Gray Markets for Pharmaceuticals in the European Union: Regulating Parallel Imports in an Uncertain Legal Environment

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Abstract

Gray markets have been a significant source of controversy. This sale of goods through channels not intended by the original manufacturer has been praised as a choice-enhancing arbitrage of a globalized free market that increases competition and lowers prices. Gray markets have also been decried as jeopardizing product safety, impinging quality, and encouraging counterfeits while mainly rewarding the gray importer and not the consumer. One of the most robust gray markets in the world is the parallel importation of pharmaceutical drugs in the European Union (EU). Drug manufacturers have tried to stop parallel importation with over thirty years of litigation. The result has been a maze of legal rules that are difficult to comprehend and nearly impossible to consistently apply. The result is a unique parallel trade marketplace that has been insufficiently examined in the literature and would benefit significantly from academic study and insight. This manuscript examines the forces underlying the EU gray market for drugs, discusses how trademark law and not patent law has become the primary basis for legal challenges, and offers strategies for manufacturers to impede importers in a truly chaotic legal environment.

Introduction

Gray markets have been a significant source of controversy. This sale of goods through channels not intended by the original manufacturer has been praised as a choice-enhancing arbitrage of a globalized free market that increases competition and lowers prices. Gray markets have also been decried as jeopardizing product safety, impinging quality, and encouraging counterfeits while mainly rewarding the gray importer and not the consumer. The result has been an active discussion in the academic literature in management/international business (Antia et al. 2004, Atkinson 2001, Berman 2004, Cavusgil and Sikora 1988, Cespedes et al. 1988, Lim et al. 2001, Howell et al. 1986, Lowe and McCrohan 1989, Myers 1999, Myers and Griffith 1999, Gopal 1998, Timur et al. 2007, Weigand 1991), marketing (Antia et al. 2006, Chaudhry and Walsh 1995, Chang 1993, Eagle et al. 2003, Huang et al. 2004, Iqbal and Feick 2003, Mathur 1995, Paila and Keown 1991), and other fields, such as economics and law (Danzon 1998, Chen 2002, Ganslandt and Kyle et al. 2008, Grossman and Lai 2008, Hays 2004, Inman 1988, Lansing and Gabriella 1993, Lilico 2006, Maskus 2004, Myers 1999, Kanavos 2000, Kanavos et al. 2004, Reed 2002, Sloane 2004, Swanson 2000, Szymanski and Valletti 2005).

One of the most robust gray markets in the world is the parallel importation of pharmaceutical drugs in the European Union (EU). Drug manufacturers have tried to stop parallel importation with over thirty years of litigation. The result has been a maze of legal rules that are difficult to comprehend and nearly impossible to consistently apply. The result is a unique parallel trade marketplace that has been insufficiently examined in the literature and would benefit significantly from academic study and insight. This manuscript examines the forces underlying the EU gray market for drugs, discusses how trademark law and not patent law has become the primary basis for legal challenges, and offers strategies for manufacturers to

impede importers in a truly chaotic legal environment. We first examine the forces underlying gray markets. After a brief review of the literature, we highlight the convergence of market conditions, legal environment, and consumer behavior that make this market an ideal system for importers to thrive and for manufacturers to suffer significant losses. We also discuss how parallel importation does not necessarily benefit the consumers that are so often cited as the reason policymakers should allow such importation to thrive.

Focusing on the European Court of Justice, the EU's highest court, we then unravel the legal environment of EU drug gray markets. We focus primarily on drug product repackaging and relabeling. This seemingly innocuous practice, undertaken by importers who must satisfy national language and safety regulations, has become a critical battleground for deciding whether gray markets for medicines grow or decline. Ambiguous and slowly-emerging legal rules, some imposed quite recently, have ensured continuous time-consuming and costly litigation between importer and manufacturer.

Finally, we present strategies for drug manufacturers to defend their markets from parallel importers. We hypothesize that a carefully designed marketing strategy combining packaging design, brand promotion, shaping of consumer opinion, and quality control can impede gray marketers by raising import costs. Drug firms can also use their trademarks in creative ways to create roadblocks for importers that will be difficult to surmount. We conclude that, although current EU law is insufficient and importers cannot be eliminated altogether, significant opportunities exist for drug manufacturers to slow gray market activity through a savvy mixture of legal and marketing tactics.

The Acute Problem of Gray Markets in the European Union

When a product manufacturer sells that product in an initial market, participants in a gray market, often know as parallel importers, purchase that product and resell it in another market where the product commands a higher price. Gray markets differ from black markets, which involve the distribution of a product or service that is illegal. Gray markets involve legal products that are sold in outlets not authorized by the manufacturer (Ghosh, 2002). In the case of pharmaceuticals, hospitals or pharmacies may purchase gray market drugs and provide them to consumers if they meet the relevant regulatory criteria. An illustration of the principal players in the parallel trade of EU pharmaceuticals is available in Figure 1.

Insert Figure 1 about here

The approximate value of the pharmaceutical market in the European Union (EU) is €133 billion (*Pharmaceuticals in Europe,* 2008, ¶1). In 2006, the major country markets for pharmaceuticals in the EU were France (19% of total market), Germany (19%), Italy (13%), United Kingdom (11%) and Spain (9%). Of this total market, the European Federation of Pharmaceutical Industries and Associations (EFPIA) reports that the diverse price fragmentation of pharmaceuticals in this trade block results in a gray market estimated to be €4,300 million (value at ex-factory prices) in 2006 (*The Pharmaceutical Industry in Figures*, 2008, p. 3). The largest markets for gray pharmaceuticals in the EU are Denmark (15.2% of total market), Germany (7.7%), the Netherlands (10.4%), Sweden (13.3%), and the U.K. (14.7%) (*The Pharmaceutical Industry in Figures* 2008, p. 5).

A gray market has been defined as the resale of manufactured goods in a market by a third party without the consent of the manufacturer (Stothers 2007). Gray markets in the global

marketplace have been widely discussed in the literature (e.g. Anita et al., 2004; Anita et al., 2006; Cavusgil and Sikora 1988; Chaudhry and Walsh 1995, Howell et al. 1986, Myers and Griffith 1999). Frequently this literature focuses on universal strategies for firms to assail gray marketers. In general, these strategies rely on the premise that pricing can be controlled to a certain extent by the firm, such as by instituting a "one price for all" policy (Howell et al. 1986) or an "aggressive confrontation by means of price cutting" strategy (Cavusgil and Sikora 1988). Overall, these studies focus on the concept of price discrimination between distinct international markets, not price variation within regulated-price markets.

The plurality of the current research debates the legality of gray markets in the United States (for example, for see Inman 1993, Lansing and Gabriella 1993). Other researchers have addressed the legality of gray markets in emerging trade blocks, such as the European Union (Chaudhry and Walsh 1995), the North American Free Trade Agreement (Lansing and Gabriella 1993), and the Asia-Pacific region (Palia and Keown 1989). Finally, a few researchers have summarized the legal status of gray markets in distinct markets, such as Taiwan (Chang 1993) and Japan (Weigand 1989).

Atkinson (2001) in his comprehensive study on *The Global Parallel Trade Outlook 2001-2006: A Country-by-Country Analysis* outlines both the advantages and disadvantages of parallel trade to provide a holistic view of the issue. The main benefits from parallel trade in pharmaceuticals are financial gain through price differential, increased competition, cheaper drugs for importing countries, industry growth for exporting countries, reduced government health care expenditure, healthcare subsidy in exporting country, rapid accession into EU drug markets through mutual recognition, and the avoidance of cost-containment measures imposed by governments. However, the principal disadvantages of parallel trade are the loss of revenue

for research-based a pharmaceutical firm, exchange rate fluctuations may yield narrow profits, highly litigious, erodes domestic sales, and reduces stock in domestic export markets.

Kanavos et al. (2004) outline the three main reasons that policymakers both support or refute parallel trade. The main reasons given to sanction parallel trade are 1) to provide restrictions on parallel trade would act as non-tariff barriers to trade for pharmaceuticals that have lost the control of its IPR owners; 2) to allow parallel trade as a countermeasure to abusive price discrimination and collusive firm behavior between territorial markets; and 3) to enforce government territorial rights invites rent-seeking. The major issues against parallel trade center on the points that 1) price discrimination can provide welfare in certain situations; 2) parallel traders are 'free riders' on the research and development, marketing and other costs incurred by the original manufacturer; and 3) goods arbitrage mainly benefits the parallel traders, not society.

Another controversial topic centers on whether parallel trade fosters the growth of counterfeit pharmaceuticals in the supply chain. Market Research analysts at Gartner and Frost & Sullivan predict the counterfeit drug business will grow by 13 per cent per year to reach a market value of $75 billion (€56 bn.) in 2010 (Megget 2007, ¶ 25). In 2007, Eli Lilly's antipsychotic drug, Zyprexa, and Sanofi-Aventis and Bristol Myers Squibb's blood clot-reducing drug, Plavix, were recalled after one of the parallel traders in the UK became suspicious of the product. This recent health scare re-ignited the calls of the drug manufacturers to abolish parallel trade of pharmaceuticals in the EU.

Although seemingly attractive due to increase of price competition, parallel importation in the EU does not necessarily promote consumer welfare. Kanovas et al. (2004) concluded that the main beneficiaries of the gray market were the parallel traders, not the consumers. Kanovas estimated that in 2002, the parallel traders reaped significant financial rewards in Germany

(€97,965 m.), Sweden (€4,707 m.), Denmark (€6,108 m.), UK (€518,013 m.) and the Netherlands (€47,688 m.) (*The Economic Impact of Pharmaceutical Parallel Trade* 2004, p. 2). There are basically two ways for the consumers in Europe to benefit from a price reduction in pharmaceuticals resulting from parallel trade. The first is to actually pay a reduced price that effects their payment for the drugs. However, under the premise of socialized medicine, the patient's final price is really the level of co-payment that h/she pay for the drug. An indirect way to think of benefits to the consumer is that the national health care system can provide better health—care benefits since parallel drugs may reduce the civil drug bill. Kanavos et al. (2004) studied these plausible benefits to the consumer in six European countries: Denmark, Germany, Greece, the Netherlands, Norway and the United Kingdom. This comprehensive study found that due to access to the medicines through national health systems, the benefits to consumers were negligible. For example, consumers in the UK and Germany were not aware of the price benefits of parallel trade since each patient pays a flat fee. The researchers' conclude:

> Consequently, it does not directly transpire that pharmaceutical parallel trade enhances patient access to medicines nor that parallel trade reduces prices to the consumers. By contrast, parallel trade may affect access to medicines in parallel exporting countries, as was shown in the case of Greece, where shortages were reported by the National Pharmacists' Association for several products (Kanavos et al. 2004, p. 88).

The regulated pricing of pharmaceuticals in Europe adds the dimension of public policy since an element of risk is involved in terms of protecting the population from unsafe medicines resulting from parallel trade. As previously mentioned, the UK drug recall in 2007 fueled the controversy about counterfeit drugs entering the supply chain via parallel trade. In a 2008 study of parallel trade sponsored by Europe Economics, *Safe Medicines Through Parallel Trade*, the researchers' claim that market access for gray marketers is damaging to patients in a number of

ways. In addition to the problems already mentioned, package leaflets may be left out of date causing patients and medical staff to receive inaccurate information that can lead to incorrect consumption decisions. Parallel importation might increase supply interruptions by creating shortages in countries where drug prices are lowest. Finally, patients might be confused when packages are changed in the course of treatment.

The parallel trade market in the EU is clearly growing and the advantages and disadvantages of the market have been discussed for several decades by managerial strategists (Antia et. Al 2004, Berman 2004, Lowe and McCrohan 1989) economists (Danzon 1998, Ganslandt and Maskus 2004, Kanavos 2000, Kanavos et al. 2004) consultants (Atkinson 2001), and marketers (Cavusgil and Sikora 1998, Chaudhry and Walsh 1995, Duhan and Sheffet 1988). In the next section, we provide a succinct overview of the academic literature that debates the leading reasons for a gray market to occur and develop this rational in context of the EU pharmaceutical market.

Factors that Encourage a Robust Gray Market in the European Union

The three prevalent conditions identified in the literature that affect the probability of a gray market to occur are price differentials, market access, and volume of demand. A variety of academic disciplines have been addressing this market phenomenon for over 20 years. Table 1 represents a review of some of the literature on gray markets in terms of factors that encourage parallel trade to develop.

Insert Table 1 about here

Price Differentials: Exchange Rates, Price Discrimination and Regulated Prices

The two prevalent themes on price in the literature center on price differentials resulting from changes in the exchange rate and the competitive pricing strategies of the firm through

price discrimination. Duhan and Sheffet (1988) describe the fact that parallel traders will buy products in weak currencies and resell in stronger currency markets. The second major area related to price differentials is the segmentation strategies of the firm that result in price discrimination among markets (Chang 1993). However, very few academic studies investigate gray markets in the context of a regulated—price environment (Atkinson 2001, Chaudhry and Walsh 1995, European Economics 2008, Kanovas et al. 2004). The fact that the price element is no longer controlled by the firm places the issues of battling a gray market in a more complex situation.

A study on *The Global Parallel Trade Outlook 2001 – 2006* reveals that, in general, the low-price markets for pharmaceuticals in this trade block are Belgium, France, Greece, Italy, Luxembourg, Portugal and Spain. The high-priced country markets are Denmark, Finland, Germany, Ireland, the Netherlands, United Kingdom and Sweden (Atkinson 2006, p. 27). Kanavos et al. (2004) in their comprehensive study of *The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis* reported various pharmaceutical product price variations in this trade block to illustrate the lucrative market for parallel traders to "buy low—sell high" in this sector. Figure 2 illustrates the price variation for Atorvastatin (Lipitor) a cholesterol-reducing prescription drug developed by Pfizer using purchasing power parity prices to allow more accurate comparisons. As shown in Figure 2, the price of Atorvastatin ranges from a low of 0.55 in Greece to a high of 1.37 in Germany.

Insert Figure 2 about here

Significant buying power wielded by the publicly funded health care systems of National Health Service tends to push drug prices down in the United Kingdom. Government policies in

Greece, Spain, and Portugal also keep drug prices artificially low. The lack of such regulation and government sponsored drug purchases in the Netherlands, for example, means that Dutch drug prices are significantly higher. Limited competition, high consumer prices generally, and the high level of patient co-payments keeps prices high in Denmark (Hays 2004, p. 823). National labeling, disclosure, and packaging requirements exacerbate price differences. A well-developed infrastructure, wealthy consumers, and a stable common market keep transport costs low. These conditions, combined with strong EU policies favoring the free movement of goods and services, encourage robust parallel trading of European pharmaceuticals.

Lilico (2006) argues that price variation in patented pharmaceuticals should be beneficial for a social reason that links 'ability to pay' to the price structure. However, under the current price regulation system in the EU, the opposite actually occurs since the low-priced markets become the source countries for the parallel traders to re-sell pharmaceuticals to the high-priced markets. Lilico states, "Thus, those that gain from parallel trade (apart from the parallel traders themselves) will, in the end, be the wealthy citizens of northern and western Europe, at the expense of higher prices (and so reduced access to affordable medicine) for the poorer citizens of eastern and southern Europe—surely a perverse outcome" (Lilico 2006, p. 37).

It is difficult to generalize the degree of price discrimination that exists in the EU drug market, but, one could argue that parallel traders provide 'shadow pricing' on the prescription drugs resold in the country supply chain. In other words, the gray marketer offers a price relatively close to the prevailing price in that country market through the authorized channel. To illustrate this point, Kanavos et al. (2004) estimated the economic impact of parallel trade in selected country markets, such as Germany. This report looked at the 2002 sales of 19 pharmaceutical products in Germany and estimated the parallel trade market share of each

product, the average price spread between locally sourced and parallel trade sourced products, the estimated savings for the national heath insurance scheme to engage in parallel trade, and the maximum profit accruing to parallel importers. Price spreads in the German market (i.e., the difference between the parallel trade price and locally sourced price) for these 19 products ranged from a high of 21% for Fluoxetine to 5% for Simvastatin, Valsartan, and Sertraline. These researchers' estimated that the savings realized by the health insurance scheme in Germany for 2002 was €17,730, but, the profits to the parallel traders were €97,965 (Kanavos et al. 2004, p. 160).

Market Access: Parallel Traders in the Distribution Channel

The primary themes related to market access include the reduction of barriers to trade and a gray marketer's ability to access the distribution channel. Chaudhry and Walsh (1995) studied the reduction of barriers to trade through emerging trade blocks, specifically the European Union. These researchers found that trade blocks were lucrative incubators for gray markets to evolve in a favorable environment. First, trade blocks advocate the free flow of goods across national markets. Secondly, price discrimination can occur between the national markets in a trade block. Thirdly, members of the trade block will have national currencies that will fluctuate against each other. Overall, a trade block is a gray marketer's nirvana. Trends in regional integration via the European Union, the North American Free Trade Agreement, MERCOSUR, and the like will decrease barriers to trade. In addition, rules that govern international trade by way of multilateral agreements, such as the World Trade Organization or the EC Treaty in the EU, will also reduce barriers to trade across national markets since these types of agreements uphold the main underpinnings of free trade that support the uninhibited flow of products.

The gray marketer must be able to purchase the product within the distribution channel. A vertically integrated firm, that is, a company that controls the product from its manufacture, distribution, to retail outlet and ultimate sale to the consumer is not likely to experience a gray market. However, in several cases where the company is not vertically integrated, the "authorized dealer" provides market access to the gray marketer. In addition, the authorized dealer may be the gray marketer. Weigand (1991) describes these gray marketers as "opportunistic middlemen" that seek profits outside of the distributor's assigned territory. Indeed, parallel traders in the EU are profit-seeking businesses that reap the reward of regulated price-discrimination in the EU pharmaceutical market. As previously discussed, a few studies have shown that the consumer is not benefiting from the reward of lower-cost medicines as a result of parallel trade (Kanovas et al. 2004, Lilico 2006, *Safe Medicines through Parallel Trade* 2008).

Volume of Demand: Profit Motives of Parallel Traders

Cavusgil and Sikora (1988) assert that the two primary reasons for why gray markets develop are price differences between national markets and supply shortages in the importing country. Thus, a gray market develops to satisfy local demand for the good. In addition, Howell et al. (1986) suggest that a gray market product must have a broad appeal to the consumer in the import market to create the necessary demand for the resale of the product. Remit Consultants (1991) addressed the need for a homogeneous product presentation to provide a better gray market for the good. These researchers claim that a gray marketer must also consider the extent to which the product resembles the original good (that is, the authorized product in the import market) and the extent of repackaging that is required to sell in the import market. These are salient issues related to parallel trade across national markets. The EU pharmaceutical market

presents a unique case study for consumer acceptance of the drug since the consumer may not even know the price of the product nor benefit from a reduced priced of the drug since the socialized health insurance pays for the product.

In general, consumer demand for prescription drugs is 'directed demand' channeled through the medical doctor and (in general) paid for by the national health-care associations in Europe. The November 2008 report of the European Commission, *Pharmaceutical Sector Inquiry* succinctly characterizes the demand for pharmaceuticals as follows:

> Demand for Pharmaceuticals: On the demand side, the pharmaceutical sector is unusual in that for prescription medicines, the ultimate consumer (the patient) is not the decision maker (generally the prescribing doctor and in certain Member States the pharmacist). Nor does the ultimate consumer usually directly bear the costs, as these are generally met by a national health scheme. Because of this unique structure, there is usually limited price sensitivity on the part of decision makers and patients (p. 4).

However, in terms of demand for parallel drugs, this case is unique since the volume of demand is really a direct result of the ability of the parallel trader to re-sell to either the government healthcare authorities and/or other wholesalers/distributors that provide the drugs to both hospitals and pharmacies in the EU (refer back to EU parallel trade flow illustrated in Figure 1). In the case of the EU pharmaceutical market the arbitrage situation occurs from the parallel traders accessing drugs in the *regulated* low-priced markets (e.g., Greece, Spain and France) in order to re-sell the pharmaceutical in high-priced markets (e.g., UK, the Netherlands, Germany, Sweden and Denmark). The fact that this is a price-regulated environment where arbitrage will not result in any type of price equilibrium presents an unique case to study the phenomenon of gray markets in context of both welfare effects and the legal decisions made in the European Court of Justice (ECJ).

The Social Market Foundation in the UK estimates that 70 per cent of all of the EU parallel trade in pharmaceuticals ends up in the UK marketplace and reduces the National Health Service civil drug bill by up to €269 million per year (Over-boxing the Answer to Parallel Trade Risks, 2004, ¶3). However significant these savings, parallel traders are in the business to profit and many sell the drug at prices just below the country market price—a so-called shadow price.

Another way of looking at volume of demand is whether the parallel trader sees the financial opportunity to profit from arbitrage. Atkinson (2001) reports that the main barriers to parallel trade are litigation from the pharmaceutical manufacturers; exchange rate variations that erode profit margins; reduced supply stream and depleted stocks as a result of high demand; direct supply from manufacturers to hospitals and pharmacies; supply restrictions from manufacturers to wholesalers; differences in brand names in parallel exporting and importing countries; discount incentives from manufacturers, price dumping and price cuts (e.g., selling direct to pharmacists at a reduce price), product withdrawals, product changes (e.g., new formulations), regulatory process bottlenecks, and delays in obtaining a parallel import license.

The EU pharmaceutical market is clearly a lucrative incubator for gray marketing since the element of price is uncontrolled by the firm, the parallel traders have legitimate access to the distribution channel, and the national health care authorities, wholesalers and pharmacists will continue to demand the gray pharmaceuticals. In the next section, a succinct review of the array of generic anti-gray market tactics discussed in the academic literature is given to highlight that several of these maneuvers are futile in this unique gray market. Thus, a synopsis of the litigation within the EU is examined to underscore the legal measures taken by drug manufacturers to suppress parallel trade.

Defending Pharmaceutical Markets from Parallel Importers in the European Union

Initial strategic studies on gray market were deliberated in the literature twenty years ago and Cavusgil and Sikora's (1988) extensive list of tactics, such as price-cutting, supply interference, and promotional bursts to implement in order to combat current parallel traders—reactive strategies. The researchers' also outline proactive methods, such as lobbying and establishing a legal precedence to discourage a gray market to evolve. In today's environment, current researchers' (for example, see Antia et al. 2004 and Berman 2004) recommend a similar assortment of tactics (e.g., tracking the distribution channel), but these maneuvers reflect the significant changes in tracking and identification technology, such as using the web to check for unauthorized resellers, that allow firms to monitor and take action against parallel traders. In the drug industry, firms are using very sophisticated technology to track and identify the product, such as e-pedigree compliant packaging (e.g., Pfizer's Radio Frequency Identification [RFID] tagging of Viagra), DNA coding-inspired solution (i.e., securing packages and products with a SigNature DNA Program), and near infrared spectroscopy (NIRS) (i.e., a machine that authenticates the product) that are used to track the pharmaceutical supply chain for both counterfeits and parallel trade diversion (RX: Three New Weapons in Pharma's Brand Protection Arsenal, 2008). Table 2 provides a succinct list of a number of the recommended anti-gray marketing stratagem given in the academic literature for the past two decades.

Insert Table 2 about here

A quick perusal of these anti-gray market maneuvers reveals that many of the tactics suggested, such as price-cutting, strategic pricing, promotional bursts, fines to the authorized

channel, are outside the control of the drug manufacturers. For example, a promotional burst designed to warn and/or educate the consumer about purchasing the product in the authorized channel (e.g., the Paul Mitchell shampoo campaign in the U.S.) is not a plausible countermeasure. First, direct-to-consumer advertising of pharmaceuticals is illegal in the EU; second, it is directed demand, not consumer demand that propels the purchase decision. Thus, in the subsequent sections, we address credible actions, such as product differentiation through packaging and interpreting the legal precedence to provide recommendations to drug manufacturers.

Parallel importers and manufacturers are fighting for nothing less than the spirit of free trade in the European drug market. Restricting freedoms to repackage could make the importer's ability to import drugs to new markets virtually impossible. Manufacturers could retake control of the market and choke off much of the parallel import industry. Allowing repackaging without limitation could enable importers to fully compete in product design and distribute imported drugs with virtually no legal risk. Parallel imports would be placed side-by-side with its higher-cost competitors with few material disadvantages. With an uncertain legal regime not likely to change anytime soon, it is not just the courts but the competitive positioning of importers and manufacturers that will determine who controls the €133 billion European drug market.

The Legal Environment of Drug Product Repackaging

Repackaging of a manufacturer's product occurs when a parallel importer modifies any aspect of a product's internal or external characteristics for sale in another market. The most invasive repackaging is the replacement of the manufacturer's box with the parallel importer's own container. Importers may also remove drugs from blister packs to resell the product in

larger or smaller containers. Parallel importers may simply relabel or oversticker medicine with a new description or remove the drug container from its box and replace it with an entirely new one.

Parallel importers do not simply repackage for aesthetic reasons. National rules may require certain information about the product be disclosed or prohibit the use of certain words or phrases. National rules may require that the package use a certain language, may dictate pack sizes, or impose packaging style requirements. Repackaging may be desirable to assuage consumers who might be suspicious of goods bearing foreign languages or prefer medicines to be delivered through different containers or sizes. Parallel traders may remove all markings indicating the source of the product in order to prevent the manufacturer from halting supplies of the product in parallel trade (Stothers 2007).

The origin of repackaging regulation stems from the EC Treaty, also known as the Treaty of Rome, which established the European Union (formerly known as the European Economic Community—EEC) and created the framework for the trade of goods. Articles 28 and 29 prohibited restrictions on imports and exports with an exception expressed in Article 30 for restrictions based upon public morality, public policy, and other national interests. Article 30 cautioned, however, that such restrictions should not impose arbitrary discrimination or a disguised restriction on trade between member states (EEC Treaty, 1957).

As parallel importation of pharmaceuticals expanded, manufacturers tried to prevent importation on patent law grounds. In 1974, Sterling Drug argued that an importer could not buy its medicine in the United Kingdom and resell it in the Netherlands because its patent rights there granted it exclusive product control. The ECJ ruled that Sterling's patent rights ended when it sold the drug in the United Kingdom (*Centrafarm v. Sterling* 1974). This doctrine, called the

'exhaustion of rights', permits a person to purchase goods and resell those goods without permission from the manufacturer. Just as a buyer of a Harry Potter book may freely resell her copy to someone else without infringing copyright, so can a buyer of medicine in one nation resell that drug elsewhere in the European Union. This doctrine, known in the United States as the 'first-sale doctrine', remains largely intact.

In response to this defeat, drug firms chose a different tack. They observed that parallel importers frequently repackaged or relabeled their products to meet legal requirements or enhance sales. Instead of asserting patent protection, drug firms claimed that importer repackaging or relabeling unlawfully infringed upon their trademark rights by harming their brand. Results were much more promising, even though manufacturers were unable to prevent importation outright.

In 1978, Hoffman-LaRoche challenged an importer's repackaging its drug from five hundred tablet bottles to one thousand tablet bottles, affixing the manufacturer's trademarks on the new bottle, and selling the bottles in a higher priced market. The ECJ acknowledged the right of a trademark owner to protect their mark when its goods were repackaged. The court said that the manufacturer could prevent the use of its mark unless such prevention would contribute to an artificial partitioning of the EU market. Furthermore, the importer must not adversely affect the product's original condition, give the manufacturer prior notice of sale, and state the firm responsible for the repackaging on the package. The court applied these four factors and permitted the repackaging (*Hoffman-La Roche v. Centrafarm* 1978).

Three years later the court had already begun to derail what appeared to be workable interpretation of the EC treaty. In *Pfizer v. Eurim-Pharm* (1981), the court acknowledged the four factors above but failed to apply two of them in its analysis. This left both drug firms and

parallel importers to speculate whether the notice and artificial partitioning requirements held any real meaning. The confusion festered in 1989 when the European Council, the highest EU political body, issued Council Directive No. 89/104/EEC, also known as the Trademark Directive. Article 7(1) of the Directive states that a trademark owner cannot prohibit the use of its mark on goods that it has already placed into the EU market. Article 7(2) limited this exhaustion rule by stating that it shall not apply when legitimate reasons exist for the trademark owner to oppose further commercialization of its goods, especially when "the condition of the goods is changed or impaired after they have put on the market." The Directive did not explicitly approve or disapprove of earlier court rulings. It also did not further define what constitutes a change or impairment.

Repeated litigation over an already murky doctrine culminated in three disputes decided jointly in 1996 (*Bristol-Meyers Squibb v. Paranova* 1996). The court now expanded the repackaging criteria to five factors, noting that trademark owners can challenge importer packaging modifications unless the following conditions exist:

1. Repackaging the pharmaceutical by the parallel importer is necessary in order to market the product in the Member State of importation because the trademark owner is selling its product in several Member States using various forms of product presentation;

2. Repackaging the pharmaceutical by the parallel importer cannot affect the original condition of the product;

3. Repackaging the pharmaceutical by the parallel importer clearly states the name of the firm that repackaged the product;

4. Repackaging the pharmaceutical by the parallel importer will not damage the reputation of the trademark and thus must not be defective, poor quality or untidy; and

5. Notifying the trademark owner that the parallel importer has repackaged the product before it is sold and if requested supplies the trademark owner with a specimen of the repackaged product.

A summary of the current legal situation and the principal concerns of both the parallel importers and the drug manufacturers are illustrated in Figure 3.

Insert Figure 3 about here

This five factor test does offer guidance to both importers and manufacturers, but application and interpretation of these factors has become so ambiguous as to be nearly unworkable. The first criteria alone, repackaging must be necessary to market the product in the new market, remains vague. On the one hand, the phrase could mean literally what permits the parallel importer to gain bare access to the imported market. On the other hand, the phrase could incorporate a requirement that the importer be allowed to do what is necessary to reasonably compete in the market against rivals. Courts have further broken down into necessary standards for reboxing with different sizes, reboxing to prevent a negative consumer reaction, relabeling, and the changing of trademarks from one package to another. As a result, this factor alone has at least four separate 'sub-tests' that are based on a definition that neither importers or manufacturers can be sure what it really means in a legal situation. The other factors, ranging from what specifically affects a product's original condition to what modifications damage a markholder's reputation, are similarly vague and complex. Figure 4 illustrates the complexity of the ECJ statement that "repackaging is permitted only when necessary" for both manufacturers and parallel traders to interpret in terms of reboxing, relabeling and changing the trademark.

Insert Figure 4 about here

As illustrated in Figures 3 and 4, such complex and ambiguous rules virtually guarantee constant litigation. No dispute typifies the disturbing consequences more than the convoluted

case of *Boehringer Ingelheim v. Swingward*. First reaching the England and Wales high court in 2000, the case joined a number of trademark challenges by manufacturers against repackaging importers. Litigants raised new issues that not surprisingly could not be answered under current rules, and the court referred eight questions with multiple subparts to the ECJ for resolution.[1] The ECJ, notorious for its slowness, took nearly two years to respond. The case returned to the English trial court, applied the law, which provoked still more appeals to the England and Wales Court of Appeal. Faced with still more questions for the ECJ and shouldered with the ballooning complexity in this case, the court lamented in 2004 that, "I think the law may be losing a sense of reality in this area - - we are, after all, only considering the use of the owner's trade mark for his goods in perfect condition. The pickle the law has got into would, I think, astonish the average consumer. . . . Despite years of repackaging cases in the ECJ, I am afraid it is necessary to refer the matter yet again." (*Boehringer Ingelheim v. Swingward* 2004, ¶¶ 79, 85). The case returned to the ECJ, where Advocate General Sharpston opined in 2006 that "[i]t seems to me that after 30 years of case-law on the repackaging of pharmaceutical products it should be possible to distil sufficient principles to enable national courts to apply the law to the constantly replayed litigation between manufacturers and parallel importers." (*Boehringer Ingelheim v. Swingward* 2006, ¶ 3).

The ECJ answered the court's five questions in 2007, and the case returned once again to the English Court of Appeal. The national court expressed its frustration in no uncertain terms: "Notwithstanding the two references to the ECJ and its answers, each 'side' (there are several claimant drug companies as claimants and two parallel importers as defendants) claims to have

[1] National courts may petition the European Court of Justice, known as reference, for a review or an interpretation of EC law. Once the ECJ gives the reference, the national court is bound by the interpretation provided. The president of the European Court of Justice described references as essentially a dialogue between the ECJ and the courts of member states where the ECJ offers guidance on EU law (Skouris, 2007).

won. That is a sorry state of affairs. European trade mark law seems to have arrived at such a state of uncertainty that no one really knows what the rules are. . . . Big brand owners want bigger rights; smaller players, no change or less. The compromises which have emerged have very fuzzy lines. So it is that in this case, notwithstanding two references and a host of cases about relabeling parallel imports going back at least 30 years . . . there is still room for argument." (*Boehringer Ingelheim v. Swingward* 2008, ¶ 2). The case was ready to conclude when one of the litigant's attorneys remarked that a question from the Austrian Supreme Court that was relevant to this case was now pending before the ECJ. The court placed the case on hold until this question was answered, and as of 2008 no response has come from the supranational court. Over eight years of litigation and the dispute remains unresolved. Virtually no gray market legal environment is in a more chaotic state than the EU's regulation of pharmaceutical drugs.

Strategies to Prevent Parallel Importation of Drugs in the European Union

The struggle over gray market drugs has been divided between two fault lines – the control over the manufacturer's trademark and the physical contents of product repackaging. The more effectively the manufacturer can assert control over its trademark and physical packaging the less successful importers can be in offering an alternative market to wholesalers, national health care schemes and pharmacists. This section describes the likely goals and practices of parallel importers and then presents strategies for manufacturers to combat these gray products.

Reassert Control over Product Packaging

The importer's goal will be to make their product packaging as competitive as possible against the manufacturer's equivalent without triggering a judicial ruling that repackaging efforts

are not necessary (and thus not permissible) for marketing the product in the target nation. The ECJ has not sufficiently clarified whether "necessary to market" means repackaging only what is essential to enter the market or whether necessity implies what is required to make the importer's product reasonably competitive. Importers will still want to repackage competitively, but should directly connect any repackaging practice to direct compulsion by national regulations. In the absence of national rules, importers can justify repackaging through insurance reimbursement requirements that demand a specific size for repayment. If a market requires a certain size, importers should resize the product in a fashion that both conforms to the requirement and enhances the product's appeal. Compliance with professional group standards may also be sufficiently necessary to protect importers from manufacturer challenges.

Parallel traders can rely on the ECJ decision in (*Boehringer Ingelheim v. Swingward* 2007), which specifically stated that importers only need to show that repackaging overall is necessary to enter the target market and do not have to justify every detail in manner, shape, or style as necessary. This ruling gives importers the flexibility to inject pro-competitive designs within compulsory legal or professional requirements. Importers may have some freedom to design packaging attractively, perhaps even build up their own consumer brand equity, within the larger requirement of satisfying a national regulation or practice. Importers will not use this discretion too aggressively, however. Importers likely know that courts are sensitive to trademark-related harm and will be quick to prohibit repackaging that diminishes the manufacturer's trademark or reputation in any fashion.

The ECJ has stated that it will consider consumer resistance toward relabeled and "over stickered" products as a factor in determining whether more invasive reboxing is necessary to enter the target market. Importers may exploit this consideration by gathering consumer data

showing that reboxing is necessary to overcome consumer resistance to relabeled products. Such data may come from anecdotal data or a more formal and expensive consumer survey like that used by U.S. mark owners to show trademark infringement. Although the ECJ has stated that reboxing would be necessary if a substantial part of a market exhibited strong resistance to relabeled products, courts have yet to specify how much resistance is 'strong' and how many consumers are 'significant'. Importer resources are not unlimited, however, and may only administer surveys as a defensive measure when challenged by manufacturers.

Alternatively, importers may pursue a more conservative strategy of repackaging the manufacturer's drugs only when absolutely necessary. Importers would select the least invasive repackaging method. The ECJ decision-makers appear to perceive a hierarchy of tolerance for repacking ranging from reboxing as the most insidious, then relabeling and finally simple overstickering of packaging as the least invasive. This would involve importer repackaging only when other methods cannot sufficiently conform to the market's legal and regulatory standards. The benefit of this strategy is that it improves the defensibility of the importer's product into the market. The cost is that the importer denies itself the competitive tools of packaging redesign and presentation that might make its market entry more effective.

The manufacturer has a number of viable responses. First, manufacturers should carefully scrutinize the importer's repackaged product for unnecessary modifications. The ECJ has stated that if the parallel trader can add new labels in a local language, add new instructions, or replace one article for another to meet national standards, then reboxing is not necessary (*Bristol-Meyers Squibb v. Paranova*, 1996). If the manufacturer can show that there is a less invasive alternative to reboxing, the parallel trader may be forced to choose a different and possibly more costly product design.

The manufacturer can raise this challenge before a court, but a much less expensive alternative would be to challenge the importer's design during the notice phase of the product's rollout. The ECJ requires that the importer give notice of importation and provide a sample if the manufacturer requests (*Hoffman La-Roche v. Centrafarm*, 1978). Analogous to a pre-litigation cease and desist letter, the manufacturer can use this notice requirement to challenge the importer's repackaging. A conservative or resource-poor importer might retreat from disseminating its product and redesign the box or label according to the manufacturer's wishes. The manufacturer benefits because it may be able to successfully delay distribution of a parallel import through a simple letter rather than a time consuming lawsuit with an uncertain outcome. The manufacturer may also impose additional costs on an importer who is forced to retool its production facility in order to meet the manufacturer's demands. Of course, the importer can refuse to make the requested changes, but the cost for the manufacturer to challenge the importer at this stage is virtually zero.

Manufacturers can also scrutinize the pervasiveness of the allegedly necessary practice that the importer is relying upon as a basis for repackaging. A manufacturer could argue that a legal requirement is not so compulsory as the importers depict. If a requirement arises from professional standards, such as a national board of physicians or an ethical code, manufacturers can argue that the standards are not sufficiently followed by the profession such that it is necessary for importers to change the product to adopt it.

Importers may rely on insurance reimbursement rules to justify size repackaging. Manufacturers may impede the reimbursement argument by encouraging insurance companies to set cross-border standards for reimbursements or otherwise incorporate more flexibility into their reimbursement systems. This would limit the ability of importers to use insurance requirements

as a shield to make changes to the product. While continent-wide unification of insurance practices is unlikely, any increased uniformity limits importer's reliance on differential practices as a basis for reboxing in different sizes.

Manufacturers can also develop packaging that impedes ready transfer from one market to the other. Like importers, manufacturers must walk a fine line. If manufacturers differentiate packaging between markets too aggressively, courts may conclude that the distinct packaging is a cloaked effort to artificially partition markets in violation of Article 28 of the EU Treaty. *See* Figure 3. If manufacturers leave packaging too uniform, it eases the ability of the importer to resell the manufacturer's products without modification. Recall that in many situations the importer repackages in order to meet the market requirements of the buyer only. *See* Figure 4. If an importer can bring drugs to the new market with no packaging changes, it virtually insulates itself from a manufacturer challenge.

The goal for manufacturers then would be to justify product packaging differentiations not only on legal requirements but on the development of brand equity. The ECJ appears sensitive to the concern that a manufacturer should be able to protect or cultivate its trademark. If a manufacturer positions its differential packaging as a brand-equity enhancing strategy targeted to local markets rather than a barrier for parallel importation, it might receive a sympathetic response from a reviewing court.

Overall, manufacturers must strive to raise importer costs and negate importer efforts to increase their product's competitiveness through packaging. The more effectively the manufacturer can question the necessity of importer product modifications, the less freedom importers have to change packaging for all but the most functional (and perhaps non-competitive enhancing) purposes. Manufacturers would retain more freedom than importers to promote their

brand through packaging as a higher quality and more trusted product compared to the importer's alternative. Potential buyers (e.g., hospital purchasing agents, pharmacists, consumers) may even be willing to pay a premium for that perceived quality and trust, eroding to some extent the importer's low cost advantage (which in some cases is a low as five percent).

Defend the Product Trademark

The ECJ has shown a ready willingness to halt importer repackaging if it perceives that such repackaging will impair the manufacturer's trademark or reputation. The court initially stated that product presentation that is somehow "defective, poor quality, or untidy" could damage the trademark's reputation and would be prohibited (*Bristol-Meyers Squibb v. Paranova* 1996). Later, the ECJ expanded this to include harm not just from the three descriptors above but from virtually any source that detracts from the perceived reliability or quality of the product (*Boehringer Ingelheim v. Swingward* 2007). Harm could potentially arise from debranding the manufacturer's product by removing its trademark from exterior packaging, cobranding by applying the importer's logo next to the manufacturer's, or obscuring the manufacturer's mark partially or completely. The importer's strategy here is mainly defensive. The response from the importer must be to protect the integrity of the manufacturer's trademark as closely as possible. Importers should review the packaging closely. At a minimum, the repackaging must not be dirty, discolored, untidy or otherwise appearing as defective to the consumer.

Even though the primary advantage importers hold over manufacturer's is low cost, smart importers will avoid a low cost strategy when it comes to presenting the manufacturer's mark. The device that prints the manufacturer's mark should produce an imprint that is of comparable quality as that printed on the manufacturer's own drugs. The colors of the trademark should be exactly the same as the original and without any possibility of blurring or fading between

manufacture and the sale to the consumer. The trademark should be presented with the same size and location as it was in the original packaging. The importer should use the same font size, shape, and lettering as the manufacturer's mark. The importer's goal is to leave no room for challenge by the manufacturer that its trademark is denigrated by the importer's presentation.

If possible, the importer should avoid reproducing the manufacturer's mark altogether and retain the original. Importers can do so by eschewing reboxing in favor of relabeling and overstickering that does not obscure the original manufacturer's mark. In *Pfizer v. Eurim-Pharm* (1981), for example, the importer successfully withstood a manufacturer challenge by repackaging original blister strips into new folding boxes with transparent fronts through which the owner's trademark on the original packaging was visible.

Protecting the integrity of manufacturer's mark should extend beyond the trademark itself to the manufacturer's trade dress. A particular shape or style might trigger a challenge from the manufacturer that its mark is in jeopardy. For example, a package design for an expensive pharmaceutical that resembles the design for a cheaper and unproven herbal alternative might trigger a dilution challenge from the manufacturer. Importers should also be ready for attacks on the internal packing. If the internal packaging or organization makes the product appear dirty, discolored, or untidy in some way, that opens the door for a manufacturer challenge. If time and cost permits, importers may gather survey data showing that a particular packaging style, presentation, or dress does not diminish the drug manufacturer's trademark.

The manufacturer's strategy is to review the importer's packaging as closely as possible for any diminution in value. Given the ECJ's prior readiness to protect diminution of trademark value, the manufacturer can pursue an aggressive and searching review of importer repackaging practices. The manufacturer can look closely at color, shape, and printing quality for potential

loss of reputation though association with inferior repackaging design. This review should consider both internal and external packaging as the consumer interacts with both packaging stages in consuming the drug. Manufacturers may also wish to test the reliability of the importer's safety seals. Weak or poorly attached seals might imply to a consumer that the product is vulnerable to tampering and thus unreliable for consumption.

A second strategy is to use sophisticated or expensive packaging. This will make the manufacturer's trade dress difficult to copy by importers. The more complex the repackaging required by importers to copy, the more likely that importers will copy the packaging imperfectly or inadvertently diminish its quality. Importers may be financially unable or willing to implement the complex assembly or production methods adopted by the manufacturer.

To reinforce the importance of their complex packaging, manufacturers could promote their innovative packaging to health-care administrators, pharmacists and medical doctors that establish links between their packaging and their mark and the product. The drug manufacturers are currently not allowed to perform direct-to-consumer advertising in the EU, but, they can still foster a brand name identity with those decision-makers that foster this type of "directed demand." Just as AstraZeneca has established a virtually indelible association between its popular drug Nexium and its purple pill design (www.purplepill.com), so can manufacturers establish secondary meaning for their complex packaging in the minds of potential buyers in the EU. The manufacturer may also design different packaging for different nations and develop secondary meaning for each consumer market. For example, GlaxoSmithKline, coated its HIV drugs, Combivir and Epivir, sold at cost to African markets in a red coating in order to differentiate this humanitarian product from more expensive white tablets destined to other markets. Thus, in 2005 GlaxoSmithKline challenged a UK parallel trader, Dowelhurst, for

allegedly supplying the 'red tablets' to the National Health Service (GSK to Use Technology to Prevent Parallel Imports, 2005).

Complex packaging may increase the cost of the importer who must either copy of the packaging or painstakingly apply their own packaging requirements to a product design already resistant to modification. This would drive up the importer's costs and assuming that the importer has less resources than the manufacturer, would make the importer's repackaging practices more difficult to sustain over time. Also, the more complex the packaging, the more easily it can be diminished. The more easily it can be diminished, the more readily manufacturers can argue that the importer's efforts, however gentle or well-meaning, negatively impact their packaging and thereby harm the manufacturer's brand equity. As long as the manufacturer can show that its complex packaging is part of a genuine marketing plan and not a proxy for impeding free markets, the complex packaging strategy could facilitate challenges against parallel importers.

Looking Ahead: The New Scrutiny of European Commission Policymakers

Although current EU law is insufficient and in our opinion, parallel importers can never be eliminated altogether, firms can slow gray market activity through a savvy mixture of legal and marketing strategies. However, we also suggest that current state of the EU pharmaceutical market is on the cusp of change stemming from recent developments in the European Commission that center on the growth of pharmaceutical counterfeits, a desire to harmonize the regulation of pharmaceutical packaging, and a perusal of the rational behind declining competitiveness of the EU pharmaceutical industry (as measured by the reduced number of new pharmaceutical products entering the EU market). In October 2008, Silverman speculated that the lucrative gray market of $5.5 billion annually in the EU pharmaceutical market would be

censured by impending decisions within the European Commission to provide new guidelines for the repackaging of pharmaceuticals (Silverman 2008). Ironically, the renewed attention to the gray market trade is attributed to recent supplies of counterfeit medicines in the EU supply chain. The parallel traders have repeatedly claimed that product diversion through a gray market versus fake drugs entering the channel are unrelated and thus claim that this public policy scare tactic is being inflamed by drug manufacturer lobbyists. The current representative of the European Association of Euro-Pharmaceutical Companies, Heinz Kobelt, continues to claim that the "parallel trade provides competition and savings to the health insurance funds across Europe" (Silverman, 2008, ¶ 5).

On November 3, 2008, the EU issued its *Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use* to outline principal measure to protect patients in the EU pharmaceutical marketplace. In 2006, the EU seizure statistics realized a 384% increase (compared to 2005 data) in counterfeit medicines entering this trade block. Thus, this initial report speculates that in addition to the internet, the counterfeiters are entering the "classical supply chain" through licensed distributors, authorized wholesalers, parallel traders, and pharmacies and thus questions deficiencies in supply chain integrity as a potential problem to aid this illicit trade (p. 4). Thus, the European Commission is considering the following tactics to protect the legal supply chain: 1) subjecting all parties in the distribution chain to pharmaceutical legislation; 2) improving product integrity and traceability; 3) sharpening the technical requirements for good manufacturing practice (GMP) and good distribution practice (GDP); 4) tightening inspections and supervision; and 5) increasing transparency (p.5).

The European Commission is also reviewing Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use in order to potentially harmonize the regulatory framework that governs changes to medicinal products (such as, a change in packaging) to provide more transparent guidelines for stakeholders in this market. The European Commission report states that appeasing the different rules of Member States consumes 60% of a company's regulatory departments and that the simplification of packaging rules in the EU should not jeopardize a patient's safety (European Commission Proposals for Fast Track Administrative Burden Reductions in 2008, ¶ 6).

On November 28, 2008, the Directorate General of Competition within the European Commission released its preliminary report, *Pharmaceutical Sector Inquiry*, to provide an executive summary of the current state of the EU pharmaceutical market. The goal of this report was to systematically review whether "information related to innovative and generic medicines suggested that competition may be restricted or distorted" to ascertain the reasons for diminishing competitiveness in this sector (p. 2). This initial report focuses on original drug manufacturers and whether these firms prohibit the growth of generic medicines once the patent expires. However, as part of this inquiry, in March – May 2008, the Directorate General of Competition also canvassed the opinion of a variety of stakeholders in the EU pharmaceutical industry: originator drug manufacturers, generic manufacturers, marketing authorization authorities in the EU, parallel traders, and national competition authorities. The results of the questionnaires were not disclosed in the Commission's preliminary report—the full report will be published in January 2009. Thus, all three of these current proposals within the governing framework of the EU have a plausible impact on the strategic underpinnings that shape the

discourse between the drug manufacturers and parallel traders. This current change in policy will unfold in 2009 and is a key area to examine in future research.

References

Antia, K., M. Bergen and S. Dutta (2004), "Competing With Gray Markets," *Sloan Management Review*, 46(1), 63-69.

Antia, K., M. Bergen, S. Dutta, and R. Fisher (2006), "How Does Enforcement Deter Gray Market Incidence?" *Journal of Marketing*, 70 (January), 92-106.

Atkinson, Timothy (2001), "The Global Parallel Trade Outlook 2001-2006: A Country-by-Country Analysis," *Reuters Business Insight Healthcare*, Datamonitor PLC, 1-187.

Berman, Barry (2004), "Strategies to Combat the Sale of Gray Market Goods," *Business Horizons*, (July-August), 51-60.

Boehringer Ingelheim v. Swingward, (2008) EWCA (Civ) 83, [2008] EMTR 36.

Boehringer Ingelheim v. Swingward, (2007) ECR I-3391.

Boehringer Ingelheim v. Swingward, (2006) Case C-348/04.

Boehringer Ingelheim v. Swingward, (2004), EWCA (Civ) 129.

Bristol-Meyers Squibb v. Paranova (1996) ECR I-3457.

Cavusgil, S. Tamer and E. Sikora (1988), "How Multinationals Can Counter Gray Market Imports," *Columbia Journal of World Business*, (Winter), 75-85.

Centrafarm v. Sterling, (1974) 2 CMLR 480.

Cespedes, Frank V., E. R. Corey, and V. K. Rangan (1988), "Gray Markets: Causes and Cures," *Harvard Business Review*, (July-August), 75-82.

Chang, Tung-Zong (1993), "Parallel Importation in Taiwan: A View from a Newly Emerged Country and a Comparative Analysis," *International Marketing Review*, 10(6), 30-41.

Chard, J.S. and C.J. Mellor (1989), "Intellectual Property Rights and Parallel Imports," *World Economy* (March), 69-83.

Chaudhry, Peggy and Michael, Walsh (1995), "Managing the Gray Market in the European Union: The Case of the Pharmaceutical Industry," *Journal of International Marketing*, 3(3), 11-

33.

Chaudhry, Peggy and Michael, Walsh (1995), “Gray Marketing of Pharmaceuticals,” *Journal of Health Care Marketing*, 15(3), 18-22.

Chen, Hsiu-Li (2002), “Gray Marketing and Unfair Competition,” *Atlantic Economic Journal*, 30(2), 196-204.

Danzon, Patricia (1998), “The Economics of Parallel Trade,” *Pharmoeconomics*, 13(3), 293-304.

Duhan, Dale F. and M. J. Sheffet (1988), "Gray Markets and the Legal Status of Parallel Importation," *Journal of Marketing*, (July), 75-83.

EEC Treaty (1957), Treaty Establishing the European Economic Community, Mar. 25 1957, 298 U.N.T.S. 3, (accessed October 1, 2008) [available at http://europa.eu/scadplus/treaties/eec_en.htm].

Eagle, L., P. Kitchen, L. Rose, and B. Moyle (2003), “Brand Equity and Brand Vulnerability: The Impact of Gray Marketing/Parallel Importing on Brand Equity and Values,” *European Journal of Marketing*, 37(10), 1332-1517.

Eurim-Pharm Arzneimittel v. Beiersdorf, 1996 ECR I-3603, 71/94, Stothers 80, 1996 WL 1093802

Europe Economics (2008), *Safe Medicines Through Parallel Trade: Contribution to an Impact Assessment.* London, England.

European Commission Proposals for Fast Track Administrative Burden Reductions in 2008 (October 10, 2008), (accessed on November 30, 2008), [available at http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/08/152&format=HTML&aged=0&language=EN&guiLanguage=en].

Evans, Gail E. (2008), “Strategic patent licensing for public research organizations: Deploying restriction and reservation clauses to promote medical R&D in developing countries”, *American Journal of Law and Medicine*, 34(2), 175-223.

GSK to Use Technology to Prevent Parallel Imports (2005). (accessed on November 30, 2008) [available at http://www.in-pharmatechnologist.com/Packaging/GSK-to-use-technology-to-prevent-parallel-imports].

Ganslandt, Mattias and Keith E. Maskus (2004), “Parallel Imports and the Pricing of Pharmaceutical Products: Evidence from the European Union,” *Journal of Health Economics*, 23, 1035-1057.

Ghosh, Shubda (2002). “Pills, Patents, and Power: State Creation of Gray Markets as a Limit on Patent Rights,” *Florida Journal of International Law*, 14(Spring), 217-260.

Grossman, Gene M. and Edwin L.-C. Lai (2008), “Parallel Imports and Price Controls,” *RAND Journal of Economics*, 39(2), 378-402.

Hoffman-La Roche v. Centrafarm (1978) ECR 1139. Case 102/77

Howell, Roy D., R.R. Britney, P.J. Kuzdrall, and J.B. Wilcox (1986), "Unauthorized Channels of Distribution: Gray Markets," *Industrial Marketing Management* (November), 257-263.

Huang, J., B. Lee, and S. Ho (2004), “Consumer Attitude Toward Gray Market Goods,” *International Marketing Review*, 21(6), 598-614.

Impediments to Parallel Trade in Pharmaceuticals Within the European Community. A report prepared by Remit Consultants for the Commission of the European Communities (1991).

Inman, James E. (1988), “Gray Marketing of Imported Trademark Goods: Tariffs and Trademark Issues,” *American Business Law Journal*, 31(1), 59-116.

Iqbal, Zafur and Lawrence Feick (2002), “Sales Managers’ Perceptions of Gray Markets: The Role of Incentives, Channel Dependence, and Type of Gray Market,” *Journal of Personal Selling & Sales Management*, 22(4), 359-369.

Kanavos, Panos (2000), “The Single Market for Pharmaceuticals in the European Union in Light of European Court of Justice Rulings,” *Pharmoeconomics*, 18(6), 523-532.

Kanavos, P., Costa-i-Font, J., Merkur, S., and M. Gemmill (2004), “The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis.” Special Research Paper, LSE Health and Social Care, London School of Economics and Political Science, (accessed on September 1, 2008), [available at http://www.lse.ac.uk/collections/pressAndInformationOffice/newsAndEvents/archives/2004/EU_pharmaceutical_paralleltrade_update.htm].

Kyle, Margaret K., Jennifer S. Allsbrook, and Kevin Schulman (2008), “Does Reimportation Reduce Price Differences for Prescription Drugs? Lessons Learned from the European Union,” c*Health Services Research*, 43(4), 1308-1324.

Lansing, Paul and Joseph Gabriella (1993), “Clarifying Gray Market Gray Areas,” *American Business Law Journal*, 31(Fall), 313-337.

Lilico, Andrew (2006), “Six Issues in Pharmaceuticals,” *Institute of Economic Affairs*, Oxford, England: Blackwell Publishing.

Lim, G., K. Lee, and S. Tan (2001), “Gray Marketing as an Alternative Market Penetration Strategy for Entrepreneurs: Conceptual Model and Case Evidence,” *Journal of Business Venturing*, 16, 405-427.

Lowe, Larry S. and K. F. McCrohan (1989), "Minimize the Impact of the Gray Market," *The Journal of Business Strategy* (November-December), 47-50.

Mathur, Lynette Knowles (1995), "The Impact of International Gray Marketing on Consumers and Firms," *Journal of Euro-Marketing*, 4(2), 39-59.

Megget, Katrina (2008), "Parallel Trade Pushing Fakes?" (accessed on November 1, 2008), [available at http://www.in-pharmatechnologist.com/Industry-Drivers/Parallel-trade-pushing-fakes].

Merck & Co. v. Stephar BV (1981), 1981 E.C.R. 2063.

Myers, Matthew (1999), "Incidents of Gray Market Activity Among U.S. Exporters: Occurrences, Characteristics, and Consequences," *Journal of International Business Studies*, 30(1), 105-125.

Myers, M. and D. Griffith (1999), "Strategies for Combating Gray Market Activity," *Business Horizons*, (November-December), 2-8.

Palia, Aspy P. and C. F. Keown (1991), "Combating Parallel Importing: Views of U.S. Exporters to the Asia-Pacific Region," *International Marketing Review*, 8(1), 47-56.

Pharmaceuticals in Europe: Facts and Figures. (n.d.) (accessed on September 30, 2008), [available at http://ec.europa.eu/enterprise/phabiocom/comp_pip_faf.htm].

Pharmaceutical Sector Inquiry (November 28, 2008) (accessed on November 30, 2008), [available at http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/exec_summary_en.pdf].

Pharmon v. Hoechst (1985), [1985] ECR 2281.

Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use (November 3, 2008), (accessed on November 30, 2008), [available at http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2008/2008_03/consult_counterfeit_20080307.pdf].

RX: Three New Weapons in Pharma's Brand Protection Arsenal. (2008) (accessed on November 30, 2008), [available at http://www.bpcouncil.com/apage/777.php].

Skouris, Vassilios (2007), "Preface: The European Court of Justice's Second Official Visit to the United States, *International Lawyer* 41(Winter), 1003-1006

Sloane, Peter (2004), "Preventing the Unauthorized Importation of Altered Gray Market Goods: Practical Suggestions for US Trademark Owners," *Intellectual Property & Technology Law Journal*, 16(6), 12-15.

Stothers, Christopher (2007), *Parallel trade in Europe: Intellectual Property, Competition and Regulatory Law*. Oxford and Portland, Oregon: Hart Publishing.

Swanson, Tait R. (2000), "Combating Gray Market Goods in a Global Market: Comparative Analysis of Intellectual Property Laws and Recommended Strategies," *Houston Journal of International Law*, 22(2), 327-343.

Szymanski, Stefan and Tommaso Valletti (2005), "Parallel Trade, Price Discrimination, Investment and Price Caps," *Economic Policy*, 705-749.

Towse, Adrian (1998), "The Pros and Cons of a Single 'Euro-Price' for Drugs," *Pharmoeconomics*, 13(3), 271-276.

Timur, A. and J. DeSimone (2007), "The Impact of European Integration on the Pharmaceutical Industry," *The Business Review*, 7(1), 315-320.

Trademark Directive (1989), Council Directive No. 89/104/EEC.

Weigand, Robert E. (1991), "Parallel Import Channels - Options for Preserving Territorial Integrity," *Columbia Journal of World Business* (Spring), 53-60.

Weigand, Robert E. (1989), "The Gray Market Comes to Japan," *Columbia Journal of World Business* (Fall), 18-24.

Wilson, W. Weldon (1985), "Parallel Importation - Legitimate Goods or Trademark Infringement?" *Vanderbilt Journal of Transnational Law* 18, 543-576.

Table 1
Selected Synopsis of Various Factors that Enhance Gray Market Activity

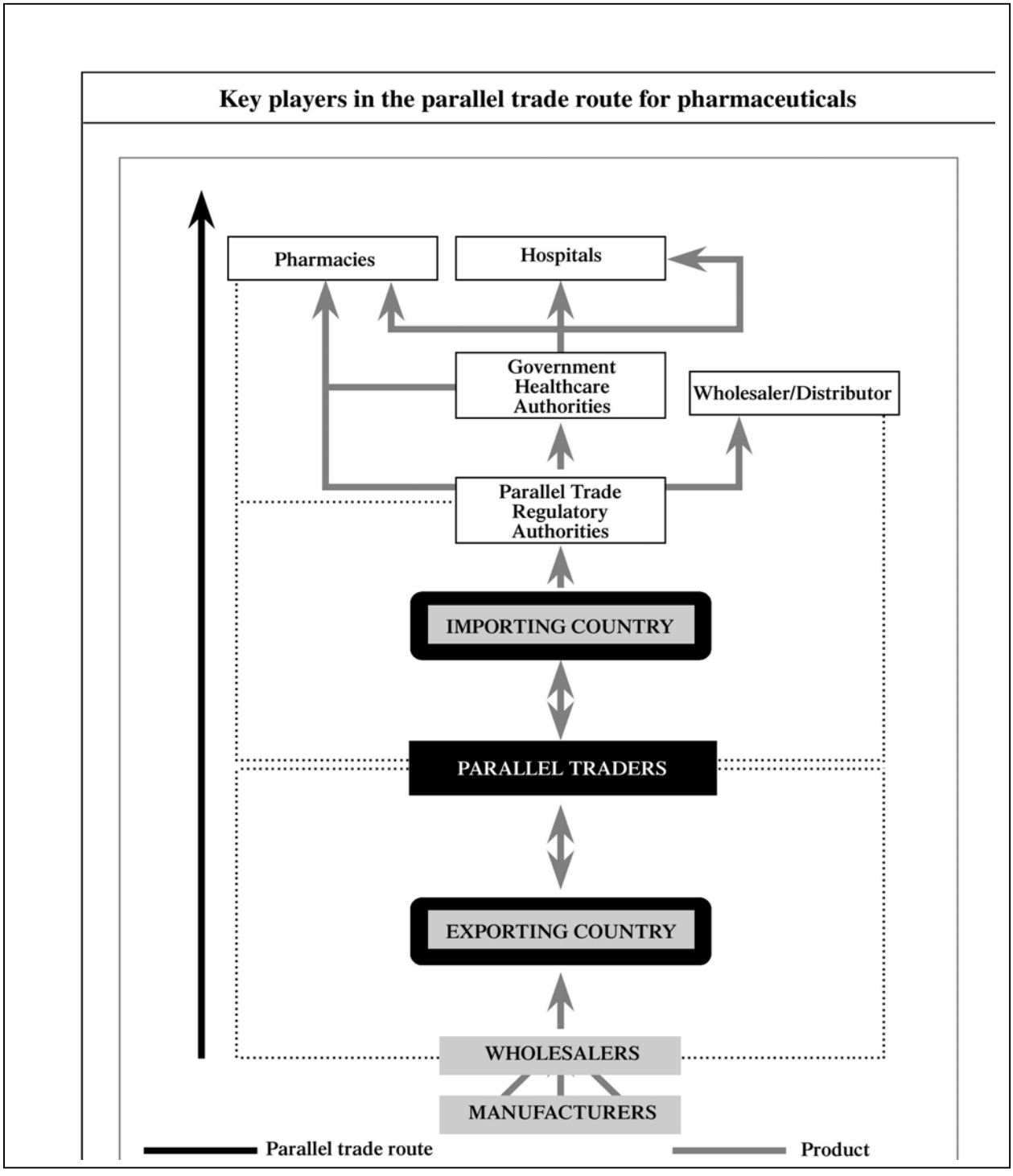
Study	Factors that Foster a Gray Market
Cavusgil and Sikora (1988)	• Substantial price differences between national markets • Supply shortages in the importing country • Competitive pricing strategies • Exchange rate fluctuations • Demand for foreign-made products not available in the local market • Relative ease that products can be moved across markets and adapted for local use
Cepesedes et al. (1988)	• Price differentials (supplier pricing, exchange rate fluctuations)
Chang (1993)	• Price discrimination • Exchange rate fluctuation • Skimming price strategy • International authorization agreements • Legal status of parallel imports
Chaudhry and Walsh (1995)	• The emergence of trade blocks to reduce barriers to trade • Regulated price differentials linked to volume of demand • Legal framework that condones parallel trade
Duhan and Sheffet (1988)	• Source of supply • Trade barriers between countries must be low enough to provide easy market access • Legal status of gray markets • Price differentials (e.g., through currency fluctuations, differences in demand, and segmentation strategies) must be large enough to encourage profit motives
Howell et al. (1986)	• Storage of product • Mass appeal of product • Access to authorized distribution channel
Myers and Griffith (1999)	• Wide price margins across markets • Lack of distribution control • Products customized to different markets • Disparate levels of multinational diffusion
Myers (1999)	• Control Specific Factors—distribution control and channel integration • Organizational Specific Factors—experience, centralization and product standardization • Market Specific Factors—number of markets, market volatility
Remit Consultants (1991)	• Volume of market demand • The extent to which the product resembles the original good • The extent of repackaging that is required • The availability of supply in the exporting country
Weigand 1991	• Exchange rate differences • Power of discriminating monopolist • Opportunistic behavior by members of administered marketing channels

Table 2
Summary of Anti-Gray Marketing Strategies

Study	Anti-Gray Marketing Tactics
Antia et al. (2004)	• Sensing—tracking the distribution channel for gray market activities • Speed—developing internal company responses to react to gray market activity • Severity—fines, "chargebacks" or fines to companies in the supply chain.
Berman (2004)	• Evaluate quantity discount schedule and price strategy by market area • Product differentiation • Checking out existing and new distributors • Use the web to check for unauthorized resellers • Deter diversion with unique labeling techniques • Make customers aware of the risks associated with gray products purchases • Offer rebates on authorized goods to reduce the price differential
Cavusgil and Sikora (1988)	• *Reactive tactics* (i.e., to use after a gray market occurs) • Strategic confrontation • Participation in the parallel trade • Price-cutting • Supply interference • Promotional bursts • Collaboration with the gray marketers • Acquisition of the parallel traders • *Proactive tactics* (i.e., to develop before a gray market occurs) • Product-service differentiation • Strategic pricing • Dealer development • Marketing information systems • Long-term image reinforcement • Establishment of legal precedence • Lobbying
Cespedes et al. (1988)	• Get accurate and timely information about gray market activity. • Reexamine the company's distributor's policies • Revisit any reseller service support • Pricing (e.g., quantity price discounts) • Reassign market priorities (e.g., is market access more important than possible gray market?)

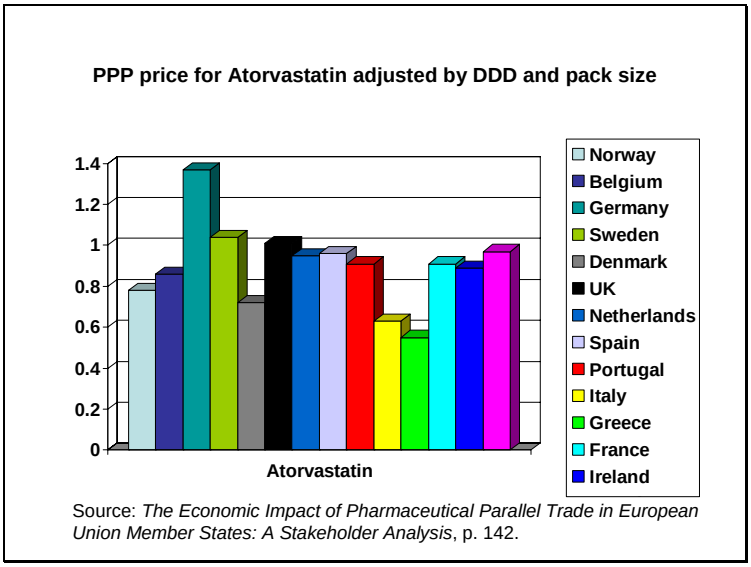
Howell et al. (1986)	• Distributor training • Warranty/guaranty agreements • Cumulative discounts • Direct payment to intermediaries for the services they perform • Vertical integration with 'buffet-style' pricing of intermediary services
Lowe and McCrohan (1988)	• Downstream distribution system integration • Tracking systems in the channel • Price competition with gray marketers • Unwillingness to service gray markets • Legal actions • Elimination of the product from the marketing mix
Myers and Griffith (1999)	• Coordinate your distribution channel horizontally • Stay apprised of changing regulations • Pay attention to differentiated products across markets • Restrict the autonomy to set prices • Stay in touch with your distributors
Palia and Keown (1991)	• Cooperative action between the exporter and agent • Reducing prices to enable the sole agent to compete with gray marketers • Stabilizing the price structure so all buyers pay equivalent prices • Identify and prosecute parallel traders • Prevent transshipments between markets served • Redefine relationship with exclusive agents (e.g., eliminating exclusive sales territories) • Establishing new channels • Providing special packaging or labeling

Figure 1
Parallel Trade Flow in the European Union



Source: *The Global Parallel Trade Outlook 2001-2006*, 2001, p. 29.

Figure 2
Price Discrimination for Atorvastatin in Selected European Markets



Source: *The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis*, p. 142.

Figure 3
The Legal Environment of Parallel Importation of Pharmaceutical Drugs in the European Union

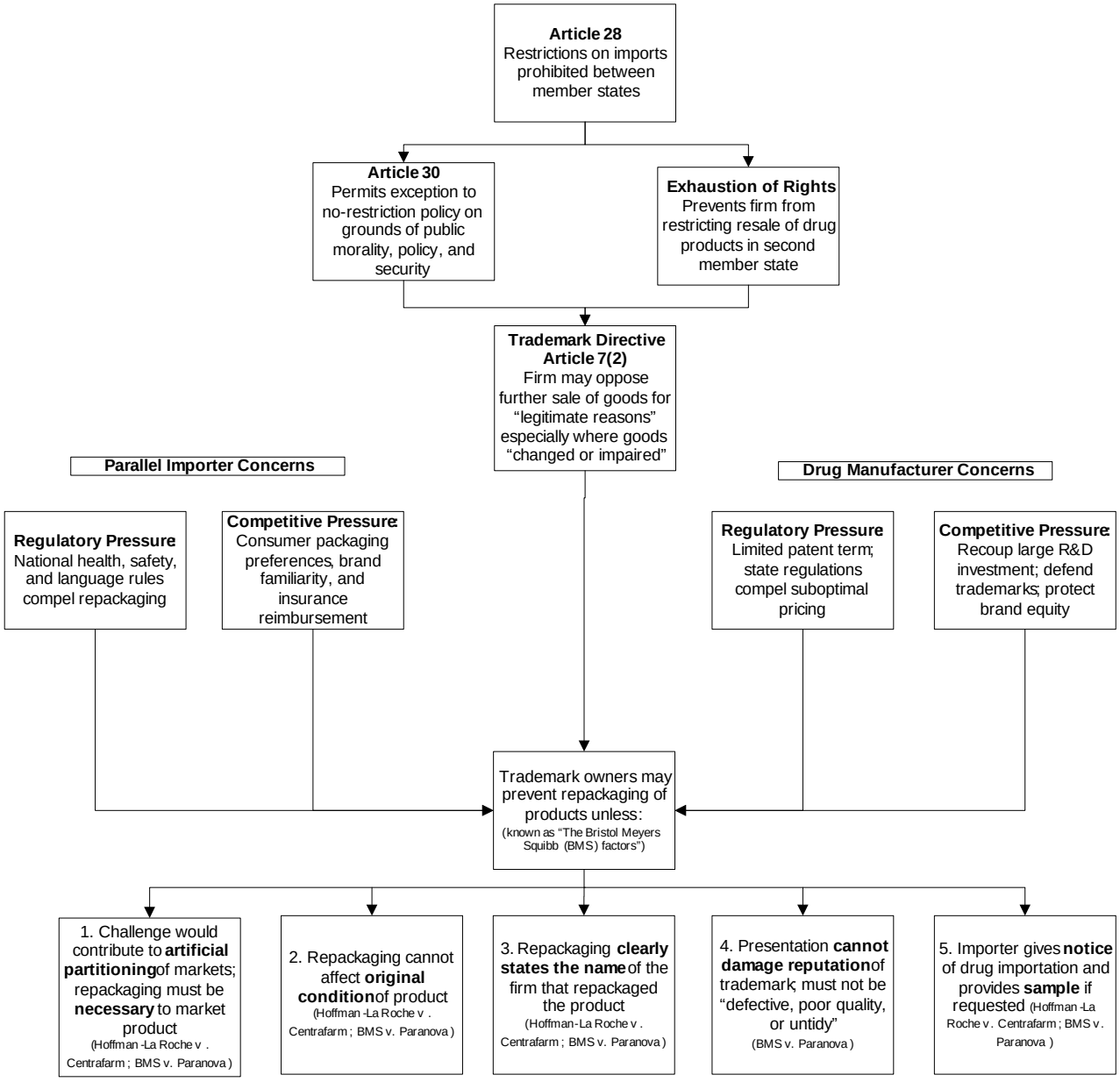


Figure 4
Legal Challenges Stemming from "Necessity" of Repackaging the Pharmaceutical Product