Pharmaceuticals and the European Union: Managing Gray Markets in an Uncertain Legal Environment

Robert C. Bird & Peggy E. Chaudhry
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ROBERT C. BIRD* & PEGGY E. CHAUDHRY**

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* Assistant Professor and Ackerman Scholar, Department of Marketing, School of Business, University of Connecticut. Support from the University of Connecticut Center for International Business Education and Research (CIBER) is gratefully acknowledged. My thanks go to Christopher Stothers and Tuomas Mylly for helpful comments. I appreciate the diligent research assistance of Jeannine DePhillips.

** Associate Professor, Department of Management & Operations/International Business, School of Business, Villanova University. I would like to acknowledge the summer research grants given by the Villanova School of Business in 2007 and 2008 to support my continued work in the area of gray markets and intellectual property rights. I would also like to recognize research funds that were provided by the Fred J. Springer Chair in Business Leadership at the Villanova School of Business.
INTRODUCTION

One of the most difficult challenges for drug companies has been the proliferation of gray markets. Gray markets occur when a firm’s products are sold or resold through unauthorized dealers in an effort to exploit price differentials in multiple markets. Drug firms, whose products are subject to regulation by governments interested in keeping low-cost drugs available to their citizens, are especially vulnerable. Nowhere is the effect of parallel importation more acute than in the European Union, where low transportation costs, varying national price controls, strong demand, and a wealthy consumer market establish nearly ideal conditions for lucrative price arbitrage.

Some articles have examined gray markets impacting multinational trade blocs, and others have studied gray markets in Asia, but most researchers study gray markets from the viewpoint of the United States. As a result, gray markets in the European Union, known commonly there as parallel imports, receive relatively little notice in U.S. law reviews.


4. See SETH E. LIPNER, THE LEGAL AND ECONOMIC ASPECTS OF GRAY MARKET GOODS 8 (1990) (“[T]he European Community . . . faced with an unauthorized importation problem, chose the term ‘parallel imports’ instead of ‘gray market.’”). Some U.S. courts apparently prefer the “gray market” term. See, e.g., Weil Ceramics & Glass, Inc. v. Dash, 878 F.2d 659 (3d Cir. 1989). In this case, the court commented on the term in the context of an objection to its use by a litigant: Appellants in the present case note that the term “gray-market” unfairly implies a nefarious undertaking by the importer, and that the more accurate term for the goods at issue is “parallel import.” We agree that the term parallel import accurately describes the goods and is, perhaps, a better term because it is devoid of prejudicial suggestion. For
This Article attempts to fill the scholarly gap. This is particularly important because a longstanding and increasingly festering problem in the EU pharmaceutical market demands academic attention. Since the 1960s, national courts, guided by the European Court of Justice (ECJ), have been moving toward an orderly regulation of parallel trade in the European Union. A proliferation of parallel importation cases filed by drug firms, however, has sent an increasing number of questions for resolution to the ECJ, whose role is to ensure equal application of European Union law across the member states. The ECJ has responded with rulings that are dilatory, complex, and at times so vague as to create more questions than answers. These problematic rulings have culminated in the convoluted handling of an important parallel importation dispute, Boehringer Ingelheim KG v. Swingward Ltd., which first reached the High Court of England and Wales in January 2000, and, after nine years and multiple trips to the ECJ, has yet to be fully resolved.\footnote{This case was litigated in the United Kingdom as Glaxo Group Ltd. v. Dowelhurst Ltd., [2000] 2 C.M.L.R. 571.}

Forty years and dozens of lawsuits later, the law of pharmaceutical gray markets in the European Union remains in relative disarray.

One of the key causes of this disarray is the repackaging of pharmaceutical products by non–trademark owners for sale in the EU market. National laws help create the repackaging problem. Ideally, parallel importers want to purchase drugs in low-cost markets and resell them unchanged in more profitable locales. However, national disclosure regulations, packaging requirements, language rules, and consumer preferences may require that medicines be relabeled and repackaged before being resold in the new market. Thus, parallel importers, aided by national laws, have state-sanctioned opportunities to repackaging medicines when moving them from one market to another.

Drug firms have adroitly exploited this repackaging obligation to challenge parallel importation, not as a violation of patent law, but as an infringement of their trademarks and trade dress on the original packaging. Drug firms claim that repackaging by parallel importers damages

that reason, we use that term in this discussion. However, we also employ the term “gray-market” good because, for better or worse, it has become the commonly accepted and employed reference to the goods at issue.

\textit{Id.} at 662 n.1. Other courts use the terms interchangeably. See, e.g., Quality King Distrib., Inc. v. L’anza Research Int'l, Inc., 523 U.S. 135, 153 (1998) ("The parties and their \textit{amici} have debated at length the wisdom or unwisdom of governmental restraints on what is sometimes described as either the ‘gray market’ or the practice of ‘parallel importation.’"); Omega S.A. v. Costco Wholesale Corp., 541 F.3d 982, 984 n.1 (9th Cir. 2008) (using the terms interchangeably). We do so as well.
the reputation of their brands and infringes their trademark rights. Accordingly, pharmaceutical manufacturers may have found a way to stem the flow of parallel imports through a legal issue not involving the drugs themselves, but the boxes and labels that identify them. The ECJ could have resolved this question long ago, but a generation of unclear legal decisions and unworkable tests, coupled with the extremely slow pace of the transitional court, has conspired to transform the law of repackaging into a doctrinal mess that aids neither importer nor manufacturer in resolving their respective problems. Therefore, product repackaging is not merely a quarrel about the minutiae of labeling requirements, but has emerged as a battleground for the heart and soul of free trade in the European drug market.

The purpose of this Article is two-fold. First, we take the necessary and important step of unraveling the precedent that should guide European national courts on how to treat product repackaging by parallel importers. We clarify the law both through a disambiguation of the relevant cases and a series of exhibits designed to provide the reader with clear guidance of both rules and exceptions. We show that the ECJ cases must be better understood, because they influence not only future ECJ precedent but also the precedent of every national court system in the EU.

The second purpose of this Article is to present strategies for both parallel importers and drug manufacturers to best navigate the legal environment and protect their respective interests. This will help bring badly needed clarity to an unclear regime, thereby enabling importer and manufacturer alike to make more efficient decisions based upon a clearer understanding of the law. A clearer understanding of repackaging rules should decrease conflict and litigation. The reduced uncertainty may also encourage smaller firms to enter the market, thus increasing competition and reducing the likelihood of cartel-like behavior. Less litigation and more competition ultimately result in more favorable prices paid by the consumer. The clarity and increased certainty our discussion brings could benefit the marketplace regardless of the position the ECJ takes now or in the future.

This Article proceeds in three Parts. Part I describes the EU drug market in the context of parallel trade. The value of the market is enormous and parallel importers have strong motivation and opportunity to exploit price differentials across national markets. Part II examines the law of repackaging of parallel traded goods in the European Union from the early 1970s to the present. Part III presents strategies to both
importers and manufacturers and offers a brief look ahead to future EU guidelines.

I. **THE EU DRUG MARKET FOR PARALLEL TRADE: A PRIMER AND CURRENT DEBATES**

The value of the EU’s pharmaceutical market is estimated at €133 billion.\(^6\) Major country markets for pharmaceuticals include France, Germany, Italy, the United Kingdom, and Spain.\(^7\) The concept of a gray market, which plays a significant role in EU drug sales, is a relatively simple one. Trade consists of the import and export of goods and services. Specialization and division of labor create comparative advantages for certain firms. These firms seek to maximize their revenue by selling in as many markets as possible. In theory, firms receive the difference between production costs and market price. In practice, traders must absorb market-imposed or government-enforced transaction costs when selling abroad.\(^8\) These trade conditions create an environment where the purchase price of goods differs from place to place.\(^9\) Parallel traders exploit these price differences by transferring goods from a low-cost national market to a high-cost one.\(^10\) Parallel traders benefit by profiting from the price difference.\(^11\) Consumers benefit from purchasing a product that is below the prevailing market price in their nation.\(^12\) Gray market products commonly find their way into markets not intended by the manufacturer.\(^13\)

In the EU, the largest markets for gray market pharmaceuticals are in Denmark (15.2% of total market), the United Kingdom (14.7%), Sweden (13.3%), the Netherlands (10.4%), and Germany (7.7%). Parallel

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8. CHRISTOPHER STOTHERS, PARALLEL TRADE IN EUROPE: INTELLECTUAL PROPERTY, COMPETITION AND REGULATORY LAW 1 (2007).

9. Id.

10. Id. at 2–3.

11. Id.

12. Id.

importers take advantage of the significant variance in drug prices across European national boundaries. For example, a comprehensive study by Kanavos and Costa-Font in the United Kingdom 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.\textsuperscript{14} Figure 1 illustrates the price variation for Atorvastatin, a cholesterol-reducing prescription drug developed by Pfizer and marketed as Lipitor, using purchasing power parity prices to allow more accurate comparisons. For example, as shown in Figure 1, the price of Atorvastatin in Greece and Italy is a small fraction of the price charged in Germany and Sweden.

\begin{figure}[h]
\centering
\caption{Price Discrimination for Atorvastatin in Selected European Markets\textsuperscript{15}}
\begin{tabular}{|l|c|}
\hline
\textbf{Country} & \textbf{Purchasing Price Parity Adjusted for Defined Daily Dose and Pack Size} \\
\hline
Germany & 1.37 \\
Sweden & 1.04 \\
United Kingdom & 1.01 \\
Austria & 0.97 \\
Spain & 0.96 \\
The Netherlands & 0.95 \\
France & 0.91 \\
Portugal & 0.91 \\
Ireland & 0.89 \\
Belgium & 0.86 \\
Norway & 0.78 \\
Denmark & 0.72 \\
Italy & 0.63 \\
Greece & 0.55 \\
\hline
\end{tabular}
\end{figure}

\textsuperscript{15} Panos Kanavos et al., The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis 142 (Jan. 2004) (London Sch. of Econ. & Political Sci., Special Research Paper), available at http://www2.lse.ac.uk/LSEHealthAndSocialCare/LSEHealth/pdf/Workingpapers/Paper.pdf.}
Significant buying power wielded by publicly funded health care systems tends to push drug prices down. Government policies also can keep drug prices artificially low. The relative lack of such regulation, along with government-sponsored drug purchases, means, for example, that Dutch drug prices are significantly higher than the average prices for the same drugs in the European Union as a whole. Limited competition, high consumer prices, and the high level of patient copayments keep prices high in Denmark as well.16 Furthermore, 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.

Some of the motivations for gray market activity can arguably be considered the “honest enterprise” of entrepreneurs.17 One parallel importer might exploit favorable foreign currency exchange rates to reduce price.18 Another may sell acceptable quality “distress goods” that have been dumped by an otherwise authorized dealer burdened with excess supply, or may sell goods that have become outdated.19 Other motives are more nefarious. Some entrepreneurs practice free-riding, which involves selling goods identical to those sold by “full-service” dealers without incurring promotion and servicing costs that accompany the product.20 Other parallel importers might sell goods that are of inferior quality without notifying the consumer.21

Consumer demand and behavior plays a significant role in the emergence of gray markets. 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.22 A product that is commonly presented in a manner that does not significantly vary from market to market can increase consumer demand, because this lessens the probability that the consumer will question the authenticity of the product. Consumer de-

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17. LIPNER, supra note 4, at 8.
18. Id.
20. LIPNER, supra note 4, at 9.
21. Id.
mand becomes particularly complex, however, when considering the EU drug market. In some markets, a consumer may not know that the price of the product benefits from a reduced price because government health insurance provides the drug. In these instances, consumer demand for drugs is considered to be “directed demand” channeled through a doctor. The ultimate decision maker on many cases, then, is not the drug user, but the prescribing doctor or pharmacist. As a result, consumers may not be as sensitive to the drug’s price as compared to the price of other products. This also means drug manufacturers cannot always use aggressive pricing strategies alone to counter the entry of parallel importers.

Further complicating the issue of gray markets is the presence of intermediaries between manufacturer and consumer. Legitimate wholesalers and distributors have an interest in reducing competition from parallel import products. Wholesalers and distributors may expect manufacturers to shield them from the competition that free-riding parallel importers bring. Other intermediaries, such as pharmacies and hospitals, make decisions about which drugs are suitable to treat what ailments and how these drugs are made available to consumers. These budget-conscious groups may have an incentive to use cheaper gray market products if these products are of sufficient quality. The result is a trading environment where numerous interest groups influence the pharmaceutical supply chain and have varying incentives regarding how parallel imports are treated. A graphical explanation revealing the complex interaction of various private and public interests is available in Figure 2.

24. Id. at 5.
25. Id.
26. See, e.g., Chaudhry & Walsh, supra note 1, at 21; Howell et al., supra note 22.
27. LIPNER, supra note 4, at 75.
While intermediaries consider a variety of incentives such as patient well-being, cost, and government interference, parallel importers focus primarily on the opportunity to profit from arbitrage. This arbitrage comes from traders buying drugs in regulated low-priced markets and selling them in higher-priced free markets. Successfully exploiting such arbitrage is not simply a matter of transporting a good from one nation to another. Importers face litigation from the pharmaceutical manufacturers, unfortunate exchange rate variations, reduced supply from high demand in the low-cost market, discount incentives from manufacturers,

price dumping, product changes, and changes in regulation, all of which can erode or eliminate any benefit from parallel trade.

Scholars are uncertain whether gray markets improve consumer welfare. The most obvious benefit is that consumers benefit from the lower price gray market sellers offer. Further, gray market products are genuine and “consumers are not confused as to the source or origin of these goods.”  Gray market products also prevent price gouging by manufacturers by providing consumers with a cheaper but equivalent-quality alternative. These products may also indirectly benefit consumers in the form of a lower tax burden. On the other hand, manufacturers counter that gray market sellers “receive the benefits of . . . expensive manufacturing and advertising campaigns without incurring any of the accompanying costs.” Additionally, distributors who hold exclusive contracts with manufacturers may find their contracts less valuable since they must fend off unanticipated gray market competition.

Ideally, consumers in Europe would benefit from a price reduction in pharmaceuticals resulting from parallel trade. However, under government-subsidized health care, the patient’s final price is really the level of copayment that he or she pays for the drug. An indirect way to think of benefits to the consumer is that the national health care system can provide better healthcare benefits since parallel drugs may reduce overall drug costs.

This does not necessarily mean, however, that all benefits of gray markets pass on to the consumer. A study conducted by Kanavos and others examined these plausible benefits to the consumer in six European countries: Denmark, Germany, Greece, the Netherlands, Norway, and the United Kingdom. The comprehensive study concluded that, due to access to medicines through national health systems, benefits to consumers were negligible. For example, consumers in the United Kingdom and Germany were not aware of the price benefits of parallel trade because patients in these countries pay a flat fee for drugs. The Kanavos-led researchers concluded:

Consequently, it does not directly transpire that pharmaceutical

30. Id.
31. Id. at 110.
32. Id.
33. Kanavos et al., supra note 15; see also Kanavos & Costa-Font, supra note 14, at 792.
34. Kanavos et al., supra note 15, at 88.
35. Id. at 87.
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.\textsuperscript{36}

Gray marketer sellers may be one of the most effective forces in negating the welfare consumers receive from gray markets. Parallel traders may negate cost savings through a practice of shadow pricing. Shadow pricing occurs when the gray marketer offers a price relatively close to the prevailing price in that country market through an authorized channel.\textsuperscript{37} To illustrate this point, the Kanavos study estimated the economic impact of parallel trade in selected country markets, for example, Germany.\textsuperscript{38} The study examined the 2002 sales of nineteen 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 health insurance scheme to engage in parallel trade, and the maximum profit accruing to parallel importers.\textsuperscript{39} Price spreads in the German market (i.e., the difference between the parallel trade price and locally sourced price) for these nineteen products ranged from a high of twenty-one percent for Fluoxetine to five percent for Simvastatin, Valsartan, and Sertraline.\textsuperscript{40} Researchers estimated that the profits to parallel traders were over five times as large as the savings to the German health insurance program.\textsuperscript{41}

The Social Market Foundation in the United Kingdom estimates that seventy percent of all of the EU parallel trade in pharmaceuticals ends up in the U.K. marketplace and reduces government health care costs by up to €269 million per year.\textsuperscript{42} However significant these savings, parallel traders are in business to profit, and many sell the drug at prices just below the country market price. One would believe that competition be-

\textsuperscript{36} Id. at 88.
\textsuperscript{38} Kanavos et al., supra note 15, at 160.
\textsuperscript{39} Id.
\textsuperscript{40} Id.
\textsuperscript{41} Id.
between parallel traders should keep prices low. Intriguingly, this does not always happen. One reason may be that threats of litigation made by manufacturers raise barriers to entry and keep all but the largest importer firms from competing. This results in fewer importer competitors and higher prices. Alternatively, importers engaging in cartel-like behavior would also cause prices to rise.

Manufacturers also contend that safety is a potential issue. The regulated pricing of pharmaceuticals in Europe implicates public policy issues. For example, protecting the population from unsafe medicines is a concern of legislatures throughout Europe. A U.K. drug recall in 2007 fueled controversy regarding counterfeit drugs entering the supply chain via parallel trade. In addition to the problems already mentioned, drug package leaflets can become outdated, exposing patients and medical staff to inaccurate information and leading to incorrect consumption. Parallel importation also 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 argument that consumers benefit from lower prices for potentially lifesaving pharmaceuticals is compelling, but there is evidence that not all benefits are passed to consumers and that parallel trade creates risks of its own.

Manufacturers have used a variety of tactics to block parallel importation, but their efforts have been met with little success. In spite of distributor discounts, changes in products, supply interference, price cuts, promotional bursts, and a variety of other practices, the parallel import market for drugs in the EU remains alive and well. One issue that could cripple or even prevent drug parallel importing rarely has been discussed in the literature. This issue, the seemingly innocuous question of product repackaging by parallel importers, is the subject of the next Part of this Article.


45. See, e.g., Antia, Enforcement, supra note 3, at 97–99; Chaudhry & Walsh, supra note 1, at 21.
II. REPACKAGING AND THE LAW OF PARALLEL IMPORTS

A. Development of the Legal Environment of Gray Market 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 container 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 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 that certain information about the product be disclosed or may prohibit the use of certain words or phrases. National rules may also require that the package use a certain language, may dictate pack sizes, or may impose packaging style requirements. Parallel importers may repackage to assuage consumers who might be suspicious of goods bearing foreign languages or who prefer medicines to be delivered through different containers or sizes. They may also remove all markings indicating the source of the product in order to prevent the manufacturer from halting supplies of the product in parallel trade.

Parallel importers and manufacturers are fighting for the soul of free trade in the European drug market. Restricting freedoms to repackage could make importers’ ability to import drugs to new markets virtually impossible. Restricted repackaging could allow manufacturers to retake control of the market and to choke off much of the parallel import industry. Allowing repackaging without limitation could enable importers, on the other hand, to fully compete in product design and distribute imported drugs with virtually no legal risk. Parallel imports would be placed side by side with higher-cost competitors, with few material disadvantages. With an uncertain legal regime not likely to change anytime soon, it is not only the courts but also the competitive positioning of importers and manufacturers that will determine who controls the lucrative European drug market.

46. STOTHERS, supra note 8, at 75.
47. Id.
48. Id.
49. Id.
The underlying legal principle governing repackaging is the law of the movement of goods in the Treaty of Rome, which established the European Community (the predecessor to the European Union) and created the framework for the trade of goods. Articles 28 and 29 prohibit quantitative restrictions on imports and exports as well as “all measures having equivalent effect.” Article 30 limits Articles 28 and 29 by permitting trade restrictions based upon public morality, public policy or security, the protection of human, plant, or animal life, the protection of national treasures, and the protection of industrial or commercial property. The second sentence of Article 30, however, admonishes that such restrictions “shall not . . . constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.”

These articles proved difficult for manufacturers to surmount when legal challenges to drug parallel importers arose in the 1970s. In Centrafarm BV v. Sterling Drug Inc., Sterling Drug owned patents on a drug marketed under the name Negram. Centrafarm, a parallel importer, purchased Negram in the United Kingdom and Germany and resold the drug at higher prices in the Netherlands. Sterling argued that Centrafarm could not import the drug because Sterling’s patent rights granted Sterling exclusive product control in the Netherlands.

The ECJ applied the doctrine of exhaustion to Sterling’s claim, which states that the patent owner has the right to place the product first within the European Economic Area. Once that right is exercised, however,

51. Id. arts. 28–29.
52. Id. art. 30.
53. Id.
57. Id.
58. Id. at 1151.
the patent owner has “exhausted” its authority to exercise control over the patent. The patent owner does not have the right to prevent movement or sales of its patented goods within the EU nations once initial placement of the product in the EU has occurred.60

The ECJ ruled that Sterling’s rights were exhausted when it or its subsidiaries sold the drug in the United Kingdom or Germany.61 The court reasoned that once someone acquires title to goods, the owner is free to sell those goods throughout the European Union.62 While the ECJ has allowed patent owners to prevent re-importation of products manufactured under a compulsory license,63 the doctrine of exhaustion remains largely intact.

When legal challenges under patent law failed to thwart parallel importers, drug manufacturers took a different approach. Manufacturers began to take advantage of the fact that parallel importers frequently repackaged or relabeled products in order to satisfy legal requirements or consumer needs.64 Instead of asserting patent rights over their medicines, drug firms argued that the modification of the product packaging or labeling in parallel imported goods infringed on their trademark rights.

A doctrine of trademark exhaustion does exist in the EU.65 Like patent rights, once an owner has placed a trademarked product into the stream of commerce, the trademark owner cannot prevent the importation of genuine products bearing its mark.66 Whereas parallel importers did not tamper with the manufacturer’s patented medicines, they did modify the labeling and packaging originally designed by the trademark owner. As a result, drug manufacturers had a strong case that importers were not only complying with the doctrine of exhaustion, but also actually harming the trademark rights of the manufacturers by repackaging the drugs.

Drug manufacturers using this line of argument were met with some success in Hoffmann-La Roche & Co. v. Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse mbH.67 In this case, Hoffmann-La

60. Evans, supra note 59, at 205.
64. See STOTHERS, supra note 8, at 74–75.
66. Id. at 49.
67. Case 102/77, Hoffmann-La Roche & Co. v. Centrafarm Vertriebsgesellschaft Pharmazeu-
Roche sold one-hundred- and five-hundred-tablet bottles of Valium in the United Kingdom. The ECJ ruled that the “essential function” of a trademark was to guarantee the identity of origin of the product to the consumer. This allows the consumer to be certain that the product purchased was not subject to interference by a third party without authorization of the trademark owner.

The ECJ acknowledged, however, that a situation might exist where a challenge to repackaging could be an improper “disguised restriction” of trade under Article 30 of the Treaty of Rome. The court established four conditions that must be satisfied in order for a repackaging importer to insulate itself from a trademark challenge.

First, the assertion of the trademark by its proprietor must contribute to the artificial partitioning of the markets between Member States. Second, the repackaging cannot adversely affect the original condition of the product. Third, the proprietor of the mark must receive prior notice of the marketing of the repackaged product. Fourth, the name of the person responsible for the repackaging must be stated on the new package.

The court considered these factors in Pfizer Inc. v. Eurim-Pharm GmbH. In Pfizer, the parallel importer repackaged original blister strips into new folding boxes with transparent fronts through which the owner’s trademark on the original packaging was visible. The ECJ concluded that the arrangement “create[d] no risk of exposing the product to interference or influences which might affect its original condition.” The consumer was also not likely to be misled by the original
mark, because the external wrapping disclosed that the product was manufactured by a subsidiary of the mark holder and that the product was repackaged by the importer. Inclusion of a patent information leaflet required by national law did not affect the court’s ruling.

This early ruling created uncertainty. In ruling for the parallel importers, the court in Pfizer focused solely on the second and fourth factors raised in Hoffmann-La Roche. The court did not address the first and third questions about notice and identity. This left both drug firms and importers to guess whether these remaining requirements held any real meaning for reviewing courts in these cases.

The EU was presented with an opportunity to clarify repackaging rules with Council Directive No. 89/104/EEC, also known as the Trade Mark Directive, which first was introduced into EU law in 1989 and was required to be incorporated into all national laws by 1991. Article 7(1) of the Trade Mark Directive states that a trademark owner cannot prohibit the use of its mark on goods that have already been placed into the European Community market by the trademark owner or with its consent by another. This exhaustion rule is limited under Article 7(2), which states that Article 7(1) 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 been put on the market.” The Trade Mark Directive does not define what constitutes a change or impairment.

B. Increasing Complexity: Bristol-Myers Squibb v. Paranova and Its Contemporaries

After the introduction of the Trade Mark Directive, the number of repackaging cases began to multiply. The next major dispute involved consolidated cases referred to the ECJ from Danish and German courts.

82. Id. at 2926–27.
83. Id. at 2927.
84. Compare id. at 2925–27 (evaluating whether a prevention of marketing constitutes a restriction of trade under Article 36 of the Treaty of Rome using only the second and fourth factors identified in Hoffmann-La Roche), with Case 102/77, Hoffmann-La Roche & Co. v. Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse mbH, 1978 E.C.R. 1139, 1166 (proposing four factors for evaluating whether a prevention of marketing constitutes a restriction of trade under Article 36 of the Treaty of Rome).
85. STOTHERS, supra note 8, at 78.
87. Id. art. 7.
88. Id.
89. See STOTHERS, supra note 8, at 79.
In a case widely known as "Bristol-Myers Squibb v. Paranova A/S," parallel importer Paranova purchased branded drugs in Greece, Spain, Portugal, and the United Kingdom in order to resell them in higher-priced markets in Denmark. Paranova placed the medicines in new and uniform white packaging with colored strips that corresponded to the manufacturers’ original packaging. The packaging displayed the manufacturers’ trademarks and a statement that the drugs were manufactured by the trademark owners and were “imported and repackaged by Paranova." In some instances, Paranova changed the size of packages, while in others, Paranova placed the medicines in new packaging with original padding. In other instances, Paranova covered the original labels with its own that featured the manufacturers’ trademarks. The mark owners unsuccessfully argued that Trade Mark Directive Article 7 prevented ECJ case law from extending exhaustion to incidences of repackaging. The ECJ stated that nothing in Article 7 restricted the scope of previous case law and that the Trade Mark Directive “cannot justify obstacles to intra-Community trade save within the bounds set by the Treaty rules.”

One of the most important contributions of "Bristol-Myers Squibb" is the articulation of five factors that now serve as the test for determining whether modification of product packaging by a parallel importer is susceptible to challenge by the trademark owner. Trademark owners can challenge packaging modifications unless:

1. The challenge would contribute to the artificial partitioning of the markets and, in particular, where the owner is selling identical products in several Member States in various forms of packaging, [and] the repackaging carried out by the importer is necessary in order to market the product in the Member State of importation.
2. Repackaging cannot affect the original condition of the produ-
3. Repackaging clearly states the firm that repackaged the product.\textsuperscript{100}

4. Presentation of the repackaged product will not damage the reputation of the trademark and thus [the product] must not be defective, poor quality or untidy.\textsuperscript{102}

5. The importer gives notice to the trademark owner before the repackaged product is sold and if requested supplies the trademark owner with a specimen of the repackaged product.\textsuperscript{103}

In joined companion cases decided on the same day, the ECJ in Eurim-Pharm Arzneimittel GmbH v. Beiersdorf AG directly addressed the viability of reproducing manufacturers’ trademarks on new packaging.\textsuperscript{104} In this case, the parallel importer engaged in repackaging activity substantially similar to Bristol-Meyers above.\textsuperscript{105} The ECJ allowed the importer to relabel the products with the manufacturers’ trademark, reasoning that there is no reason in principle to distinguish between the situation where a third party reaffixes the trade mark after repackaging the product, and the situation where, after the product has been repackaged, he uses the trade mark affixed to the original packaging by the manufacturer by leaving it visible through new external packaging or by retaining the original external packaging itself.\textsuperscript{106}

\textit{Beiersdorf} obfuscated the meaning of the first factor—namely, whether the manufacturers challenge of the importer would contribute to the “artificial partitioning” of free markets. \textit{Beiersdorf} stated that manufacturers cannot challenge an importer’s repackaged use of the manufacturer’s mark if that use is “necessary in order to market” the product in the target market.\textsuperscript{107} The court did not clarify what the term

\begin{flushleft}
\textsuperscript{100} Id. at I-3536.
\textsuperscript{101} Id. at I-3539.
\textsuperscript{102} Id. at I-3540.
\textsuperscript{103} Id. at I-3541.
\textsuperscript{105} Compare id. at I-3611–13 (detailing importer’s repackaging practices), with Bristol-Myers Squibb, 1996 E.C.R. at I-3521–23 (discussing Paranova’s repackaging practices).
\textsuperscript{107} Id. at I-3622 (“The power of the owner of trade mark rights protected in a Member State to oppose the marketing of repackaged products under the trade mark should be limited only in so
“necessary in order to market” means. The phrase could be interpreted literally, and mean only what is absolutely needed to give the importer bare access to the market. The phrase could also be interpreted in a context of reasonableness, and could mean that the importer may do whatever is necessary to reasonably compete in the market against rivals. There has been no clear answer to these questions.

\textit{Beiersdorf} broadened the discretion of parallel importers by allowing them not only to retain the manufacturer’s mark, but also to reproduce their mark on drug products as they see fit. The court no longer just condones “passive” reselling of branded products, but enables resellers to actively reproduce the manufacturer’s brand.\textsuperscript{108} At the same time, however, \textit{Beiersdorf} also allowed manufacturers more easily to challenge repackaging on the grounds of omission of or inaccurate information concerning the nature, composition, effect, use, or storage of the product.\textsuperscript{109} This would also encompass inclusion of extra articles (such as a medicine dropper) that aid ingestion, and monitoring dosage levels in a fashion that the manufacturer did not intend.\textsuperscript{110} \textit{Beiersdorf}’s granting of increased discretion to both the importer to rebrand and the manufacturer to challenge this rebranding virtually guarantees litigation will continue over these issues.

\section*{C. The Near-Perpetual Saga of Boehringer Ingelheim v. Swingward}

Opaque as these cases might be, they were merely a prelude for the labyrinthine dispute of \textit{Boehringer Ingelheim KG v. Swingward Ltd}. The saga began in the High Court of England and Wales, where the case had the name of \textit{Glaxo Group Ltd. v. Dowelhurst Ltd}.\textsuperscript{111} The court there faced trademark challenges to a range of repackaging activities. In some cases the parallel importer attached labels to the original packaging while other drugs were repackaged using the manufacturer’s trademark.\textsuperscript{112} Still other repackages did not bear the manufacturer’s trademark on the outer packaging but retained it for the inner packaging.\textsuperscript{113}

\begin{footnotes}
\item[108] See Hays, supra note 16, at 842–43 (arguing that this conclusion expands the exhaustion doctrine beyond its typical construction).
\item[110] See \textit{id}.
\item[112] \textit{Id.} at 577.
\item[113] \textit{Id.} at 578.
\end{footnotes}
Patient information leaflets with the manufacturer’s trademark were also added.\textsuperscript{114}

The parties offered predictable arguments. The parallel importers relied on previous ECJ cases to assert that the manufacturers cannot use their trademark rights to impede the defendants’ marketing and sale of the products within the European Community.\textsuperscript{115} The manufacturers responded that the ECJ cases only permit an importer to infringe upon a trademark to the extent that such infringement is necessary to participate in the import market.\textsuperscript{116}

In a lengthy opinion, the court rejected the notion that manufacturers could challenge any use of its mark that was not necessary in order to market the product, because the court concluded that prior ECJ cases did not sufficiently justify this interpretation.\textsuperscript{117} Parallel importers can use manufacturers’ trademarks to commercialize their products. The court concluded that the mark owner could only prohibit repackaging activities that would substantially damage the trademark’s “subject matter,” such as the reputation of the mark.\textsuperscript{118} When this harm occurs, the mark owner can object unless the use is necessary to enter the market, or the objection amounts to an arbitrary discrimination or disguised restriction on trade.\textsuperscript{119}

The court then referred eight questions, some with multiple subparts, to the ECJ.\textsuperscript{120} Among other questions, the court asked whether trademark owners could object to repackaged goods when repackaging was not necessary for the importation but caused no substantial harm to the trademark.\textsuperscript{121} The court also inquired, assuming that the necessity requirement existed, whether necessity meant what is required to market the goods or simply what is indispensable to enabling the goods to be placed on the market.\textsuperscript{122}

Two years later, the ECJ replied in \textit{Boehringer Ingelheim KG v. Swingward Ltd.}\textsuperscript{123} The court stated that importer repackaging of a product is likely to create “real risks” to a trademark’s guarantee of origin.\textsuperscript{124}

\begin{footnotes}
\item 114. \textit{Id.}
\item 115. \textit{Id.} at 578–79.
\item 116. \textit{Id.} at 579.
\item 117. \textit{Id.} at 649.
\item 118. \textit{Id.}
\item 119. \textit{Id.}
\item 120. \textit{Id.} at 651–52.
\item 121. \textit{Id.} at 651.
\item 122. \textit{Id.}
\item 123. Case C-143/00, Boehringer Ingelheim KG v. Swingward Ltd., 2002 E.C.R. I-3759.
\item 124. \textit{Id.} at I-3778.
\end{footnotes}
The repackaging of trademarked pharmaceutical products is inherently prejudicial and it is not required for a court to assess the actual effect of the repackaging by the parallel importer. In other words, the manufacturer has the right to prevent repackaging except where it is “necessary” for the importer.

The court also addressed the impact of negative consumer perceptions toward foreign-labeled products. A trademark owner could oppose the use of replacement packaging if the less-invasive relabeled alternative would permit effective access to the market concerned. If consumer resistance to relabeling exists, this does not necessarily mean that repackaging by the importer is permissible. However, the court explained that if the market exhibits strong resistance from a significant proportion of consumers to relabeled pharmaceutical products, a hindrance to market access exists and repackaging will be permitted to achieve effective market access. The court was careful to say that repackaging under these circumstances would not be permitted solely to secure a commercial advantage.

The court concluded that replacement packaging is objectively necessary if, without such repackaging, effective access to the market or a substantial part of that market would be hindered as a result of “strong resistance” from a “significant proportion of consumers” to relabeled pharmaceutical products.

The ECJ decision shows that what is “necessary” for a parallel importer will be interpreted narrowly. The decision, however, does not explain what constitutes a “strong resistance” and how many consumers constitute a “significant proportion” such that a parallel importer would be allowed to repackage rather than only relabel. This task would be left to the over two dozen European national courts, potentially creating still more questions requiring further time-consuming references to the ECJ.

The case returned to the English court, which grudgingly applied the ECJ’s judgment. The judge wrote with apparent disdain for the ECJ’s restrictive views on repackaging, remarking that the ECJ’s notion that
repackaging is always prejudicial to a trademark’s subject matter is “an irrebuttable legal fiction unconnected with the facts.”\textsuperscript{133}

On appeal, the Court of Appeal of England and Wales concluded that repackaging of pharmaceuticals can be necessary to overcome strong resistance to relabeled boxes.\textsuperscript{134} Repackaging was not irrefutably prejudicial to the owner’s trademark.\textsuperscript{135} Yet, the Court of Appeal felt it needed to refer still more questions to the ECJ further defining the meaning of necessity.\textsuperscript{136} The court lamented the overwhelming reams of documents submitted by the parties in hopes of defining the term, so much so that it suggested holding hearings to protect the parties from their lawyers’ legal fees.\textsuperscript{137} The court commented on the ballooning complexity in this case, stating 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.”\textsuperscript{138} In spite of this, the court concluded that “[d]espite years of repackaging cases in the ECJ, I am afraid it is necessary to refer the matter yet again.”\textsuperscript{139}

Before the case reached the ECJ, Advocate General Sharpston (who is not a member of the court but is relied upon to offer public, non-binding opinions on most cases before the ECJ hears them) authored an opinion.\textsuperscript{140} In 2006, the Advocate General stated: “It 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.”\textsuperscript{141} In 2007, the ECJ responded to the English court’s reference. The references can be encapsulated into five issues. First, the court stated that repackaging would be permitted if it were shown that repackaging or relabeling in general was necessary and that each and every aspect of the repackaging need not be justified.\textsuperscript{142} Second, drug manufacturers may show damage to their reputa-
tion from relabeling or repackaging from virtually any source and not just defective, poor quality, or untidy packaging.\footnote{Id. at I-3459.} Third, de-branding, co-branding, partial or total obscuring, or printing the parallel importer’s name in capital letters are not per se detrimental and should be resolved on a case by case basis by a national court.\footnote{Id. at I-3460–61.} Fourth, the parallel importer has the obligation to show the legitimacy of his actions: the trademark owner need not show the importer’s actions are impermissible.\footnote{Id. at I-3464–65.} Fifth, failure to notify the manufacturer of relabeling or repackaging may result in a proportionate and effective sanction with financial remedies being determined in light of the injury to the manufacturer.\footnote{Id. at I-3468.}

The case then returned once again to the English Court of Appeal.\footnote{Boehringer Ingelheim KG v. Swingward Ltd., [2008] 2 C.M.L.R. 22.} The 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 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 relabelling parallel imports going back at least 30 years . . . ), there is still room for argument.\footnote{Id. ¶ 2.}

The court was prepared to conclude that the parallel importers had complied with the fourth \textit{Bristol-Myers Squibb} condition, namely, that their repacking and relabeling activities have not caused damage to the reputation of the manufacturers’ trademarks.\footnote{Id. ¶¶ 43–50, 60.} However, the court learned of another pending reference to the ECJ about repackaging originating from the Austrian Supreme Court in May 2005.\footnote{Id. ¶ 60.} The reference asked the ECJ two questions. The first question inquired into whether the importer must show that either repackaging is necessary or that each individual aspect of the repackaging is necessary.\footnote{Id. ¶ 61.} If the
ECJ’s answer to the first question was “no,” then the second asked whether the harm incurred by the new packaging was measured according to a “minimum intervention” guideline or with reference to the reputation of the trademark and its owner.\textsuperscript{152}

These questions, however, apparently already had been answered by the most recent \textit{Swingward} ECJ opinion.\textsuperscript{153} The importer must show only that repackaging is necessary, and no principle of minimum intervention exists in the \textit{Bristol-Myers Squibb} factors.\textsuperscript{154} The court stated that the second question “is surely answered . . . . Yet it is only [that question] which is being maintained by the Austrian court.”\textsuperscript{155} The ECJ could have simply referred the Austrian court to the most recent \textit{Swingward} opinion, but instead decided to separately address the Austrian reference.\textsuperscript{156}

In December 2008, the ECJ addressed these questions in \textit{Wellcome Foundation Ltd. v. Paranova Pharmazeutika Handels GmbH}.\textsuperscript{157} In this case, the court stated that the answer to the first question was “no,” and that it was already answered by \textit{Swingward} in April of 2007.\textsuperscript{158} The court then addressed the second question, and interpreted the necessary requirement: “the presentation of the packaging should be assessed only against the condition that it should not be such as to be liable to damage the reputation of the trade mark or that of its proprietor.”\textsuperscript{159} At the time of this Article, the \textit{Swingward} dispute continues in the English courts.

So then what is the state of drug repackaging law in the EU? No one knows for sure. The above discussion represents only the tip of the proverbial iceberg of cases, rulings, and factors mentioned by the ECJ.\textsuperscript{160} Yet, comprehension of the current legal environment is a necessary precursor for any guidance to firms or for the discussion of reform.

Toward this end, we attempt to reduce the complexity of these rulings through a series of exhibits explaining the requirements and nuances of importation. Exhibit 1 provides an overview of the legal environment of parallel importation in the EU. Underlying the aforementioned legal challenges are principles embedded in the Treaty of Rome

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\begin{itemize}
  \item \textsuperscript{152} \textit{Id.}
  \item \textsuperscript{153} \textit{Id.} \¶ 62.
  \item \textsuperscript{154} \textit{Id.}
  \item \textsuperscript{155} \textit{Id.}
  \item \textsuperscript{156} \textit{Id.} \¶ 63.
  \item \textsuperscript{157} Case C-276/05, \textit{Wellcome Found. Ltd. v. Paranova Pharmazeutika Handels GmbH}, C-lex No. 605J0276, 2008 WL 5332027 (Dec. 22, 2008).
  \item \textsuperscript{158} \textit{Id.} \¶¶ 20–21.
  \item \textsuperscript{159} \textit{Id.} \¶ 30.
  \item \textsuperscript{160} \textit{See, e.g., Stothers, supra} note 8, at 74–126.
\end{itemize}
\end{flushleft}
and the Trade Mark Directive prohibiting restrictions on imports between member states with certain limited exceptions. After highlighting the incentives and concerns of manufacturers and importers, Exhibit 1 presents the five *Bristol-Myers Squibb* factors that guide repackaging cases today.

If courts and companies understood these five factors, no more explanation would be necessary. Each of these five criteria, however is trapped in a maze of interpretations and limitations that have been imposed by prior and subsequent cases. It is this jurisprudential tangle that we hope the other exhibits will, perhaps modestly, help unravel.

Exhibit 2 explains the interpretation of the “necessary” prong. In other words, Exhibit 2 shows what specific repackaging practices are considered necessary for importers to sell the product and what practices, if prevented, would artificially partition markets in violation of EU law. Deliberately or not, EU cases tend to concern themselves with three repackaging practices: reboxing, relabeling, and changing trademarks. Of the three, reboxing attracts the most discussion, with separate criteria for reboxing motivated by consumer preferences or accommodation of different sizes.

Exhibit 3 addresses what types of repackaging will amount to a negative impact on the original condition of the product. Courts seem to allow internal package modifications that do not tamper with the product itself and protect the product from harm in transport and sale. The manufacturer disclosure requirement in Exhibit 4 remains relatively uncontroversial. Similarly, Exhibit 6 gives relatively clear guidance for importers to provide a sample to manufactures if requested.

Exhibit 5, however, remains a legal battleground. Manufacturers have zealously argued that importer repackaging damages the reputation of their trademark. Courts seem particularly sympathetic to this argument and have enunciated a variety of conditions that may be potentially injurious to the manufacturer’s mark. Although these conditions are not considered *per se* harmful, even minor changes such as printing the importers name in parallel to the manufacturer’s lettering can provoke a challenge by a manufacturer from which a court will consider a further factual inquiry. Even if the manufacturer fails to show harm, the ensuing legal costs and time delay can slow parallel importers and increase their costs. With at least six conditions worthy of factual inquiry and certainly more to come, the reputational damage argument is likely to be a major point of contention by manufacturers in future challenges.
In spite of extensive litigation over the decades before and after the 
Bristol-Myers Squibb factors, repackaging remains largely unresolved 
and there is little doubt that litigation between importer and manufactur-
er will continue. Broad change resolving unanswered questions is un-
likely. As a result, navigating the current legal environment is of prima-
ry importance. The next Part of this Article offers navigating strategies 
for manufacturers and importers.

III. STRATEGIES FOR IMPORTERS AND MANUFACTURERS IN THE 
CURRENT LEGAL ENVIRONMENT

The struggle over gray market drugs has been waged across an un-
usual fault line: 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 packag-
ing, the less successful importers can be in offering an alternative mar-
ket to wholesalers, national health care schemes, and pharmacists. Con-
versely, the more discretion an importer retains to repackage as it sees 
fit, the easier it is for the importer to sell products in lucrative markets. 
This Part summarizes the likely goals and practices of parallel importers 
and then presents strategies for manufacturers to combat these gray 
market products.

The importer’s goal will be to make its product packaging as compet-
tive as possible with 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. Importers 
also want to repackage as cheaply as possible. The ECJ has not suffi-
ciently 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. Im-
porters will still want to repackage competitively, but should directly 
tailor any repackaging practice to direct compulsion by national regula-
tions. 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 KG v. Swingward Ltd.*, which specifically stated that importers need only show that repackaging is necessary to enter the target market and need not 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 should not use this discretion too aggressively, however. 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 national courts should consider consumer resistance toward relabeled and “overstickered” 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 be anecdotal or may take the form of more formal and expensive consumer surveys like those used by U.S. mark owners to show trademark infringement. Although the ECJ has stated that reboxing is necessary if a substantial part of a market exhibits 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 importers 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 have created a hierarchy of tolerance for repacking, ranging from reboxing treated as the most insidious, then relabeling, and finally 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.

162. *Id.* at I-3457.
The manufacturer has a number of viable responses. First, manufacturers should carefully scrutinize the importer’s repackaged product for unnecessary modifications. 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.\textsuperscript{163} Analogous to a prelitigation 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. This strategy is beneficial to the manufacturer because it may allow the manufacturer to successfully delay distribution of a parallel import through a simple letter rather than a time-consuming lawsuit with an uncertain outcome. Additionally, the manufacturer may 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, even if the challenge is ignored, any costs the manufacturer sustains at this stage are low.

Manufacturers can also scrutinize the pervasiveness of the allegedly necessary practice that the importer is relying upon as a basis for repackaging. A manufacturer may argue that a legal requirement is not as compulsory as the importers depict. If a requirement arises from professional standards, such as a national board of physicians or 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 also 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 importers’ reliance on differential practices as a basis for repackaging 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 the Treaty of Rome. If manufacturers leave packaging too uniform, this 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. If an importer can bring drugs to the new market with no packaging changes, the importer can shield itself from a repackaging challenge.

The goal for manufacturers then would be to justify product packaging differences not only on legal grounds, but also on the importance of developing 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, the manufacturer 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 noncompetitive enhancing) purposes. Manufacturers would retain more freedom than importers to promote their brand as a higher quality and more trusted product through packaging as compared to the importer’s alternative. Potential buyers (for example, hospital purchasing agents, pharmacists, and consumers) may even be willing to pay a premium for this perceived quality and trust, eroding to some extent the importer’s low cost advantage.

The ECJ has shown a 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. Later, the ECJ ex-

panded this to include harm not only from the three descriptors above but also from virtually any source that detracts from the perceived reliability or quality of the product. Harm could potentially arise from debranding the manufacturer’s product by removing its trademark from exterior packaging, co-branding by applying the importer’s logo next to the manufacturer’s logo, 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 appear as defective to the consumer.

Even though the primary advantage importers hold over manufacturers is the lower cost of business, 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 should not blur or fade between manufacture and the sale to the consumer. The trademark should be the same size and location as it was on 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 should 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 Inc. v. Eurim-Pharm GmbH*, 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 the 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 packag-

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ing of medicine. If the internal packaging or organization makes the medicine appear dirty, discolored, or untidy in some way, this opens the door for a manufacturer challenge. If time and cost permit, 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 should be to review the importer’s packaging as closely as possible for any diminution in trademark 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 through association with inferior repackaging design. This review should consider both internal and external packaging as the consumer interacts with both packaging stages when using 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. 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 unwilling 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, and establish links between their packaging and their mark and the product. Drug manufacturers are currently not allowed to perform direct-to-consumer advertising in the EU. Manufacturers, however, 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, so can manufacturers establish secondary meaning for their complex packaging in the

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minds of potential buyers in the EU. Manufacturers may also design different packaging for different nations and develop secondary meaning for each consumer market. For example, GlaxoSmithKline sold its HIV drugs Combivir and Epivir 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.\textsuperscript{169} Thus, in 2005 GlaxoSmithKline challenged a U.K. parallel trader, Dowelhurst, for allegedly supplying the red tablets to the National Health Service.\textsuperscript{170}

Complex packaging can increase the cost to the importer who must either copy the packaging or painstakingly apply its own packaging requirements to a product design already resistant to modification. Either method will drive up the importer’s costs and, assuming that the importer has fewer resources than the manufacturer, will make repackaging practices more difficult to sustain over time. Also, the more complex the packaging, the more easily it can be diminished. The more easily the packaging can be diminished, the more readily manufacturers may argue that the importer’s efforts, however gentle or well-meaning, negatively impact the manufacturer’s 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.

CONCLUSION

Parallel importers and manufacturers are fighting for nothing less than the spirit of free trade in the European drug market to determine who controls the €133 billion European drug market. Importers want to exploit the lucrative price differentials present in European markets. Manufacturers who benefit from differentiated pricing want to isolate their products in national health systems.

Drug manufacturers and gray marketers provide conflicting information about the merits of their position. Gray marketers claim that parallel trade provides competition and savings to consumers and health insurance funds across Europe. Manufacturers, they argue, charge the highest possible price in each country market and use supply restrictions to


\textsuperscript{170} Id.
block parallel trade. Drug manufacturers respond that traders exploit the regulatory price systems set up by EU governments and do not create benefits for health care, consumers, or the economy of Europe. Manufacturers also suggest that parallel trade results in safety and quality issues that stem from these distributors handling the pharmaceuticals.

The result has been a direct tension between these two interests and a near-continuous stream of litigation in European courts. Disputes over trademark repackaging have resulted in a legal environment that is far from conclusive. Multiple layers of review and a plodding legal system create a climate of uncertainty that can provoke even more litigation. The future does not seem bright for a clear resolution.

Although current EU law is insufficient and in our opinion, parallel importers can never be eliminated altogether, several tactics were provided that firms can use to slow gray market activity through a savvy mixture of legal and marketing strategies. 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. However, unfettered importation could deprive low-cost markets of badly needed drugs and create problems with counterfeiting and negative consumer perceptions. 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. With an uncertain legal regime not likely to change anytime soon, it is not just the courts, but also the competitive positioning of this market that will affect both parallel traders and manufacturers in Europe.
EXHIBIT 1: THE LEGAL ENVIRONMENT OF PARALLEL IMPORTATION OF PHARMACEUTICAL DRUGS IN THE EUROPEAN UNION

- **Article 30**
  - Restrictions on imports prohibited between member states

- **Exhaustion of Rights**
  - Prevents firm from restricting resale of drug products in second member state

- **Trademark Directive Article 7(2)**
  - Firm may oppose further sale of goods for "legitimate reasons" especially where goods "changed or impaired"

- **Parallel Importer Concerns**
  - Regulatory Pressure: National health, safety, and language rules compel repackaging
  - Competitive Pressure: Consumer packaging preferences, brand familiarity, and insurance reimbursement

- **Drug Manufacturer Concerns**
  - Regulatory Pressure: Limited patent term; state regulations compel suboptimal pricing
  - Competitive Pressure: Recoup large R&D investment, defend trademarks, protect brand equity

- **Trademark owners may prevent repackaging of products unfairly (like as the photo below) (fake product in market)**

- **Exhibit 2**
  - 1. Challenge would contribute to artificial partitioning of markets; repackaging must be necessary to market product (Biihler v. AstraZeneca, 556 F Supp 2d 802)

- **Exhibit 3**
  - 2. Repackaging cannot affect original condition of product (Nestle v. Cenedol, 392 F Supp 1st Carlin v. Carbeston, 266 F Supp)

- **Exhibit 4**
  - 3. Repackaging clearly states the name of the firm that repackaged the product (Molnar v. P&G, 194 F Supp 2d 201)

- **Exhibit 5**
  - 4. Presentation cannot damage reputation of trademark; must not be "defective, poor quality, or unhygienic" (Raffy v. Parallel)

- **Exhibit 6**
  - 5. Importer gives notice of drug importation and provides samples if requested (Kark v. Reva, 14 F Supp 2d 201)
EXHIBIT 2: DRUG FIRMS CANNOT ARTIFICIALLY PARTITION; REPACKAGING PERMITTED ONLY WHEN “NECESSARY” (BMS FACTOR #1)

Drug firms cannot challenge importers if result would artificially partition markets (Hoffman-La Roche v. Commissioner).

Artificial partition - firms can oppose repackaging except when “necessary” to “market the product” (BMS v. Permeos).

Rerboxing inherently prejudicial; not necessary to prove actual effects (Bachrach, Banker v. Director).

What is “necessary” to market a product for parallel importation?

Rerboxing (consumer preferences)
- Necessary if “effective access” to “substantial part” of market hindered due to “strong resistance from a significant proportion of consumers to repackaged products” (Bachrach, Banker v. Director).
- Importer only has to show that repackaging overall is necessary, not every detail in manner or style is necessary (Bachrach, Banker v. Director).

Rerboxing (different sizes)
- Necessary when: (BMS v. Permeos)
  - National rate reduces package size
  - National practice makes package size
  - Insurers reimbursements depend on package size
  - Professional groups and associations recommend standard sizes
- Not necessary when: (BMS v. Permeos)
  - Importer can add new labels in local language, and make one article for and similar to meet national standards.

Retabling
- Will not be permitted when overstocking will suffice (FMC, Landespost v. Biersack).

Changing Trademarks
- Necessary when: (BMS v. Permeos)
  - Consumer protection - repackaging probably set in origin of trademark.
  - Original trademark might suffer damages if used in origin.

Permitted only when “necessary” (BMS FACTOR #1).
EXHIBIT 3: REPACKAGING MUST NOT HAVE IMPACT ON ORIGINAL CONDITION OF PRODUCT (BMS FACTOR #2)

EXHIBIT 4: REPACKAGING MUST DISCLOSE FIRM THAT REPACKAGED PRODUCT (BMS FACTOR #3)
EXHIBIT 5: PRESENTATION OF REPACKAGING CANNOT DAMAGE REPUTATION OF TRADEMARK (BMS FACTOR #4)

EXHIBIT 6: IMPORTER MUST GIVE NOTICE OF IMPORTATION AND PROVIDE SAMPLE IF REQUESTED (BMS FACTOR #5)