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

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

By:

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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 examine gray markets impacting multinational trade blocks1 and others study gray markets in Asia.2 However, most researchers study gray markets from the viewpoint of the United States.3 As a result gray markets in the European Union, known commonly there as parallel imports,4 receive relatively little notice in U.S. law reviews.

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This article attempts to fill the scholarly gap. This is particularly important because a long-standing 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. However, a proliferation of parallel importation cases filed by drug firms has sent an increasing number of questions for resolution to the ECJ, whose role it is to ensure of 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. This problematic behavior has culminated in the convoluted handling of an important parallel importation dispute, *Boehringer Ingelheim v. Swingward*, which first reached the United Kingdom high court in January, 2000, and after nine years and multiple trips to the ECJ has not yet been fully resolved. 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 pharmaceutical products by non-trademark owners for sale in the European Union market. National laws help create the repackaging problem. Ideally, parallel importers want to purchase drugs in

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> 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 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.

Id. at 662 n.1. Other courts use the term interchangeably. E.g., *Quality King Distributors, Inc. v. L’anza Research Int’l, Inc.*, 523 U.S. 135, 153 n.28 (1998) (“The parties and their amici have debated at length the wisdom or un wisdom 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.*, 514 F.3d 982, 984 n.1 (9th Cir. 2008) (using terms interchangeably). We do so as well.


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 repackage 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 the company’s trademarks and trade dress on the original packaging. Drug firms claim that repackaging by parallel importers harms the reputation of their brand and infringes on their trademark rights. The result is 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, unworkable tests, and the extremely slow pace of the transitional court has all 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 minutia 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 twofold. First, we take the necessary and important step of unraveling the very 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, as they influence not only future ECJ precedent but 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 section 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 encourage smaller firms to enter the market, thus increasing competition and reducing the likelihood of cartel-like behavior. Less litigation and more competition ultimately results in more favorable prices paid for by the consumer. The clarity and increased certainty this section brings could benefit the marketplace regardless of the position the ECJ takes now or in the future.

Part I of this article describes the drug market in the EU 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 of this article 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. Part IV concludes.

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 Euros.\(^7\) Major
country markets for pharmaceuticals include France, Germany, Italy, United Kingdom,
and Spain.\(^8\) 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 creates 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.\(^9\) These trade conditions create an
environment where the purchase price of goods differs from place to place.\(^10\) Parallel
traders exploit these price differences by transferring goods from a low cost national
market to a high cost one.\(^11\) Parallel traders benefit by profiting from the price
difference.\(^12\) Consumers benefit from purchasing a product that is below the prevailing
market price in their nation.\(^13\) Gray market products commonly find their way into
markets not intended by the manufacturer.\(^14\)

In the EU, the largest markets for gray market pharmaceuticals are in Denmark (15.2% of
total market), Germany (7.7%), the Netherlands (10.4%), Sweden (13.3%), and the U.K.
(14.7%).\(^15\) Parallel importers take advantage of the significant variance in drug prices
across European national boundaries. For example, a comprehensive study in the U.K.
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.\(^16\) Figure 1
illustrates the price variation for Atorvastatin (known as Lipitor) a cholesterol-reducing
prescription drug developed by Pfizer 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.

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\(^7\) European Commission, Pharmaceutical Sector, http://ec.europa.eu/trade/issues/sectoral/industry/chem/pharma.htm (last visited July 29, 2009) ("With an estimated share in 2007 of 35.2% of world pharmaceutical output, a global output of
nearly €182 billion, and sales of €133 billion the EU pharmaceutical industry is one of Europe’s
best-performing sectors. The EU is the second global manufacturing location for
pharmaceuticals behind the US and ahead of Japan.").

\(^8\) European Federation of Pharmaceutical Industries and Associations, The Pharmaceutical Industry in

\(^9\) Christopher Stothers, Parallel Trade in Europe: Intellectual Property, Competition and Regulatory Law
1 (2007).

\(^10\) Id. at 1.

\(^11\) Id. at 2-3.

\(^12\) Id.

\(^13\) Id.

\(^14\) Peggy Chaudhry & Alan Zimmerman, The Economics of Counterfeit Trade: Governments Consumers,

\(^15\) Id. at 5.

\(^16\) Panos Kanavos & John Costa-Font, Pharmaceutical Parallel Trade in Europe: Stakeholder and
Significant buying power wielded by publicly funded health care systems tends to push drug prices down. Government policies generally can also keep drug prices artificially low. The relative lack of such regulation and government sponsored drug purchases, such as what is seen in the Netherlands for example, means that Dutch drug prices are significantly higher. Similarly, limited competition, high consumer prices generally, and the high level of patient co-payments keeps prices high in Denmark. 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. One parallel importer might exploit favorable foreign currency exchange rates to reduce price. Another may sell otherwise acceptable quality ‘distress goods’ that have been dumped by an otherwise authorized dealer burdened with excess supply or goods that have become outdated. Other motives are more nefarious. Some 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. Other parallel importers might sell goods that are of inferior quality without notifying the consumer.

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. If a product is commonly presented in a fashion that does not significantly vary from market to market, it can increase consumer demand because it lessens the probability that the consumer will question the authenticity of the product. Consumer demand becomes particularly complex, however, when considering the EU drug market. In some markets a consumer may not know the price of the product benefits from a reduced price because government health insurance provides the drug. Consumer demand for drugs is considered to be ‘directed demand’ channeled through a doctor. The ultimate decision maker on many cases is not the drug user but the prescribing doctor or

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18 Lipner, supra note 4, at 8.
19 Id.
21 Lipner, supra note 4, at 9.
22 Id.
pharmacist. As a result, consumers may not be as sensitive to price when compared to other products. That 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 the goods are of sufficient quality. The result is a trading environment whereby numerous interest groups influence the pharmaceutical supply chain and have varying incentives toward how parallel imports are treated. A graphical explanation revealing the complex interaction of various private and public interests is available in Figure 2.

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. That arbitrage comes from traders buying drugs in regulated low-priced markets and selling them in higher-priced free markets. Exploiting such arbitrage successfully is not simply a matter of transporting a good from one nation to another. 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 can all erode or eliminate any benefit from parallel trade.

The evidence appears to be mixed regarding whether gray markets improve consumer welfare. The most obvious benefit is that consumers benefit from the lower price that gray market sellers offer. 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 the consumers in the form of a lower tax burden. Manufacturers respond that gray marketers receive the benefits of expensive advertising campaigns without incurring any of the accompanying costs. Distributors who hold exclusive contracts with the manufacturer find those contracts less valuable as they fend off unanticipated gray market competition.

25 Id.
26 Id.
27 See, e.g., Howell et al., supra note 23; Chaudhry & Walsh, supra note 1, at 21.
28 Lipner, supra note 4, at 75.
30 Id.
31 Id. at 110.
32 Id.
Two venues exist for 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 regulated medicine, the patient’s final price is really the level of co-payment 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.

That does not necessarily mean, however, that all benefits of gray markets pass onto the consumer. A U.K. study examined these plausible benefits to the consumer in six European countries: Denmark, Germany, Greece, the Netherlands, Norway and the United Kingdom. The U.K. 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 concluded:

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.

One of the most effective forces at negating benefits to consumer welfare from gray markets might be the gray marketers themselves. 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 the authorized channel. To illustrate this point, the U.K. study 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 health 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

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34 Kanavos et al., supra note 33, at 88.


36 Kanavos et al., supra note 33, at 160.

37 Id. at 160.
products ranged from a high of 21% for Fluoxetine to 5% for Simvastatin, Valsartan, and Sertraline. These researchers estimated that the profits to parallel traders were over five times as large as the savings to the German health insurance program.

The Social Market Foundation in the UK estimates that seventy percent of all of the EU parallel trade in pharmaceuticals ends up in the UK marketplace and reduces government health care costs by up to €269 million per year. 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. One would believe that competition between parallel traders should keep prices low. Intriguingly, this does not always happen. One reason may be that manufacturer lawsuit threats raise barriers to entry and keep out all but the largest importer firms from competing. This would result 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 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. For example, a UK drug recall in 2007 fueled the controversy about counterfeit drugs entering the supply chain via parallel trade. 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 argument that consumers benefit from lower prices for potentially life-saving pharmaceuticals is compelling, but there is evidence 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 with little success. In spite of distributor discounts, changes in product, 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 which could cripple or even prevent drug parallel importing is of major importance to both importers and the manufacturers but has been rarely discussed in the literature. This issue, the seemingly innocuous

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38 Id.
39 Id.
43 See, e.g., Antia, Bergen & Dutta, supra note 3, at 67-69; Chaudhry & Walsh, supra note 1, at 21.
question of product repackaging by parallel importers, is the subject of the next section of this article.

II. REPACKAGING AND THE LAW OF PARALLEL IMPORTS

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 overstickier 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.

Parallel importers and manufacturers are fighting for the soul 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 lucrative European drug market.

The underlying legal principle governing repackaging is the law of the movement of goods in the EU Treaty, also known as the treaty of Rome, which established the European Union (formerly known as the European Community) 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

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44 STOTHERS, supra note 9, at 75.
45 Id.
46 Id.
47 Id.
49 Id. arts. 28 & 29.
national treasures, and the protection of industrial or commercial property.\textsuperscript{50} 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.”\textsuperscript{51}

These articles proved difficult for manufacturers to surmount when legal challenges to drug parallel importers took place in the 1970s.\textsuperscript{52} In \textit{Centrafarm v. Sterling},\textsuperscript{53} Sterling Drug, Inc. owned patents on a drug marketed under the name Negram.\textsuperscript{54} Centrafarm, a parallel importer, purchased Negram in the United Kingdom and Germany and resold the drug at higher prices in the Netherlands.\textsuperscript{55} Sterling argued that Centrafarm could not import the drug because its patent rights granted exclusive product control to Sterling in the Netherlands.\textsuperscript{56}

The ECJ applied the doctrine of exhaustion to Sterling’s claim. The exhaustion of rights doctrine states that the patent owner has the right to place the product first within the European Economic Area.\textsuperscript{57} Once that right is exercised, however, 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.\textsuperscript{58}

The ECJ ruled that Sterling’s rights were exhausted when it or its subsidiaries sold the drug in the United Kingdom or Germany.\textsuperscript{59} The court reasoned that once someone acquires title to goods, the owner is free to sell those goods throughout the European Union.\textsuperscript{60} While the ECJ has allowed patent owners to prevent re-importation of products manufactured under a compulsory license,\textsuperscript{61} the doctrine of exhaustion remains largely intact.

\textsuperscript{50} Id. art. 30.
\textsuperscript{51} Id.
\textsuperscript{54} Centrafarm, 2 C.M.L.R. at 484.
\textsuperscript{55} Id.
\textsuperscript{56} Id. at 504.
\textsuperscript{57} Deutsche Grammophon v. Metro, Case 78/70, (1971) E.C.R. 487. \textit{See also} Gail E. Evans, \textit{Strategic Patent Licensing for Public Research Organizations: Deploying Restriction and Reservation Clauses to Promote Medical R&D in Developing Countries}, 34 AM. J.L. & MED 175, 205 (2008).
\textsuperscript{58} Evans, \textit{supra} note 57, at 205.
\textsuperscript{60} Id. at 503-04.
When legal challenges under patent law failed to thwart parallel importers, drug manufacturers took a different tack. Manufacturers took advantage of the fact that parallel importers frequently had repackaged or relabeled their products in order to satisfy legal requirements or consumer needs.\textsuperscript{62} Instead of asserting patent rights over their medicines, drug firms argued that the modification of the product packaging or labeling in parallel imported goods infringes on their trademark rights.

A doctrine of trademark exhaustion does exist in the European Union.\textsuperscript{63} 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.\textsuperscript{64} Whereas parallel importers did not tamper with the manufacturer’s patented medicines, they were modifying the labeling and packaging originally designed by the trademark owner. As a result, drug manufacturers had a stronger case that importers were not simply complying with the doctrine of exhaustion, but through repackaging actually harming the trademark rights of the manufacturers.

Drug manufacturers using this line of argument met with some success in \textit{Hoffmann-La Roche v. Centrafarm}.\textsuperscript{65} In this case, Hoffmann La Roche sold five-hundred tablet bottles of Valium in the United Kingdom which the Centrafarm repackaged into one-thousand tablet bottles, affixed the Valium and Roche trademarks, and sold the drug in Germany.\textsuperscript{66} The ECJ ruled that the ‘essential function’ of a trademark was to guarantee the identity of origin of the product to the consumer.\textsuperscript{67} This would allow the consumer to be certain that the product purchased was not subject to interference by a third party without authorization of the trademark owner.\textsuperscript{68} The ECJ affirmed the right of the trademark owner to challenge their trademark being applied to repackaged goods.\textsuperscript{69}

The ECJ acknowledged, however, that a situation could exist where a challenge to repackaging could be an improper ‘disguised restriction’ of trade under Article 30.\textsuperscript{70} The court established four conditions which must be satisfied in order for a repackaging importer to insulate itself from a trademark challenge.\textsuperscript{71} First, the assertion of the trademark by its proprietor will contribute to the artificial partitioning of the markets between Member States.\textsuperscript{72} Second, the repackaging cannot adversely affect the original condition of the product.\textsuperscript{73} Third, the proprietor of the mark receives prior notice

\textsuperscript{62} See \textit{S. Others}, supra note 9, at 74-75.
\textsuperscript{64} \textit{Id.} at 49.
\textsuperscript{66} \textit{Id.} ¶2.
\textsuperscript{67} \textit{Id.} ¶7.
\textsuperscript{68} \textit{Id.}
\textsuperscript{69} \textit{Id.} ¶8.
\textsuperscript{70} \textit{Id.} ¶9.
\textsuperscript{71} \textit{Id.} ¶14.
\textsuperscript{72} \textit{Id.}
\textsuperscript{73} \textit{Id.}
of the marketing of the repackaged product.\textsuperscript{74} Fourth, the name of the person responsible for the repackaging is stated on the new package.\textsuperscript{75}

The court considered these factors in \textit{Pfizer v. Eurim-Pharm.}\textsuperscript{76} In this case, the parallel importer repackaged original blister strips into new folding boxes with transparent fronts through which owner’s trademark on the original packaging was visible.\textsuperscript{77} The ECJ concluded that the arrangement did not create any risk of exposing the product to interference or influence which might affect its original condition.\textsuperscript{78} The consumer was also not likely to be misled as the original mark was visible as well as the disclosure on the external wrapping that the product was manufactured by a subsidiary of the mark holder and was repackaged by the importer.\textsuperscript{79} Inclusion of a patent information leaflet required by national law did not affect the result.\textsuperscript{80}

This early ruling created uncertainty. In ruling for the parallel importers, the court focused solely on the second and fourth questions raised in \textit{Hoffmann-La Roche v. Centrafarm.}\textsuperscript{81} The court did not address the first and third questions about notice and identity.\textsuperscript{82} 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 a good opportunity to clarify repackaging rules with Council Directive No. 89/104/EEC, also known as the Trade Marks Directive (Directive), was first introduced into EU law in 1989 was required to be introduced into national laws by 1991 with the purpose of harmonizing trademark law.\textsuperscript{83} Article 7(1) of the Directive states that a trademark owner cannot prohibit the use of its mark on goods that have already placed into the EC market by the trademark owner or with its consent by another. \textsuperscript{84} 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 put on the market.”\textsuperscript{85} The Directive does not further define what constitutes a change or impairment.\textsuperscript{86}

After the Directive, the number of repackaging cases had begun to multiply. The next major dispute involved consolidated cases referred to the ECJ from Danish and German courts. In a case widely known as \textit{Bristol-Myers Squibb v. Paranova,}\textsuperscript{87} parallel

\textsuperscript{74} Id.
\textsuperscript{75} Id.
\textsuperscript{77} Id. ¶ 4.
\textsuperscript{78} Id. ¶ 11.
\textsuperscript{79} Id.
\textsuperscript{80} Id. ¶ 12.
\textsuperscript{81} Hoffmann-La Roche & Co. v. Centrafarm, 1978 E.C.R. 1139.
\textsuperscript{82} See STOTHERS, supra note 9, at 78.
\textsuperscript{84} Id., art. 7.
\textsuperscript{85} Id.
\textsuperscript{86} See STOTHERS, supra note 9, at 79.
\textsuperscript{87} (1996) E.C.R. I-3457.
importer Paranova purchased branded drugs in Greece, Spain, Portugal and the United Kingdom in order to resell them in higher-priced Denmark.\textsuperscript{88} Paranova placed the medicines in new and uniform white packaging with colored strips that corresponded to the manufacturers’ original packaging.\textsuperscript{89} The packaging displayed the manufacturers’ trademarks and a statement that drugs were manufactured by the trademark owners and “imported and repackaged by Paranova.”\textsuperscript{90} In some cases Paranova also changed the size of packages while in others placed the medicines in new packaging with original padding.\textsuperscript{91} In other cases Paranova covered the original labels with its own that showed the manufacturers’ trademarks.\textsuperscript{92} The mark owners unsuccessfully argued that Trademark Directive Article 7 prevented ECJ case law from extending exhaustion to incidences of repackaging.\textsuperscript{93} The ECJ stated that nothing in Article 7 restricted the scope of previous case law and that the Trademark Directive “cannot justify obstacles to intra-Community trade save within the bounds set by the Treaty rules.”\textsuperscript{94}

One of the most important contributions of \textit{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.\textsuperscript{95} 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, the repackaging carried out by the importer is necessary in order to market the product in the Member State of importation.\textsuperscript{96}

2. Repackaging cannot affect the original condition of the product.\textsuperscript{97}

3. Repackaging clearly states the firm that repackaged the product.\textsuperscript{98}

4. Presentation of the repackaged product will not damage the reputation of the trademark and thus must not be defective, poor quality or untidy.\textsuperscript{99}

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{100}

\textsuperscript{88} Id. at ¶ 10.
\textsuperscript{89} Id. ¶ 11.
\textsuperscript{90} Id.
\textsuperscript{91} Id. ¶ 12, 15.
\textsuperscript{92} Id.
\textsuperscript{93} See id. ¶¶ 32-33, 37.
\textsuperscript{94} Id. ¶ 36. See generally Hays, supra note 17, at 842-44 (discussion of repackaging under the Trade Mark Directive).
\textsuperscript{95} These five factors and courts’ interpretation of them are summarized in Exhibits 1-5, \textit{infra}.
\textsuperscript{96} \textit{Bristol-Myers Squibb} v. Paranova, 1996 E.C.R. I-3457, at ¶¶ 52-57.
\textsuperscript{97} Id. ¶ 59.
\textsuperscript{98} Id. ¶ 70.
\textsuperscript{99} Id. ¶ 75-76.
In joined companion cases decided on the same day, the ECJ in *Eurim-Pharm Arzneimittel v. Beiersdorf*\(^{101}\) addressed directly the viability of reproducing manufacturers’ trademarks on new packaging. The parallel importer engaged in repackaging activity substantially similar to *Bristol Meyers* above.\(^{102}\) 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.”\(^{103}\)

*Beiersdorf* obfuscated the meaning of the first factor, whether the manufacturers challenge of the importer would contribute to the ‘artificial partitioning’ of free markets. *Beiersdorf* stated that manufacturers cannot challenge an importer’s repackaged use of its mark if that use is “necessary in order to market” the product in the target market.\(^{104}\) The court did not clarify what exactly “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 mean that the importer may do whatever is necessary to reasonably compete in the market against rivals. No clear answer exists.

*Beiersdorf* broadened the discretion of parallel importers by allowing them to not only retain the manufacturer’s mark, but reproduce their mark on drug products as they see fit. The court no longer just condones ‘passive’ reselling of branded products, but enables res-sellers to actively reproduce the manufacturer’s brand.\(^{105}\) At the same time, *Beiersdorf* allowed manufacturers to more easily challenge repackaging including on the grounds of omission of or inaccurate information concerning the nature, composition, effect, use or storage of the product.\(^{106}\) This would also include placement of extra articles designed for ingestion and dosage that do not comply with use and doses envisaged by the manufacturer.\(^{107}\) *Beiersdorf*’s granting of increased discretion to both the importer to rebrand and the manufacturer to challenge it virtually guarantees that litigation will continue over these issues.

Opaque as these cases might be, they were just a prelude for the labyrinthine dispute of *Boehringer Ingelheim v. Swingward*. The saga began in the England and Wales high

\(^{100}\) *Id.* ¶78.

\(^{101}\) 1996 E.C.R. I-3603.

\(^{102}\) *See id.* at ¶¶ 10-18.

\(^{103}\) *Id.* ¶38.

\(^{104}\) *Id.* at ¶ 46. (“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 far as the repackaging undertaken by the importer is necessary in order to market the product in the Member State of importation.”).

\(^{105}\) Hays, *supra* note 17, at 842-43. This conclusion expands the exhaustion doctrine beyond how it is typically interpreted. *Id.*

\(^{106}\) *Beiersdorf*, at ¶156.

\(^{107}\) *Id.*
court, where the case had the name of *Glaxo Group v. Dowelhurst Ltd.* 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. Still other repackages did not bear the manufacturer’s trademark on the outer packaging but retained it for the inner packaging. Patient information leaflets with the manufacturer’s trademark were also added.

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 their products in the EC. 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.

After a lengthy opinion, the court rejected the notion that manufacturers could challenge any use of its mark that was not ‘necessary’ because the ECJ cases did not sufficiently justify this interpretation. 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. 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.

The court then referred eight questions, some with multiple subparts, to the ECJ. Among other questions, the court asked whether trademark owners could object to repackaged goods when repackaging was not necessary for the importation but also caused no substantial harm to the trademark. 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.

Two years later, the ECJ replied in *Boehringer Ingelheim v. Swingward*. The court stated that importer repackaging of a product is likely to create “real risks” to a trademark’s guarantee of origin. The repackaging of trademarked pharmaceutical

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109 *Id.* ¶ 4.
110 *Id.*
111 *Id.*
112 *Id.* ¶ 6.
113 *Id.*
114 *Id.* ¶ 193.
115 *Id.*
116 *Id.*
117 *Id.* ¶ 195.
118 *Id.*
119 *Id.*
121 *Id.* ¶ 29.
products is inherently prejudicial and it is not required for a court to assess the actual effect of the repackaging by the parallel importer.\textsuperscript{122} In other words the manufacturer has the right to prevent repackaging except where it is necessary for the importer.\textsuperscript{123}

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.\textsuperscript{124} If consumer resistance to relabeling exists, that does not necessarily mean that repackaging by the importer is permissible.\textsuperscript{125} However, if the market exhibits strong resistance from a significant proportion of consumers to relabeled pharmaceutical products, a hindrance to market access exists and repackaging would be permitted to achieve effective market access.\textsuperscript{126} The court was careful to say that repackaging under these circumstances would not be permitted solely to secure a commercial advantage.\textsuperscript{127} 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.\textsuperscript{128}

The ECJ decision shows that what is necessary for a parallel importer will be interpreted narrowly. The court does not explain, however, 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 just relabel. The 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 courts, where the court grudgingly applied the ECJ’s judgment.\textsuperscript{129} 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{130}

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{131} Repackaging was not irrefutably prejudicial to the owner’s trademark. Yet, the court felt it needed to refer still more questions to the ECJ further defining the meaning of necessity.\textsuperscript{132} The court lamented the overwhelming reams of documents submitted by the parties, so much so that it suggested holding hearings to protect the

\begin{itemize}
  \item[\textsuperscript{122}] Id. \textsuperscript{¶} 30.
  \item[\textsuperscript{123}] Id. \textsuperscript{¶¶} 31-35.
  \item[\textsuperscript{124}] Id. \textsuperscript{¶} 50.
  \item[\textsuperscript{125}] Id. \textsuperscript{¶} 51.
  \item[\textsuperscript{126}] Id. \textsuperscript{¶} 52.
  \item[\textsuperscript{127}] Id.
  \item[\textsuperscript{128}] Id. \textsuperscript{¶} 54.
  \item[\textsuperscript{129}] Glaxo Group Ltd. v. Dowelhurst Ltd. \textsuperscript{[2003]} 2 C.M.L.R. 8.
  \item[\textsuperscript{130}] Id. \textsuperscript{¶} 15.
  \item[\textsuperscript{131}] Boehringer Ingelheim KG v. Swingward Ltd., \textsuperscript{[2004]} C.M.L.R. 3, at \textsuperscript{¶¶} 38, 45 & 49.
  \item[\textsuperscript{132}] Id. \textsuperscript{¶¶} 85-99.
\end{itemize}
parties from their lawyers’ legal fees.\textsuperscript{133} 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{134} 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{135}

Before reaching the ECJ Advocate General Sharpston, who is not a member of the court but is relied upon to offer public and non-binding opinions on most cases before the ECJ hears them, authored an opinion.\textsuperscript{136} In 2006, the Advocate General stated that, “(t)he law should be able to distil sufficient principles to enable national courts to apply the law to the constantly replayed litigation between manufacturers and parallel importers.”\textsuperscript{137} In 2007, the ECJ responded to the English court’s reference.\textsuperscript{138} The references can be encapsulated into five questions. First, the court stated that repackaging would be permitted if it was shown that repackaging or relabeling in general was necessary and that it need not be justified.\textsuperscript{139} Second, drug manufacturers may show damage to their reputation from relabeling or repackaging from virtually any source and not just defective, poor quality or untidy packaging.\textsuperscript{140} Third, de-branding, co-branding, partial or total obscuring, or printing the parallel importer’s name in capital letters are not \textit{per se} detrimental and should be resolved on a case by case basis for a national court.\textsuperscript{141} Fourth, the parallel importer has the obligation to show the legitimacy of his actions rather than the trademark owner being required to show the importer’s actions are impermissible.\textsuperscript{142} 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 injury to the manufacturer and proportionality.\textsuperscript{143}

The case then returned once again to the English Court of Appeal.\textsuperscript{144} The court expressed its frustration in no uncertain terms:

\begin{quote}
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
\end{quote}

\begin{footnotes}
\textsuperscript{133} Id. ¶ 113.
\textsuperscript{134} Id. ¶ 79.
\textsuperscript{135} Id. ¶ 85.
\textsuperscript{137} Id. ¶ 3.
\textsuperscript{139} Id. ¶ 39.
\textsuperscript{140} Id. ¶ 44.
\textsuperscript{141} Id. ¶ 47.
\textsuperscript{142} Id. ¶ 54.
\textsuperscript{143} Id. ¶ 64.
\textsuperscript{144} Boehringer Ingelheim KG v. Swingward Ltd., (2008) E.W.C.A. (Civ) 83 (Eng.).
\end{footnotes}
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.\textsuperscript{145}

The court was prepared to conclude that the parallel importers have complied with the fourth \textit{Bristol-Myers Squibb} condition, namely that there repacking and relabeling activities have not caused damage to the reputation of the manufacturers’ trademarks.\textsuperscript{146} However, the court learned of another pending reference to the ECJ about re-packaging originating from the Austrian Supreme Court in May, 2005.\textsuperscript{147} The reference asked the ECJ (known as question 1(a)) whether the importer must show simply that repackaging is necessary or that each individual aspect of the repackaging must also be necessary.\textsuperscript{148} If the answer is no, the reference then asked (known as question 1(b)) if any harm incurred by new packaging measured with reference to a principle of ‘minimum intervention’ or with reference to the reputation of the trademark and its owner.\textsuperscript{149}

These questions, however, have apparently already been answered by the most recent \textit{Swingward} ECJ opinion.\textsuperscript{150} The importer must show only that repackaging is necessary and no principle of minimum intervention exists in the \textit{Bristol-Myers Squibb} factors.\textsuperscript{151} The court stated that “(q)uestion 1(b) is surely answer ed . . . Yet it is only Question (1)(b) which is being maintained by the Austrian court.”\textsuperscript{152} The ECJ could have simply referred the Austrian court to the most recent \textit{Swingward} opinion, but instead has decided to separately address the Austrian reference.\textsuperscript{153}

In December of 2008, the ECJ addressed these questions in \textit{Wellcome Foundation Ltd v. Paranova}.\textsuperscript{154} In this case, the court stated that the answer to question 1(a) was ‘no’, and that it was already answered by \textit{Swingward} in April of 2007.\textsuperscript{155} The court then addressed 1(b), which interpreted the necessary requirement by stating: “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{156} The \textit{Swingward} dispute continues in the English courts.

\begin{enumerate}
\item Id. ¶ 2.
\item Id. ¶¶ 43-50, 60.
\item Id. ¶ 60.
\item Id. ¶ 61.
\item Id.
\item Id. ¶ 62.
\item Id.
\item Id. ¶ 63.
\item Id. ¶ AG-16.
\item Id. ¶ 30.
\end{enumerate}
So then what is the state of drug repackaging law in the EU? No one knows completely. The above discussion represents only the tip of the proverbial iceberg of cases, rulings, and factors mentioned by the ECJ. Yet, comprehension of the current legal environment is a necessary precursor for any guidance to firms or discussion of reform.

Toward this end, we attempt to reduce the complexity through a series of Exhibits explaining the requirement 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 EC treaty 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 these five factors were understood by all, no more explanation would be necessary. However, each of these five criteria is influenced by a maze of interpretations and limitations imposed by prior and subsequent cases. It is this jurisprudential tangle that we hope the exhibits will, perhaps modestly, help unravel.

Exhibit 2 explains the interpretation of the ‘necessary’ prong. In other words, this Exhibit shows what specific repackaging practices are considered necessary for importers to sell the product and 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 trade marks. Of the three, reboxing attracts the most discussion with separate criteria for reboxing motivated by consumer preferences or to accommodate different sizes.

Exhibit 3 addresses what repackaging constitutes 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 manufacturers 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 a variety of conditions 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 lettering can provoke a challenge from 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 more certainly to come, the reputational damage argument is likely to be a major point of contention by manufacturers in future challenges.

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157 See STOTHERS, supra note 9, at 74-126.
In spite of extensive litigation over the decades preceding and subsequent to \textit{Bristol-Myers Squibb} factors, repackaging remains largely unresolved and there is little doubt that litigation between importer and manufacturer will continue. Broad change resolving unanswered questions is unlikely. As a result, navigating the current legal environment is of primary importance, and the next section of this Article offers strategies for manufacturers and importers.

\section*{III. Strategies for Importers and Manufacturers in the Current Legal Environment}

The struggle over gray market drugs has been waged across an unusual 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 packaging the less successful importers can be in offering an alternative market to wholesalers, national health care schemes and pharmacists. Conversely, the more discretion an importer retains to repackage as it sees fit, the easier time the importer has in selling products in lucrative markets. This section summarizes the likely goals and practices of parallel importers and then presents strategies for manufacturers to combat these gray products.

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. Importers also want to repackage as cheaply as possible. 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 \textit{Boehringer Ingelheim v. Swingward}, 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 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.

\begin{itemize}
  \item \textsuperscript{158} (2007) \textit{E.M.T.R.} 71.
  \item \textsuperscript{159} \textit{Id.} \textsuperscript{¶} 38.
\end{itemize}
The ECJ has stated that national courts should 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 overstickerling 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. 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. 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 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 could 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 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 the EU Treaty. 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. 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 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 as small as five percent).

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. 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. 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 manufacturers, 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 manufacturers 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, 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 packaging of medicine. If the internal packaging or organization makes the medicine appear dirty, discolored, or untidy in some way, that 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.

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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 through 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. 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 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 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. Thus, in 2005 GlaxoSmithKline challenged a UK parallel trader, Dowelhurst, for allegedly supplying the ‘red tablets’ to the National Health Service.

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

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167 Id.
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.

CONCLUSION

Parallel importers and manufacturers are fighting for nothing less than the spirit of free trade in the 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. The result has been a direct tension between these two interests and a near continuous stream of litigation in European courts.

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. 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.
**Figure 1**
Price Discrimination for Atorvastatin in Selected European Markets

<table>
<thead>
<tr>
<th>Country</th>
<th>PPP Price Adjusted for DDD and pack size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>1.37</td>
</tr>
<tr>
<td>Sweden</td>
<td>1.04</td>
</tr>
<tr>
<td>UK</td>
<td>1.01</td>
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<td>Austria</td>
<td>0.97</td>
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<td>The Netherlands</td>
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<td>0.91</td>
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Figure 2
Parallel Trade Flow in the European Union

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. Centrafarm).

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

Repackaging inherently prejudicial; not necessary to prove actual effects (Boehringer Ingelheim v. Swingward I).

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

Reboxing (consumer preferences)

Necessary if “effective access” to “substantial part” of market hindered due to “strong resistance from a significant proportion of consumers to relabeled products” (Boehringer Ingelheim v. Swingward I).

Importer only has to show that repackaging overall is necessary, not every detail in manner or style is necessary (Boehringer Ingelheim v. Swingward II).

Reboxing (different sizes)

Necessary when:
- National rule requires package size
- National practice exists for package size
- Insurance reimbursements depend on package size
- Well-established prescription practices exist
- Professional groups and insurance companies recommend standard sizes

Not necessary when:
- Importer can add new labels in local language, add new instructions, or replace one article for another to meet national standards

Relabeling

Will not be permitted when overstickering will suffice (Frits Londersloot v. Ballantine)*

*non-drug case

Changing Trademarks

Necessary when:
- Consumer protection regulation prohibits use of original trademark

Original trademark might mislead consumers as to origin

National practice requires package size

Original practice exists for package size

Insurance reimbursements depend on package size

Well-established prescription practices exist

Professional groups and insurance companies recommend standard sizes
Exhibit 3: Repackaging Must not Have Impact on Original Condition of Product (BMS Factor #2)

- Repackaging cannot expose product to tampering or affect original condition (BMS v. Paranova)
  - Can repackage when internal packaging kept intact or when inspected by public authority for adverse effects (Hoffman-La Roche v. Centrafarm)

  - Does not affect original condition
  - May affect original condition

- Removal of blister packs, ampoules, inhalers, etc., and placed in new packaging (BMS v. Paranova)
- Affixing self-stick labels to blister packs, ampoules, inhalers, etc. (BMS v. Paranova)
- Additional label to meet national law (Phytheron Intl v. Jean Bourdon)
- Insertion of an extra article, such as a spray (BMS v. Paranova)

  - But, if article does not comply with use or doses envisioned by manufacturer, possible indirect effect (BMS v. Paranova)

- Blister packs cut or batch numbers reprinted (BMS v. Paranova)

  - But, no harm if supervised by public authority to insure intact product (BMS v. Paranova)

- Repackaging does not give product “adequate protection” (BMS v. Paranova)

  - But, harm from light sensitivity and mixed use-by dates too “hypothetical” of a risk (BMS v. Paranova)
Exhibit 4: Repackaging Must Disclose Firm That Repackaged Product (BMS Factor #3)

Importer must disclose repackager identity to avoid consumer confusion of product origin
(Hoffman-La Roche v. Centrafarm)

Need not disclose that repackaging unauthorized (would imply illegitimate product)
(Hoffman-La Roche v. Centrafarm)

Must be readable by person with normal eyesight and attentiveness
(Hoffman-La Roche v. Centrafarm)
Exhibit 5: Presentation of Repackaging Cannot Damage Reputation of Trademark (BMS Factor #4)

Public demanding of pharmaceutical integrity; "defective, poor quality, or untidy packaging could damage reputation"
(BMS v. Paranova)

Sold to hospital; product presentation has "little importance"
(BMS v. Paranova)

Sold to consumer; product presentation has "greater importance"
(BMS v. Paranova)

Harm can arise from any source that detracts from perceived reliability and quality of product
(Boehringer Ingelheim v. Swingward I)

Not harmful

Removal or obliteration of batch code numbers
(Zino Davidoff v. ABD Importers, "scouring case"

Cutting of blister packaging
(BMS v. Paranova)

Failing to affix trademark to new exterior carton (de-branding)
(Boehringer Ingelheim v. Swingward I)

Application of importer’s logo or design alongside original (co-branding)
(Boehringer Ingelheim v. Swingward I)

New label wholly or partially obscures trademark
(Boehringer Ingelheim v. Swingward I)

Failure to state on new label that firm trademark belongs to owner
(Boehringer Ingelheim v. Swingward I)

Printing parallel importer’s name in capital letters
(Boehringer Ingelheim v. Swingward I)

Potentially harmful, possible court inquiry
Exhibit 6: Importer Must Give Notice of Importation and Provide Sample if Requested (BMS Factor #5)

Importer must give prior notice of repackaging to manufacturer (Hoffman-La Roche v. Centrafarm)

Fifteen days notice likely reasonable time if contemporaneous with product sample (Boehringer Ingelheim v. Swingward I)

Sanction for failure to notify must be "proportionate" but also a "sufficient deterrent" (Boehringer Ingelheim v. Swingward II)

Importer must give sample of product to manufacturer if requested (BMS v. Paranova)

Importer must show that it took all reasonable steps to provide sample (Boehringer Ingelheim v. Swingward II)*

*Advocate General opinion