EU. The case involved *Merck*, which had an IP protected drug on the Dutch market, and sold the same drug on the Italian market where such IP protection was not possible.¹⁸⁷ *Stephar* imported the cheaper drugs from Italy, where no IP rights existed, and sold them in the Netherlands. The ECJ held that:

*'It is for the proprietor of the patent to decide, in the light of all the circumstances, under what conditions he will market his product, including the possibility of marketing it in a Member State where the law does not provide patent protection for the product in question. If he decides to do so he must accept the consequences of his choice...'*¹⁸⁸

It is clear from the wording that the ECJ took no pity on Merck's circumstance of not having any IP protection on the Italian market, and promoted the needs of the common market clearly above the need for intellectual property rights. For parallel traders, it was apparent from this judgment that the EU had a ripe legal environment in which to conduct parallel trade.

This ruling seemed perplexing to some observers for its blind adherence to common market principles. In Italy, there was no patent protection available for any pharmaceutical products, and Merck was still told that they could not rely on another MS's patent protection and that they were subject to the consequences of their actions. This could have prevented a plethora of pharmaceutical introductions in MS like Italy where no patent protection existed. Korah sees the only reason the ECJ may have ruled

¹⁸⁴ C-15/74, *Centravarm BV and others vs. Sterling Drug* (Rec. 1974, p. 1147), paragraph 23 and 24

¹⁸⁵ C-15/74, *Centravarm BV and others vs. Sterling Drug* (Rec. 1974, p. 1147), paragraph 9

¹⁸⁶ Snell, Jukka, *Free Movement of Pharmaceutical Products: An Overdose of Cheap Drugs?* European Business Law Review, 14 (5), pg 513, pgs 507-521, 2003

¹⁸⁷ Merck tried to distinguish this case from the *Centrafarm* cases because there was no patent protection available for their drug in Italy. The ECJ held that this fact did not diminish the need to promote the Free Movement of Goods

¹⁸⁸ C-187/80, *Merck vs. Stephar and Exler* (Rec.1981,p.2063) Paragraph 11

in this manner would have been to encourage MS governments not to control the prices of patented prices too tightly.¹⁸⁹ Another possible reason could have been that the ECJ wanted to encourage countries like Italy to provide patent protection for pharmaceuticals. And if the Court thought that pharmaceutical companies would not introduce new products on the Italian market if they couldn't get protection, the State may have been inclined to provide such protection. In this latest round of EU expansion, the 'special mechanism' that is discussed below makes it so that such cases will not be a possibility.

In *Pharmon vs. Hoechst*, the ECJ proved that it would grant exemptions to the free movement of goods principle in certain circumstances. The British compulsory licensee attempted to import the drug they were licensed to manufacture in the UK to the Netherlands. Hoechst attempted to stop the importation by relying on their patent-protection rights. The ECJ held that a State-granted compulsory licensee is: '*deprived of his right to determine freely the conditions under which he markets his product. The substance of a patent right lies essentially in according the inventor an exclusive right of first placing the product on the market so as to allow him to obtain the reward for his creative effort.*'¹⁹⁰ Thus the ECJ held that the patent holder could sue Pharmon in the Dutch court for IP infringement despite the exhaustion principle because of the fact that the Hoechst did not agree with the licensee that they could export the product and the fact the license was compulsorily granted under UK law.

The ECJ had a chance to review its controversial *Stephar* decision in the case of *Merck vs. Primecrown* in 1995.¹⁹¹ The case involved a parallel trader that bought drugs in Spain and Portugal where IP rights were not available for pharmaceuticals that had been put on the market there, and subsequently imported to the United Kingdom. Despite a well thought opinion by Advocate General (AG) Fennelly, the Court upheld the *Stephar* decision.

The opinion of Advocate General Fennelly mentioned the 'scant regard paid to reward the innovator to by finding exhaustion of rights in such circumstances'¹⁹². The concern was raised that the limited protection of IP rights would affect investment in innovation and R&D. He pointed out that exhaustion should occur only when the IP right holder had a chance of being rewarded for his creative effort by using the IP right when placing a product on the market. In this case the creative efforts were not rewarded, as there was no patent protection in the exporting country. He added that the *Pharmon vs. Heochst* case had deemed the *Stephar* ruling obsolete when it stated that the core of a patent right lies in the exclusive right of product placement and the subsequent reward.¹⁹³ He attempted at compromise by recommending where Merck could not gain IP protection, there should be no exhaustion, and if they could, exhaustion should stand.¹⁹⁴

¹⁸⁹ Korah, Valentine, *An Introductory Guide to EC Competition Law and Practice*, 2000, pg. 262

¹⁹⁰ C 19/84, *Pharmon BV vs. Hoechst AG*, , paragraph 2

¹⁹¹ C-267 – 268/95, *Merck and Company vs. Primecrown Ltd* ECR I-6285

¹⁹² Weatherill, Susan, Recent Case Law Concerning the Free Movement of Goods: Mapping the Frontiers of Market Deregulation, *CMLR* 36: pg. 73, pages 51-85, 1999

¹⁹³ Opinion of Advocate General Fennelly, Cases 267-95 and 268-95, Paragraph 123, *Merck vs.*

Primecrown

¹⁹⁴ *Ibid.* third recommendation

Despite the influential opinion, the full ECJ upheld their previous decision of the *Stephar* case concluding that: ‘Articles 30 and 36 of the Treaty preclude application of national legislation which grants the holder of a patent for a pharmaceutical product the right to oppose 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 state’¹⁹⁵. The Court upheld the belief outlined in *Stephar* that if a company releases a product onto a market in the EU without patent protection being available, the patent will be exhausted, and the company will suffer the consequences of parallel imports.¹⁹⁶

After the ruling, the President of Merck’s Human Health unit, Per Wold-Olsen declared, ‘Incredibly, the court dismissed the ethical obligation to supply medicines which, for many of our patients, such considerations are not legal abstractions but matters of life and death.’¹⁹⁷ In addition to this, the Court recognized the difficulty in the EU in regards to MS cost control initiatives by encouraging the European Authorities to act: ‘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.’¹⁹⁸

It became apparent to pharmaceutical companies, from the *Primecrown and Stephar* (among others)¹⁹⁹ rulings that using their patent rights against parallel traders who had the Community’s free movement of goods principle on their side, would ultimately fail. The strategic avenue of relying on patent rights to shut down parallel importers had become pointless in the sense of seeking a win. It however, still would tie the hands of parallel traders for the time in which the decision is made, and could potentially bankrupt smaller parallel importers if they are not granted interim relief. Still, there are other avenues for the pharmaceutical companies to pursue legal action that are explored below. It was mentioned by Kim Jensen that patent cases usually arise after accessions. (Appendix C) The possibility of witnessing a ruling such as *Primecrown* or *Stephar* will be unlikely in the current accession round because of the ‘special mechanism’ for pharmaceutical products discussed below.

6.2.4 Repackaging of Pharmaceuticals

N.B. In Appendix G, pictorial examples are given of re-labeling that does not injure the trademark (Figure 1), Re-labeling that does obscure the trademark (Figure 2), Re-boxing (Figure 3), Re-boxing with creation of a distinct package (Figure 4) and complete re-branding with an entire new brand created by the importer (Figure 5).

As with most everything concerning parallel importation of pharmaceuticals, there are two distinct sides to the re-packaging/re-labeling of products. On one side, the importers argue that they need to repackage goods to put on the market in importing MS, and any objection to this by IP holders in cases where the products are not

¹⁹⁵ C-297/95, Judgment of 05/12/1996, Merck vs. Primecrown and Beecham vs. Europharm, paragraph 54

¹⁹⁶ C-297/95, Judgment of 05/12/1996, Merck vs. Primecrown and Beecham vs. Europharm paragraph 36

¹⁹⁷ Author Unknown, *Parallel Imports not Illegal*, Manufacturing Chemist, January 1997

¹⁹⁸ C-297/95, Judgment of 05/12/1996, Merck vs. Primecrown and Beecham vs. Europharm, paragraph 47

¹⁹⁹ C-266/87, 267/87, *The Queen vs. Association of Pharmaceutical Importers*, C-9/93, *IHT Internationale Heitztechnik vs. Ideal Standard*, and C-207/91, *Eurim-Pharm vs. Bundesgesundheitsamt*

damaged is an unjustifiable interference with the functioning of the internal market. The flip side, as argued by pharmaceutical companies is that importers are taking a free riding advantage of the trademarks and building up their own trademarks and good will while doing so. They are also concerned that importers who label the patented/ trademarked drugs generically are using the IP right as a spring board for their own generic operations upon patent expiry.²⁰⁰

Another legal tool employed by the manufacturers of pharmaceuticals is to bring trademark infringements to court for trademark use by parallel importers who 'have' to re-package or re-label pharmaceuticals. The concern arising from re-packaging of pharmaceutical products are obvious concerns because of health and safety related issues. Nevertheless similar to the issues raised in the cases above, the ECJ has generally taken the side of parallel importers, holding the same torch of free movement of goods over IP rights. However, there seems to have been a lightened grip on the torch in recent years. It has also developed a poorly developed test of necessity of repackaging in later cases. However, some questions still beckon regarding the differences between re-boxing and re-labeling as well as whether IP holding firms should be able to use Article 30's exemptions in cases where the specific subject matter of the trademark (guarantee of origin) is not affected.

In *Hoffman LaRoche vs. Centrafarm*²⁰¹, Hoffman brought an infringement proceeding against Centrafarm who had repackaged the goods to comply with German trademark laws. Hoffman argued that Centrafarm had not applied the trademark correctly. The Court admitted that derogations from Article 28 of the EC Treaty are allowed to the extent that they are objectively justified in order to safeguard the rights that constitute the specific subject matter of the industrial property concerned. The ECJ rejected the arguments presented by *Hoffman* and held that if the use of the trade mark would have the effect of artificially partitioning the internal market, it cannot be relied upon, provided that goods in question are not harmed and that the firm which repackages the goods does so in a way that the users will not be confused.²⁰² Thus, having different packaging in different is certainly allowed, and the trademark infringements can certainly be brought to court and be upheld unless it is shown that differentiated packaging constitutes a disguised restriction on trade between Member States. Such is the case where:

- a) It is established that the use of a trademark right by the proprietor, having regard to the marketing system which he has adopted, will contribute to the artificial partitioning of the markets between Member States;
- b) It is shown that the repackaging cannot directly or indirectly adversely affect the original condition of the product;
- c) The proprietor of the mark receives prior notice of the marketing of the repackaged product; and
- d) It is stated on the new packaging by whom the product has been repackaged.²⁰³

²⁰⁰ Gross, Naomi, and Harrold, Lucy, *Fighting for Pharmaceutical Profits: The Decision of the ECJ in Boehringer Ingelheim v. Swingward*, E.I.P.R., Issue 10, 2002, pg. 497, pages 497-503

²⁰¹ C-102/77, *Hoffman LaRoche and Company AG vs. Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse mbH* ECR 11/39

²⁰² C-102/77, *Hoffman LaRoche and Company AG vs. Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse mbH* ECR 11/39, paragraph 14

²⁰³ *Ibid*, Conclusion poing 1 b)

These four points are known as the ‘Hoffman La-Roche test’, and it is used to determine if repackaging an imported pharmaceutical can withstand the pressure of IP holders fight in Court. This case was cited by both Kim Jensen and Markos Montmar Stavroulakis as being among the most important ECJ decisions since it provided some clarity as to when repackaging is allowed by parallel importers.²⁰⁴ (Appendix C and H)

This line of reasoning in *Hoffman-LaRoche* was continued in further cases, however. The Court reverted back to viewing that if the *effect* of the differentiated packaging was to partition the common market,²⁰⁵ the IP owner couldn’t rely on their IP Rights for an exemption from Article 30.²⁰⁶

In 1993, three cases were decided upon with similar facts surrounding the case. These ‘*Paranova Cases*’ clarified some questions that remained regarding repackaging after the *Hoffman LaRoche* case. In all cases, parallel importers had repackaged the drugs, and the pharmaceutical firms were trying to rely on their IP rights looking for an infringement. In joined cases C-427/93, C-428/93 and C-436/93,²⁰⁷ the Court stated unequivocally that:

*‘Save in the circumstances defined in Article 7(2), Article 7(1) of Directive 89/104 precludes the owner of a trade mark from relying on his rights as owner to prevent an importer from marketing a product which was put on the market in another Member State by the owner or with his consent, even if that importer repackaged the product and reaffixed the trade mark to it without the owner’s authorization.’*²⁰⁸

The final ruling in the case borrowed heavily from and clarified the four points (Hoffman) necessary to allow repackaging of pharmaceuticals:

- a) Reliance on the trademark rights by the owner would contribute to the artificial partitioning of the markets between Member States;
- b) It was shown that the repackaging could not affect the original condition of the product inside the packaging;
- c) The new packaging clearly stated who repackaged the product and who manufactured it;
- d) The presentation of the repackaged product was not such as to be liable to damage the reputation of the trade mark and of its owner (new addition to Hoffman’s four points);
- e) The importer gave notice to the trademark owner before the repackaged product was put on sale, and, on demand, supplied him with a specimen of the repackaged product.

Furthermore, in this case the ECJ stated that the simple fact that there were different package sizes in Member States led to the conclusion that there was an artificial

²⁰⁴ Correspondence with Markos Montmar Stavroulakis, May 17, 2004, and Interview with Kim Jensen, May 6, 2004

²⁰⁵ After switching focus for a time to the intention of package/brand differentiation in C-3/78 Centrafarm vs. American Home Products, studied below

²⁰⁶ C-427/1993 Bristol-Myers Squibb and others vs. Paranova, C-428/1993, C-429/93C, paragraph 57

²⁰⁷ C-427/1993 Bristol-Myers Squibb and others vs. Paranova, C-428/1993, C-429/93C. H. Boehringer Sohn, Boehringer Ingelheim KG and Boehringer Ingelheim A/S v Paranova A/S and C-436/93 Bayer Aktiengesellschaft and Bayer Danmark A/S v Paranova A/S (C-436/93)

²⁰⁸ Ibid. paragraph 2 of conclusion

partitioning. It was not deemed necessary to prove the intention of carving the market.²⁰⁹

The case also importantly noted in paragraph 55 that repackaging is not necessary in cases where the importer could market in the importing MS by affixing a new label or adding in new instructions.

Soon after, there was another series of cases at the ECJ's doorstep regarding the same issue of repackaging of pharmaceuticals. The Court ruled, almost verbatim²¹⁰ on the main points of EC law that provided the 5 points were established²¹¹. However, some questions and varying points of view arose from the cases.

In the ECJ case *Boehringer vs. Swingward*, and *Merck vs. Paranova*²¹² the parallel traders were again sued for trademark infringement at the national level (Austria-Merck, and UK – Boehringer). The question raised by the Austrian court related to the question of necessity of repackaging, while the British Court asked questions regarding the use of IP rights' specific subject matter to restrict the free movement of goods and the notice necessary for repackaging. It was held that opposition to repackaging would contribute to the artificial partitioning of the market where repackaging is necessary in order to gain effective access to the importation market because of a strong resistance of relabeled products from a significant part of the market. The Austrian court found consumer resistance, and the UK case is waiting for responses of a second round of questions.

The ECJ in this case re-affirmed the *Upjohn* decision and stated that an objective necessity is required by the importer to repackage the product.²¹³ They also noted that: *'The parallel importer should cause as little damage as possible to the specific subject-matter of the mark. It cannot, for example, replace the packaging where it is possible to attach labels.'*²¹⁴ It was found that a notice of 15 working days suffices to warn the IP owners of repackaging, and that no notice will result in allowing the IP owner the right to oppose entry of the repackaged product. When asked which cases were the most important decisions regarding parallel importations, Mr. Jensen also indicated the importance of this case because it outlines when repackaging can be done, and when it cannot.

British Justice Laddie did not agree with the Court's decision noting that where the specific subject matter of the right was not broken, and the IP holder suffered no harm, Article 30 should not be applicable for exemption.²¹⁵ The ECJ disagreed stating that it is the repackaging itself that injures the specific subject matter. The ECJ did not provide guidance on what constitutes 'strong resistance', and who exactly the consumers are.

²¹⁰ C.M.L.R. 34, pg. 1044, pages 1039-1048, 1997

²¹¹ C-71/94, Eurim-Pharm Arzneimittel GmbH v Beiersdorf AG, C-72/94, Boehringer Ingelheim KG, C-73/94 and Farmitalia Carlo Erba GmbH

²¹² C-443/1999, Boehringer Ingelheim vs. Swingward; Merck, Sharp and Dohme vs. Paranova Pharmazeutika

²¹³ Ibid. paragraph 25

²¹⁴ Ibid. paragraph 21

²¹⁵ Gross, Naomi, and Harrold, Lucy, *Fighting for Pharmaceutical Profits, The Decision of the ECJ in Boehringer Ingelheim v. Swingward*, EIPR, issue 10, 2002, pg. 501, pages 497-503

Justice Laddie's re-packaging approach to be used under British law is compared with a re-packaging approach using more strict interpretation of ECJ law in **Appendix F**.

Appendix H shows the different types of repackaging and re-labeling used by parallel traders. As is apparent, not all cases are the same; some involve over-stickering, whereas others involve taking off the IP owner's trademarks and using a generic name.

Judging from where the case law currently stands, the ECJ will likely face more questions from national courts regarding repackaging since the national courts still are able to have divergent opinions due to the ambiguity of the term 'necessity' of repackaging and the required rulings in cases where the specific subject matter is not injured. Since the use of a trademark in itself is not necessary in view that a generic name could be used, further questions could arise whether parallel traders are allowed to use the trademarks of others at all, or are required to do so.

6.2.5 Re-branding

Re-branding is considered separately from repackaging because the ECJ has treated the two kinds of cases differently in its jurisprudence in that it seems to have ruled less strongly in favour of parallel importation in re-branding cases. The following two cases consider situations where the IP holder uses different brand names in different Member States.

A step back was taken by the ECJ from the prior *Hoffman* decision in its adherence to the exhaustion principle. In *Centrafarm BV vs. American Home Products*,²¹⁶ Centrafarm used the different brand name used in the importing MS than the exporting MS. The Court ruled on a similar case to *Hoffman LaRoche*, but stated that the re-branding would be a disguised restriction on trade if the *intention* of differentiated packaging was to carve the common market.²¹⁷ This changed the *effect* test used in the *Hoffman* case. This change of emphasis made it easier to prevent PI by relying on Article 30's exemption of commercial and industrial property. The Court found that the guarantee of origin or 'specific subject matter' would be jeopardized if an importer were allowed to use the mark, but warned that different trademarks could not be used to partition the internal market.

As would be expected, the pharmaceutical industry was not expecting positive news when the Pharmacia/Upjohn case came around in 1998. The *American Home Products* case was cited in the *Pharmacia & Upjohn vs. Paranova*,²¹⁸ due to the similarity between the cases. The Upjohn Case also provided a further 'chink in the armour'²¹⁹ of parallel traders in regards to EC law. The Court agreed with Advocate General Jacobs in affirming that repackaging related to an 'objective necessity' to repackage that had to be prove by the importer . The Courts ruling stated that: 'the condition of necessity will not be satisfied if replacement of the trade mark is explicable solely by the parallel importer's attempt to secure a commercial advantage.'²²⁰

²¹⁶ C-3/78, Centrafarm BV vs. American Home Products Corporation

²¹⁷ Ibid. Paragraph 21

²¹⁸ Case C-379/97 Pharmacia & Upjohn SA v Paranova AS

²¹⁹ Mutimear, Jane, *ECJ Offers Glimmer of Hope to Brand Owners*, Managing Intellectual Property, issue 94, pg. 5, November 1999

²²⁰ Case C-379/97 Pharmacia & Upjohn SA v Paranova AS, paragraph 44

In contrast to what the Court found²²¹, the Opinion of Advocate General Jacobs thought that commercial reasons could be a necessity: *'I do not find it helpful to postulate a category of "purely commercial reasons" which can never fall within the concept of necessity... The decisive test is whether in a given case prohibiting the importer from re-branding would constitute an obstacle to effective access by him to the markets of the importing State.'*²²² This disagreement on what constitutes a necessity could have repercussions. In view that it is always possible for a parallel trader to market an imported product under the generic name, pharmaceutical companies may be able to use this point and open this crack in the law. The only reason for an importer to use the branded name is to gain a commercial advantage of using a TM funded by somebody else. As it stands, the Court has more weight than the Opinion, and the issue could be raised in a question to the ECJ.

In addition to the discussion above, in paragraphs 43 and 44 of the *Upjohn* case created the rule of necessity of repackaging. Specifically, paragraph 43 states:

'The view that the condition of market partitioning defined in Bristol-Myers Squibb applies to the case where a trade mark is replaced also implies, contrary to what Paranova argues, that this replacement of the trade mark must be objectively necessary within the meaning of that judgment if the proprietor is to be precluded from opposing it.'

This places the onus of proving necessity on the shoulders of the parallel traders. To a certain extent, the tables were turned in this case. It is up to the national courts to determine the level of re-packaging necessity. Different national courts have varied in their definition of necessity as will be shown below.

6.2.6 Co-Branding

The latest legal strategy that manufacturers are employing to prevent PI is to argue co-branding is a TM infringement in cases where the parallel importers affix their trademark, or change the packaging significantly when they re-package products. Two recent judgments highlight the issue. In discussing this issue, Kim Jensen of Paranova noted: *'it is a huge strategy of manufacturers to fight co-branding. And I think the problem is on a way to solve these cases. OK we have to wait for the ECJ answers for the UK court of appeals, but at least from the EFTA court we have very good guidance.'*²²³ (Appendix C)

The first case hails from the Norwegian Supreme Court, which posed some questions to the EFTA Court, which is a parallel court to the ECJ. Both Courts use each other's judgments in their rulings. The case involved Paranova and Merck.²²⁴ The issue in the case was that when Paranova first entered the Norwegian market, they affixed their own coloured pentagonal logo in a particular font, as well as vertical or horizontal stripes that were not on the original packaging sold in the Norwegian market. A picture below gives an example of the packaging at issue in the case:

²²¹ Ibid. paragraph 44 states: 'In contrast, the condition of necessity will not be satisfied if replacement of the trade mark is explicable solely by the parallel importer's attempt to secure a commercial advantage.'

²²² Jacobs, Advocate General, Opinion, European Court of Justice, Case C-379/97, *Upjohn SA vs. Paranova AS*, paragraph 54

²²³ Interview with Kim Jensen, Advokat, Paranova A/S

²²⁴ E-3/02, *Paranova AS vs. Merck and Co. Inc & others*, Decision of July 8, 2003

Figure 9: Repackaging Example in Recent EFTA Ruling



The package on the left is the original packaging, and the one on the right is the repackaged product. The stripes are vertical as opposed to horizontal on the original pack. Also, you cannot see it, but Paranova also affixed their logo and a particular typeset to some of the repackaged products. The lower Norwegian Court found that the repackaging blurred the distinction between the importer and the IP holder, thus disallowing the co-branding to continue. Paranova appealed this decision on the basis of Article 7 (2) TMD as to whether Merck had ‘legitimate reasons’ to oppose characteristics of the package design leading to infringement. It was only the stripes that were at issue in the EFTA judgment.

The EFTA Court concluded that ‘legitimate reasons’ may exist to oppose further commercialization of repackaged pharmaceutical products when the package has stripes around the edges *if this is liable to damage the reputation of the trade mark*. (emphasis added). It was left for the national courts to decide on this. The Court directed the national court that because the duty of the importer to state the name of the manufacturer as well as his own exists to lessen any blurriness between the two parties, such blurriness shouldn’t exist. Therefore, the coloured stripes alone could not constitute a ‘legitimate reason’ under Article 7 (2) TMD. Unless the specific subject matter of the trademark (guarantee of origin) was damaged, there is no legitimate reason to oppose repackaging of pharmaceuticals. In assessing whether damage existed to the specific subject matter, the EFTA Court gave direction to the national courts again. Citing that in cases where there the repackaging may give the impression that there is a commercial connection between the importer and the IP holder, or the importer is part of the official distribution chain, damage can be found. The Court further stated that *‘the mere fact that a parallel importer gains additional advantage from a particular type of graphic design is, in itself, immaterial.’*²²⁵

If the jurisprudence of this case is followed by the ECJ, parallel importers may have greater room to maneuver than they previously have in repackaging. This ruling is a stark contrast from the Boehringer case, C-443/99 in that the specific subject matter in this case was not deemed to be inherently damaged by repackaging (as was indicated in C-443/99 Judgment). In this case, Paranova would be allowed to change the packaging so long as no damage was found to the guarantee of origin of the product. Thus in cases where repackaging is deemed ‘necessary’ such as in situations where different package

²²⁵ E-3/02, Paranova AS vs. Merck and Co. Inc & others, Decision of July 8, 2003

sizes exist across MS, the importers will have some room to maneuver in veering from original package design and may be allowed to apply their own logo.

In a recent judgment by the UK Court of Appeals²²⁶ is waiting to answer the question if the importers can re-box at all, and if so how to do so legally (ie. Is it legal to co-brand and de-brand).²²⁷ This case is the legal next step in the ECJ case C-443/99 which has yet to be completed on the national level. The judgment supports Laddie J's decision that re-boxing should be allowed in cases where there is significant customer resistance, as was shown in this case according to the courts. The Court of Appeal stated that: 'if this (repackaging resistance existed) were not so I cannot imagine why the claimants are spending so much effort on this case or why the defendants are bothering to defend.'²²⁸ Sometimes, simple logic such as this stands to reason, even for the highest courts.

Regarding the case of de-branding, where the importer labeled the trademarked goods simply by its generic name, and not as the trademarked good, the court concluded that this is perfectly legal, citing the argument of passing-off as being: 'To my mind the alleged misrepresentation is no more than a lawyer's ingenious construct. There is no evidence that any pharmacist or patient has ever been deceived.'²²⁹ This is very interesting for a number of reasons. Firstly, why would TM holders, who seem to fight infringement every chance they get not want the importers not to use their TM at all? This contradiction is discussed in more detail below. They argued that they are worried that when the patent protection is over, there will already be a recognizable generic package in use that the importers will use in their generic trade.

For the case of co-branding, the court ruled that co-branding could indeed injure the specific subject matter of the TM if a perception was created that the importers brand was a brand of the actual manufacturer, or if a perception was created the importer and manufacturer were in some kind of joint venture.

Despite the opinions given by Justice Jacob outlined above, they are unfortunately subject to another round of questions to be referred to the ECJ. The lack of clarity in repackaging, de-branding, co-branding and necessity will hopefully be circumvented in the ECJ's ruling on this matter.

6.2.7 Supply Restriction – The Bayer Adalat Case

On January 6, 2004, the ECJ handed down its decision on an appeal to a Commission appeal²³⁰ to overturn the Court of First Instance's decision of T-41/96²³¹, which overturned the Commission Decision finding that Bayer had concluded an agreement with its French and Spanish wholesalers to enact an export ban.

²²⁶ [2004] EWCA (Civ) 129, Boehringer Ingelheim, KG vs. Swingward Ltd., Boehringer Ingelheim KG vs. Dowelhurst Ltd., between Glaxo Group Ltd. Vs. Dowelhurst Ltd., Smith Kline Beecham plc. Vs. Dowelhurst Ltd. And Eli Lillyand Company vs. Dowelhurst Ltd. Judgment of May 3, 2004

²²⁷ Ibid. paragraph 11

²²⁸ Ibid. paragraph 54

²²⁹ [2004] EWCA (Civ) 129, Boehringer Ingelheim, KG vs. Swingward Ltd., Boehringer Ingelheim KG vs. Dowelhurst Ltd., between Glaxo Group Ltd. Vs. Dowelhurst Ltd., Smith Kline Beecham plc. Vs. Dowelhurst Ltd. And Eli Lillyand Company vs. Dowelhurst Ltd. Judgment of May 3, 2004, paragraph 58

²³⁰ C-02/01 and C-03/01, Judgment of January 6, 2004, Commission of the European Communities and others vs. Bayer AG and others

²³¹ T-41/96, Judgment of October 26, 2000, Bayer AG vs. Commission of the European Communities

Bayer manufactures a drug named Adalat in EU Member States. The drug was directly or indirectly subject to price controls by MS which distorted the price such that the price was 40% lower in Spain and France than in the UK, thus, creating impetus for parallel trade. Parallel trade was deemed to have started between Spain and UK in 1989, and between France and the UK in 1991.²³² The result was a 50% reduction in sales of Bayer's UK subsidiary entailing a 230 M DEM turnover loss of the UK subsidiary, and a 100M DEM revenue loss to Bayer.²³³ In reaction, Bayer changed its delivery policy and ceased fulfilling the increasingly large orders of the Spanish (in 1989) and French (in 1991) wholesalers. The wholesalers complained to the Commission, and the Commission started an Article 81 (1) infringement investigation into Bayer's and the wholesaler's dealings.²³⁴

The Commission found that Bayer and its wholesalers in France and Spain had concluded a tacit agreement amounting to an export restriction infringing Article 81 (1) TEC. They fined Bayer 3 M ECUs, and demanded that within two months they send circulars to its French and Spanish wholesalers stating that exports are allowed in the Community including an outline of the general terms and conditions of sale for France and Spain, with a late fee for action equal to 1000 ECUs per day.²³⁵ Bayer was granted interim relief from the circular requirement, and the late fee, after the CFI found that Bayer's contention that there was no tacit agreement to restrict exports existed, that their request was not unfounded and that the threat to Bayer of imposing the decision would have been out of proportion to the interests of their Spanish and French wholesalers in increasing their exports.²³⁶

It should be noted that in the Commission's decision, the relevant market was deemed to be the national market because: marketing authorization falls exclusively within MS competence (not true anymore with EMEA); sale of medicines is influenced by administrative/purchasing policies in MS²³⁷; and the differences in price fixing methods. The product market was defined as consisting of products with identical therapeutic use. Adalat was not deemed have a dominant position on the market.

In C-41/96, Bayer was attempting to get the Commission decision against them overturned. They openly admitted that in response to parallel importation, they reduced the quantities delivered to wholesalers, seeing it as a softer alternative to ceasing supply to wholesalers altogether.²³⁸ They admitted to monitoring product movements inasmuch as they tracked historical ordering, and stated they did not track goods to find if they had been exported and admitted to unilaterally limiting supply to historical orders, allowing for a 10% increase in volume per annum.²³⁹ They stated that the Commission's finding extends the scope of the Treaty, particularly the scope of Article 81 to a unilateral refusal of delivery which could only fall under Article 82 TEC thus

²³² Ibid. paragraphs 2-4

²³³ C-2/01, and C-3/01, Commission vs. Bayer AG, paragraph 3

²³⁴ Case IV/34.279/F3 – Adalat, OJ 1996 L 201 pg. 1

²³⁵ Ibid. Articles 1-3

²³⁶ Anonymous, Case T-41/96R, Bayer AG vs. Commission of the European Communities, Order of 3 June 1996, CMLR, 36: 1309-1317, 1997

²³⁷ Case IV/34.279/F3 – Adalat, OJ 1996 L 201, Recital 154

²³⁸ T-41/96, Judgment of October 26, 2000, Bayer AG vs. Commission, paragraph 34

²³⁹ Ibid. paragraph 35

entailing a very wide obligation on non dominant firms in that they could not refuse to fulfill orders.²⁴⁰

The Commission claimed that Bayer identified exporting wholesalers, drastically reduced their deliveries, monitored the final destination of the goods, and penalized the wholesalers who exported by cutting future deliveries. They claimed that the wholesalers consented or acquiesced to this 'export ban', which was apparent by their continued commercial relationship, lest their orders not be fulfilled.²⁴¹ They cited examples of instances where Bayer had cut supply by much more than the traditional demand plus 10%, as stated by Bayer (CERP Lorraine, Hufasa, Cofares). They further cited ECJ cases Sandoz²⁴² and Tipp-X²⁴³ (among others) as supporting their case²⁴⁴ before claiming that parallel trade will bring about price harmonization in the EU.²⁴⁵

The CFI declared that the wording of Article 81 makes it clear that it applies to bilateral or multilateral agreements, but not to unilateral agreements,²⁴⁶ unless the case involves a situation where the unilateral conduct is merely apparent, and not genuinely unilateral. The 'apparent unilateral' conduct must have at least tacit acquiescence of the dealers, reflected by a concurrence of wills (joint intention), as well as a penalty for non-compliance in order to be considered a unilateral agreement under Article 81.²⁴⁷ The CFI firstly concluded that the Commission did not present any documentation proving the existence of an export ban,²⁴⁸ an export tracking system,²⁴⁹ nor successive penalization resulting from conducting exports. The CFI looked past the supply reduction to wholesalers CERP Lorraine and OCP because export bans were not mentioned. It was found that Hefame used small wholesalers to trick Bayer into supplying more Adalat than necessary for the national market, thus leading to the Court's conclusion that there was no tacit agreement, and on the contrary, demonstrated the 'negation of their alleged acquiescence'.²⁵⁰ It was found that in some cases Bayer even directly supplied pharmacies encountering shortages due to the high amounts of exports.²⁵¹

Regarding the case law cited by the Commission to prove acquiescence, none of the cases were found to be factually similar to the Adalat case at hand. Firstly, in the *Sandoz* case, it was found that Sandoz made the export restriction intent clear to the dealers by stating 'export prohibited' on its invoices, thus forming this intent into part of the contractual relations between Sandoz and their customers. Furthermore, the dealers

²⁴⁰ Ibid. paragraph 38

²⁴¹ Ibid. paragraph 49

²⁴² C-277/87, *Sandoz Prodotti Farmaceutici vs. Commission of the European Community*, (1990) ECJ I-45

²⁴³ C-279/87, *Tipp-Ex GmbH. & Co. KG vs. Commission of the European Community*

²⁴⁴ Ibid. paragraph 54

²⁴⁵ Ibid. paragraph 59

²⁴⁶ Ibid. paragraph 64 and 66

²⁴⁷ Ibid. paragraph 71, 74

²⁴⁸ T-41/96, Judgment of October 26, 2000, *Bayer AG vs. Commission*, paragraph 109

²⁴⁹ In C-02/01 and C-02/01, paragraph 79-83 It should be noted that product tracking is not in itself against Article 85. It is only if punishments ensue from tracking that it is. Tracking is simply an indicator of an agreement. This is important to note for IP holding manufacturers who track their product movements.

²⁵⁰ T-41/96, Judgment of October 26, 2000, *Bayer AG vs. Commission*, paragraph 155, repeated for the case of wholesaler, Cofares in paragraph 134

²⁵¹ Ibid. paragraph 141

not supplying exporters proved the tacit acquiescence existed.²⁵² The Advocate General later stated that Bayer adopted a strategy that ‘enabled it autonomously to achieve the result of eliminating or reducing parallel imports, without the collaboration of the wholesalers being needed.’²⁵³ The Tipp Ex case was also different from the case in question because, although no written export ban existed, since there was no doubt of the co-operation of the distributors as indicated in oral and written contracts and thus tacit acquiescence was found. For the same reasons in BMW Belgium²⁵⁴, AEG²⁵⁵ and Ford²⁵⁶ tacit acquiescence was also found, and thus could not be relied upon by the Commission. It was found that the mere fact that wholesalers continued the business relationship with Bayer is not indication enough that acquiescence existed.²⁵⁷

The CFI thus concluded in paragraph 176:

‘The right of a manufacturer faced with an event harmful to his interests, such as parallel imports, to adopt the solution, which seems to him to be the best is qualified by the Treaty provisions on competition only to the extent that he must comply with the prohibitions referred to in Articles 85 and 86 (now 81 and 82). Accordingly, provided he does so without abusing a dominant position, and there is no concurrence of wills between him and his wholesalers, a manufacturer may adopt the supply policy which he considers necessary, even if, by the very nature of its aim, for example, to hinder parallel imports, the implementation of that policy may entail restrictions on competition and affect trade between Member States’

The Commission proceeded to appeal this decision the ECJ. Following the Opinion of Advocate General Tizzano on almost every point, the appeal failed on almost every step. Firstly, the AG stated, and the ECJ agreed, that the first appeal was based on fact, not law, and could not be appealed.²⁵⁸ Secondly, Tizzano found the CFI considered documents regarding the actual conduct of wholesalers following the supply restriction without distortion, and implicitly referred to the actions by wholesalers to dupe Bayer.²⁵⁹ The Court and the AG also found that the Commission has onus to prove a meeting of the minds.²⁶⁰ Again, the AG and the ECJ agreed on the fact that the CFI didn’t hold that there couldn’t be an export ban without product monitoring.²⁶¹ Both Tizzano recommended and the ECJ turned down the appeal that the CFI required an agreement banning exports could not have been concluded without an adhering line of conduct to the export ban by the wholesaler.²⁶² Again, both parties agreed to turn down

²⁵² Tizzano, Advocate General, Opinion, C-02/01 and C-03/01, of May 22, 2003, paragraph 56-57 and C-41/96, Bayer vs. Commission, paragraph 163

²⁵³ Tazzini, Advocate General, Opinion, C-02/01 and C-03/01, of May 22, 2003, paragraph 59

²⁵⁴ C-70/93, Bayerische Motorenwerke (1995) ECR I3439

²⁵⁵ C-107/82 AEG vs. Commission (1983) ECR 2725

²⁵⁶ C-25/84 and C-26/84 Ford and Ford Europe vs. Commission (1985) ECR 2725

²⁵⁷ T-41/96, Judgment of October 26, 2000, Bayer AG vs. Commission, paragraph 172

²⁵⁸²⁵⁸ Tizzano, Advocate General, Opinion, C-02/01 and C-03/01, of May 22, 2003, paragraph 36 and C-41/96, Confirmed by: Bayer vs. Commission, paragraph 48

²⁵⁹ Tizzano, Advocate General, Opinion, C-02/01 and C-03/01, of May 22, 2003, paragraph 40 and C-41/96, Confirmed by: Bayer vs. Commission, paragraph 54

²⁶⁰ Tizzano, Advocate General, Opinion, C-02/01 and C-03/01, of May 22, 2003, paragraph 63 and C-41/96, Confirmed by: Bayer vs. Commission, paragraph 104

²⁶¹ Tizzano, Advocate General, Opinion, C-02/01 and C-03/01, of May 22, 2003, paragraph 84 and C-41/96, Confirmed by: Bayer vs. Commission, paragraph 79

²⁶² Tizzano, Advocate General, Opinion, C-02/01 and C-03/01, of May 22, 2003, paragraph 91, 96 and C-41/96, Confirmed by: Bayer vs. Commission, paragraph 111

the appeal stating that the CFI failed to take account for intentions of the wholesalers actions.²⁶³

From the Commission's perspective the Appeal was fruitless. The CFI decision, which must have been embarrassing for the Commission, stood in whole to the scrutiny of the ECJ after the appeal. Looking on the case as an outsider, it seems somewhat perplexing that the Commission would have been so headstrong as to attempt to conclude what it did in its findings. After all, it does not make logical sense that there would be a concurrence of wills and acquiescence in a case where the desires 'agreeing' parties are diametrically opposed such as was the case.²⁶⁴ Furthermore, Bayer's Adalat was not in a dominant position in any case²⁶⁵ and as such would have likely been covered by the block exemption regarding vertical agreements.²⁶⁶

Indeed, it appears that the Commission may have had an easier time getting away with using Article 82 in the Adalat case. Indeed, as Bayer claimed in paragraph 40 of C-02/01, 'the Commission's argument extends the scope of Article 85 (now 81) of the Treaty to a unilateral refusal of delivery which could only fall under Article 86 (now 82) of the Treaty, in such a way as to eliminate the systematic delimitation between the scope of Article 85 and that of Article 86.'²⁶⁷ In paragraph 101 of C-2/01, the ECJ agreed with this contention. When asked whether Article 82 could have been successful in the Bayer ruling, Mr. Jensen of Paranova declared that he would not criticize the Commission, and that they probably used the best tool available to them given the circumstances of the case. (Appendix C)

For now, it is permissible for non-dominant IP holding firms to limit supply to wholesalers based on traditional orders in an effort to stifle parallel trade under Article 85. This gives the pharmaceutical companies a powerful strategic weapon to use.

Regarding the immediate effects of the case, the traders themselves have not felt a particular supply pinch since the ruling. As Mr. Jensen noted: *'I don't think you could say we have experienced anything after the judgment. But in recent years we have experienced limited supply. They are using supply quota systems. We actually have had problems buying what we want to buy.'* He went on to add that: *'the supply quota system used in the Bayer case is very old compared to the ones currently used. They have developed a lot since the case. It has been increasingly difficult to source the products as time goes on.'* (Appendix C) He later pointed out that supply quota systems are the most common strategy employed against the parallel traders. Such modern supply quota systems gained some kind of legal recognition after the Bayer case.

When asked about the importance of this ruling, Mr. Jensen noted that the ruling was a very case-specific, ruling on a particular situation, and not on the use of Article 81 in such cases in general. Because of this, he did not see the case as being one of the most important cases in the Court's jurisprudence.

²⁶³ Tizzano, Advocate General, Opinion, C-02/01 and C-03/01, of May 22, 2003, paragraph 108, 109 and C-41/96, Confirmed by: Bayer vs. Commission, paragraph 123

²⁶⁴ Opposed in that the French and Spanish wholesalers would have wanted to increase supply in order to engage in parallel trade, while Bayer wished to limit supply in order to stop parallel trade.

²⁶⁵ T-41/96, Judgment of October 26, 2000, Bayer AG vs. Commission, paragraphs 26

²⁶⁶ Regulation (EC) No. 2790/1999 'the Block Exemption Regulation', OJ L 336

²⁶⁷ -41/96, Judgment of October 26, 2000, Bayer AG vs. Commission, paragraphs 40

An interesting case that is on the horizon regarding the applicability of Article 82 in refusal to supply of dominant firms and should be mentioned. In the case, SIFAIT and others vs. Glaxowellcome Avee. (C 53/03), the extent that a dominant firm can refuse supply in order to limit the damage caused by parallel trade will be looked by the ECJ. The questions referred to the ECJ ask if it matters that true matters of competition in the European pharmaceutical market place do not exist. It also asks how abuse of a dominant position in order to stop parallel trade should be looked at and if a balancing of interests should be used to determine effect on the market. This case is a make or break case for the pharmaceutical companies and the parallel importers. If dominant IP holding firms can limit supply under Article 82, they will be able to effectively cut off all excess supply to lower priced national markets that is not needed within those Member States, as opposed to the current situation where they can only do so if they are in a non-dominant position.

6.2.8 Licensing

Licensing agreements occurs when an IP holder grants the right of manufacturing or marketing of a product to another entity for a time. Such agreements can confuse rules regarding parallel trade because licensees are often not part of the same corporate group. It follows that rules regarding parallel imports of licensed pharmaceuticals may be slightly different from the drugs in the importation state, since the licensees (or IP owners) may be different across national borders.

The issue was addressed in the *Smith and Nephew vs. Primecrown*²⁶⁸ case in 1996. The case concerned Primecrown (the Belgian licensee), which was seeking to get an approval to import a drug into the UK that was licensed for sale by Smith & Nephew. The ECJ stated that when a marketing authorization is granted in one MS, the drugs are manufactured by individual companies pursuant to agreements concluded with the same licensor, and the drugs are essentially the same, the importing MS must treat the imported product as if it were under the marketing license of the home MS. The case brought up the issue of common origin in paragraphs 24 and 25 of its judgment. It was required by the Court that the goods be licensed by the parts of the same corporate entity and have a 'common origin' in order to avoid partitioning the internal market.

A very recent case decided upon in April 2004 brought up the issue of whether a drug imported by a parallel trader has to have a common origin as the drug sold in the importing Member State. The case involved a trader, *Kohlpharma* requesting a marketing authorization to import the drug Jumex into Germany where the drug Movergan was sold with the same active ingredient, initially from the same source but through different means (license versus supply agreements). *Kohlpharma* was refused entry by the German authorities because the medicines had to have a common origin, were produced by members of the same corporate group, or the original authorizations to independent companies were pursuant to license agreements with the same licensor.²⁶⁹ This was not allowed by the ECJ because the two drugs were essentially the same. The lack of a 'common origin' was not deemed to be essential in order to disallow parallel importation. Thus, goods produced under parallel licenses originating from different corporate entities are now allowed to be parallel imported.

²⁶⁸ C-201/94, *Smith and Nephew vs. Primecrown*

²⁶⁹ Case 112/02, Judgment of 01/04/2004, *Kohlpharma GmbH vs. Bundesrepublik Deutschland*

This could widen the potential for parallel trade in that there is no required link between products other than that they suffice similarity criteria set out in previous cases. Common origin will cease to be a prohibition to parallel trade provided products are sufficiently similar. It used to be, in Europe that a requirement that medicines were produced by parts of the same corporate entity²⁷⁰, later amended to take into consideration licensing. This judgment is significant for parallel traders because the Court held in principle, that if two medicines, in source and destination markets are identical in active ingredients, even commercial agreements (such as licensing and supply agreements) will not stand in the way of the free movement of goods. This increases the possibilities for parallel traders in that they can use different sources for active ingredients if they were to move into generics, an option that will be discussed below. The implication for generics is that the distinction between generics and parallel imports will be blurred, allowing for generics to apply for parallel import registrations, allowing them to only to show an existing marketing authorization in the export state.

6.2.9 National Rulings

As will be shown through reviews of relevant case law, national courts and also have a powerful role in determining the fate of parallel trade and the legal environment in which importers and pharmaceutical companies operate. After all, for every ECJ decision, the national court has the opportunity to make the final decision.

It has to a large extent been left to National Courts to decide if there has been a breach of IP rights in the case of repackaging in light of the stipulations set out in *Hoffman LaRoche* and the *Paranova* cases. They do not always rule in favour of the traders. There seems to be a deep contrast between the very pro parallel-trade rulings of the ECJ, and the national rulings, which take a dimmer view on free movement principles. Mr. Jensen summarized the situation as follows: *'I think at the end of the day, what you see is at least the parallel importers have been very successful in the ECJ, but has been less successful in the national courts.'*²⁷¹ (Appendix C) He explained that while the national judges are inherently open-minded individuals, they see the national intellectual property principles, which can be protected in constitutions as being, as being very powerful. He went on to note that *'the national judges are still, after 30 years for Denmark's membership in the Community, they are still not thinking internationally, or European'*.

In 2003, after referencing to the ECJ in two of the cases²⁷², the Supreme Court of Denmark in five connected cases ruled that Paranova was guilty of trademark infringement. Four of the cases considered on-to-one re-packaging, and the other case concerned re-branding. In every single case, the Court upheld the decision by the Maritime and Commercial Court, and found in favour of the IP holder. Paranova's main defense tactic needed to prove the necessity of repackaging. They tried using a survey of pharmacists indicating they prefer repackaged pharmaceuticals, by stating that sealing of a product meant that it needed repackaging in order to unseal and insert Danish inserts, and by asserting that the removal of a mouthpiece (in order to meet Danish standards) made it necessary to repackage. All defenses failed for the

²⁷⁰ C-201/94 Smith & Nephew and Primecrown

²⁷¹ Interview with Kim Jensen, Advokat, Paranova A/S, May 6, 2004

²⁷² C-427, C-428, C-436/93, Bristol Myers Squibb vs. Paranova AS, C-379/97 Pharmacia & Upjohn

repackaging, as did the attempt to use a 'window' label that covered up the original package leaving the original trademark. The necessity (to repackage) requirement was not proven sufficiently according to the Danish Court. According to one observer: *'In view of the fact that access to the parallel import market is indeed easy, blessed by the benevolent legislature and almost automatic access to the customers without any need for marketing, it is not in itself surprising that the court has expressed its skepticism as to the alleged necessity or reorganizing the imported products.'*²⁷³

When asked about these decisions, Mr. Jensen, who served Paranova A/S as 'Advokat' in the Supreme Court in these cases had several things to say. He noted that at the time (early 1990s) there was consumer resistance to the re-labeled drugs in Denmark, although that resistance no longer exists: *'What we argued was that consumer resistance existed in the early 90s, but though we had a market survey presented to the Supreme Court, it didn't apparently lift the burden of proof.'* (Appendix C) When asked what he thought could have been done in the case to lift the burden of proof of necessity of repackaging, he noted that in this situation: *'I don't know what we could have done, I think it was impossible.'* He went on to add that the first recognition of necessity because of customer resistance was granted to Paranova in 2002 by the ECJ for an Austrian case.

The Danish Court findings was not surprising when considering previous rulings. Astra AB, Astra Danmark A/S and Bayer AG vs. Paranova in 1999 used the necessity test, finding that the re-boxing of the Bayer product was necessary where package sizes differed due to 'national practice', but the re-boxing of the Astra product was not necessary to gain Swedish market access. The later court ruled that *Lövens Kemiske Fabrik vs. Orifarm AS* ruling in 2002 found that it is not necessary to re-box where pack sizes do not differ between MS, and use of the importers logo was unnecessary in the re-boxing. Re-branding was likewise barred.²⁷⁴

The United Kingdom recently Court of Appeals case mentioned above in the co-branding section is waiting for a second round of questions to the ECJ before it makes its final decision in the Boehringer cases.

The German, Austrian Supreme Courts and the Swedish court of Appeal have all made similar rulings, citing that the parallel importer went too far in its repackaging. While it is clear that the ECJ supports parallel traders from their jurisprudence, the final decisions are left to the national courts, and they do not always rule with the same deemed necessity of protecting the free movement of goods. In many member states IP rights are held to very important, and since many national judges do not see many European level cases, it is understandable that they would rule in favour of IP rights over the free movement of goods.

The national courts have been less forgiving to parallel traders. They have also had very different opinions on the current state of European law. Some courts believe that repackaging inherently affects the specific subject matter of trademarks, thus requiring the importer necessity onus (Danish Supreme Court); while others think that this is the case only when other damages are proved to the trademark because of the repackaging (EFTA ruling, and possibly UK court).

²⁷³ E.I.P.R. Issue 12, 2003, pg. N-84

²⁷⁴ E.I.P.R. Issue 5, 2003, pg. N-68

6.2.10 National Measures

As with pharmaceutical companies, Member States cannot attempt to partition the internal market. Likewise the defense of exemption from Article 28 in Article 30 will not stand in such circumstances where they have.

In *Commission vs. Germany*²⁷⁵ the ECJ found that a law prohibiting marketing authorizations for medicinal products in Germany by firms having head offices outside of Germany violated Article 28 and was not granted an exemption. It was found that such a measure would act as a measure equivalent to a quantitative restriction.

Similarly, in *Officier van Justitie vs. De Peijper*,²⁷⁶ the ECJ declared that Dutch regulations requiring parallel importers to produce documents for marketing authorizations for drugs for which they already had such information was against Article 28. As the Court saw it: '*national rules or practices which do restrict the imports of pharmaceutical products or are capable of doing so are only compatible with the Treaty to the extent to which they are necessary for the effective protection of health and life of humans.*'²⁷⁷ There was no exemption granted under Article 30. In another Dutch case, the Court found that higher fees granted to parallel imported drugs than domestic drugs also artificially partitioned the internal market. Health and Safety of Humans was used as an unsuccessful defense.²⁷⁸

There is one case where the protection of health was accepted as a defense from partitioning the internal market. In a case hailing from the UK, the Court of Justice declared that the pharmaceutical society of GB was permitted to prohibit pharmacists from dispensing a licensed drug with the same active ingredient bearing a trademark different from that different from what was written in the doctoral prescription.²⁷⁹ The Court declared that this was the case '*even where the effect of such a rule is to prevent the pharmacist from dispensing a therapeutically equivalent product*'.²⁸⁰ The reasoning of this judgment aimed to '*leave the entire responsibility for the treatment of the patient in the hands of the doctor treating him,*'²⁸¹ in order to prevent psychosomatic difficulties.

6.3 Strategic Implications of ECJ and National Cases

The cases mentioned above were all mentioned for a reason. They all have strategic implications for the pharmaceutical manufacturer. The cases mentioned above all had a part in determining what can and cannot be done by IP holders in efforts to stop parallel traders, and what importers can do when importing products. Due to space constraints, full strategic implications will not be analyzed in detail. A chart below summarizes the strategic implication that the above ECJ and national court cases had on the pharmaceutical manufacturers.

²⁷⁵ Commission of the European Communities vs. Germany, 1984, ECR 1111, (1985), CMLR, 640

²⁷⁶ C-104/75, *Officier van Justitie vs. Adrian De Peijper*

²⁷⁷ *Ibid*, paragraph 2

²⁷⁸ C-32/1980, *Officier van Justitie vs. Kortmann*, paragraph 29

²⁷⁹ C-266/87, C-267/87, *The Queen vs. Pharmaceutical Society of Great Britain, ex parte, Association of Pharmaceutical Importers*

²⁸⁰ *Ibid*. paragraph 2

²⁸¹ *Ibid*. paragraph 22

Figure 10 Strategic Implications of ECJ and National Court Decisions on Parallel Importation

Case and Legal Area	Summary of Decision	Strategic Implication
Exhaustion		
C-355/96, Silhouette	An importer, when agreeing not to do so, cannot import products from outside the EEA	When agreeing to sell to importers who are selling outside the EEA, a clause banning re-import should be included
C-173/98, Sebago	An importer does not have implied consent to re-import goods when a clause banning is not included in the contract	When agreeing to sell to importers who are selling outside the EEA, a clause banning re-importation does not necessarily have to be included to legally stop the products from re-entering the EEA
C-414/99, C-415/99 and C-416/99 Zino Davidoff	The onus is on the importer to prove where the goods came from; allows IP right holders to file an allegation of a TM infringement to find out where the products were sourced	IP holders can file an allegation of TM infringement to find where goods were sourced, which can help in tracking products and detractors from 'official' distribution chain
Patent Rights		
C-15/74, C-16/74, Centrafarm vs. Winthrop and Sterling	IP holding firms cannot generally control the distribution or marketing of products after first release upon the EU market; Matter of no significance that cost containment exists, it is up to MS to harmonize prices	Initial product launch should be in Member States that maximize innovation reward (see figure 5), and lobby Member States to harmonize cost containment measures
C-187/8, Merck vs. Stephar	Once a product is released in an EU Member State, control over marketing and distribution is lost, even if the MS of release does not provide patent protection	Firms will be exposed to parallel trade from MS with no IP protection in MS with patent protection; IP holding firms should re-consider launching in MS with no IP protection, and press for protection as was seen with the 'special mechanism' found in the latest Accession Agreement
C-19/84, Pharmon vs. Hoechst	No export' clauses in compulsory licensing agreements (imposed by MS), can hold in Court and prevent parallel importation	IP holding firms should include a 'no export' clause in any license it is compelled by law to issue to parallel importers
Repackaging - Trademarks		
C-102/77, Hoffman LaRoche	Parallel importers are entitled to repackage pharmaceuticals provided the four criterion cited in the case are met	Pharmaceutical firms should use differentiated packaging as far as is necessary in attempt to make importing costs higher while keeping in mind use the four points raised
C-427, C-428, C-436, C-93, Paranova Cases	Creation of fifth point, making it possible to prevent repackaging where it damages the TM reputation; IP holder can oppose repackaging where re-labeling is can be used to gain market access	Pharmaceutical firms should oppose repackaged goods where re-labeled goods could have gained market access, and where TM is damaged in any way. Diligent package differentiation should be used.

C-443/1999, Boehringer Ingelheim vs. Swingward	Confirmation of proving objective necessity to repackage (onus on importer); 15 day notice necessary to repackage; Repackaging itself injures the specific subject matter of the TM	Greater use of differentiated packaging should be used b-c onus on importer to prove necessity of repackaging; Since repackaging itself injures the specific subject matter of goods, IP holders will always have legal recourse in unnecessarily repackaged goods, they should use the Courts where possible
National Repackaging Cases		
Danish repackaging cases of 2003	Objective necessity of repackaging defined very strictly	Firms should have differentiated packaging in different MS so as a) TM infringements can be used and b) costs of repackaging will rise
Danish repackaging case of 1999	Objective necessity of repackaging granted in cases where MS have differing package sizes	Firms should lobby against harmonizing package sizes, and promote safety needs (no confusion) of differing package sizes
UK repackaging case of 2003/0678	Re-labeling was allowed due to necessity, but repackaging was not allowed as it went beyond what was necessary to be granted effective market access	Firms should use the courts to prevent re-boxing, and should warn importers of the court's stance on re-boxing when being given notice of such activity
Re-branding		
C-3/78, Centrafarm BV vs. American Home Products Corporation	For a time made it that if the intent (not the effect) of packaging differentiation was to partition the market, an IP holding firm could not use Article 30; Companies can restrict the sale of a product being marketed by a third party where the guarantee of origin is affected	Firms cannot use trademarks to artificially partition the market but can use their TM rights to prevent importation where the guarantee of origin is affected
C-379/97 Pharmacia vs. Upjohn	Objective necessity of repackaging re-iterated; Purely commercial reasons cited as not being a necessary reason for repackaging	Again, where repackaging is not necessary, infringement should be pressed. If TM breaches are legitimately important to mfrs. They can perhaps force importers to use generic packaging using this case.
Supply Limitation		
C-2/01, C-3/01 Bayer vs. Commission	Supply limitation is allowed under Article 81-1 by firms not in a dominant position who act unilaterally in limiting supply	Firms employ some supply quota systems to known PI suppliers if they are not in a dominant position
Licensing		
C-201/94 Smith and Nephew	It was required by the Court that the goods be licensed by the parts of the same corporate entity and had a 'common origin' in order to avoid the partitioning of the internal market.	IP holding firms should license their products outside their own corporate entity if they want to prevent parallel importation legally
C-112/02 Kohlfarma	Court determined that parallel importation can occur between MS even where there is lack of a common origin when the drugs are essentially similar	Using licenses in different MS with ingredients that differ slightly should be used in order to prevent PI because lack of common origin can no longer prevent PI
National Measures		

Commission v. Germany, 1984	National Law prohibiting imports of pharmaceuticals from firms without a head office in Germany is not in line with Article 28	In some circumstances, the IP holders' spending on lobbying and promotion to the national government could be put to waste since national rules are still subject Article 28. Focus efforts on areas that would be allowed under Article 28
C-104/75, Officier van Justitie vs. Adrian De Peijper	Documentation of pharmaceutical goods must not be used as a barrier to prevent parallel trade. Thus, an individual Ms cannot require different documentation for goods for which they already have documentation	The need for different documentation for marketing the product depends upon the existence of a distinct therapeutic advantage.
C-266/87, C-267/87, The Queen vs. Pharmaceutical Society of Great Britain	A MS of pharmaceutical society can have rules requiring pharmacists to dispense brand-name goods	Firms should actively encourage 'official stream' brand loyalty among pharmacists/doctors in order to prevent parallel-substitution and firms should encourage such laws in MS through political advertising

After having looked at the case law surrounding the PI and the pharmaceutical market in the EU, it becomes apparent that that at least the PI industry is very dependent on the rulings of European Courts. In fact, it would not be a stretch to say that the entire industry is but one ECJ decision away from extinction if the Court suddenly were to decide to switch its tack in existing jurisprudence. Over time the ECJ has slowly been cutting back on its adherence to the free movement of goods in its decisions regarding parallel trade. This should be good news for the manufacturers.

As is seen from the manufacturer's perspective, the ECJs jurisprudence must have been frustrating to follow over the last 30 years. However, there have been some cracks that have developed in the free movement of goods protection of the parallel traders that is allowing the manufacturers some strategic maneuvering room. The possible strategies that are available to manufacturers are summarized below. It appears that stated generally, patent rights will no longer to work to prevent parallel importation since the products sold are the same as the 'official' stream goods, combined with the facts that 'common origin' is no longer a necessity for licensed goods and because all EU MS have patent rights, or are protected via EU 15 patent rights through the 'special mechanism'.

There are some legal options available to manufacturers regarding pressing TM infringements in cases of repackaging where it is unnecessary because the importers are required to lift the onus of proof of necessity of repackaging. The ECJ may change its course if it rules that repackaging must injure the specific subject matter of the TM if the IP holder is to have an infringement case in the UK Court of Appeals set of questions. Co-branding is still an option that is available to the IP holders, but is subject to some ECJ decisions that are to come.

Regarding exhaustion, it is now clear that products imports from outside of the EU, Norway, Iceland and Liechtenstein can be prevented as no IP 'exhaustion' has been occurred. The Courts have been reluctant to get in between the Doctor-Patient

relationship, so in cases where this relationship could be compromised, the IP holders will have a good chance in EU Courts.

The IP holders, when not dominant can limit supply to national demand, and possibly could employ some other supply quota systems. This is a powerful mechanism at their disposal. In strictly unilateral cases involving non-dominant parties, the Court will likely not find Article 81 breaches. Likewise, the Commission will probably be more selective in what cases they press using Article 81 regarding parallel trade of pharmaceuticals. Regarding infringements of Article 82, the situation is currently unclear, so only risk takers would be advised to abuse a dominant position on their market.

7.0 Economic Analysis and Recommended Strategies

This section of the paper begins with an empirical analysis of price movements in Denmark between 1999-2004 to test three hypotheses. One is supported. The following section makes strategic recommendations and advice in light of the information learned above.

7.1 Economic Analysis

This section will start by testing three hypotheses. The Danish Medicines Authority publishes bi-weekly prices of all pharmaceuticals sold in the country for the last five years. This data was used to conduct an economic analysis under which four hypotheses were tested. All of the data was taken from the web site www.dkma.dk. The drugs chosen for the analysis were from the top 25 drugs sold by volume, and sales in Denmark in 2002 (from www.dkma.dk), the top 25 selling drugs of 2001 (taken from York Health Economics Consortium's report in PI from 2003), and some drugs were taken from those used in the London School of Economics report from 2003. Secondly, only pharmaceuticals that have seen consistent supply over the last five years were used. This was done to get a full idea of the five-year time span looked at. So drugs with sporadic supply, often parallel imported drugs, did not pass this criterion.

The first hypothesis tested was on the average bi-weekly price movements. The average percentage price movement was calculated for two categories of pharmaceuticals and compared: parallel imported pharmaceuticals and official stream pharmaceuticals. The hypothesis being tested was that if manufacturers have been successful in their reactionary strategies against parallel imports, the prices of parallel imported products should rise more over time than the prices of official stream goods. Seven drugs in 30 variations were looked at for official stream goods, and six drugs in 18 variations were looked at for parallel traded goods. Because successful strategies would make it more difficult to source products for importers, authorizations would be more difficult to obtain, and product adaptation costs should be higher, it was hypothesized their prices would go up over time, especially in relation to official stream goods which were hypothesized to have more stable price levels. The results for this hypothesis were inconclusive, and did not indicate this hypothesis was true. The findings are represented in **Appendix E**. One thing that is observed from the graph is that generally, the price changes of parallel imported goods seems to be more volatile in 4 of the five years, with average prices going up, or down more than the official stream goods.

The second hypothesis again believed that if pharmaceutical manufacturers were successful in their strategies of preventing parallel imports, the prices of parallel imports would rise faster than the prices of official stream goods for the same reasons mentioned above. Setting the price of July 1999 at 100, and comparing subsequent prices to this base of 100 created an index that was used. The index price was tracked over time. The same number of drugs and variations were tracked. Again, the results found did not match the results that were hypothesized. It was found that prices of imported and non-imported products went up and down with a great degree of correlation. The results of this hypothesis are shown in **Appendix D**. It is seen in the graph that whenever the price of official stream goods rose or fell, the price for parallel traded goods rose or fell in step. It is not clear if the importers were employing a tit-for-tat strategy on pricing since the drugs left their highs and lows during the same time frames. Again the peaks

seen for the parallel traded products are slightly higher or lower than the official stream goods indicating slightly more price volatility.

Appendix F shows uses the same index as used for Appendix E with the July 1999 price set at a base of 100 for comparison reasons. The hypothesis that was tested here was that drugs with no parallel competition will be able to have more freedom in pricing since there is no competitive pressures from gray goods. Thus, the index prices should be higher for drugs with no PI competition. The results agreed with this hypothesis as is seen in the graph. What this may show is that the competitive pressures because of parallel importation puts a limitation on the ability of the manufacturer to raise prices, and thus limits profits. This profit constraint due to competition combined with the lost profits from forgoing selling for a higher price in more expensive Member States because the importers are purchasing in lower priced Member States leads to the conclusion that the manufacturers should at least employ some kind of preventative strategies. Possible strategies in light of ECJ rulings follow.

7.2 Recommended Strategies

N.B. This section of the paper more or less uses the same categorization as Chapter 3.3 'The Effects of Parallel Trade', and Chapter 3.4 'General Strategies for Parallel Import Prevention' in order to provide for easy reference and comparison when reading this paper.

7.2.1 Place (Distribution) Strategy Recommendations

One of the options presented by many authors²⁸² is disenfranchisement of suppliers that do not adhere to the official distribution network. This reactive strategy, which would be a strong sign to existing dealers not to deal into the export market could run into legal difficulties, not to mention is rather callous to the wholesaler. This unilateral move could be found to breach Article 82 if the firm employing this strategy holds a dominant position because trade would be restricted between MS because dealers would be afraid to supply the PI export market lest they have supplies cut.

One thing that must be noted is that at no time should there be any indication that exports of pharmaceuticals are not acceptable. Any 'no export' clauses will not be allowable. This is not only the case where a firm is in a dominant position, but since restriction concerning the territory which customers may sell is a 'hard core restriction', firms can be legally punished for such clauses even if they are below the 30% market share cap.²⁸³ This is the reason why the Commission probably thought that using Article 81 might have worked against Bayer even though they did not have a dominant position since they could have been construed to be applying an implied export ban. Some

²⁸² Cespedes, Frank, V., Corey, Raymond, E., Kasturi, Rangan, V., Geay Markets: Causes and Cures, Harvard Business Review, July-August, 1988, pages 75-82, Bergen, Mark, Heide, Jan, B., and Dutta, Shantanu, *Managing Gray Markets Through Tolerance of Violations: A Transaction Cost Perspective*, Managerial and Decision Economics, May, 1998, pg. 158, pages, 157-165, Weigland, Robert, E., *Parallel Import Channels – Options for Preserving Territorial Integrity*, Columbia Journal of World Business, Spring 1991, pages 53-61

²⁸³ Guidelines on the applicability of Article 81 to horizontal cooperation agreements, OJ C 3, 6.1.2001, paragraph 49-52

exceptions exist for this rule to allow selective and exclusive distribution systems, however, restrictions on passive sales are never allowed.

The ECJ has indicated many times that the prevention of parallel importation via punishment of detractors from the official network is not acceptable. However, a question that the ECJ has not answered in regards to pharmaceuticals is if rewarding value-adding distributors is allowable. Manufacturers, it would seem are free to reward value adding distributors under current ECJ case law. If by adding value, it is deemed by such objective criteria as not detracting from corporate revenue, and ensuring profit maximization by not supplying parallel trade applies (but remains unstated), manufacturers could possibly reward dealers who do not detract from the official supply stream. This reward could be done in a number of ways including providing management, finance, MIS, marketing, and HR support. Financial incentives could also be a possibility. This strategic confrontation when combined with dealer education on the effects of parallel trade, and how to prevent it could be used by manufacturers to limit supply to the parallel market. The Commission will likely scrutinize such measures under the EC Treaty, so caution is given not to breach competition rules in using this strategy

General dealer development should also be used in order to strengthen the relationship between the wholesalers and the manufacturer. Providing help in marketing, finance, service as well as supplying necessary marketing information will hopefully build a level trust between the two parties that may work discourage the re-seller from participating in PI supply.

Since traders have to keep a sample from each batch group for safety reasons, it is recommended that small batches are used in order to raise the costs of the parallel importers. It has been shown that some firms already do this. Seeing as the price margins between MS necessary for profitable parallel trade need to be quite high,²⁸⁴ raising the costs of the importers in this manner could make the difference between an importer choosing to import and not to import a product. Another method could be to use variable delivery dates to the wholesalers so as they are unable to continuously supply the PI market, which is increasingly becoming a competitive necessity in the maturing PI industry.

Cutting off supply to source MS is a strategy that should only be used when the manufacturer is under extreme pressure from PI. Since the variable costs of producing pharmaceuticals is quite low, they generally still make a profit in the lower priced MS, and would forgo all revenue and profit gains from selling on an entire national market if this strategy is taken. It is hypothesized that this is the reason that manufacturers continue to supply all MS of the EU. However, this is a strategy that could be considered when prices are set too low in a Member State. For example, Pharmacia opted to not launch its drug Detrusitol in Greece because the prices were set too low, and it feared vast parallel importation.²⁸⁵

²⁸⁴ Several Authors, *The Pharmaceutical Parallel Trade Outlook: Challenges to Pharmaceutical Companies Across Europe and the US*, Reuters Business Insight, 2004, pg. 8. A margin of 15-20% is required to make parallel trade profitable

²⁸⁵ Multiple Authors, *The Pharmaceutical Parallel Trade Outlook: Challenges to Pharmaceutical Companies Across Europe and the US*, Reuters Business Insight, Reuters Business Insight, 2003, pg. 185

Firms can also join the PI distribution chain, or simply to choose to tolerate PI. According to Chaudhry, there has been a grudging acceptance of parallel trade in Europe for some time, but she later points that the viability of this occurring is low because of the negative view that manufacturers have of importers.²⁸⁶ It is not recommended to join the PI chain unless firms are relatively unaffected by the trade. Some level of tolerance is obviously necessary in consideration of the prevalence of PI in some countries, but it is not necessary for manufacturers to support their activities. This would not likely contribute to the goals of the manufacturer.

Buying back parallel imported goods to show the official distribution chain strong commitment to protecting their needs is a choice that should probably not be considered very seriously. In effect, support is given to the importers. The fact that the buy-back cost would be much higher than the cost of manufacturing the product, this strategy does not make very much sense. Similarly, providing compensation for lost sales to official distributors in high priced MS is not recommended since this again raises costs without building value in the distribution chain. It's only positive effect would be to prove commitment to official distributors.

In-house distribution gives the ultimate control over the distribution chain. Pharmaceutical manufacturers can supply the pharmacies and hospitals directly using this technique. According a memorandum submitted to the UK Parliament during an investigation into international exhaustion, it is clear that some pharmaceutical companies are already taking this approach in supply.²⁸⁷ In some cases, vertical integration into distribution can be justified if losses to PI are particularly high. There are many positives to this approach: any movement of goods between subsidiaries is not subject to exhaustion, distribution is controlled, more control over price is held, and such movements are not subject to Article 28, 81 or 82 of TEC (as long as a dominant position is not held). This sounds good to be true, and it kind of is since it's drawback is that is expensive, laborious, and the manufacturers do not generally have great experience in the distribution area. Under Article 82, if a DP is held, refusal to supply existing customers could be found to be an abuse. However, it is conceivable that if the IP holding firm adopts a policy of direct supply (to pharmacists and hospitals), and refuses to supply wholesalers, claiming that their qualitative supplier selection criteria (trained pharmaceutical staff, provide minimum of handling to ensure quality to final user etc.), it could hold up in Court. This would especially the case for new drugs where there is no refusal to supply existing customers. It is recommended that if parallel trade is affecting a firm particularly heavily, that some kind of in-house, supply strategy be used to directly supply doctors and pharmacists be adopted to take hold of the distribution chain. For firms that do not have expertise in distribution, it is recommended to purchase an existing, reputable, and profitable distributor to attain their expertise since developing these skills in-house can be expensive. Acquiring an existing, quality downstream distribution partner will ease the transition into the new business area. If relations are already strong and trusty between the two parties, all the better. Caution should always be given when refusing to supply in light of Article 82 however.

²⁸⁶ Chaudhry, Peggy, and Walsh, Michael G., *Managing the Gray Market in the European Union: The Case of the Pharmaceutical Industry*, Journal of International Marketing, Vol. 3, Issue 3, 1995 pg. 27, 28

²⁸⁷ Eighth Report of the United Kingdom Parliament, Select Committee on Trade and Industry, Minutes of Evidence, Memorandum Submitted by the Association of Pharmaceutical Importers, 1999 pg. 7

As it stands currently, there has never been a completed case brought in front of the ECJ regarding Article 82 in relation to pharmaceutical companies restricting parallel trade.²⁸⁸ So it is difficult to hypothesize whether in house direct distribution tactics would be allowable. It is not clear how the Commission, and how the ECJ, if questioned on the issue, would define the relevant market. Because of the lack of legal clarity in this area, a good deal of caution should be used when using direct, in-house supply to pharmacies, doctors and hospitals.

In regards to licensing, a couple of recommendations should be noted. Considering the *Pharmon vs. Hoechst* case,²⁸⁹ in any cases where a mandatory license is invoked, a 'no export' clause should be included in all cases, since in such cases it is allowed according to Community law. Considering the *Kohlpharma* case,²⁹⁰ when licensing to outside manufacturers, and where possible, slight differences in formulation should be licensed out because lack of common origin defenses will no longer prevent PI. Again, the firm must be sure not to artificially partition the market when using this tactic.

One possible legal loophole found regards market testing. The European Commission's paper, *Competition Policy in Europe*,²⁹¹ outlines an exemption to Article 81 in cases where genuine testing of a new product in a particular territory with a particular customer group is taking place. A restriction on active selling outside the territory, even if the firm is in dominant position is allowed for one year in such cases. Therefore, such a restriction could allow for bans on active sales to the export market when product and market testing is occurring. This loophole should be used when possible.

With successful and wise contract negotiation, exclusive agency is another alternative that guarantees your goods will not find their way into the parallel network. Genuine agency agreements fall outside of Article 81-1 depending on the risk borne by the agent. The risk taken by pharmaceutical agents would be somewhat high because they would likely have to finance stock, which would make the agreement non-genuine. This agency alternative is not widely used by pharmaceutical companies however. Agency use is not widely used because of Directive 86/653 Articles 13-20, particularly Article 17, which allows agents to terminate the contract at any time (within 1-4 months), to declare indemnity according to increased business/good will, and allows the agent to seek damages. According to Farquharson, it would likely not be allowed under Article 81 (1) for a principal (manufacturer) in a dominant position to require the agent (wholesaler) not to sell into the parallel network, however, competition rules are relaxed when the agent's business with the principal is less than one third of their total business.²⁹² This distribution strategy is not recommended unless the manufacturer is certain that they can trust the agent. Seeing as agency is rarely in use in the industry, it is presumed that such an element of trust is difficult to find.

²⁸⁸ Interview with Kim Jensen, Legal Advisor for Paranova A/S, May 6, 2004

²⁸⁹ C-19/84, *Pharmon vs. Hoechst*

²⁹⁰ Case 112/02, Judgment of 01/04/2004, *Kohlpharma GmbH vs. Bundesrepublik Deutschland*

²⁹¹ Commission of the European Communities, *Competition Policy in Europe: The Competition Rules for Supply and Distribution Agreements*, 2002, pg. 18.

²⁹² Farquharson, Melanie and Smith, Vincent, *Parallel Trade in Europe*, Sweet and Maxwell, 1998, pg. 45

Chaudhry noted that manufacturers in her analysis of the industry could use supply interference to slow PI.²⁹³ The Bayer case generally considered a case of supply restriction. In their judgment, the CFI, by referring to Commission evidence, spelled out what strategy Bayer was employing to restrict supply, and allowed it. Thus pharmaceutical companies can:

- a) Establish direct contact with wholesalers telling them of plans to limit supply according to traditional monthly and yearly levels;
- b) Block orders exceeding attributed quantity automatically to allow for manual treatment.²⁹⁴

IP holding firms in non-dominant positions can use the actions of Bayer as a template as to how they can legally act with some certainty in supplying the European market. Firms should duly note that they should never explicitly require their wholesalers to stop supplying the export market. Furthermore, they should watch out not to explicitly track the movements of their goods too obviously since this is an indication that an agreement could exist to stop export supply.

The effects of this ruling could be enormous if the pharmaceutical industry acted together, while not explicitly doing so (as in the petrol industry). If all pharmaceutical firms in non-dominant positions strictly limit supply to lower priced MS according to national needs, or if IP holding firms have a non-dominant, but supply a popular drug on the market, the following strategy could work to raise the prices in low-priced MS in the medium term, or at least make them source some of their pharmaceuticals from higher priced MS.

The first step is for firms to limit supply to wholesalers strictly according their national needs. In this case, the wholesalers could either supply the whole market internally, or as was seen in the Bayer case, could continue to supply the export market because of the higher margins rewarded. In the likely case that wholesalers would continue to supply to the export market, the result would be that pharmacies and hospitals would see shortages of either non-dominant drugs in general, or shortages for a particular popular drug for which supply has been limited.

In the case of a supply shortage due to supply limitation strategies and wholesalers subsequently supplying the export market, the manufacturing firms have two options. Individual firms can supply the pharmacies directly, seeing it as a moral obligation to do so, as Bayer appeared to do. In order for the pressure chain below to work, this cannot be done using this strategy. Alternatively, the IP holding firms could let the Member States with draconian cost containment strategies deal with the supply problems themselves.²⁹⁵ If all IP holding firms acted together in doing this, strength would be built (although, again not explicitly to avoid cartel regulations), and the supply to lower priced Member States will be severely compromised. Again, acting alone in doing this could work if the drug is particularly popular.

In this scenario, the Member State has three options, to parallel import the necessary supply from higher priced MS, to let their nationals suffer by having no access to

²⁹³ Chaudhry, Peggy, and Walsh, Michael G., *Managing the Gray Market in the European Union: The Case of the Pharmaceutical Industry*, Journal of International Marketing, Vol. 3, Issue 3, 1995 pg. 28

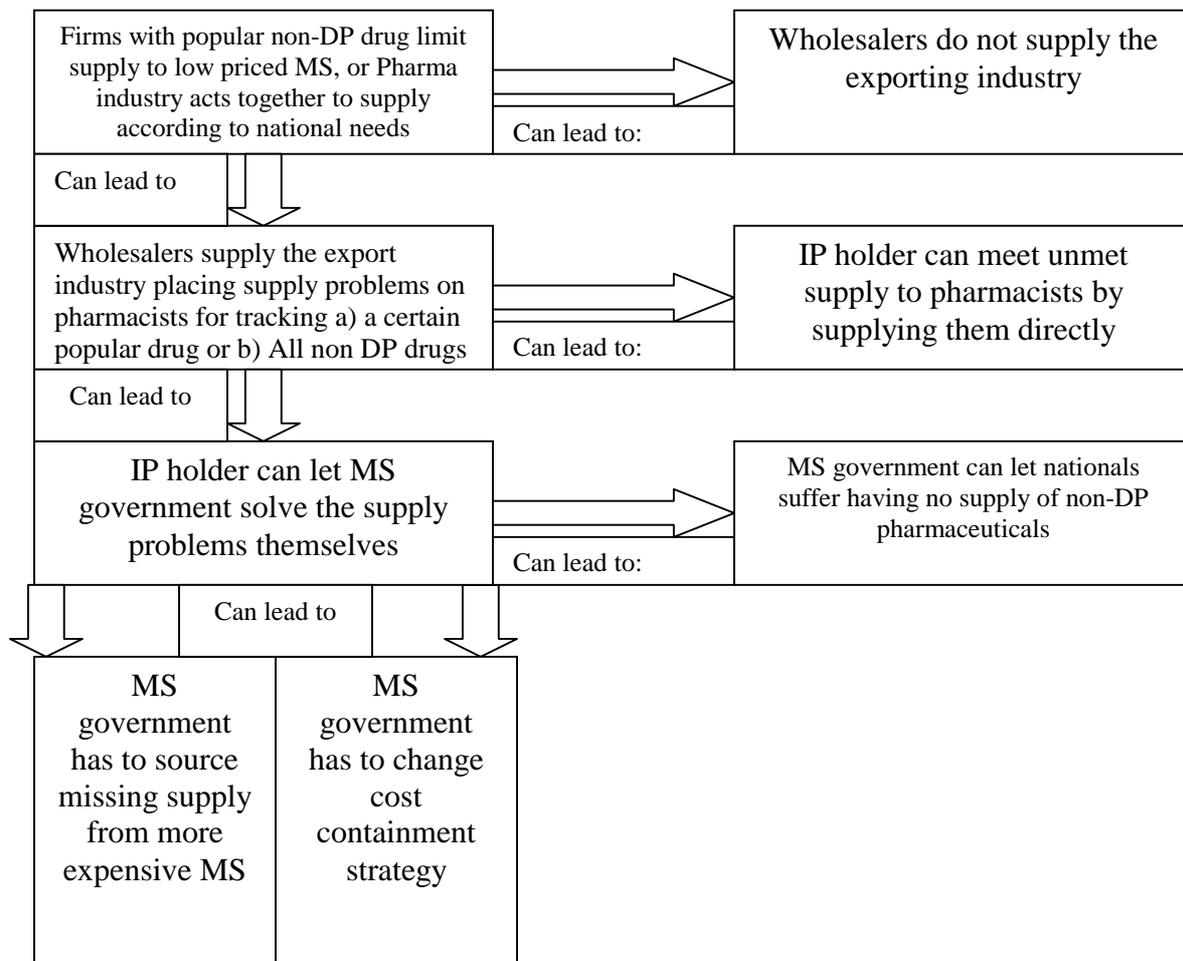
²⁹⁴ T-41/96, Judgment of October 26, 2000, Bayer AG vs. Commission, paragraphs 85-87

²⁹⁵ According C-367, 268/1996, Merck vs. Primecrown, the pharmaceutical manufacturer is under no obligation to supply all patients.

necessary medication, or to change their cost containment strategies. Two of these options, which would be the most likely scenarios in such a case would benefit the pharmaceutical industry. If the MS gains necessary supply from higher priced MS, the pharmaceutical industry will benefit from the increased revenue than would have been gained in the lower priced MS. Even better for the IP holder would be for the lower priced, exporting MS that feel the national supply pressure to change their national supply policy. The third national option is beneficial to no party involved, and would thus be unlikely. If the nationals are allowed to suffer supply shortages of previously available pharmaceuticals, the pharmaceutical industry would be seen as highly unethical, and the MS governments would appear not to be caring for their nationals' basic needs.

Two of the three alternatives available to MS governments benefit the manufacturer. This is firstly because they attain higher prices for their goods, and secondly, if the MS changes their cost containment policy, margins will be slimmer for traders, thus eliminating some of the incentive to partake in gray marketing.

Supply Restriction Cost-Containment Pressure Chain²⁹⁶



In consideration of all of the above, it is recommended that a three-tiered distribution system be adopted. The first distribution chain would be through normal means where

²⁹⁶ Author's own

supplies go through a wholesaling intermediary before reaching the pharmacists and hospitals. This should be used for products that see no or very little parallel importation. Secondly, for drugs that do see significant gray marketing, it is recommended that the firm limit supply according to national needs, and use the Supply Restriction Cost Containment Pressure Chain in the hope of attaining higher prices for their products in the future. If the firm is risk adverse, the first distribution chain should obviously be used for products that have a dominant position on the market as opposed to the second. The third chain should be used for new drugs to market (so as the problem of cutting existing buyers off is mitigated), and drugs that have very difficult parallel problems. Direct, in house supply to pharmacies and hospitals is recommended for this section of products. Keeping a diligent eye on possible abuses of Article 82 is recommended for this third distribution chain. Over time as drugs move from on-patent to off-patent, and as new drugs are introduced as they veer down the R&D pipeline, more and more drugs should be supplied directly to pharmacies and hospitals via in-house delivery methods. If this could stand up to the scrutiny of Article 81 and 82, which it could conceivably could, a great drop in parallel trade should be seen over time.

Supply quota systems, such as the one presented above, can run into difficulty. There are currently 30 anti-trust complaints that have been filed with the EC.²⁹⁷ No doubt, if the manufacturers were not careful in employing this strategy, they may be found foul under EC competition laws. As with most of these strategies, professional legal advice is recommended.

Regarding launching order, when the *Centrafarm vs. Winthrop* case of 1974 concluded that pharmaceutical companies cannot generally control distribution of their products after first release on the common market, it should have been clear to them that they would need to re-adjust their launching order in a profit-maximizing manner. With due regard to reference pricing patterns, firms need to launch products in an order that allows the maximum price for their goods. Figure 5 outlines the launch order that should be used among the five major pharmaceutical markets in the EU.

7.2.2 Product Strategy Recommendations

It is recommended in light of all of the above that pharmaceutical manufacturers should as far as possible use different packaging in different Member States in order to dissuade imports while not obviously partitioning the internal market. Due to the state of harmonization of packaging of pharmaceutical products in the EU, this is however, becoming more difficult to do so.²⁹⁸ Objective necessity of repackaging needs to be proved by the importer. This is easily done in cases where different package sizes exist because of national requirements. It is not so easily done in cases where the repackaging has taken place when different package sizes had not existed, as indicated by Mr. Jensen.

However, the differentiated packaging should not solely be seen as a tool to enable TM infringements. It also should raise the costs to parallel importers, which would make them less competitive on price. It is apparent that firms are currently doing this to some

²⁹⁷ Macarthur, Donald, *The Myths of Parallel Trade in Medicines*, Managing Intellectual Property, March, 2004

²⁹⁸ Farquharson, Melanie, and Smith, Vincent, *Parallel Trade in Europe*, page 37.

extent,²⁹⁹ and it is recommended they continue to do so. Indeed, Mr. Jensen acknowledged the fact that firms are using differentiated package sizes to achieve these ends.³⁰⁰

In consideration of the ECJ jurisprudence, the Paranova/Bristol Myers Squibb case of 1996 outlined the circumstances where importers can repackage³⁰¹, and when they should re-label products. Selective use of package differentiation should be used to increase the costs of the importers in an effort to decrease their margins. However, the case also made it clear to parallel importers when and when they cannot repackage, so it is probable that TM infringement cases may diminish in the future.

This package differentiation should be combined with an effort to change the dosage, shape, colour, size and method of use along national lines as far as is allowed by EU law in order to raise PI costs. This can raise consumer resistance to the imported products still in some Member States. Seeing as national differences still exist, for example in packaging, firms should use this to their advantage. During the UK Parliament's investigation into the effects of adopting an international exhaustion regime, a memorandum was sent by the Association of Pharmaceutical Importers that outlined some of the strategic back-lash they are experiencing from the pharmaceutical industry.³⁰² It was mentioned that pharmaceutical companies in the EU use different formulations in different MS. Having different formulations of medicinal products in different MS complicates 'piggy-back' licenses. Since the importer has to prove that the product is the same therapeutically, small product differences can cause minor variance in therapeutic effects. The firm must be careful not to partition the single market in doing this.

Chaudhry also promotes use of this strategy on the European pharmaceutical market: 'the pharmaceutical manufacturer can differentiate the drug, even though the active ingredient is the same, by using a brand name or color, or both to create doubt about authenticity.'³⁰³ When employing this maneuver, the firm must not run a foul in regards to Article 28 TEC, and avoid using differentiation as a disguised restriction to partition the internal market.

Having small batch size is another technique utilized, and is recommended. To parallel import in some countries, batch numbers must be recorded with a sample kept by the importer from each batch.³⁰⁴ Having batch numbers as small as a dozen or two will dig into potential profits of parallel importers. The ability to legally do this will increase if there is a national taste difference (ie. if one MS prefers a certain formulation/ colour/ shape/ delivery mode). When such national taste differences exist, advantage should be taken of them.

²⁹⁹ Eighth Report of the United Kingdom Parliament, Select Committee on Trade and Industry, Minutes of Evidence, Memorandum Submitted by the Association of Pharmaceutical Importers, 1999 pg. 8

³⁰⁰ Interview with Kim Jensen, Legal Advisor for Paranova A/S, May 6, 2004

³⁰¹ C-427, C-428, C-436/93, Bristol Myers Squibb vs. Paranova AS,

³⁰² Eighth Report of the United Kingdom Parliament, Select Committee on Trade and Industry, Minutes of Evidence, Memorandum Submitted by the Association of Pharmaceutical Importers, 1999 pg. 6-8

³⁰³ Chaudhry, Peggy, and Walsh, Michael G., *Managing the Gray Market in the European Union: The Case of the Pharmaceutical Industry*, Journal of International Marketing, Vol. 3, Issue 3, 1995 pg. 29

³⁰⁴ Eighth Report of the United Kingdom Parliament, Select Committee on Trade and Industry, Minutes of Evidence, Memorandum Submitted by the Association of Pharmaceutical Importers, 1999 pg. 8

Several authors recommended product tracking,³⁰⁵ and is a recommended practice here for companies wanting to prevent PI. Peggy Chaudhry recommends product tracking via Marketing Information Systems (MIS).³⁰⁶ It was shown by the Commission that Bayer had tracked products from Spanish wholesalers to the UK by use of serial numbers, a strategy discussed earlier. The ECJ noted that product tracking in itself is not against the Treaty, but it merely indicates the existence of an agreement to stifle exports. If no direct punishment follows the product tracking, it is recommended that firms actively engage in product tracking via serial numbers. In consideration of this, the firm should conduct product tracking, the level of monitoring should depend on how the firm sees the 'indicative' risk of doing so. Mr. Jensen indicated that the tracking and supply quota systems used by Bayer at the time of the Bayer case were rather archaic in comparison to the systems currently used. Thus it appears that firms are currently employing this tactic. If firms do employ some kind of tracking system, they will only be able to guess at which wholesalers are breaching the 'official' distribution chain. It should be kept in mind that the actions taken following product tracking are all subject to Treaty and national law scrutiny, so firms should be wary of explicit and obvious tracking methods when in a dominant position of are illegally limiting supply.

7.2.3 Promotion Strategy Recommendations

Chaudhry seems to heavily recommend promotional strategies in efforts to prevent parallel importation. She recommends pharmaceutical representatives promote the negative aspects of parallel imports to re-sellers, doctors, pharmaceutical societies as well as lobbying and strategic product release.³⁰⁷

A strong promotional effort to doctors, pharmacists and pharmaceutical societies is recommended. This is for several reasons. As was decided in Cases 266 and 267/87³⁰⁸, rules enacted by a pharmaceutical society requiring pharmacists to dispense the trademarked product when specifically written as such by the doctor were in line with Community law. Because of this, strong brand building promotion to doctors is particularly recommended. Doctors in their prescribing orders to pharmacists would likely use a very strong brand name that has become synonymous with an active ingredient or therapy. Considering some countries such as Finland, Denmark, Germany and the UK have adopted rules whereby the cheapest alternative is to be dispensed (or is rewarded to do so such as in the UK) unless a doctor specifically indicates a brand name³⁰⁹ makes promotion to doctors all the more important. Chaudhry recommends promotional bursts and dealer development.³¹⁰ She points out that past research by Slatter and Spiker on the multinational pharmaceutical industry indicates that company image and brand loyalty influences the prescribing of doctors.³¹¹ The end users however, should not be the targets of the promotion. Rather, the doctors, and

³⁰⁶ Chaudhry, Peggy, and Walsh, Michael G., *Managing the Gray Market in the European Union: The Case of the Pharmaceutical Industry*, Journal of International Marketing, Vol. 3, Issue 3, 1995 pg. 29

³⁰⁷ Chaudhry, Peggy, and Walsh, Michael G., *Managing the Gray Market in the European Union: The Case of the Pharmaceutical Industry*, Journal of International Marketing, Vol. 3, Issue 3, 1995 pg. 29

³⁰⁸ C-266/87, 267/87, The Queen vs. Association of Pharmaceutical Importers

³⁰⁹ Interview with Kim Jensen, Legal Advisor for Paranova A/S, May 6, 2004

³¹⁰ Chaudhry, Peggy, and Walsh, Michael G., *Managing the Gray Market in the European Union: The Case of the Pharmaceutical Industry*, Journal of International Marketing, Vol. 3, Issue 3, 1995 pg. 28, 29

³¹¹ Spiker, Bert, *Multinational Drug Companies: Issues in Drug Discovery and Development*, 1989. And Slatter, Stuart, *Competition and Marketing Strategies in the Pharmaceutical Industry*, 1977

pharmacists should be targeted since legally, they can determine whether a trademarked product is used instead of a parallel traded product.

Using such promotional methods as seminars on the dangers of parallel importation, leaflets, and advertising in trade journals expressing the same dangers should be combined with active campaign participation by the sales representatives. Brand building in the eyes of doctors who can personally limit PI by specifically prescribing trademarked goods is a strategy that should see primary use.

Creating brand value in pharmaceuticals is a multi-faceted strategy. One report outlines seven ways to create brand value.³¹² Creating products that are more effective than existing products with less side effects requiring a lower dosage and an improved medicinal delivery system are all product attributes that contribute to brand value. Furthermore, creating drugs that help untreated diseases, preferably in high value markets can help this as well. Being scientific by nature, having clear clinical data proving all aforementioned benefits will help convince the medical professional decision makers of the value of the brand. All of this must be combined with the traditional promotional methods above (seminars, trade journal advertising, leaflets etc.) in order to be effective.

It is further recommended that some kind of promotion take place further up the distribution chain, to the wholesalers in the lower priced MS. Having seminars on PI indicating possible safety problems, the effect on R&D among other side effects for the wholesalers could make it clear to them that their supplier, while not banning their participation in the parallel chain, is concerned about it.

Acquisition of importers is a possibility that was presented above. Chaudhry discounts the alternative because of ‘the apparent abhorrence of the industry toward these gray market “charlatans”’. However, almost ten years have passed since the report, and much has changed. Market shares of imports have grown to well above 10 or even 15 % in some markets. It is no longer a market that can be easily ignored. The PI industry itself is maturing and the larger firms are moving into more ‘legit’ generic manufacturing.³¹³ Furthermore, given that PI has been around for so long, it could be hypothesized that the research-based industry has grown accustomed to, and accepts the practice. These points should make acquisition a more palatable idea to manufacturers than it was a decade ago.

Given that a firm such as Paranova had sales of 140 M € in 2002³¹⁴, and a firm such as Glaxo Smith Kline has turnover of over 21 000 M £ in 2002³¹⁵ (32130 M € using exchange rate 31-12-2002)³¹⁶, such an acquisition would not have a huge negative financial effect on a firm like GSK. Since a company like Paranova has seen rising sales consistently since it started, the move could well be financially wise for a research-based manufacturer. This alternative could have the negative side effect of poaching the business of their competitors from a level that could seem unethical in the

³¹² Multiple Authors, *The Pharmaceutical Parallel Trade Outlook: Challenges to Pharmaceutical Companies Across Europe and the US*, Reuters Business Insight, Reuters Business Insight, 2003, pg. 172

³¹³ Interview with Kim Jensen, Legal Advisor for Paranova A/S, May 6, 2004

³¹⁴ www.paranova.com, May 9, 2004

³¹⁵ www.gsk.com, May 9, 2004

³¹⁶ Calculated using <http://www.x-rates.com/cgi-bin/hlookup.cgi>

eyes of the competition. Subsequent reaction from competition would be likely. Acquisition is not recommended here per se, but it is an option that should not be ruled out automatically. If a firm is experiencing a lot of pressure from importers, and currently works in or is planning on moving into generics, acquisition should be at least considered. Acquisition would be a move that the manufacturing firms could employ to show that they understand the 'rules of the game' in the EU, and that if these rules are unlikely to change, than participation is a logical outcome.

Lobbying and industry-wide influence should be and is used by pharmaceutical companies to create favourable political inertia in PI prevention. Chaudhry recommends this as well, stating that 'lobbying for future pricing on a pan-European basis and changing the distinct attitudes of national governments toward the purchase of parallel imports to defray the civil drug bill are two principal issues to be addressed.'³¹⁷ The industry in Europe as a whole is huge, and working as a cohesive unit, they can draw a lot of water in Brussels, as is indicated from the work done on the G-10 High Level Group in Innovation and Provision of Medicines.³¹⁸ Further industry collaboration such as this is recommended, and collective lobbying influence should be utilized as well. This political advertising, if effective, should influence beneficial political changes in the pharmaceutical arena. For example, regarding harmonization of the pharmaceutical market, the industry could place pressure for desired outcomes, pushing for harmonization in some areas such as pharmaceutical pricing/reimbursement, while pressuring against harmonization in areas such as package size harmonization because the necessary re-boxing raises the costs of the importers.

7.2.4 Pricing Strategy Recommendations

One strategic area that justly receives a lot of attention in the academic literature regarding countering gray markets is pricing. It is perhaps the most obvious strategy to first time observers to counter parallel trade. Taking away the parallel importing profitability with various pricing strategies is mentioned by most of the authors considered.

Stated generally, a firm has the options to a) lower the price in the higher priced MS, b) raise the price in the lower priced MS, or c) a combination of both, in order to prevent parallel trade. Looked at under state pricing and reimbursement framework presented above, it seems that firms would usually not have freedom to heighten price on a whim to prevent parallel trade in the lower priced MS because prices are negotiated, or set at a limit. It is more probable that they would be able to lower prices in high priced, importing MS. Even if a price has been fixed for several years, it seems unlikely the state would refuse an offer to save money on rising health care costs.

Lowering prices in higher priced MS is a dangerous practice, and can lead to a price war. The point of using this strategy is to strangle any profits to parallel traders. The firm

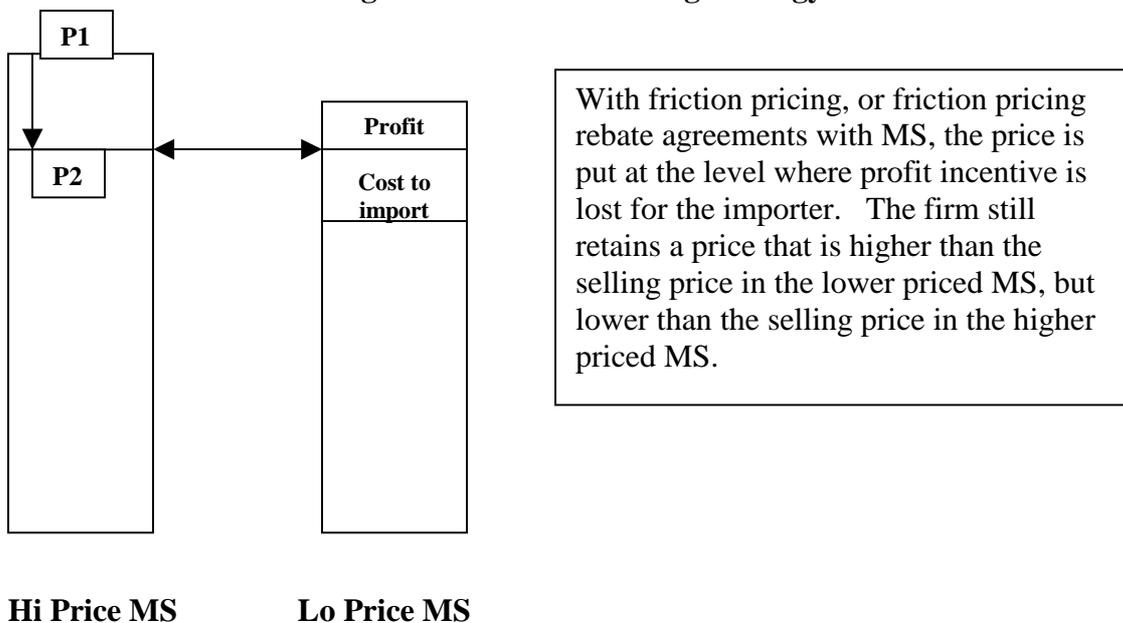
³¹⁷ Chaudhry, Peggy, and Walsh, Michael G., *Managing the Gray Market in the European Union: The Case of the Pharmaceutical Industry*, Journal of International Marketing, Vol. 3, Issue 3, 1995 pg. 29

³¹⁸ Final Report of the G-10 High Level Group in Innovation and Provision of Medicines made several recommendations for strengthening the R&D base for pharmaceuticals in Europe that resulted in a Commission Communication COM (2003) 283, which outlined the beneficial specific mechanism for EU expansion countries among other beneficial steps for the industry.

employing this tactic should have deep enough pockets to outlast its importing competition.

Yang and Simon³¹⁹ propose ‘friction pricing’ that sets the difference of prices between the importing and exporting state at precisely the level of the purchase price (in the lower priced MS by the importer) plus the cost of parallel importation. Thus any profit motivation for importation no longer exists. This strategy makes sense, but that largely depends on the currently existing price differential. The lost revenues of lower prices in high priced MS must be weighed against the continued lost revenues in the importing MS because the sale has taken place in a lower price MS. If the benefits gained from erasing parallel importation are greater than the revenues lost from accepting lower price levels in the state of importation, this option could and should be employed. It must be stressed again that this maneuver should be used against financially weak importing competition that would not be able to endure the time of having little or no profits. It is not a likely strategy to be employed because the manufacturers are likely still earning a profit from sale in the lower priced MS because of relatively low variable costs of pharmaceutical production.

Figure 11: Friction Pricing Strategy



It was suggested by an author that frequent price changes could make importing more difficult. Where it is possible to change prices frequently and without notice to gray marketers under national price agreements, this tactic should be used. Given that parallel importers are currently trying to give consistent supply in order to build stronger relationships with their customers, making this consistent supply more difficult through un-scheduled price fluctuations and infrequent delivery to wholesalers will work against this. The firm must be aware that sudden price changes will upset wholesalers in the normal distribution chain, and may not be possible in the pricing agreements in some MS.

³¹⁹ Simon, Hermann, and Kucher, Erckhard, *The European Pricing Time Bomb: And How to Cope with it*, European Management Journal, vol. 10, issue 2, 1992, pages 136-146, Yang, Rachel, B., Ahmadi, Reza, H., Monroe, Kent, B., *Pricing in Separable Channels: The Case of Parallel Imports*, Journal of Product and Brand Management, vol. 7, issue 5., pg. 446, pages 433-440

Dual pricing is a strategy that was mentioned by Kim Jensen as being one of the primary strategies used against parallel importation.³²⁰ It was surprising to hear that this is a major strategy employed since it seems to blatantly counter Article 81/82 and carve the internal market. This strategy attempts to raise the costs of parallel importation by offering different conditions on similar purchases. Under this strategy, the manufacturer charges a higher price for products that get subsequently exported. Glaxo Smith Kline employed this strategy in Spain, and after investigation, the Commission, on a decision of May 8, 2001 found GSK guilty of breaching Article 81. The ECJ appeal is forthcoming. It will be interesting to see how the case turns out, if dual pricing is deemed to be acceptable under EC law, the manufacturers will have a powerful tool in their hands to counter PI.

Uniform (identical) pricing across all markets is not really an option in the EU, and can be quickly discounted. The only option available for the manufacturers in consideration of pricing agreements with MS to adopt the lowest common denominator by charging the price received in the lowest priced MS. This is not an option to prevent PI.

An option available to manufacturers is to launch a new product outside of reimbursement altogether. The advantage of this is that price can be chosen to maximize profits, however, if patients choose not to pay for the drug, this is not a wise option. This option could be used when reimbursement prices are set too low. Products with a strong medical need, or lifestyle drugs such as Viagra can benefit from this strategy. This strategy was employed by Pfizer when marketing its schizophrenia drug, Aricept on the Italian market.³²¹ This is not an option for most drugs however.

Overall, none of these pricing strategies would work in all situations. The firm employing changes in prices should look at their own operations, the effects that PI is having on their revenues, and act accordingly. Pricing strategies such as dual pricing are legally questionable, while raising prices in lower prices in many MS is simply not an option. Any departure from the traditional profit maximizing price strategy should be considered very carefully.

7.2.5 Technological Strategy Recommendations

Myers and Griffith recommend broadly that firms employ technology in their battle against importers.³²² It is assumed that pharmaceutical manufacturers are doing so as part of their wider technological strategy. Having MIS systems in place can help in product tracking, co-ordination and control of distribution channels, help in staying up date on changing laws and regulations, communication and information dissemination. Involving wholesalers in extranets will hopefully build a certain amount of trust between the two parties, as well as hopefully flag sales anomalies, give the wholesaler consistent, quality supplies, and help in information sharing. Chaudhry sees the main benefit of MIS as it's tracking capability, particularly noting package encoding so as to estimate and deter PI. Such a method should obviously only be used for products that

³²⁰ Interview with Kim Jensen, Legal Advisor for Paranova A/S, May 6, 2004

³²¹ Multiple Authors, *The Pharmaceutical Parallel Trade Outlook: Challenges to Pharmaceutical Companies Across Europe and the US*, Reuters Business Insight, Reuters Business Insight, 2003, pg. 184

³²² Myers, Matthew B. and Griffith, David A., *Strategies for Combating Gray Market Activity*, Business Horizons, November-December, 1999, page 6, pages 2-8

the manufacturer is quite certain will not be repackaged (ie. not in different package sizes across MS). It is recommended that if the manufacturer does not have a MIS system in place to track product, to share information between distributors and among themselves, that such an intra/extranet MIS system be introduced. If PI is of such a primary concern across the whole industry, as is indicated by some manufacturers, it is even possible for information regarding PI be shared between companies in view of PI prevention.

7.2.6 Legal Strategy Recommendations

Using the law to work for the manufacturer is a strategy that has been used since PI started in the 1970s as is indicated from the case law emanating from that time. From the analysis above, it is clear that some legal tools are more useful for PI prevention than others. Various strategies will be assessed, recommended and discounted here.

In an interview with Kim Jensen, it was indicated that patent trials traditionally follow EU expansions. This could indicate that with the expansion of May 1, 2004, of 10 new Member States, that there could be a wave of patent trials. However, seeing as the specific mechanism is in place protecting the manufacturer's patents in this expansion, there probably won't be as many patent cases, or cases that involve product releases in MS with no patent protection such as the *Stephar* or *Primecrown* cases.³²³ Unless a breach of the specific mechanism takes place, the IP holders will not have a valid case.

Regarding exhaustion, it is clear from ECJ jurisprudence,³²⁴ that any pharmaceutical products imported outside of the EEA are not allowed, and the manufacturers will have a sound case to bring to national courts if such imports occur. Any imports from outside the EEA should be contested.

As it currently stands, pressing TM infringement to prevent re-boxing is certainly allowed by IP holders. The national courts will be left assess the necessity of re-boxing the products. According to Kim Jensen, who defended *Paranova* in the 2002 Danish Supreme Court trials claimed that proving necessity in that case would have been impossible, not seeing what else could have been done to show the necessity of their re-packaging actions a decade previously.³²⁵ Given that court cases often last several years, necessity is a very difficult onus to prove for the importer given that the re-packaging often took place so long ago. However, it is clear that in cases where different package sizes are used in various MS, necessity is much easier to prove. In light of this, any re-boxing activity that takes place outside of circumstances where different package sizes exist between MS, cases should be pressed since the outcome would likely be positive for the manufacturer.

An interesting contradiction was pointed out during the interview with Kim Jensen. He noted that the pharmaceutical companies bring cases regarding trademark infringement against the importers. However, the importers do not want to use the trademark at all, and would rather sell the product using the generic name. The contradiction lies in the fact that the manufacturers do not want this to ever happen, despite the fact that they

³²³ C-187/80, *Merck vs. Stepfar and Exler* (Rec.1981,p.2063), C-267 – 268/95, *Merck and Company vs. Primecrown Ltd* ECR I-6285

³²⁴ C-355/96, *Silhouette*, C-173/98, *Sebago*, and C-414, C-415, C-416, *Zino Davidoff*

³²⁵ Interview with Kim Jensen, Legal Advisor for *Paranova A/S*, May 6, 2004

themselves could solely use the trademark without the possibility of breaches if the importers used generic labeling. Mr. Jensen indicated that this shows the manufacturers are not concerned about the trademark infringement per se, but rather are simply use the infringements to work against PI.³²⁶ If the parallel importers did not use the trademark at all, although the manufacturer would regain full control over they trademark, they would lose all right to pose infringement proceedings. Thus, in consideration the Upjohn case analysis above,³²⁷ which considered the possibility of forcing importers to sell under the generic name, it is not recommended that firms do as such, because they would lose all right to press trademark infringements in the future.

The IP holders, when not dominant can limit supply to national demand, and possibly could employ some other supply quota systems. This is a powerful mechanism at their disposal. In strictly unilateral cases involving non-dominant parties, the Court will likely not find Article 81 breaches. Likewise, the Commission will probably be more selective in what cases they press using Article 81 regarding parallel trade of pharmaceuticals. Regarding infringements of Article 82, the situation is currently unclear, so only risk takers would be advised to abuse a dominant position on their market.

Establishing legal precedents is a very expensive strategic option. When asked if he thinks manufacturers bring cases before courts in circumstances they do not feel they can win, Mr. Jensen responded that he does not see firms doing this. There are not many legal tools available to manufacturers to dissuade parallel trade after looking at the above case law.

8.0 Conclusion

This section of the paper will draw the Conclusions reached from the analysis above as well as provide some ideas for future research.

It is clear from poring into the academic literature that there are many strategies that can be employed by manufacturers to prevent gray markets. It becomes clear that not all of these strategies can stand to scrutiny under the European legal framework.

It is clear that the EU market for pharmaceuticals sees a perfect market in which parallel trade should flourish, as it has been doing for some time now. The main reason that this is so is that national price and reimbursement cost containment methods are employed by EU Member States, and will likely continue to have authority in this area.

It is plain to see from looking at the current state of harmonization that while much has been done in relation to harmonizing the market for pharmaceuticals, much also remains to be done. It is not foreseeable that a completely harmonized market for pharmaceuticals is likely to arise because health care is controlled by EU Member States under the subsidiarity principle. Health is a policy area that is almost synonymous with sovereignty, and will remain a national concern for some time.

The coming EU expansion will undoubtedly have an affect on the parallel trading industry, and the problems that this presents to manufacturers. The sourcing area will

³²⁶ Interview with Kim Jensen, Legal Advisor for Paranova A/S, May 6, 2004

³²⁷ C-179/97, Pharmacia vs. Upjohn

be expanded by ten new countries, as will the market be expanded to sell parallel imports into these countries. The pharmaceutical industry proved their lobbying strength by having the 'Special Mechanism' included in the Accession Treaty.

The legal environment in the EU regarding parallel trade of pharmaceuticals is complex, constantly changing, and somewhat exciting to observe. The parallel trade industry of pharmaceuticals in Europe works on the basis of the free movement of goods within the European. While some may not deem this as being fair in consideration of the price and reimbursement controls enacted in Member States, it is a fact in the EU currently, and likely for some time to come that free movement principles will form the spine of EU law. In consideration of this EU level courts have usually ruled in favour of the importers. The National Courts have not been so forgiving, and seem to provide more strategic maneuverability for the pharmaceutical industry.

Possible strategies that the pharmaceutical manufacturing industry can employ depend largely on their position of dominance on the market. Where firms are not in a position of dominance, provided they do not employ 'hard core' restrictions in their reactive strategies, they should be clear from breaches in the Treaty. Strategic maneuverability is limited severely if firms are in a position of dominance.

A three-pronged distribution approach was recommended for manufacturers seeing considerable parallel trade competition. Traditional distribution was recommended for goods not seeing much parallel trade competition or that is in a position of obvious dominance. Using a cost-containment pressure chain was recommended for in-patent drugs not in a dominant position in order to reap higher costs. In house direct supply to doctors, pharmacists and hospitals were recommended for new drug releases, and possibly some drugs that see significant PI competition that are not in a dominant position. Other distribution techniques were also assessed, and their use is dependent on the operations and PI effect on revenue that the individual firm sees.

Using product differentiation across geographical areas can work to raise the costs of the importers, and to raise customer resistance in the importing state. Using diligent package, brand, colour, formula and delivery method differentiation can achieve these ends. Product tracking is also recommended so as leaks in the official distribution chain can be located. Small batch sizes also increase the costs of importers in some MS, and should be used where this is the case.

Promotion to pharmacists, health service schemes, hospitals, and particularly doctors should be done to raise questions about parallel trade and to boost the manufacturer's brand image in the eyes of decision makers. Promotion to wholesalers can also make it obvious to them while not explicitly saying so, that parallel trade is a major concern to the manufacturer.

Departing from use of traditional profit-maximizing price structures should be used in cases where extreme parallel trade competition is seen, and could be countered with price changes.

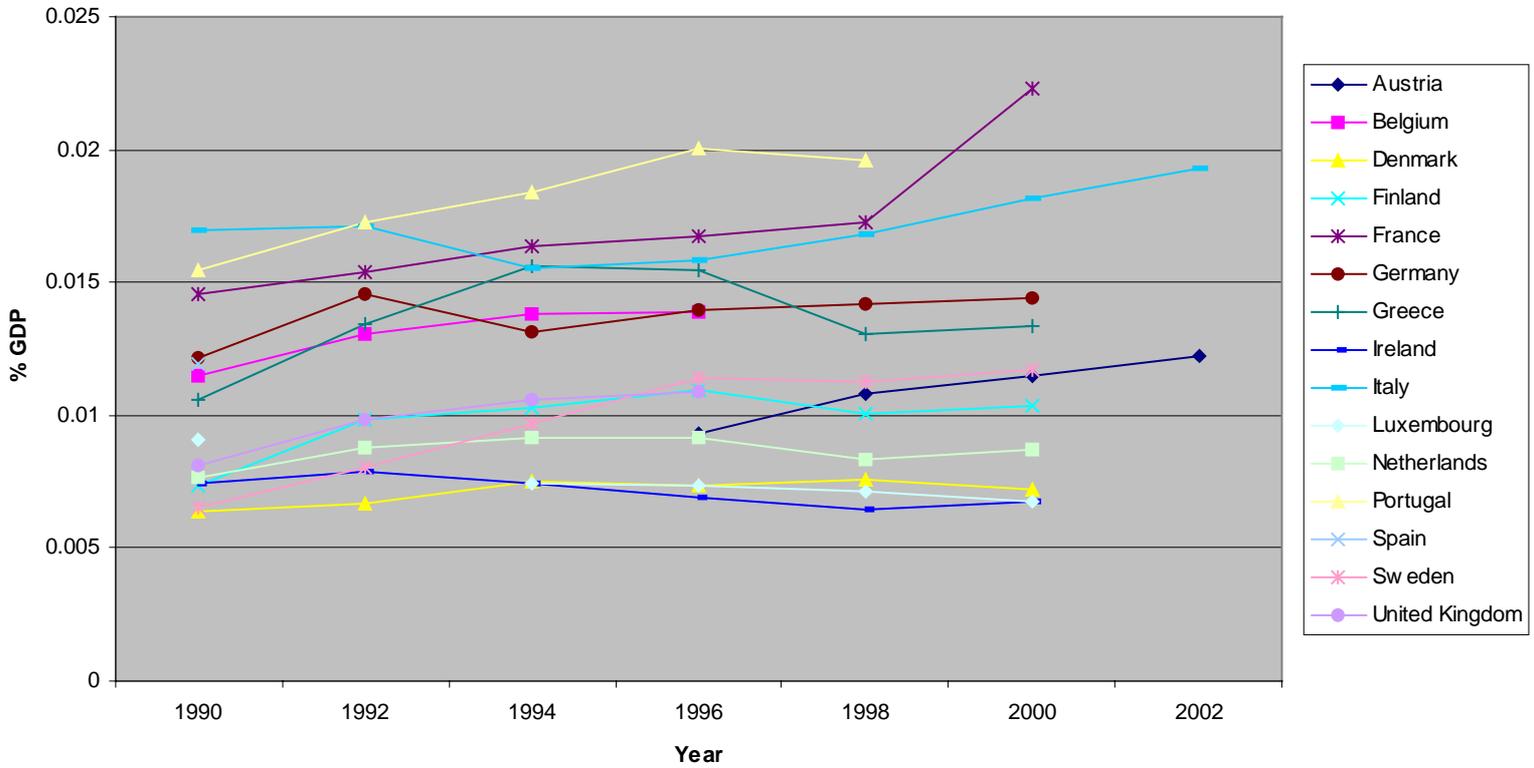
In sum, while many of the options to prevent parallel trade cannot be used in the European environment for pharmaceuticals, many strategies are still employable. Internal analysis of the effects of parallel trade should take place, and with due

consideration to the legal and political framework in which parallel trade and the pharmaceutical industry operates, strategies should be chosen that attack the root of the negative effects seen from parallel importation.

Much more research can be done, even in this specific area of parallel trade prevention. More work could be performed in this area via surveys as to what prevailing attitudes are towards the strategies presented in this paper in the pharmaceutical industry itself. This would give some greater validity to the research already performed. There is probably a reason why there has not been extensive academic research has been done in this area. It is assumed that the pharmaceutical companies themselves are doing much of the work specifically in this area; however, access of such work to the public is likely extremely limited. It is hoped that this publicly accessible work will be useful to future researchers in the future.

Appendix A³²⁸

Pharma Spending as % of GDP



³²⁸ Data taken from OECD Health Data 2003

Appendix B: Re-imburement and Price Control Chart³²⁹

Country	Pricing Control Mechanism	Reimbursement Mechanism
Austria	Price contracting with price/volume agreements	Positive list following price-volume agreements
	Rebate on excess sales	Contractual relationship of physician with Krankenkassen monitoring prescribing
Denmark	There is no policy of price control	
	Price agreement between the industry and the Ministry of Health, (price reductions)	Positive list
		Reference pricing for generic products
		Generic substitution
		European price comparisons
		Economic data in reimbursement (voluntary agreement)
Netherlands	Maximum price fixing (twice per year) through European price comparisons (reference countries are Germany, France, Belgium, UK)	Therapeutic reference pricing
		Positive list
		Promotion of dispensing parallel imports
		Explicit use of pharmaco-economic studies for reimbursement
Germany	Price freedom for new products	Reference price for off-patent sector
		Drug budgets with caps re-introduced in 1999
		Negative list
		Positive list
UK	PPRS: Agreement with industry on profit control, renewed on July 13, 1999 for a five year period	Negative list
	Price cut, as part of PPRS of 4.5%	Homogeneous budget given to PCGs
	Free price modulation	Practice guidelines
		Guidance on cost-effective by NICE, influences prescribing
Ireland	Maximum authorized wholesale price is average of Danish, French, Dutch, German and UK prices	Positive list
	Agreement with the industry	Indicative drug budget for doctors contracted into the GMS scheme
	Price freeze for duration of the above agreement	Use of economic data in reimbursement decisions

³²⁹ Kanavos, Panos, *Overview of Pharmaceutical Pricing and Re-imburement Regulation in Europe*, LSE Health and Social Care, February 2001. Due to constantly changing national regulation, this chart is subject to inconsistencies with current legislation due to its age.

	Review of price freeze with comparisons	
	Wholesale prices are the same but retail prices differ due to different pharmacy margins on GMS and private sales	
	Price modulation permitted in exceptional cases	
Finland	Control through reimbursement system (manufacturer can launch at desired price, but needs to seek reimbursement)	Acceptance of a 'reasonable' wholesale price by Ministry of Social Affairs and Health; this is the maximum price for the product; Same rules for generics
		All new products remain in basic reimbursement category (50%) for two years
		Prices of existing products should be reevaluated within 2 years
		Submission of pharmacoeconomic data necessary when companies apply for a reasonable price
		Control of prescribing in certain product categories
		Positive list
Sweden	Price control if reimbursement is sought	Reference price at pharmacy buying in level
	Reimbursement price takes into account price in 10 European countries; exchange rate used for conversion	Health economic evaluation if price premium is requested (for innovative products)
	Price should be lower than Denmark, the Netherlands, Germany, Switzerland, and similar to those in Norway and Finland	Price-volume agreement for innovative products
	Annual negotiations between the industry and the National Social Insurance Board for price revisions	Positive list
		Negative list for Over the Counter drugs (OTCs)
Belgium	Price control with price comparisons and weights given to R&D	Positive list
	Regular price cuts/freezes especially for older products	Prescribing control through Pharmnet
		Controls on specific categories of drugs (antibiotics, NSAIs)
		Controls on the veracity of reimbursement claims by pharmacists
		Generics must be at least 20% cheaper than branded product to qualify for re-imburement
France	Price fixing through negotiation (product's medical value, prices of comparable medicines, volume sales, conditions used)	Comite Economique du medicament decides on reimbursable prices on advice from Transparency committee
	Comparisons with other European countries for 'innovative' products	Positive list
	Periodic price reductions for new and expensive products	Medical References
		Targets for 'gate-keeping' GP's
		Pharmacoeconomic guidelines under development

		Prices of generics 30% lower than those of the original
Italy	Average European Price (all EU countries) for 'old' products and products registered with the national procedure; AEP is calculated on ex-manufacturer's price level(excl. VAT), of top five selling equivalents, including generics	Positive list
	Price negotiation (Contractual model) for new and innovative products (for drugs registered with EMEA or for those for which AEP cannot be calculated)	Reference pricing and 'same prices for same drugs' principle for off-patent drugs
	Price freedom for non-reimbursable drugs	Formal requirement for economic evaluation during price negotiations
	Generics are priced at least 20% below the original	guidelines and protocols defined and managed at local level
	Frequent use of price cuts/freezes	Official earmarked budget for innovative drugs introduced in 1998, representing 1% of national drug budget
Greece	Price fixing for imported medicines (lowest EU price for the same molecule)	Positive list
	Basic Cost formula for locally produced pharmaceuticals	Clustering (reference price) for calculating the average daily treatment cost
	Cannot grant a price unless product is marketed in one European country	Requirement to be included in reimbursement lists of 3 of the following countries: France, Germany, Switzerland, UK, USA, Sweden
Portugal	Two step process with Ministry of Finance agreeing to the new maximum price for every new price for every new medicinal product and, subsequently INFARMED processes reimbursement applications	Positive list
	Price control (Average pricing of Spain, France and Italy): additional restrictive criteria apply	Submission of cost benefit data
	Price increases in 1998 and 1999 below the rate of inflation	
	Generics priced at least 20% below equivalent branded product	
Spain	Price Control through negotiations on a cost-benefit basis	Positive list
	International price comparisons	Negative list
	Price-volume agreements for expensive products	Reference pricing for estimating maximum reimbursement for multi-source products

Appendix C

Interview with Kim Jensen, Chief Legal Advisor of Paranova A/S, May 6, 2004

N.B. The recording device used did not work throughout the whole interview, and the tape cut out intermittently during the interview. The direct quotations are written in *italics*, otherwise, the responses are written from the notes that I took during the interview session. Also note that the conversation ensued for an extra hour after recording stopped.

Q: Can you explain in a few sentences what parallel trade is and how it works? (whole question and answer did not get recorded)

KJ (not verbatim): The free movement of goods principle is the legal basis of our business. It allows us to conduct the exporting of products. In addition to this, the price differentials in European Member States allow us to source goods in lower priced Member States and export them to higher priced Member States. These two points make our business of exporting interesting.

Paranova has almost seen almost continual proceedings since its inception in 1990. who is this so? (whole question and answer did not get recorded)

KJ (not verbatim): Firstly, Erik Pfeiffer, our founder is a lawyer himself, so he does not shy away from legal confrontation, although he did not want it. Furthermore, there was, and currently still is many holes in the case law that needed to be filled, and Paranova has been involved in the business for a long time.

Why would pharmaceutical manufacturers want to stop parallel trade? (whole question and answer did not get recorded)

KJ (not verbatim): Pharmaceutical companies want to maximize their profits. The result of parallel trade is that they lose revenues in higher priced Member States, although they are still making a profit.

What do you think the three most important ECJ cases of the last decade? (whole question and answer did not get recorded)

KJ (not verbatim): There aren't too many that have been too important for us in the last decade. Going before this time period, the Hoffman LaRoche case that set out the four conditions was a landmark case. For Paranova, the Bristol Myers Squibb cases of 1996 were important because they set out when we are allowed to repackage. We are allowed to repackage generally when the pack sizes are different. Re-labeling is the norm, and is permitted when pack sizes are the same. This case was a milestone for parallel importation and Paranova. The other cases have dealt with partial issues of concern to the manufacturers and us. There is recent EFTA case (E 3/02) that is soon before the Norwegian Supreme Court regarding the presentation of the repackaging that is very important for us. The EFTA court interprets EU law and EFTA law, so it could provide a good indication how the ECJ would rule in such a case. The Court decided that the re-branding is possible when the trademark is not negatively affected. The Court cited BMW and Dior cases of the ECJ. Also the UK Court of Appeals decision of March 5,

2004 was important for us, and we are anxiously awaiting the ECJ's responses the questions asked.

How have these cases affected your business? (whole question and answer did not get recorded)

KJ (not verbatim): The BMS case of 1996 made it clear when repackaging is allowed, and when re-labeling should be used. This gave our operations some legal clarity.

Regarding the Bayer case, do you think the Commission would have succeeded in a case such as Adalat if they used Article 82? (question partially recorded)

KJ: 'I wouldn't criticize the Commission, I am sure that the Commission is very able in these cases and they must have a reason for not filing Article 82 in this case. Perhaps the Commission felt they could not prove the existence of a dominant position. I don't think the market shares were very high.'

I think it was around 19% in the United Kingdom.

'Also, it was lower in the other countries.' (not verbatim) They probably use the best tool at their disposal.

Have you felt a particular supply pinch since the Bayer ruling?

KJ: 'What you must understand is that this market is a large market. The market for pharmaceuticals in Europe is a huge one. And it does not change overnight. So, I don't think you could say we have experienced anything after the judgment. But in recent years we have experienced limited supply. They are using supply quota systems. We actually have had problems buying what we want to buy.'

Has this been more so the case recently? (question partially recorded)

KJ: Yes, you see, the supply quota system used in the Bayer case is very old compared to the ones currently used. They have developed a lot since the case. It has been increasingly difficult to source the products as time goes on.

Continuing with the strategies used against Paranova, can you outline some of the primary deterring strategies used by pharmaceutical companies to stifle parallel trade?

They have tried dual pricing. There is a pending case on dual pricing with the CFI, where in Spain, I don't remember the product but... Well the price was one price if sold inside Spain, and another if it was exported. So this dual pricing is one example. There some different schemes, I don't know them, but the one we see the most is Supply quota restrictions.

Do the pharmaceutical companies try to raise your costs through differentiated packaging, dual pricing etc. and the cost to source the products?

I am not sure that strategically that is what they are doing because actually what they want us to do is I think is they don't want us to repackage, they would rather us to re-label.

Do you think there is strong customer resistance to re-labeled products?

'Not in Denmark no, not anymore. In Austria we had a case where the Austrian court asked the ECJ that question, if consumer resistance was enough for the PI to repackage and the ECJ said it was in a judgment from the 23rd of April 2002, the same day as the Boehringer case from the UK, Laddie's case. These two judgments were from the same day. So when there is consumer resistance, we are allowed to repackage. But, in DK at least, and I saw in your thesis that you mentioned these five Supreme cases from May last year. The Danish Supreme Court didn't think that we lifted the burden of proof. Even though we acknowledged that after 1999 at least there was no consumer resistance. But these cases, at least two of them were starting in 1992, and in 92, parallel imports were very new in DK, they started in 1990. What we argued was that consumer resistance existed in the early 90s, but though we had a market survey presented to the Supreme Court, it didn't apparently lift the burden of proof.'

What do you think could have been done to lift the burden of proof, because you had the survey in there?

'The problem is that Paranova has been using that argument from day one, that it was necessary to repackage because of consumer resistance. But national courts have never acknowledged that argument. So first in 2002, with the ECJ verdict in our Austrian case, it was actually stated that this argument is valid. So after 2002 we could go back to the Danish courts at least, and say it is now established that is a valid argument. But now we have to lift the burden of proof as to how it was ten years ago. That is very difficult, even though we said that, I had these cases in the Supreme Court, and I said to the court that Paranova is in an impossible situation because of the facts I just told you. It is impossible to after ten years to have some surveys about how consumer attitudes were ten years ago. So what we did was we went to the pharmacists, because if you asked the average consumer how their attitudes to that ten years ago, they couldn't remember that. But, the employees, the pharmacists, and the employees, they of course could remember the development from the early days of parallel imports to how it is today. And, so that was the best way to lift that burden of proof, but we didn't succeed even though I think I think it was right. It was a very professional survey, not only established by us, but established in one particular case involving the other party. So it was really, very legally valid. But it showed a remarkable development, and it supported our argument, but it didn't support the Supreme Court. I don't know what we could have done, I think it was impossible.'

OK, are you seeing the pharmaceutical manufacturers starting to directly supply the pharmacists and hospitals in the lower priced countries? Is that a trend that is happening at all?

Going around the wholesalers?

Going around the wholesalers?

Well I am a lawyer, and I don't know the market that well, so I couldn't tell you that.

Parallel importing, well in Denmark, the UK and the Netherlands is a maturing industry, you know, it is no longer young. Would you know how Paranova has changed its strategies in recent years in light of more competition?

Maturing, of course it has been developing from 1990 for us, and our major competitor, at least in Denmark and the Nordic countries, Orifarm started in 96-97. After that, Paranova and Orifarm have been the two major players at least in Denmark, and somewhat in Sweden and Norway. I think it has been a mature business for at least 5,6,7 years, of course there was a start up period, how long that was, I couldn't say. I think very early, this business was being taken quite seriously by politicians and the market, but Erik Pfeiffer, he never expected it would grow as it has been growing.

Yeah, it has been exponential.

He also thought that only a few products could be attractive for parallel imports. But the development has been somewhat different. There are a lot of products that are attractive for parallel importers. The market share is 10-12%, and has been quite stable for the last 3, 4, 5 years. But going back to, if you look regulations, as early as 91, 92, there were some substitutions introduced to make parallel imports more attractive.

That was in Denmark?

Yes, I am talking about Denmark now. But I think it was in 91, 92, the Danish rules were changed where the doctor had to prescribe the cheaper product.

I think it is like that in Sweden now as well.

Yes but it has changed over time. When it was introduced, the doctor had to actively choose and write on the prescription, this must be substituted, and because parallel imports were still not too important. Because of that in 97 in DK, the rules were changed where the doctor actively had to state on the prescription 'this must not be substituted'. This has changed things dramatically.

I could imagine.

The penetration of parallel imports, if you could say that changed dramatically because of these substitution rules. And you must understand that the market in that that the market is very dependent on how the regulation is. This was the most important regulation introduced. Some of our countries like Finland and Austria have not had these substitution rules. So penetration of PI is very low. But now, only last years, Finland introduced they actually introduced generic substitution. And we can see that the market is growing

And is that only generic substitution, or is generic/ parallel imported substitution?

Both

And, this question, I suppose already know but, can you outline the company's move into generics and why this is, I understand the business platforms are ideal for setting up generic manufacturing, but can you explain how Paranova has done this?

Well you must understand that these are very different markets and that parallel importing is only attractive as long as the product is protected by a patent, because when they no longer have patent rights, because the generic products are common. As a rule, there are probably exceptions, but as a rule when patents expire, there are no longer any parallel imports. But the strategic view from Paranova is that, the market exists still, so why just leave the market? It just changes from a regular product plus a lot of generic products. The question should rather be, why not go into generics? Because we know the market very well, the same products, there is a lot demand for these products, and now we can supply in generics, so why not be there also? So I think that is the main argument.

So had the generic part of the company been growing quite well recently?

It is very new, so we are in the upstart stage, it only started one year ago, but, yeah, it has been growing quite fast.

Now, I can think of one Norwegian company that is doing the same thing. I forget the name, but are there any other PI companies moving into the generic sector?

Yes, our main competitor, Orifarm is also, they have a subsidiary called Copyfarm, and our company is called Alternova as you saw.

What kind of legal difficulties do you see as you move into the generic sector as opposed to the PI sector?

The legal basis is different. In PI, the manufacturers, their major arguments are mainly TM law, where in generics of course, if they have any arguments, they are based on patent law, so it is quite different. And I think it is only in some interim period that they pursue their patent rights. I don't know If you are aware of the Danish anti-depressant,

Yeah,

Well they have been fighting very aggressively their product Cipramil. The last one or two years before the patent expires, they have been fighting a lot of generic companies. When the patent actually expires, they won't have any legal arguments anymore.

Patent infringements do not seem to have been successful in the ECJ, Why would pharmaceutical companies still use this approach?

Have they? I don't think they have. I think you see it when the EU expands. It happened with Spain in 1995. It is really only in expansion periods when the pharmaceutical manufacturers have a legal argument. But the industry lobbied a lot to have the specific mechanism put in place.

How will the EU expansion affect your business?

I don't know if you know the specific mechanism,

Well I read over it, but I wouldn't be able to explain it to you.

Well within the accession treaty, there is a derogation from the free movement of goods. And the thing is that parallel imports from these countries if they have their protection in the country importation at a time where it was not possible to have the same protection in the country exportation. So what we see is that after 91-93/4, it depends on what country it is, but in most of the new countries they have these patent rules like the western countries in the period from 91-93/4. So what we see is that when a product is patented in for instance, Denmark, after that time, when they could have the same patent protection, then parallel imports are allowed. So it goes for products that are patented in the western countries, the target countries of PI before 91-93. So if you are hearing anybody saying that it is not possible to import from the new countries, that is not the truth, it depends on how new the product is.

So anything released in the last 10 years should be OK?

Ah, released, they apply for patent applications quite early, so, and the period of developing is very long.

This should give Paranova a huge opportunity for sourcing, would that be a correct assumption?

Huge, I don't know, it is very specific products, well, what you can say is that in the early days of parallel imports the cheaper countries were the selling countries, and the more expensive countries were buying countries. That is not the fact anymore. For some products, the prices can be more expensive in the Southern countries than the Nordic countries. And with my brief knowledge of the market of new countries, some of the countries are actually quite expensive. Many of these countries have more expensive than in western countries.

Yeah, I was surprised to come across a report claiming that parallel imports is a problem in Spain, but there was a full report written up on it, explaining that certain drugs, they are have difficulties with importation, as opposed to exportation. The has more to more to do with repackaging, why would re-boxing necessary when re-labeling could be done?

If it is the same pack size it is not necessary. Of course we have to put on some labels because there are some health regulations saying that this pack should be in the national language. So if we are sourcing in Spain or Greece, where we don't recognize letters, we have to put on labels. But you cannot say it is necessary to repackage if it is the same pack size. But it is necessary if the pack size is different, because you cannot see the market just as 'Adalat', the pharmaceutical itself, there is also a market for different pack sizes. So if the market in DK is, the therapeutic practice for doctors to prescribe is 20 and 100, but we can only source packs of 10 or 20, then we don't have access to the market for 100, so we have to make a package of 100 or around 100, it could be 98. Because some countries the blister cards only contain..

Seven or

Yeah, week days, and not divided by 10 or 20.

Do you see any harmonization coming in this area?

No. It is now the national health insurance is, how they pay. They pay for treatment for one week, or one month. But it could also be a strategy from the manufacturers to try to partition the market. I think the explanation is a combination of both.

Since we are on the topic of harmonization, as far as pharmaceuticals goes for the EU, what areas of harmonization do you see coming forth in the coming years?

Actually this month, the Commission, the directives are becoming harmonized, they are improving on the European legislation. So what harmonization is different things, it is legislation from the Commission or Council, but it can also be the result of ECJ judgments.

Yeah, but I suppose I am specifically asking about any forthcoming directives or regulations in harmonization of the pharmaceutical market.

I wouldn't say I know enough the area. I think most of the harmonization is not connected to parallel importers. Things about recognizing trials on a Community basis, also the result of EMEA, do you know EMEA?

Yeah, absolutely.

I think it is quite new, it was established in 96. I think more products are getting a Community marketing authorization, so that is of course is harmonization that marketing authorizations are not national anymore, it still is a lot of cases.

Does it make it easier to get one piggy back authorization through EMEA rather than getting national piggy back authorizations.

The easiest is EMEA authorization. It takes a longer time, but you only have to file one application.

Are the costs much higher?

Yeah, I am not sure. I think you can have to be in so or so many countries.

Patent infringements, they don't seem to be successful in front of the ECJ, why would manufacturers still use this approach?

Are they doing that in PI?

Not so much anymore, but why would they?

I think they are doing it every time the EU expands. When Spain came into the community in 1995, the manufacturers based some of their legal arguments on patent

rights. And that is the same thing with the new expansion, with this specific mechanism. What the industry has learned when Spain came into the EU,

Yeah they must have,

So they have been lobbying a lot to have the specific mechanism. But, I think it is only in these situations that they have arguments regarding patent rights.

Do you find that pharmaceutical companies use cases against parallel importers just as another strategy, even if they know they will not win a case?

I don't they would pursue cases they know they will lose. But definitely, they are using these cases as one strategy. I don't know if the strategy is to make it as costly as possible, that the parallel importers have to have some legal costs of a certain amount. But what you can say is the other way around, is that they are having a lot of legal costs themselves. So I can only see that it is a strategy used, and it is of course to make it as difficult as possible to be a parallel importer. But I think at the end of the, what you see is at least the parallel importers have been very successful in the ECJ, but has been less successful in the national courts.

Yeah, I have found that.

That is quite surprising.

Why do you think this is, do you think it is a political thing, nationally or...?

I think the problem is the judges are very national in their thinking. A right like a patent right of a trademark right is a very strong right that is protected in our constitution. So in their legal mind, this is a very strong right that needs to be protected. And, the national judges are still after 30 years for Denmark of membership in the Community, they are still not thinking internationally, or European. I can speak for Danish courts, the number of cases involving European law is very few. So that is the explanation. The ECJ is thinking European, of course they are thinking and looking at the Treaty and interpreting that. That is very different from the laws that the national courts have to interpret even though that we are arguing 'well you see that this is the Treaty, this is Article 28, 30, this is the trademark directive'. Still they are thinking very nationally.

Yeah, I have heard the same complaints about national judges, but it is surprising since it still so prevalent because I remember reading over half the laws in Europe are now created at the European level, and there is still a resistance to actually using them.

Well, Judges are very open-minded, they have to be because they hear arguments from two different parties. They are doing the best they can, they are just seeing to little cases involving a European level.

Do you have any final comments that might be helpful in writing this?

Well you have this paragraph about re-branding, or was it re-labeling.

Yeah, I separated re-branding.

Re-branding is in practice a very small problem where at least in our countries where we have substitution, but this co-branding is a much larger practical problem. I think you have a paragraph on co-branding, but go into the EFTA judgment, and also the court of Appeals judgment of March 5th, because this court, even though it sent some questions to the ECJ, the judge writing the judgment had some good comments on co-branding.

I will look into co-branding a bit more,

It depends on how you want to weight your thesis but

Yeah, I think it is something that should be included as well, it is very recent

It is very recent, but you don't have to include things just because they are recent, but also relevant. But you are writing about strategies, and it is a huge strategy of manufacturers to fight co-branding. And I think the problem is on a way to solve these cases. OK we have to wait for the ECJ answers for the UK court of appeals, but at least from the EFTA court we have very good guidance.

Can the EFTA Court be referenced directly by the ECJ?

They are parallel courts, but they are referring to each others judgments. So of course, mostly the EFTA court because by the treaty they have to base their judgments on the case law from the ECJ. But there are judgments from the ECJ about issues they have not dealt with before, but where the EFTA court had a ruling. Also the ECJ can refer, well, it depends on what you mean by reference, they are expanding on each others judgments, but the ECJ cannot ask the EFTA court and the EFTA court cannot ask the ECJ.

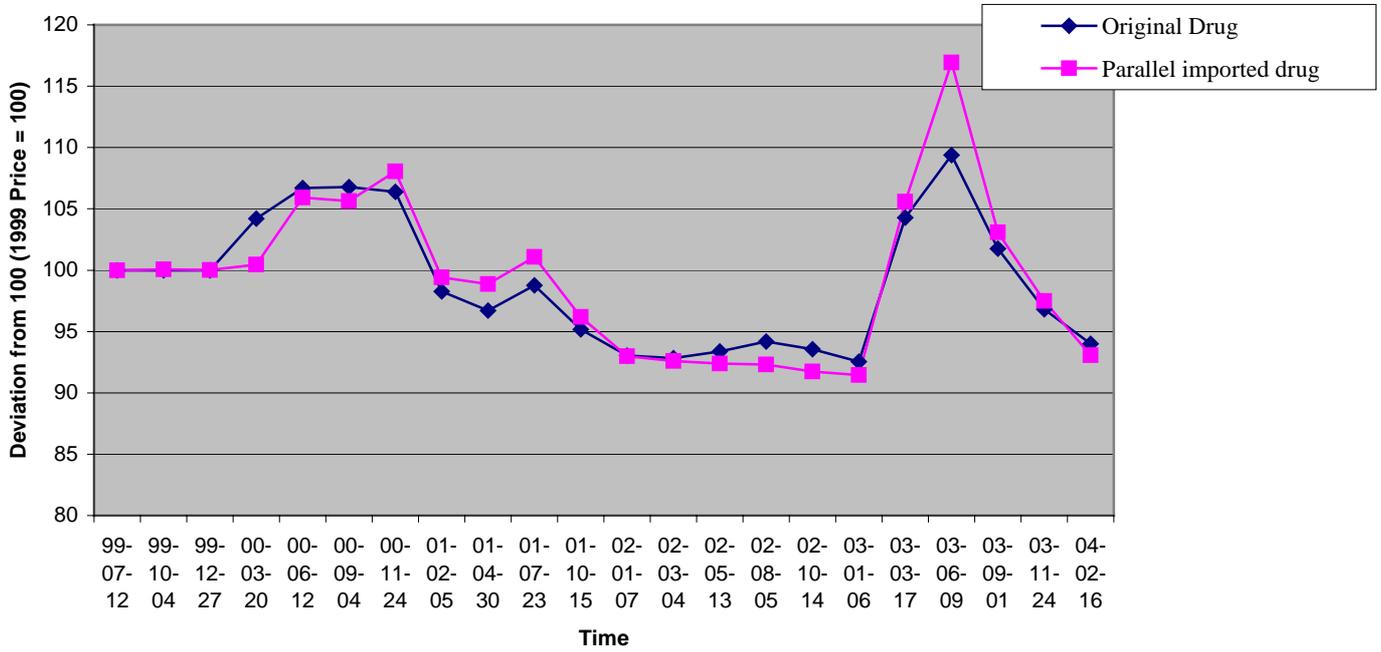
And the courts have equal weight?

No, I don't think so. At least, the ECJ consists of one judge from each MS, fifteen judges if it is in plenum, and there are only three judges in the EFTA Court, I think the EFTA court is the little brother of the ECJ. But of course in judgments, the authority is in the arguments, so I think you made an adjustment from EFTA judgment it is very valid for the ECJ.

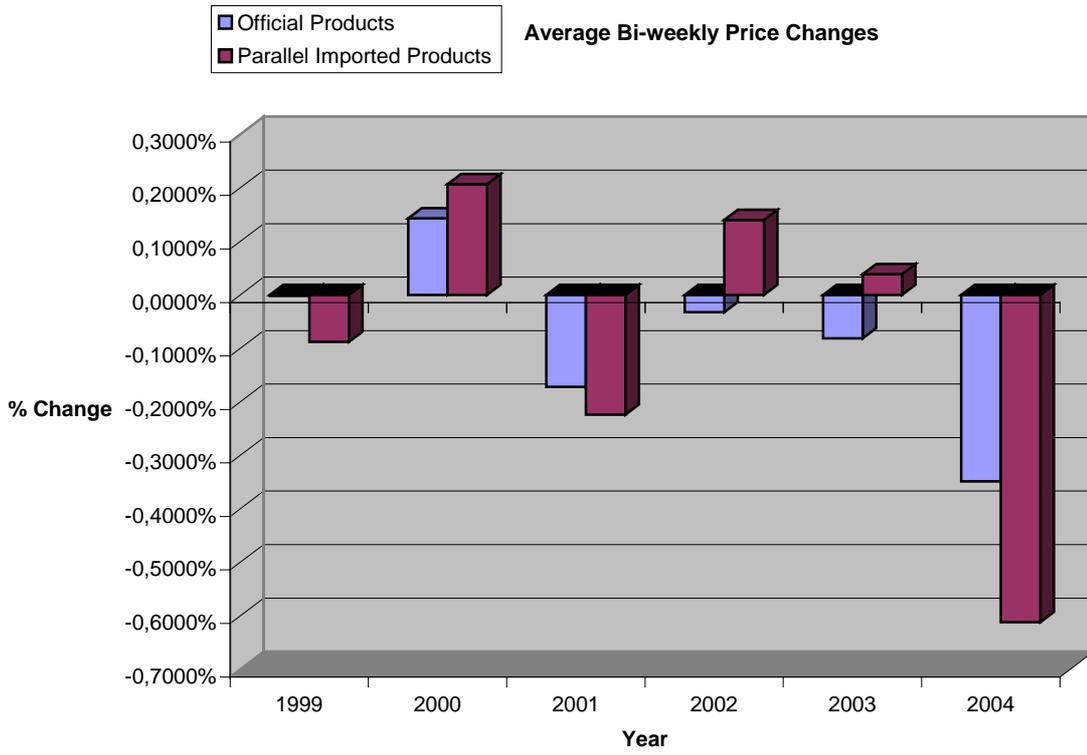
Well, that is about all the questions I have for you. It has been really handy to learn what you have to say. Thanks a lot.

Appendix D

Price Deviation Comparison b/w Original and Imported Drugs

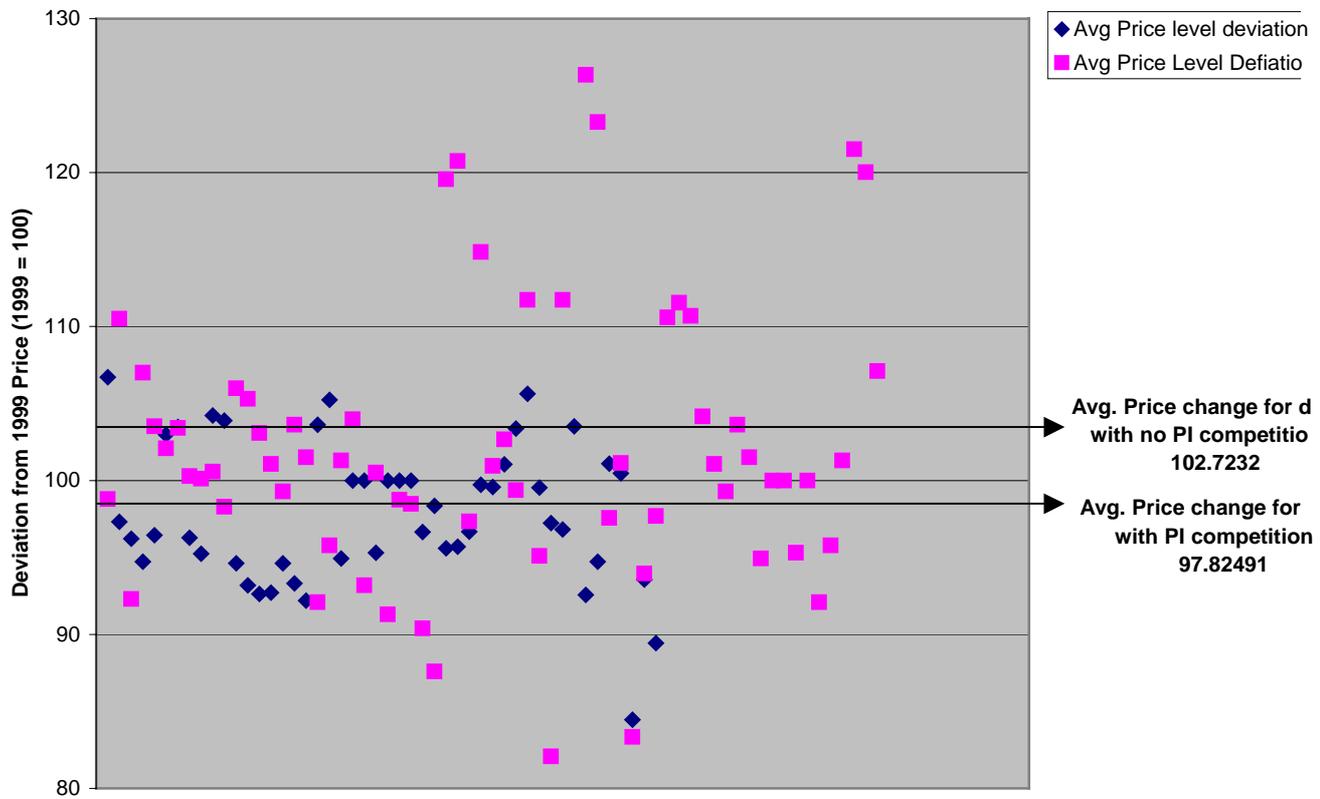


Appendix E



Appendix F

Average Price Level Deviation



Appendix H: Interview with Markos Montmar Stavroulakis

I thank you for your questions. Unfortunately my workload only permits me to give short answers to a few of them .

1. My expertise in the field is based on thesis I wrote back in 1998 at the Stockholm University at the masters programme "National Trademarks and the free movement of goods". Further, as part of my dossier at the National Board of trade I handle matters concerning parallel imports. I would like to stress however that my answers to you only is in the capacity of a lawyer not in the capacity as an employee at the National Board of trade.

2. The Ideal Standard case, the Silhouette-case and the Hoffman la Roche case.

3. These cases have clarified the legal possibilities and limitations of parallel trade and constitute a steady ground for parallel trades in frequent legal proceedings with direct importers.

4. The fact that we now have a regional exhaustion principle may influence direct importers to try to give the pharmaceuticals different names in different member states in order to weaken the possibilities of parallel trader to take advantage of investments in a particular brand that has been placed on the market of a certain member state.

5. The reason why Sweden would favour parallel trade is that Sweden is a small country and small countries generally benefit from a high degree of free trade. In contrast to other European countries we don't have any strong trade marks of our own to protect. Further, historically Sweden has always been in favour of the principle of global exhaustion.

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