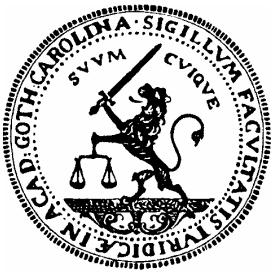

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Repackaging of Pharmaceuticals: Safety, Free Movement, & Intellectual Property Rights

How do safety concerns factor into the regulation of parallel imports of pharmaceuticals: An EU US comparison.

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Contents

1 Introduction

Why talk about parallel trade in pharmaceuticals? As the "Baby Boom" generation ages, they will put more and more pressure on social welfare systems. They are a generation that has experienced the technical and social advancement of the past half century. They are one of the most affluent demographics in history, and have spent considerable sums in order to prolong their youthful lifestyles. They have never been denied anything, they want what they want, and they expect that they won't have to pay that much for it. However, with the extremely high cost of prescription drugs, this aging generation is on a collision course with nationally regulated payor systems. Even in the US, the closest thing the pharmaceutical industry has to a free market, the price of prescription drugs is politically explosive when discussing access to affordable pharmaceuticals.

Pharmaceutical companies try to protect their research and development costs in markets where they can set higher prices. However, their differential pricing is undermined when they are forced to compete with parallel importers who bring the same drugs in from countries where local governments set an artificially low price. Pharmaceutical companies have tried a number of strategies to prevent these parallel imports: explicitly forbidding them, choking off supplies, arguing intellectual property rights, and even arguing on behalf of consumer safety.

In the EU, the overarching goal of a free market has prevented the use of national intellectual property rights from artificially partitioning the market. Without the ability to rely on their national intellectual property rights to protect their higher priced markets from cheaper parallel imports, the pharmaceutical companies have tried a number of interesting and creative strategies to protect their investment. One particularly interesting strategy is advocating for consumer safety in the context of trademarks.

In the US patient safety has been at the forefront of the policy behind the prohibition of parallel imports of pharmaceuticals. However, recently the safety argument is wearing thin as bus loads of senior citizens and a number of state and local municipalities import their pharmaceuticals from Canada where the prices are considerably lower due to national and regional price controls. As the US is the last bastion of free pricing for pharmaceutical companies the rhetoric is high to protect their investment from low cost parallel imports.

The US also has a great interest in protecting their intellectual property rights as a way to promote innovation. There is a very fine line between allowing parallel imports and upholding the goals behind intellectual property protection as enshrined in the US Constitution.

There is much rhetoric tied up in the issue of parallel trade in pharmaceuticals and it takes a while to get past the words and down to the core principles. This paper will explore the core principles behind the rhetoric. So with the rhetoric as a starting point - let the analysis begin!

1.1 Question/ Purpose

This paper will explore whether the rules pertaining to the regulation of parallel trade of pharmaceuticals in the EU and the US consider the safety of consumers with respect to repackaging.

1.2 Method

This paper will look at the regulation of parallel imports of pharmaceuticals in the European Union and in the United States. It will address the use of intellectual property rights (IPRs) to prevent parallel imports; in particular, the use of trademarks, the IPR historically used to protect the well being of the consumer.

It will investigate whether the goals behind the European free market jeopardize the safety of European consumers by encouraging parallel imports, especially by allowing for the repackaging of pharmaceuticals contrary to national trademark rights. It will compare the current regulations of parallel imports in the EU to those of the US and compare how arguments of safety are used regarding pharmaceuticals.

Finally, this paper will discuss whether, as the political pressure for access to affordable pharmaceuticals grows in the US, should the US look to the EU as a model to follow or as an example to be avoided?

This paper is based on a traditional method of legal analysis. The relevant cases, identified through a thorough search of the body of literature written about parallel imports, trademarks, repackaging and safety, have been gathered and reviewed. The paper will go through the case law with a textual analysis, examining the words the courts have used to interpret the regulation of parallel imports as they pertain to pharmaceuticals.

This textual analysis will then be subject to both a contextual and teleological analysis. That is, trying to fit the words of the law into the big picture context while recognizing and identifying the underlying goals of the lawmakers.

Once the relevant legal framework has been established, this paper will go through a comparative analysis, comparing the underlying principles as expressed in the case law of the European Union and the United States. Again using a contextual and teleological analysis, this paper will look at

the underlying goals that drive the different regulatory structures and markets of the EU and the US within the context of a globalization.

The paper will then discuss how safety factors impact the regulation of parallel imports of pharmaceuticals in each market.

Sources for this paper include: relevant case law from the European Court of Justice (ECJ), the Unites States Supreme Court, and lower US Federal Courts; and laws and regulations from both the European Institutions and the American Federal Government. Numerous books, journals, law review articles, and industry opinions that contribute to the doctrine surrounding parallel trade, the use of intellectual property, and theories of exhaustion, have provided a solid foundation for this analysis.

This paper seeks to build upon established doctrine and draw comparisons between the regulation of parallel trade of pharmaceuticals in the two largest markets in the developed world. The comparison raises questions regarding consumer safety and intellectual property protection and may offer possible suggestions for future consumer access to pharmaceuticals.

1.3 Delimitations

Parallel imports of pharmaceuticals is a very large and politically explosive topic. There are many angles and many ways to approach the issue. This is a broad field and has a fairly well developed area of European case law. Instead of analyzing the evolution of the law as it stands today, I will provide an overview and then focus on the repackaging issues and current issues pertaining to safety and trademarks; therefore I will not delve deeply into the history of the doctrine. This paper will leave to the reader the task of digging into the earlier case law and the detailed development of the doctrine.

In the EU parallel imports and parallel trade refer to goods moving from Member State to Member State within the common market, while in the US parallel imports refer to goods coming from outside the US. In the EU such parallel trade of pharmaceuticals is actively promoted, while in the US it is banned.

This paper starts with the presumption that pharmaceuticals on the European market are safe. Each Member State has stringent rules and regulations that are meant to guarantee the safety of the EU consumer, this paper does not look at those regulations, rather, it digs into the question whether in the repackaging scenario, concerns of safety factor into the ECJ's analysis. Their analysis is then compared to the rhetoric of safety in the US.

It is impossible to discuss parallel imports without touching upon the intellectual property rights that are inherently connected with the protected products, in this case pharmaceuticals. A full analysis of whether all intellectual property rights (patents, copyrights, trademarks) are in conflict with parallel imports is beyond the scope of this paper. However they will be discussed briefly to compare the different positions of the EU and the US.

The analysis of trademarks and the way the ECJ has interpreted the specific trademark legislation will be discussed in more detail. However, this is also an very large subject, so the analysis will be brief and focused.

Much of this paper rests upon the notion of free movement of goods within the common market and the historical case law that has developed around the subject. While familiar concepts of free movement and terms such as "measures having an equivalent effect" will be mentioned and used, an in depth analysis of their background and development will not be analyzed in detail. The author assumes that the reader will have a familiarity with the basic tenets of European law.

Economists often study parallel imports and there is a large body of literature on the relative benefits and disadvantages of parallel imports. This material was helpful in my research for framing my question, but it goes beyond the scope of this paper to discuss it in detail. Therefore there will be brief mention of specific points and ideas, but for purposes of this thesis there will not be an in depth law and economics analysis.

Competition law is very important in the regulation of parallel imports in both the EU and the US. The impact of vertical restraints and other contractual means of limiting parallel imports will not be analyzed here, as they are less relevant to a safety analysis. Competition law may be briefly mentioned in passing, but a thorough analysis of the competition regulations falls outside the scope of this paper.

I mention market authorizations as they are the primary regulatory action intended to ensure and protect the safety of the pharmaceuticals with in the EU. The misuse of the market authorization as a tool to prevent parallel trade is beginning to be scrutinized by the Commission as a possible abuse of a dominant position. There is also recent case law regarding the withdrawals for non-safety issues as a violation of the principle of free movement.

However, because I was investigating issues regarding repackaging, I do not go into a thorough analysis of the regulatory requirements of market authorization except as they pertain to repackaging. Again, this paper does not discuss safety as it pertains to regulatory approval; rather it looks to where, if at all, safety factors into the repackaging analysis in the EU. It

then compares that to the material difference test for consumer confusion in the US.

This paper does not discuss the benefits or problems associated with differential pricing between developed and developing countries, rather it looks at parallel trade in the context of the industrialized world.

1.4 Brief Structure /Overview/ Notes for the reader

This paper is divided into three main factuals sections, a compativie section and a conclusion. Each section starts with an overview and brief outline of the section. It is folloewd by subsections which also try to indicate the purpose and layout of their information. Finally each section ends with a summary of main points and an indication of where the paper is heading next. The analysis runs throughout the paper and the comparitive section highlights major themes previously discussed.

The factual chapters are:

● Free Movement and Parallel Trade in General
This section will set the global stage for parallel imports of pharmaceuticals. It will define parallel trade and will briefly explain the pharmaceutical market.

● EU Rules on Parallel Trade, IPRs, and Repackaging
This section will define the concept of Free Movement, illustrate the EU's exhaustion principle, discuss the existence/ exercise dichotomy of intellectual property rights in the EU, discuss the repackaging case, and finally touch upon market authorizations.

● US Rules on Parallel Trade, IPRs, and Safety
This section will define the concept of innovation, illustrate the US's exhaustion principle discuss intellectual property and finally the regulation of safety of pharmaceuticals.

The terms Parallel Trade, Gray Market, Parallel Imports are often used interchangeably. As are the terms Community and Union and the terms Common Market and Internal Market.

Use of the term parallel import in the EU refers to products moving about the internal market and not those imported from outside of the Internal Market.

Treaty Articles have been changed to reflect the current treaty. Even when quoting directly from case law where the former treaty articles were used. In such situation it is marked with a * eg., Articles 28* and 30* .

The footnotes often contain relevant ideas that did not fit into the flow of the text so the reader may find useful information as well as citations.

2 Free Movement and Parallel Trade in General

2.1 Setting the Stage for Parallel Trade: Globalization, the WTO & TRIPS

Over the past few years, the world has become a smaller place as forces of globalization created an international system where free trade is the norm. Major trading blocks created by free trade agreements like the North American Free Trade Agreement (NAFTA) or the more complex supra national organization of the European Union dominate this system. The World Trade Organization (WTO) established in 1994 regulates trade and sets harmonized standards and procedures for its members to follow. It offers a dispute resolution system intended to keep trade free and open and to prevent retaliatory or protectionist behavior among its members.

The increase of global free trade under the WTO system has impacted far more than tariffs and trade barriers; it has created a whole new set of norms that impact the regulation of health and safety in domestic settings. It has been said that "in addition to its economic consequences, globalization has a major effect on domestic governance, and on public health, economic development, social and environmental policy."[1]

An example is the agreement on Trade Related Aspects of Intellectual Property (TRIPS), which was drafted and adopted as part of the Uruguay Round of negotiations that created the WTO. The TRIPS Agreement attempts to establish a minimum level of intellectual property protection and harmonization among WTO members, but unlike most WTO provisions the TRIPS Agreement affirmatively requires members to enact domestic legislation establishing such minimum levels.[2]

By requiring all WTO members to harmonize their minimum level of intellectual property protection, the TRIPS Agreement has been criticized as hindering a sovereign nation's ability to protect its public health by restricting a country's ability to access affordable medicines.[3] While this is

[1] Lori M. Wallach, *Accountable Governance in the Era of Globalization: The WTO, NAFTA, and International Harmonization of Standards*. Symposium: Globalization and Sovereignty, University of Kansas Law Review, May 2002, 50 U. Kan. L. Rev. 823.

[2] Thomas A. Haag, *TRIPS Since Doha: How Far Will the WTO Go Toward Modifying the Terms for Compulsory Licensing?* Journal of the Patent and Trademark Office Society, December 2002, 84 JPTOS 945, 948.

[3] This debate has focused primarily on the inability of developing countries to access essential medications at affordable prices due to new patent restrictions and is outside the scope of this paper.

primarily discussed as a problem for developing countries, access to affordable medicines is also a growing problem in developed countries. Discussions to resolve the issue have sparked many questions relating to the use of intellectual property rights, differential pricing, international and regional exhaustion all in the context of parallel trade in pharmaceuticals.

As discussed below in detail, exhaustion of an intellectual property right is an integral part of a parallel trade analysis. While TRIPS was successful[4] in establishing a harmonization of intellectual property protections among WTO members, it was unable to agree on a theory of exhaustion. The Agreement is silent on whether regional or international exhaustion should apply to the protection of intellectual property rights. In fact, Article 6 of the TRIPS Agreement specifically agrees to disagree on the issue of exhaustion.[5]

The EU and the US have similar standards for intellectual property protection, and even arguably similar views on exhaustion, however in relation to the parallel imports of pharmaceuticals, they have taken different positions based on safety.

It is against the background of international harmonization of intellectual property rights that the rules regulating parallel imports of pharmaceuticals in the European Union and in the United States will be discussed.

2.2 Definition of Parallel Imports: How and why they work

What are parallel imports? Parallel imports are "goods brought into a country without the authorization of the patent, trademark, or copyright holder after those goods were placed legitimately into circulation elsewhere."[6] In its simplest definition, a parallel import is a legitimate good put on the market by or with the consent of the IPR holder, where it is purchased by someone who buys it at a low price and then imports and resells it on a higher priced market. A parallel import or gray market[7] good

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[4] There is heated debate whether TRIPS has been successful for developing nations or if it is merely a tool for the developed world. This debate is beyond the scope of this paper. For purposes of this analysis, TRIPS successfully set out standards for minimum levels of intellectual property protection for WTO members.

[5] Article 6 of the TRIPS Agreement states: For the purposes of dispute settlement under this Agreement…nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

[6] Keith Maskus, INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY, Institute for International Economics, (Washington, D.C. 2000) p 208.

[7] The term gray market goods often implies negative connotations as it is associated with the black market, and while not illegal, it is not fully on the "up and up". You see the

is a legitimate good, i.e., not a counterfeit or pirated good, which has been imported "outside (or in parallel with) the original supplier's 'official' network".[8]

Gray market goods generally fall into one of three categories: 1) Unintended goods – goods authorized for sale in one country but diverted to another, this may be divided further into goods manufactured domestically and goods manufactured abroad by an entity under common control or foreign license. 2) Licensed goods – goods manufactured through a trademark license agreement but sold through unauthorized channels 3) Distressed goods – goods dumped by an authorized dealer who has an excess supply or outdated goods.[9]

Parallel imports of pharmaceuticals will generally fall into the first category of unintended goods. For example, pharmaceuticals intended for sale to consumers in Spain are bought by parallel importers who divert the goods to Britain where they end up being sold to consumers in the UK.

Parallel imports allow an importer to import a good from a low cost market to a higher cost market and sell it on the higher cost market at a substantial discount. The discount in price is what generally attracts consumers to parallel import goods. Parallel imports occur when the price differential is large enough for the importer to buy, transport and sell the parallel product at a lower cost and still make a hefty profit. Consumers attracted by the lower price are likely to purchase from the parallel importer and not the authorized dealer or supplier.

Parallel imports compete at a lower price with the same products distributed through the authorized channels. This creates a problem for firms, authorized distributors, and manufacturers because parallel imports end up cannibalizing their market. Since parallel importers have none of the costs or responsibility associated with developing, servicing or marketing the product they are often referred to as free riders.[10]

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difference in terminology used by the EU where "parallel trade" is encouraged and in the US where intellectual property rights holders often trump importers of gray market goods.

[8] Melanie Farquharson, Vincent Smith, PARALLEL TRADE IN EUROPE, Simmons & Simmons, Sweet & Maxwell, (1998, London).

[9] Tait R. Swanson, *Combating Gray Market Goods in a Global Market: Comparative Analysis of Intellectual property Laws and Recommended Strategies,* Houston Journal if International Law, Winter 2000 22 HOUJIL 327.

[10] Maskus supra note 6 at 213. Also see discussion of the free rider theory in Darren Donnelly, *Parallel Trade and International Harmonization of Exhaustion of Rights Doctrine*, Santa Clara Computer and High Technology Law Journal, May 1997 13 SCCHITLJ 445 at 513-514.

In the world of globalization, it has been argued by some that: "proscribing parallel imports amounts to a non tariff barrier to trade, which is counter to the basis of the WTO."[11] It is thought that parallel imports are good for consumers because they lower the prices of the imported products and allow the consumer more choice.[12] A study done by the Swedish Competition Authority concluded that parallel imports "do in fact lead to increased consumer benefits in Sweden".[13] However, others have argued that parallel imports actually harm economic welfare,[14] especially in technological areas like the pharmaceutical industry.[15]

In order for parallel trade to function for particular goods, there must be large price differentials between countries, the market must be fairly transparent, and the goods must be transportable.[16] Currency fluctuation also facilitate parallel imports, where parallel importers use the difference in currencies to their advantage, although this is less of a concern in the EU with the establishment of the Euro.

Parallel imports are particularly successful in high value goods,[17] e.g., designer clothing and accessories, books and publishing, computer hardware and software, electronics, watches, jewelry, toys, fragrances, cosmetics,

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[11] Id., Maskus at 209, referring to Frederick M. Abbott.

[12] PARALLEL TRADE IN EUROPE, supra note 8 at 1.

[13] David Perkins, Marleen van Kerckhove, David Rosenberg, *Exhaustion of Intellectual Property Rights*, Practicing Law Institute, Patents, Copyrights, Trademarks, and Literary Property Course Handbook Series, 1999. 574 PLI/ Pat 41 at 110-111 quoting the Swedish Authority's report originally commissioned to investigate effects of regional exhaustion.

[14] Charles E. Barfield, Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare and Health Policy*, Fordham Intellectual Property, media and Entertainment Law Journal, Autumn 1999, 10 Fordham Intell. Prop. Media & Ent. L.J. 185 at 187.

[15] Id., Barfield argues that this rational is based upon an economic identification of four market areas where parallel imports are likely to reduce economic welfare. They include areas where high levels of sunk research and development costs need to be recovered, and competition with parallel importers inhibits the ability to recoup such costs, and therefore arguably reduces the ability to innovate. The second situation is where price discrimination will enhance overall economic welfare by allowing entry into new low priced markets, thus expanding output. The third situation involves a situation where public authorities create price distortions and drive prices below averaged fixed costs. The forth situation occurs where free rider problems exist and the parallel importers freeze out authorized distributors through lower prices, thus under cutting information and service activities. He argues that all four of these conditions are met in the pharmaceutical industry.

[16] Synthesis of numerous articles on parallel trade.

[17] PARALLEL TRADE IN EUROPE, supra note 8 at 1.

automotives, and pharmaceuticals[18] because generally there is a large price differential between markets in these industries.

Parallel trade is intrinsically connected to the concept of exhaustion of intellectual property rights. Exhaustion occurs when the IPR holder puts his IP right on sale and looses, or exhausts, the ability to further control the right. It is said the holder has "exhausted" his IP right. There are two types of exhaustion that factor into the discussion of parallel trade and intellectual property rights. Regional or territorial exhaustion: where sale within the territory will exhaust the IP right within the territory but a sale outside the territory will not exhaust the territorial right. The second view is international exhaustion, where once an IPR holder puts the protected good on the market anywhere in the world the IP rights are exhausted. These concepts will be elaborated in sections 3 and 4 in the context of EU and US law.

2.3 Why The Pharmaceutical Market Is A Good Place For Parallel Imports

The pharmaceutical market differs from markets for other goods. It is said that pharmaceutical products are subject to three constraints that do not apply in most other markets, mainly 1)the high price of research and development, [19] 2) the long time period for development, essentially shortens the time a patented good can recoup its costs on the market free from competition, and 3) pharmaceuticals are heavily regulated, specifically in terms of pricing, where prices are set by different national governments.[20]

These special factors contribute to the reality that prices for pharmaceuticals are not based on the traditional free market concept of supply and demand. Even in the US, where American consumers pay more for prescription drugs than any other consumers in the world[21] the pharmaceutical sector is not

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[18] A non exhaustive list, William Richelieu, *Gray Days Ahead?: The Impact of Quality King Distributors, Inc. v. L'Anza Research International, Inc.*, Pepperdine Law Review 2000, 27 PEPLR 827 at 828-829.

[19] It costs approximately 802 million dollars over a period of ten to fifteen years to bring a drug to market and of every 5000 drugs tested, only five make it to clinical trials. Of those five, only one is approved for patient use. http://pfizer.com/download/public_pricing_guide.pdf, quoting Boston Consulting Group. A revolution in R&D: the impact of genomics. BCG Focus. June 2001, and DiMasi J. Risks in new drug development: approval success rates for investigational drugs. Clinical Pharmacology & Therapeutics. May 2001: 69(5):297-307

[20] *Exhaustion of Intellectual Property Rights*, PLI, supra note 13 at 57.

[21] Michele L. Creech, *Make a Run for The Border: Why the United States Government is Looking to the International Market for Affordable Prescription Drugs,* Emory International Law Review, Fall 2001, 15 Emory Int'l L. Rev. 593.

truly a free market.[22] This can, and does, lead to large price differentials between different countries, the most important requirement for parallel trade.

In the EU there are large price differentials between Member States. The Member State, or its national health system, are the main consumers of pharmaceuticals. They are able to set their own price when negotiating with pharmaceutical manufactures; this is done directly by naming a price, or indirectly by setting a maximum reimbursement from the national health system.[23]

Parallel importers often pick which drugs they will offer based on the price differentials and the demand for the drug.[24] Generally the drugs that are the most successful for parallel importers are the high priced popular drugs that have a wide patient population.[25]

The parallel importer is able to free ride on the research and development costs, the marketing and advertising costs, the distribution costs, and the regulatory approval costs from the manufacturer.[26] The free rider problem is often overlooked as parallel imports of pharmaceuticals are supported and often encouraged by Member States looking to take advantage of the lower price.[27]

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[22] Id. at 598. Although the Federal Government does not play a role in price setting, Health Maintenance Organizations and Pharmacy Benefit Managers negotiate price discounts based on volume sales for a large portion of the insured population.

[23] Russell Graeme Hunter, THE PHARMACEUTICAL SECTOR IN THE EUROPEAN UNION: INTELLECTUAL PROPERTY RIGHTS, PARALLEL TRADE AND COMMUNITY COMPETITION LAW: Institutet för Europeisk rätt vid Stockholms Universitet 51, 2001, p 10. PARALLEL TRADE IN EUROPE, supra note 9 at 67.

[24] Id., Graeme p 17.

[25] This has been criticized as these drugs are the ”blockbuster” drugs often used to recoup R&D costs.

[26] See the De Peijper Case infra note 105 where the ECJ did not allow a Member State to require a parallel importer to provide documentation that had already been provided by the manufacturer.

[27] Britain’s National Health Service assumes that a percentage of their pharmaceuticals will be from parallel trade sources and therefore available at a discount. See PARALLEL TRADE IN EUROPE, supra note 8 at 67. In Germany, consumption of some drugs may be supplied up to seventy percent by parallel importers, leaving only thirty percent of the market to the German authorized distributor. See Ian Forrester, *The Repackaging of Trademarked Pharmaceuticals in Europe: Recent Developments,* European Intellectual Property Review, 2000, EIPR 22(11), 512-519 at 512. In the US, where the parallel import of pharmaceuticals is illegal, the Federal government has looked the other way as busloads of senior citizens and even state municipalities import their pharmaceuticals from Canada to capitalize on the cost savings.

In addition to the substantial price difference between countries, pharmaceuticals are small, light weight, easy to transport and represent "high value for their small size."[28] This satisfies another requirement needed for successful parallel trade.

The production and distribution of pharmaceuticals is highly regulated. In the past few years there has been much harmonization within the European Union with the creation of European Medicines Evaluation Agency and the centralized process for obtaining market authorizations and pharmaceutical approval. In addition to harmonization on the European level, there has been harmonization and mutual recognition between the United States and other highly developed countries regarding manufacturing practices and distribution of pharmaceuticals as set by the FDA.[29] This harmonization creates a fairly transparent market that makes the pharmaceutical industry attractive for parallel trade.

The pharmaceutical market is very attractive for parallel imports. The large price differentials across markets, coupled with the global harmonization of standards for pharmaceuticals, and high value for their small size makes pharmaceuticals ideal for parallel importers.

Access to affordable medicine is an issue in developed nations as well as developing nations. In addition to the economic and regulatory factors that make parallel trade in pharmaceuticals attractive, the parallel importers have found support from politicians of countries that are looking to control their heath care budget while providing their citizens' affordable access to pharmaceuticals.[30]

Large pharmaceutical companies are consistently portrayed as big bad profit hungry multinational corporations looking to gouge the market and charge exorbitant prices for their life saving drugs, and parallel importers are "transformed into Robin Hoods that provide cheap medicine, only fleecing rapacious drug companies not consumers."[31] It is very tempting for politicians and governments to support the parallel import of pharmaceuticals, but at what cost?

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[28] Id., PARALLEL TRADE IN EUROPE at 67.

[29] Wallach supra note 1 at 853-854. Also see Code of Federal Regulations PART 26--Mutual Recognition Of Pharmaceutical Good Manufacturing Practice Reports, Medical Device Quality System Audit Reports, And Certain Medical Device Product Evaluation Reports: United States And The European Community 21 CFR 26 et seq.

[30] See discussion supra note 27.

[31] Slightly sarcastic summary of the way pharmaceutical companies are portrayed by some consumer groups. Quote from Donald E. deKieffer, Esq., *The Mexican Drug Connection: How Trade in Pharmaceuticals has Wrecked the FDA*, Southwestern Journal of Law and Trade in the Americas 2002-2003, 9 SWJLTA 321 at 328.

Because governments artificially set prices, the typical price convergence that generally occurs with parallel imports of other goods is not seen in the pharmaceutical market.[32] So are parallel imports of pharmaceuticals allowed at the expense of IPRs, while incurring potential safety risks for the consumer, without the benefit of real economic gain?

This section has defined parallel imports and explained the peculiarities of the pharmaceutical market. The following sections will lay out the underlying rationale regulating parallel imports in the European Union and the United States.

[32] Forrester, supra note 27 at 512.

3 EU Rules on Parallel Trade, IPRs, and Repackaging

The European Union has a unique rational for promoting the concept of parallel trade, at least within the Union. Particularly, the goal to create an ever closer union among the peoples of Europe[33] and fostering the creation and integration of the Common Market.[34]

The free movement of the "tools of production," i.e., goods, services, capital, and labor, was thought to be essential for European integration and the creation of a common market.[35] These freedoms, specifically the free movement of goods, have been the driving force behind European support and encouragement of parallel trade.

To this end, the European Court of Justice and the Community Institutions have actively promoted parallel trade by upholding the consumer's right to seek out the lowest priced goods available on the common market, as well as the parallel importer's right to access national markets. They have done this by using both the Competition Rules as set out in Articles 81 and 82 of the TEC, and also the Treaty provisions guaranteeing free movement of goods under Articles 28-30 TEC.

While a full analysis of the Competition Rules fall outside the scope of this paper, it is clear from enforcement by the Commission and the ECJ that they do play a large role in upholding the goals of the common market in respect to regulating the parallel imports of pharmaceuticals.[36]

In promoting parallel imports, the European Court of Justice has had to balance the free movement of goods within the Common Market with the existence and use of national industrial and commercial property rights. Article 295 of the TEC requires that the Treaty "in no way prejudice the rules in the Member States governing the system of property ownership," this includes intellectual property rights, which are a national property

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[33] First recital of the Preamble to the Treaty establishing the European Community (TEC), reiterated in Title I, Article I of the Treaty Establishing the European Union (TEU).

[34] Article 2 TEC sets out the task of developing a Common Market, and Article 3(c) TEC sets out the establishment of an internal market characterized by the abolition, as between Member States, of obstacles to the free movement of goods, persons, services and capital.

[35] PARALLEL TRADE IN EUROPE, Supra note 8 p 3.

[36] James Dilley, *The Effect of EC Competition Law on Intellectual Property Valuations: Implications for Corporate Strategies*, Oregon Review of international Law, Spring 2002, 4 ORRIL 104. PARALLEL TRADE IN EUROPE, Supra note 8.

right.[37] The case law has achieved this balance by allowing for the existence of national IPRs but holding that their exercise or enforcement may be in violation of the Treaties when such exercise or enforcement artificially partitions the market.[38]

The ECJ case law covers all forms of intellectual property, although this paper will focus mainly on the treatment of trademarks within the European Union, as trademarks are historically used to protect the consumer as a guarantee of origin.[39]

The concept of exhaustion is very important to any analysis of parallel imports. As a part of its promotion of parallel imports the ECJ has created a substantial body of law that focuses specifically on the concept of regional exhaustion, and when an intellectual property right holder has exhausted his rights.

This section will discuss the concept of free movement as it has been laid out in the treaties and interpreted by the European Court of Justice. It will look at the use of IPRs, keeping in mind that the ECJ has consistently held that the use of industrial or commercial property rights can not be used to hinder free movement by artificially partitioning the market.

From there the analysis will turn to the parallel importation of pharmaceuticals specifically looking at trademark rights in terms of the repackaging cases and asking if the repackaging cases undermine the safety of the EU consumer or do the requirements set out in the case law provide adequate protection. Market authorization will be briefly discussed in this context.

3.1 Background - Free Movement

Free movement of the tools of production is crucial in the development of the Common Market and is actively pushed forward by EU policy makers and the ECJ. The rules guaranteeing free movement of goods under Articles 28-30 TEC and the subsequent case law, are very important to the development of parallel imports. The balance of national intellectual property and free movement of goods is especially relevant to the discussion of parallel imports of pharmaceuticals within the EU. This section will give a brief overview of the rules pertaining to free movement.

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[37] Article 295 TEC, Hans Henrik Lidgard, IPR & TECHNOLOGY TRANSFER READING MATERIAL, Jurdiska Fakulteten vid Lunds Universitet, Spring 2004, p 64. Article 295 TEC.

[38] Numerous ECJ rulings including: Consten & Grundig; Joined Cases 56 and 58/64 Consten & Grundig v. Commission; Deutche Grammophon v Metro, Case 78/70; Hoffman-La Roche & Co. AG v Centrafarm Vertiebsgesellschaft Case 102/77; and others.

[39] Id., Hoffmann-La Roche.

Article 28 of the TEC states: "Quantitative restrictions on imports and all measures having an equivalent effect shall be prohibited between Member States."[40] In its famous Dassonville[41] ruling the ECJ clarified this to mean that:

> All trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra Community trade are to be considered measures having an effect equivalent to quantitative restrictions.[42]

Such measures would only be allowed if they fell within an allowed exception found in Article 30. Article 30 states:

> The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports… justified on grounds of public morality, public policy or public security; the protection of the health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic, or archaeological value; or the protection of industrial or commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.[43]

Further case law established that Member States could not rely on an Article 30 exception when there was comprehensive Community legislation in an area, This meant that Member States could not prevent such goods from their markets.

After the Dassonville ruling, the case law continued to develop and a few years later the ECJ handed down its Cassis de Dijon[44] ruling. Cassis reiterated that in the absence of harmonization, Member States were allowed to regulate; however, they could not infringe Article 30 of the treaty. It also set forth the principle that the Member State could not enact indistinctly applicable rules that unfairly impacted imports. Indistinctly applicable rules are measures that do not directly discriminate against imports, but because they differ from the rules applicable in the country of origin, inhibit trade.[45] The Cassis judgement has stood for the principle that

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[40] Article 28 TEC.

[41] Procureur du Roi v. Dassonville, Case 8/74.

[42] Id., quoted from P. Craig and G. de Búrca, EU LAW – TEXT, CASES, AND MATERIALS, (Oxford University Press, 3rd ed., 2003) p. 616-617.

[43] Article 30 TEC.

[44] Rewe-Zentrale AG v Bundesmonopolverwaltung für Branntwein, Case 120/78. "Cassis de Dijon".

[45] See Craig and de Búrca supra note 42 at 635-668.

once goods have been lawfully marketed in one Member State they should be admitted into any other Member State without restriction. Unless the Member State of import could successfully invoke one of the mandatory requirements,[46] the goods must be allowed on the market.

In the context of parallel trade this means that Member States are unable to enact measures that would block imports lawfully put on the Internal Market. This applies even if such goods are put on the market elsewhere and are imported outside of authorized channels.

Although the pharmaceutical market has characteristics that make it different from other markets, free movement principles still apply. The Commission has stated:

> Parallel importation of a medicinal product is a lawful form of trade within the Internal Market based on Article 28 TEC and subject to the derogations provided by Article 30 TEC.[47]

While pharmaceuticals are clearly subject to the rules of free movement, it is acknowledged that there may be special concerns of health and safety and national intellectual property rights. The Commission refers to the fact that while medicinal products (pharmaceuticals) are not exempt from the rules of the internal market, measures restricting parallel imports may be justified on the grounds of protection of industrial and commercial property and the protection of human health and life.[48]

The pharmaceutical market is not really a free market because the Member States regulate and control prices creating artificial price differences. The Commission has acknowledged that Member States may resort to direct price setting, or indirect price setting through reimbursement policies, in order to allow their citizens access to medicinal products, while maintaining the financial stability of their social welfare systems.[49] This is in line with Community law as long as such intervention "does not discriminate de jure or de facto between national or imported products."[50]

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[46] Id., Mandatory Requirements include the effectiveness of fiscal supervision, the protection of public health, the fairness of commercial transactions and the defense of the consumer. They have been expanded upon in subsequent case law to include environmental concerns as well. They are only available for indistinctly applicable measures.

[47] Commission Communication On Parallel Imports Of Proprietary Medicinal Products For Which Marketing Authorizations Have Already Been Granted. Brussels, 30.12.2003 COM(2003) 839 at p 6.

[48] Id.

[49] Id.

[50] Id.

As summarized here, these established principles of free movement set out in the Treaty and as explained by the case law, provide the fundamental basis and rational for the support of parallel imports in the European Union. These principles are used at the expense of national intellectual property rights in order to protect the common market.

3.2 Intellectual Property Rights[51]

The role of intellectual property rights in the European Union has been the subject of "passionate discussion" from the beginning of the Community.[52] The main issue has been whether the territorial nature of intellectual property rights is a threat to market integration.[53] Although there have been some attempts to harmonize intellectual property rights,[54] for the most part intellectual property protection remains at the national level. As previously mentioned, the EU has to delicately balance the need for free movement on the internal market with the respect for national IPRs.[55]

While an extensive analysis of intellectual property rights exceeds the scope of this paper, a brief summary of the case law is presented in this section along with a more in depth discussion of exhaustion. Finally a discussion of trademarks within the context of parallel trade is set out, laying the foundation for the repackaging rules.

Intellectual property rights begin with the notion that an inventor or other creative mind should be rewarded for sharing their knowledge with society as a whole. This concept has evolved over time, and with the signing of the TRIPS Agreement, intellectual property is afforded protection in the laws of all WTO members.

3.2.1 IPRs can not artificially partition the market

Consistent with the underlying goals of the internal market, and the guarantee of the free movement of goods, the ECJ has held that the exercise

[51] For purposes of this discussion intellectual property rights will refer to Patents, Copyrights and Trademarks. Other forms of intellectual property, such as Trade Secrets or Plant protection, fall out side this analysis.

[52] Andreas Reindl, *Intellectual Property and Intra- Community Trade*, Fordham International Law Journal, March 1997, 20 FDMILJ 819.

[53] Id.

[54] The creation of the European Patent Office, the Office for Harmonization in the Internal Market (trademarks and designs) the strength of international treaties like TRIPS, and various attempts at European legislation.

[55] H.H. Lidgard, Supra note 37.

of a national intellectual property right may not be allowed where it is used to "artificially partition the market".[56]

The active enforcement of national IPRs in national courts to prevent the sale or distribution of an "infringing" product that has been imported from another Member State has the potential to prevent the free movement of goods on the Internal Market.[57]

As discussed above, the free movement rules as set out in the Treaty and in the subsequent case law are directed at member states. However, those rules have been used by parallel importers to challenge national intellectual property laws that prevent parallel importers from bringing in authentic products without the permission of the local (national) IPR holder.[58]

So in balancing the national intellectual property rights with the goals of market integration, the ECJ differentiated between the existence of national intellectual property rights and the exercise of those rights:

> [A]lthough the Treaty does not effect the existence of rights recognized by the legislation of Member States with regard to industrial and commercial property, the exercise of such rights may nevertheless fall within the prohibitions of the Treaty.[59]

While this initial groundbreaking case dealt with copyright rights, its holding has been expanded to patent and trademark rights as well.[60]

The exercise of a national intellectual property right is limited to protecting the central aspects of the specific subject matter of the right in question. The essential subject of the right has been further defined by the ECJ, for example, in Centrapharm v. Sterling Drug, the ECJ held that the specific subject matter of a patent right was;

> [T]he guarantee that the patentee, to reward the creative effort of the inventor, the exclusive right to use an invention with the view to manufacturing industrial products and putting them into circulation for the first time, either directly or by grant of licenses to third parties, as well as to stop infringements[61]

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[56] Hoffmann-La Roche supra note 38 at paragraph 10.

[57] PARALLEL TRADE IN EUROPE, Supra note 8 at 12

[58] Id.

[59] Deutsch Grammophon supra note 38, as quoted from H.H. Lidgard supra note 37.

[60] For example see Centrapharm v Sterling Case 15/74, Hoffman la Roche supra note 38.

[61] Centrapharm v Sterling. Graeme supra note 24 at 33, PARALLEL TRADE IN EUROPE, Supra note 8 at 15, H.H. Lidgard supra note 37 at 70.

The Court went on to say that once the right owner has the benefit of the particular right in question, his rights are exhausted. This is important for parallel importers, because once exhaustion occurs, the right holder can no longer use his national rights to block the parallel imports from the Member State of import.

3.2.2 Exhaustion

The concept of exhaustion is crucial for an analysis of parallel imports. Exhaustion occurs when a product is placed upon the market by the right holder or with his consent.[62] It is reasoned that because the right holder has benefited from his intellectual property protection by placing the product on the market the first time, he should not be allowed benefit again by, for example, blocking parallel imports by exercising his national IPR. Consistent with this reasoning, his rights are considered exhausted after the first sale.[63]

After the Silhouette case,[64] it became very clear that the EU subscribes to a regional theory of exhaustion of intellectual property rights. This means that once the right holder directly, or by his consent, places a product anywhere on the common market, his rights are exhausted. He can no longer control the sale of the product or use his national intellectual property rights to block parallel imports.

Once a good is legitimately placed anywhere on the common market, the right is exhausted. However, there are transitional rules for the new Member States. Many of the new Member States only recently began applying intellectual property protection to pharmaceuticals. In such cases, there may be pharmaceutical products previously placed on the market in the new Member States without the IPR protection that the products are entitled to in the rest of the EU. Parallel imports of these pharmaceuticals from new Member States will not be allowed into the rest of the EU if the intellectual property right holder objects. These transitional rules will be

[62] The ECJ held in the Pharmon v Hoechst case 19/84. A drug that has been compulsory licensed by one Member State does not imply that it has been placed on the market with the IPR holders consent.

[63] The first sale doctrine is used extensively in the United States to describe this concept, however the term is used less frequently in discussions of European exhaustion.

[64] Silhouette International Schmied v Hartlauer Handelsgesellschaft C-355/96. In this case Silhouette, a manufacturer of high-end glasses frames, sold outdated frames to a distributor for sale in the former Soviet countries, these frames were not to be sold in Europe, an Austrian company purchased the frames in Bulgaria, reimported them and began to sell them in Austria. The ECJ held that when the first sale was outside of the European Union, exhaustion did not apply. Thus confirming the EU ascribed to a regional theory of exhaustion. Was a very important case!

reviewed on an ongoing product by product basis for each new member state.[65]

3.2.3 Trademark Discussion in the context of parallel trade of pharmaceuticals

The history of the trademark protection has humble origins in Community law. It was initially though of as a less important intellectual property right than patent or copyright. However, the trademark has evolved and has rapidly taken center stage in the parallel imports cases

In the pharmaceutical context both patents and trademarks are very important intellectual property rights. A full discussion of the scope of patent rights exceeds the bounds of this analysis. However, as mentioned above, the specific subject matter of a patent relates to rewarding the inventor for his creative works by allowing him the right to industrially manufacture his invention and blocking others from doing so without his permission. Once the product has been put on the market, the ECJ has ruled that the patent holder's rights are exhausted. He has benefited from the specific subject matter of his right, and can not use it to block parallel imports.

For a trademark analysis, the concept is a bit trickier. The essential function of a trademark is historically associated with the protection of the consumer, not to reward a creative invention. Since this paper is investigating the safety of consumers, it makes sense to focus on trademarks. Trademarks are particularly important with regards to the parallel import of pharmaceuticals, because they indicate a guarantee of origin that is sometimes used as a guarantee of safety.[66]At least in the mind of some consumers. In discussing the importance of a trademark, Advocate General Gulmann refers to the presentation of a pharmaceutical product. He says the appearance and presentation is important if it is sold through pharmacies to consumers. He stresses that it is important even when considering that consumers already have some degree of confidence in the quality of the product because it is the subject of a doctor's prescription[67].

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[65] In addition, the process for market authorizations is also subject to transitional rules. See Freshfields Bruckhaus Deringer Briefing, *EU Enlargement: Pharmaceutical Issues*, October 2003. http://www.freshfields.com/practice/ipit/publications/6777.pdf last viewd 20th May 2004.

[66] See Advocate General paragraph 41, in reviewing the status of the Bristol Myers Squibb cases in his joined opinion in Merck, Sharp & Dohme GmbH v Paranova Pharmazeuitka Handels GmbH c- 443/99, Boehringer Ingelheim KG, Boehringer Ingelheim Pharma KG, Glaxo Group Ltd, The Wellcome Foundation Ltd, SmithKline Beecham Plc, Beecham Group, Plc, SmithKline & French Laboratories Ltd., and Eli Lilly and Co v. Swingward Ltd and Dowelhurst Ltd. C- 143/00

[67] Id., Advocate General.

Perhaps because of its special status representing a guarantee of origin for consumers, the ECJ has allowed a trademark holder more room to block a parallel import by using its definition of the specific subject matter of trademarks, when compared to the specific subject matter of patents. As a result, trademarks are the national intellectual property right that has been most often asserted by a right holder in order to prevent the import of a pharmaceutical.[68]

The ECJ identified the specific subject matter of a trademark in its Hoffman-La Roche landmark decision on repackaging:

> The essential function is to guarantee the identity of origin of the trademarked product to the consumer or ultimate end user, enabling him without risk of confusion to distinguish that product from the products of another origin. The effect of that guarantee of origin is that the consumer or ultimate user can be certain that without the authorization of the proprietor of the mark there has been no third party involvement in a trademarked product such as to affect its original condition. The proprietor's right to prevent any use of the mark which is liable to impair the guarantee of origin so understood is therefore part of the specific subject matter of the trademark right.[69]

This paragraph makes clear that the essential function of a trademark is to guarantee origin of the trademarked product. Within the pharmaceutical context this is important because it is the equivalent of a guarantee of safety. The manufacturer would not distribute an unsafe product, and if there were indications of safety issues, the manufacturer is responsible under the marketing authorization regulations to report them and either correct the problem or remove the product.

In this ruling, the ECJ continued to hold the protection and promotion of free movement above the protection of a trademark holder's national rights. However, the court went on to say that:

> Where the essential function of the trademark is to guarantee the origin of the product is protected, the exercise of his rights by the proprietor of the trademark in order to fetter the free movement of goods between Member States may constitute a disguised restriction within the meaning of the second sentence of article 30* if it is established that the use of the trademark right by the proprietor, having regard to the

[68] Graeme supra note 23 at 37-38.

[69] Hoffmann-La Roche supra note 38.

> marketing system which he has adopted, will contribute to the artificial partitioning of the markets between Member States. [70]

If a trademark holder tried to use his trademark in a way that would artificially partition the market, and then tried to block parallel imports by exercising his national rights under the mark, his actions would be in violation of the treaty and would not be allowed.

The case reinforced the principle of free movement as essential for market integration. Intellectual property rights are protected to the extent that they do not artificially partition the market and are subject to regional exhaustion once they have been placed anywhere on the common market by the right holder or with his consent.

Despite these clear principles, questions about trademarks continued to arise, when is a trademark exhausted if it is a guarantee of origin and when can a trademark holder intervene in blocking goods where the trademark has been tampered with?

The Trademark Directive of 1989 was an attempt to answer these questions. Its goal was to harmonize the laws of Member States with regards to trademarks as they "most directly affect the functioning of the Internal Market."[71] The directive has been the center of much litigation over the exact meaning of its provisions. Particularly the meaning of Article 7 concerning the exhaustion of a trademark and specifically when it is legitimate for a trademark holder to oppose further commercialization of the goods, especially when the condition of the goods is changed or impaired after they have been put on the market.[72]

3.2.4 Repackaging

As reiterated again and again in the Treaty, the case law, community communications, regulations and directives, completion of the common market is a core tenet of the Community's existence and is central to its ongoing survival. In order to maintain the market, the free unhindered movement of goods across national boundaries is essential. National measures having an equivalent effect to a quantitative restriction are not allowed unless they fall into one of the specific derogations allowed for under Article 30 of the Treaty, and only then if the measure is reasonable, proportional and otherwise fits within community norms.

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[70] Id.

[71] First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trademarks. Official Journal L 40, 11/02/1989 p.1. Preamble

[72] Id., Article 7(2).

The exercise of a national industrial or commercial right is allowed under Article 30 unless it has the effect of artificially partitioning the market. The case law has held that once a product has been put on the market, the specific subject matter of its intellectual property right has been exhausted. After this point, the right holder can not interfere with the free movement of parallel imports by claiming or exercising the national property right.

The ECJ's landmark decision in Hoffman-La Roche set the standard for repackaging case law within the Union.[73] In addition to setting forth the specific subject matter of a trademark, and clearly stating that trademark holders could not use their marks to artificially partition the common market, the ECJ set out four requirements to protect the trademark and its guarantee of origin. When these requirements were satisfied, a trademark holder could not use his trademark to block the parallel importation of his product, even when it had been repackaged. These requirements became a set of rules for parallel traders to follow when determining whether or not a national trademark holder could challenge a repackaged pharmaceutical product without violating Community law.

Those four requirements, which have been refined over more than two decades of repackaging case law have been reexamined within the past few years.[74]

Advocate General Gulmann[75] in his joined opinion C-443/99 and C-143/00[76] gave an in depth analysis regarding the current status of repackaging law in the EU as it relates to the repackaging of pharmaceuticals by a parallel importer in order to obtain market access. He began by stating:

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[73] Hoffmann-La Roche supra note 38.

[74] Merck, Sharp & Dohme GmbH v Paranova Pharmazeuitka Handels GmbH c- 443/99, Boehringer Ingelheim KG, Boehringer Ingelheim Pharma KG, Glaxo Group Ltd, The Wellcome Foundation Ltd, SmithKline Beecham Plc, Beecham Group, Plc, SmithKline & French Laboratories Ltd., and Eli Lilly and Co v. Swingward Ltd and Dowelhurst Ltd. C-143/00. Pharmacia & Upjohn SA v Paranova AS C-379/97; Aventis Pharma Deutschland GmbH v Kohlpharma GmbH and MTK Pharma Vertriebs GmbH C433/00.

[75] The English version of this Avocate General report states Mr Advocate General Gulmann delivered the report. However, in both judgments and in other AG reports delivered by Advocate General Jacobs, it is indicated that AG Jacobs delivered the report. For citations in this paper I will refer to Gulmann as the AG in these joined cases. See supra note 66 for full citation.

[76] Merck, Sharp & Dohme GmbH v Paranova Pharmazeuitka Handels GmbH c- 443/99, Boehringer Ingelheim KG, Boehringer Ingelheim Pharma KG, Glaxo Group Ltd, The Wellcome Foundation Ltd, SmithKline Beecham Plc, Beecham Group, Plc, SmithKline & French Laboratories Ltd., and Eli Lilly and Co v. Swingward Ltd and Dowelhurst Ltd. C-143/00

> The proprietor of a trade mark right that is protected in two Member States at the same time is justified pursuant to the first sentence of Article 30* in preventing the product to which the trade mark has been lawfully applied in one of those States from being marketed in the other Member State after it has been repacked in new packaging to which the trade mark has been affixed by a third party.[77]

Essentially saying that national trademark rights give the trademark holder the right to prevent parallel imports that have been repackaged. However following the free movement analysis, he went on to say:

> [S]uch prevention of marketing constitutes a disguised restriction on trade between member States within the meaning of the second sentence of Article 30* where:
>
> ● It is established that the use of the trademark right by the proprietor, having regard to the marketing system that he has adopted, will contribute to the artificial partitioning of the markets between Member States;[78]
>
> ● It is shown that repackaging cannot adversely affect the original condition of the product;
>
> ● The proprietor of the mark receives prior notice of the marketing of the repackaged product; and
>
> ● The new package clearly states who repackaged it.[79]

These conditions as set out by the Advocate General limit the national trademark holder's right to block a repackaged pharmaceutical product. They clearly promote free movement at the expense of the trademark holder.

The impact of allowing a parallel trader to repack pharmaceuticals also raises concerns regarding safety. The AG briefly touches upon this when remarking on the ECJ's "reluctance to unduly limit the trademark owner's right to oppose repackaging."[80] He states that "consequences of careless repackaging of pharmaceutical products may have repercussions on public

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[77] Id.,

[78] Case law has clarified that it does not need to be an intentional partitioning. See AG paragraph 34 , explaining previousl case law and clearly establishing the partiitioning of the market does not need to be deliberate. Supra note 66.

[79] Id.,

[80] Id., See paragraph 113

health and hence go beyond damage to the trademark owner's rights."[81] So each of the above requirements for repackaging can be analyzed from a safety perspective.

The first requirement preventing a trademark holder from artificially partitioning the market, may not be consistent with realities of language or other national customs. The artificial partitioning of the market may be necessary to prevent undue consumer confusion. In such a situation where consumer confusion is likely, allowing a parallel import may cause harm to the consumer, even if the product is repackaged or stickered over. Consumer confusion regarding pharmaceuticals could create a potentially life threatening situation. In this type of situation the principle of free movement may jeopardize consumer safety by allowing for products that may confuse the consumer.

The second requirement may be construed as protecting the safety of the consumer. If the inner packaging, or the original condition of the product, has not been harmed, then it is unlikely that the product has been tampered with in a way that would harm the consumer. However, although the blister packs may not change, the repackaged pharmaceutical product may have a different shelf life of the product, which if not clearly identified, may harm the consumer, but the court rejected these arguments.[82] Also, if the appearance is shabby or otherwise untidy, the consumer's confidence in the product may be lowered and that may effect their compliance with the directions associated with taking the medicine.

The third requirement mandating that the trademark owner receive an advance sample of the repackaged product can also be construed as supporting consumer safety. If there is anything that the original trademark owner objects to, or feels would jeopardize safety, they could try to assert their national rights asserting an Article 30 protection of life and health to counter the free movement argument. A trademark holder will not allow unsafe products, so if they have adequate time to inspect the repackaged product, it is unlikely that it will be unsafe.[83] However, such an inspection is an additional cost for the trademark holder to endure, so in effect, the cost for this requirement supporting safety is shifted to the trademark holder. In a sense, the trademark holder must pay twice to support the principle of free movement, first by loosing their national intellectual property rights, and second by paying to inspect the repackaged product.

Finally the last requirement mandating the name of the parallel importer who repackaged the product to be clearly stated can also be construed in favor of the safety of the consumer. First, by requiring the parallel

[81] Id., See paragraph 112.

[82] See Forrester supra note 27 at 515.

[83] The Boehringer case supra note 76 extended the time allowed for a trademark owner to reject a repackaged product, it also clearly reinforced the requiremnt of prior notice.

importer's name, it is more likely that reputable companies will be involved in the parallel trade. Second, by clearly identifying the entity who repackaged the product, it will be easier if it is necessary to recall the product.

As discussed before, the pharmaceutical industry is a heavily regulated market worldwide. There are specific requirements pertaining to the packaging, informational leaflets, dosage instructions and other general information required by law to be included at the sale of a pharmaceutical. So why does a parallel importer need to repackage pharmaceuticals in order to gain effective market access?

In Europe much of the regulation relating to the marketing of pharmaceuticals is harmonized by Community legislation discussing market authorizations. However, individual Member States still have requirements for size and packaging, there are also prescribing habits and cultural preferences to be considered,[84] and of course the need to have the information in the native language of the Member State where the product is sold. In addition, reimbursement for pharmaceuticals under national health insurance plans may require certain size packages or doses.[85]

In the context of parallel trade in pharmaceuticals, there are specific rules that need to be followed in terms of marketing, packaging and otherwise placing such products on the market. These rules were elaborated on by the ECJ in three cases from the mid nineties.[86] These cases also confirmed that the Trademark directive did not alter the requirements as set out in the Hoffman La Roche decision.[87]

In a number of cases the ECJ has held that national trademark rights may still be available to trademark holders if the repackaging of the goods is done in such a way as to harm the reputation of the trademark holder, e.g., defective packaging, poor quality or untidy.[88] This expands the concept of trademark from the protection of the consumer, and as a guarantee of origin, to include the good will of the trademark holder. This analysis creates

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[84] AG paragraph 49 supra note 66.

[85] Id., AG paragraph 34.

[86] Bristol-Myers Squibb, Eurim-Pharm and MPA Pharma joined cases C-427/93, 429/93, 426/93.

[87] AG paragraph 31 supra note 66.

[88] Bristol-Myers Squibb, Eurim-Pharm and MPA Pharma joined cases C-427/93, 429/93, 426/93. Also see discussion on ECJ Exhaustion Principles in Repackaging and Advertising Litigation by Theodore H. Davis, Jr., *Territoriality and Exhaustion of Trademark Rights Under the Laws of the North Atlantic Nations,* The Trademark Reporter, July/ August 1999 89 TMARKR 657.

barriers to the parallel import of pharmaceuticals that go beyond the confusion of the consumer, and therefore will not be fully discussed here.[89]

As discussed, in order for parallel traders to access a market for their imports of pharmaceutical products, it may be necessary for the importer to repackage, or otherwise tamper or change the appearance of the packaging in order to be in compliance with the rules of the particular Member State. This sometimes includes changing the name/ brand on the packaging to the name used in the Member State of import. When such repackaging is necessary for access to the market has been discussed in great length in the case law.

The ECJ set out in Pharmacia & Upjohn v Paranova[90] that the conditions must be "objectively necessary" for market access in order for a parallel importer to repackage and relabel the product. What objectively necessary meant was to be determined by the national court in question:

> In order to determine whether the proprietor of a trade mark may, under national law, prevent a parallel importer of pharmaceutical products from replacing the trademark used in the Member State of export by that which the proprietor uses in the Member State of import, to assess whether the circumstances prevailing at the time of marketing in the member State of import make it objectively necessary to replace the original trademark by that used in the Member State of import in order that the product in question may be marketed in that State by the parallel importer.[91]

In the same holding the ECJ distinguished what was objectively necessary for marketing from a situation where a parallel importer replaced a trademark solely for the "attempt to secure a commercial advantage.[92]

The objectively necessary standard was "softened" in the subsequent case law in Boehringer,[93] where Advocate General Gulmann concludes that:

> A parallel importer will be justified by virtue of Community law in repackaging pharmaceutical products in so far as such

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[89] Except see above note 66 regarding the confidence of consumers as summarized by AG Gulmann.

[90] Pharmacia & Upjohn SA v Paranova A/S C-389/97.

[91] Id., at paragraph 46.

[92] Id., at paragraph 44.

[93] Boehringer supra note 76. Also see analysis of repackaging cases by Sebastien J. Evrard, *Trademark Law in the European Union: An Overview of the Case Law of the Court of Justice and the Court of First Instance* (1997-2001), Columbia Journal of European Law, Fall 2002, 9 CLMJEURL 175.

> repackaging is reasonably required to enable the importer to obtain effective access to the market of the importing Member State…and in so far as other, less intrusive, methods of repackaging will not enable him to obtain effective access to that market.[94]

He continues that barriers to such effective access will include:

> [N]ot only obstacles which exist in law such as regulatory requirements of the importing Member State, but also of obstacles that exist in fact, including the resistance of consumers, for example, to over stickered boxes, which is such as to affect prescription or dispensing practice.[95]

So under the repackaging rational as set out above, the national trademark holder can not block the parallel import of a pharmaceutical product if the parallel importer has complied with the requirements set out in the case law. The priority of free movement is very clear, especially after the discussion of what effective access will be considered effectively necessary.

Another very important repackaging case that ties together safety and repackaging in a rather absurd way is the Aventis case.[96] In Aventis the issue at hand was, in order to sell Aventis insulin products in Germany, the parallel importer was reboxing packages of five to create a box of ten. Aventis argued that a less intrusive way of repackaging would be to bundle two boxes of five together to make ten, and therefore not change Aventis's trademark on the boxes.

The question came down to the marketing authorization and whether, when there is a marketing authorization for boxes of five and a marketing authorization for boxes of ten, a parallel importer could bundle together two packages of five, without repackaging them, in order to make a package of ten. The analysis of Advocate General Jacobs said no and the ECJ agreed.[97] The AG argued that according to the market authorization the packages must be distributed only as they were authorized and if a parallel importer need to comply with a marketing authorization and repackaging was the only way, than it was the only way, but bundling was not an acceptable alternative. He spent much of his discussion on the package description submitted in the marketing authorization.

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[94] AG in Boehringer paragraph 118 supra note 66.

[95] Id.

[96] Aventis Pharma Deutschland GmbH v Kohlpharma GmbH and MTK Pharma Vertriebe GmbH Case C- 433/00.

[97] Id., AG paragraph 42

This case, while perhaps a bit extreme in undermining a trademark holder's rights, does display the relative importance of a market authorization and the associated safety concerns, on the ECJ's principle scale for repackaging. Free movement of goods on the internal market is the number one priority. It is closely followed by the market authorization, in an acknowledgement of safety concerns. Finally in a distant third place, the national rights of intellectual property holders.

As seen from the repackaging case law, the ECJ has continued to place free movement of goods above the exercise of national intellectual property rights. If the requirements set out in the case law are satisfied, a trademark holder can not use his trademark to block the parallel importation of his product, even when it had been repackaged.

So where does repackaging leave safety? As discussed above, the repackaging requirements could generally be construed to protect consumer safety. In addition, the importance placed on the market authorization is encouraging for safety concerns. However, it is slightly disconcerting that there is so little direct consideration of safety concerns when allowing for the infringement of a national trademark used to guarantee origin. Ian Forrester accurately depicted the situation when he said:

> There is no other jurisdiction in the world where potent drugs are removed from their original boxes and repackaged in a completely new trade dress. This is done not to help the doctor, the pharmacist or the patient; nor to avoid confusion; but in the name of market integration, to allow the trader to build a name and reputation for products which he has bought in a country where the price is fixed low and resell them in another country where the price is fixed higher.[98]

Free movement has been the driving principle behind the promotion of parallel trade, even in the pharmaceutical market where free market forces do not apply.

3.3 Beyond Repackaging - Safety in the Structure of Pharmaceutical Regulation

While it goes beyond the scope of repackaging, it is important to briefly mention market authorizations as a measure to protect safety.

In Europe, pharmaceuticals are highly regulated in order to promote patient safety and protect against "ineffective and dangerous products."[99]

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[98] See Forrester supra note 27 at 519.

[99] PARALLEL TRADE IN EUROPE, Supra note 8 at 68.

Pharmaceuticals are regulated both on a European level and on a national basis in each individual Member State. Before being placed on the market, a pharmaceutical product must comply with the requirements of the directive 65/65 and its amendments that set out the requirements for a market authorization.[100] A marketing authorization is based on the testing of substances and the licensing operators at different levels of the supply chain to ensure the proper handling of the pharmaceuticals.[101]

The European Medicines Evaluation Agency (EMEA)[102] was created to harmonize the procedure for a market authorizations[103] by providing a centralized procedure for the approval of pharmaceuticals and medical devices, as well as to provide safety data gathered throughout the EU and the rest of the world. However, the national systems of marketing authorizations are also still in place.

There is a system of national marketing authorizations with a process for mutual recognition among Member States. These standards are very stringent. There are transitional rules to ensure that the new Member States market authorizations are consistent with the level set by the centralized market authorization, before a market authorization from a new Member State will be recognized.[104]

In an early case relating to market authorizations, the ECJ held that it ran counter to Article 28* to require a parallel importer to duplicate efforts and provide the Member State with the same information required for a marketing authorization in order to import the same pharmaceutical. The ECJ held that the Member State had already received the information from the original manufacturer, and to require it from the parallel importer ran counter to Article 28* especially when such information might be difficult and costly for the importer to obtain.[105]

Each Member State retains exclusive control over its welfare system, and sets prices and methods of reimbursement for pharmaceuticals. Since parallel imports generally compete on price within the Member State of

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[100] These include requirements that try to harmonize labeling and disclosure requirements across Member States see directives 92/27, 92/28.

[101] See discussion in PARALLEL TRADE IN EUROPE, Supra note 8 at 68-69.

[102] Created by Council Reg. 2309/93, effective 1995.

[103] See discussion in PARALLEL TRADE IN EUROPE, Supra note 8 at 68-69.

[104] See Freshfields Briefing supra note 65

[105] De Peijper Case 104/75, Similar to language that was taken out of US MEDS law, to be discussed in further detail below. Also discussed in PARALLEL TRADE IN EUROPE, Supra note 8 at 69.

import, in the De Peijper case, the Court stated that in relying on the derogations under Article 30* the Member State health authorities should:

> [N]ot place parallel imports at a disadvantage since the effective protection of health and life of humans also demands that medicinal preparations be sold at reasonable prices.[106]

As discussed above in the Aventis case, market authorizations are important to the regulation of parallel imports. This was reaffirmed by the ECJ in a recent preliminary ruling in a Swedish case.[107] The case involved the withdrawal of a national market authorization. The question was, whether a parallel importer could still sell on the national market after the withdrawal of the national marketing authorization (for issues unrelated to safety), when the same drug continued to be sold in other Member States and was covered by their marketing authorizations.

The ECJ held that yes the parallel importer could continue. Articles 28 and 30 preclude national legislation that requires the automatic withdrawal of a parallel importer's license when the national marketing authorization was withdrawn at the request of the holder for reasons unrelated to safety. The argument that the parallel importer's license should be revoked because it mentioned the original marketing authorization was not sufficient. The ECJ, made clear that the Member State could still revoke the parallel importer's license if there was a risk to health and humans as a result of the continued existence of the product on the importing Member State.[108] For example, a public health risk associated with the coexistence of two versions of the same medicinal product on the market of the importing Member State.[109]

The ECJ states that the safeguarding of the public health is the primary objective and it is up to national authorities to make sure that health and safety are protected through national legislation. [110] However, the free movement argument surfaces in this case as well and the ECJ goes on to say:

> The principle of proportionality, which is the basis for the last sentence of Article 30, requires that the power of the Member States to prohibit imports of products from other Member States be restricted to what is necessary in order to achieve the aims concerning the protection of health that are legitimately pursued. Thus national legislation or practice can not benefit from the derogation laid down in Article 30 when the health

[106] Id., De Peijper paragraph 25.

[107] Paranova Läkemedel AB and Others v Läkemedelsverket Case C-15/01

[108] Id. paragraph 33.

[109] Id., paragraph 32.

[110] Id.,paragraph 23, referring to Directive 65/65.

> and life of humans can be protected equally effectively by measures less restrictive of intra Community trade.[111]

From a reading of this case, it can be inferred that safety is only protected as long as there are no other means that are less restrictive of "intra Community trade."

So where does the parallel imports of pharmaceuticals leave the consumer? In summary, in the EU parallel imports of pharmaceuticals are supported and protected by the principle of free movement and regional exhaustion. The case law balances free movement of goods with national intellectual property rights by creating a legal fiction. The law allows for the existence of the national right, but holds that the exercise of such same right to prevent free movement, or otherwise artificially partition the market, would be considered a measure having an equivalent effect to a quantitative restriction and in violation of the treaties.

The ECJ has enthusiastically supported a parallel importer's right to effective market access. However, this access comes at a cost to a trademark[112] holder's rights, and may also jeopardize the guarantee of origin and safety that is inherent in a trademark.

Finally, in the repackaging context, a market authorization with its safety protections seems to rank above an intellectual property right, but somewhere below free movement. Perhaps a market authorization's values of safety are automatically protected by Article 30.

This section has defined the underlying rationale of free movement as the force regulating parallel imports of pharmaceuticals in the European Union. In implementing this regulation and allowing for repackaging, intellectual property rights have been marginalized, while safety concerns have not been mentioned.

The next section will give an overview of the underlying rational in the regulation of parallel imports of pharmaceuticals in the United States.

[111] Id., paragraph 24.

[112] Or any IPR holder.

4 US Rules on Parallel Trade, IPRs, and Safety

The United States' approach to parallel trade is different than that of the European Union, especially as applied to parallel imports of pharmaceuticals.

In the US, the parallel import of pharmaceuticals is currently prohibited because of safety concerns. Aside from pharmaceuticals, the rules pertaining to parallel imports in the US are not driven by an overwhelming need to foster market integration at any cost. Rather the United States balances intellectual property protection, seen as necessary to promote an innovative society, and the concept of exhaustion so an IPR holder does not benefit twice from his intellectual property protection. The US has taken a mixed view towards parallel imports to reflect this balance.[113]

Within the United States an intellectual property right holder's rights are exhausted at first sale. The first sale doctrine is well developed in copyright law under 17 USC § 109(a).[114] This concept was tested in sales to foreign distributors in the pivotal copyright case on exhaustion in Quality King Distributors, Inc. v. L'anza Research International to be discussed in more detail later on. Although enshrined in copyright law, the first sale doctrine and the concept of exhaustion applies to all intellectual property rights sold in the US. However, at the moment it is unclear whether a foreign sale satisfies the first sale doctrine, thus exhausting the IPR holder's rights, in patent and trademark cases.

This section will briefly discuss the US position on parallel imports under patent, copyright and trademark laws. Then it will summarize the trade mark case law that would be applicable to repackaging. While parallel imports of pharmaceuticals are not currently allowed, an analogous situation may be drawn from the current trademark case law.

Then this section will go on to discuss the regulation of pharmaceuticals in the context of parallel trade, focusing particularly on safety. Since 1987 the US has had a very strict ban on the reimportation by anyone other than the manufacturer.[115] This law, which originally passed amid fears of counterfeit

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[113] Parallel Imports are often referred to as gray market goods in the US, perhaps implying negative under tones when associated with products on the black market.

[114] Robert P. Merges, Peter S. Menell, and Mark A. Lemley, INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE, Second Edition, Aspen Publishers, Inc. Legal Education Division. (2000) at 471.

[115] Prescription Drug Marketing Act of 1987, Pub L N 100-293, 21 USC § 381(d)(1)

products infiltrating the American drug stream,[116] may be on its last legs. In 2000 the Congress passed the Medicine Equity and Drug Safety Act[117] that allows for the reimportation of pharmaceuticals from Canada[118] in order to benefit from lower drug prices. However, this law was passed with the restriction, that before it could take effect, the Secretary of Health and Human Services would need to certify to Congress that the reimportation could be done safely and that there would be cost savings. This certification has not occurred. Both the former Secretary of HHS under the Clinton administration and the current Secretary of HHS under the Bush administration have said that it is not possible to guarantee the safety of the American consumer and still maintain the cost savings. However, this view may change as the political climate grows steadily more attuned to the price differentials between pharmaceuticals for sale in the Unites States and else where in highly developed countries such as Canada and the European Union.

4.1 Background – Innovation

Intellectual property rights are very important in the Unites States. The Constitution calls for the promotion of the useful arts and sciences by rewarding the inventors with a monopoly of rights for a limited time.[119] This limited monopoly creates tension between encouraging innovation and allowing a monopoly, which goes against free trade. So in the US there is a similar tension between a free market and intellectual property protection, as there is in Europe.

However, where market integration is the driving principle in the EU, in the US, innovation could be called the driving principle. The policy behind intellectual property rights promotes the sharing of information in order to foster innovation and growth.[120] The IPR rewards inventors and creators for

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[116] William Davis, *The Medicine Equity and Drug Safety Act of 2000: Releasing the Gray Market Pharmaceuticals*, Tulane Journal of International and Comparative Law, Spring 2001, 9 TLNJICL 483.

[117] 21 USC §384, Pub L N 106-387 § 745.

[118] And other contries as identified by the Secretary of HHS.

[119] United States Constitution, Article I, Section 8, Clause 7.

[120] Traditional trademark protection is historically based on the protection of the consumer, and as a guarantee of origin and quality. It differs from patent and copyright, in that it does not reward creativity, but rather it rewards consistent quality by building up consumer goodwill. However, the concept of the misappropriation of goodwill is well established, and in addition, the concept of a Brand as an important asset is frequently recognized. For further discussion see *A Brief Overview of Trademark Theory* in INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE supra note 94, Also see Lisa Harlander, *Exhaustion of Trademark Rights Beyond the European Union in Light of Silhouette international Schmied v Hartlauer Handelsgesellschaft – Toward Stronger Protection of Trademark Rights and*

their contribution to society, and at the same time encourages them to continue to invent and develop.[121]

The US has taken a utilitarian approach to intellectual property rights. The Constitution gives Congress the right to create a balance between an individual's right to intellectual property and society's right to an "intellectual commons".[122]

However, innovation and protection of IPRs are not the only forces at play in regulating parallel imports. In addition, the protection of American consumers is very important. The regulation of parallel imports prevents goods that are likely to cause consumer confusion, or goods that have material differences that will cause consumer confusion.

At the moment, parallel imports of pharmaceuticals are forbidden under the Prescription Drug Marketing Act.[123] However, the issue of parallel imports of pharmaceuticals is a hotly contested political issue, and in the current political climate this prohibition may change. If the safety issue can be resolved, then the US will need to balance greater access to cheaper pharmaceuticals with the innovation of the US pharmaceutical industry.

Because parallel imports of pharmaceuticals are currently forbidden there is no case law on point. However, there is analogous case law that does deal with the parallel importation of other goods. Specifically, the law regarding what constitutes a material difference is relevant to an analysis of the parallel import of pharmaceuticals.

The following section will briefly summarize US law as it regards parallel imports.

Eliminating the Gray Market, Georgia Journal of International Comparative Law, Spring 2000, 28 GAJICL 267 at 283-285.

[121] See John W. Schlicher, PATENT LAW: LEGAL AND ECONOMIC PRINCIPLES, (West Group, 2001) viii, for a good explanation of the policy behind a patent: The patent idea has two parts: 1) an economy controlled by market forces rather than a government depends on private incentives and initiative to produce the right amounts of the right kind of goods. 2) a market economy will not provide adequate incentives to produce technical information, unless the law provides patent rights. An economy that fails to produce that information will fail to grow at the rate it should. (as cited by author in unpublished paper)

[122] James Thuo Gathii, *Rights, Patents, Markets and the Global AIDS Pandemic*, 14 FLJIL 261, (2002) at 321.

[123] PMDA supra note 115.

4.2 Intellectual Property Rights[124]

As discussed above, the evolution of intellectual property rights in the US, begins with the notion that an inventor or other creative mind should be rewarded for sharing his knowledge with society as a whole. This concept has been enshrined in the US Constitution in Article I, Section 8, Clause 7, which states:

> To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries[125].

In the US, federal statutes and case law protect intellectual property. Title 35 of the United States code covers patents, Title 17 covers copyrights and Title 15, Chapter 22, (the Lanham Act) covers trademarks. These statutes have been analyzed extensively in the case law, providing an expansive body of law regulating intellectual property rights. In addition to federal protection, state protection exists for copyrights and trademarks, although patent protection is exclusively with within the federal jurisdiction.

For an analysis of parallel imports, the federal laws relating to the exhaustion of intellectual property rights are the most important. Exhaustion controls when an IPR holder can block a parallel import from entering the US market, and since the regulation of parallel imports falls within the Commerce Clause, the federal government has jurisdiction.[126]

The following section sets out the case law pertaining to exhaustion.

4.2.1 Exhaustion

The concept of exhaustion is very important in the regulation of parallel imports, for if the intellectual property right is not exhausted upon a foreign sale, and an IPR holder can use his right to block the imports, than there can be no parallel trade.

In the US, it is clear from the case law and statutes that, once a right holder places a product on the US market, directly or with his consent, his intellectual property right has been exhausted in the US market. This concept is referred to as national or territorial exhaustion.

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[124] For purposes of this analysis intellectual property rights will only refer to Patents, Copyrights, and Trademarks.

[125] United States Constitution Article I, Section 8, Clause 7.

[126] Article I, Section 8, Clause 3.

What is less clear is whether a sale abroad would have the same effect on an American IPR holder's rights. That is, would a sale made by the right holder directly, or with his consent, anywhere in the world, exhaust his rights. This concept is referred to as international exhaustion.

For many years US case law interpreted the copyright and trademark statutes to allow IPR holders to block imports of legitimate goods not originally put on sale in the US. Patent law moved from a clear position of territorial exhaustion in early case law, to a modified rule of international exhaustion. Under modified international exhaustion theory, a patent holder could contractually restrict or prohibit the resale of the product in the US without the patent holder's consent, however, without such limitations, the patent holder's rights were exhausted.[127]

In the past few years, there have been a few landmark cases that have changed, or at least challenged the status quo of exhaustion under United States intellectual property law. Without going into a deep analysis, the following two case summaries illustrate the diverging views with regard to exhaustion in the patent and copyright areas of law.

4.2.1.1 Patent – Jazz Photo[128]

The Jazz Photo case involved a Federal Circuit Court of Appeals[129] decision regarding the sale in the US of refurbished disposable cameras. The US patentee had originally sold the cameras abroad, where they were refurbished and then subsequently resold on the US market. The Federal Circuit held that such reimportation infringed the US patent. In this holding the Federal Circuit adopted a clear rule of territorial exhaustion.[130] The Supreme Court refused to reconsider the decision of the Federal Circuit, so for the time being, US law reflects a regional theory of exhaustion for patent rights. This goes against the trend towards more international exhaustion in the fields of copyright and trademark rights.

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[127] Daniel Erlikhman, *Jazz Photo and the Doctrine of Patent Exhaustion: Implications to TRIPS and International Harmonization of Patent Protection,* Hastings Communications and Entertainment Law Journal, Winter 2003, 25 COMENT 307 at 311.

[128] Jazz Photo Corporation v. Int'l Trade Comm., 264 F.3d 1094 (Fed. Cir 2001), cert. denied, 122 S. Ct. 2644 (2002).

[129] The Federal Circuit Court was established in 1982 and has exclusive jurisdiction over appellate patent matters see http://air.fjc.gov/history/landmark/22a_frm.html for more information.

[130] Erlikhman supra note 127 at 313.

4.2.1.2 Copyright – Quality King[131]

The Quality King case involved a recent Supreme Court decision that arguably extends the first sale doctrine to sales of American manufactured goods sold to distributors located outside of the country. The Supreme Court held that the first sale doctrine[132] applies to such a sale, and thus exhausts a copyright right. The case involved the copyright on instructions and labels placed on L'anza hair care products, that were sold to a UK distributor for shipment to another foreign distributor for sale in Malta. These goods were then reimported to the US without L'anza's permission.[133] The defendant Quality King argued that L'anza had exhausted its rights under the first sale doctrine. While an extensive analysis of the Court's ruling exceeds the scope of this paper, the Court held that the first sale doctrine did apply to the sale, and therefore the copyright holder's right was exhausted upon the sale to the UK distributor.

Justice Stevens delivered the opinion for the Court, and in his conclusion specifically referred to the terms gray market and parallel imports as defined in the Court's Kmart decision.[134]

> We are not at all sure that those terms appropriately describe the consequences of an American manufacturer's decision to limit its promotional efforts to the domestic market, and to sell its products abroad at discounted prices that are so low that its foreign distributors can compete in the domestic market. But even if they do, whether or not we think it would be wise policy to provide statutory protection for such price discrimination is not a matter relevant to our duty to interpret the text of the Copyright Act.[135]

In the concurring opinion by Justice Ginsburg, it was clear that she would only apply the first sale doctrine to foreign sales when the product was originally manufactured in the US. She refers to the situation as a "round

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[131] Quality King Distributors, Inc. v. L'anza Research Intl., 523 U.S. 135 (1998)

[132] The first sale doctrine enshrined in 17 U.S.C.§ 109(a), holds that once a work is lawfully sold or even transferred gratuitously the copy right owner's interest has been exhausted. For further discussion see Marshall Leaffer, UNDERSTANDING COPYRIGHT LAW, Third Edition, Matthew Bender & Company Inc. (New York, 1999) at 310-312.

[133] Richelieu supra note 18 at 843 and INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE supra note 114 at 470-476.

[134] K Mart Corp. v. Cartier, Inc., 486 U.S. 281.(1988)To be discussed further under the trademarks section.

[135] Quality King supra note 131, and INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE supra note 114 at 470-476.

trip journey", indicating that they would start and end in the United States.[136]

From these cases it can be surmised that US law is unsettled as it deals with reimportation. On one hand a modified version of international exhaustion has been challenged in favor of national exhaustion in patent law, but on the other hand, in copyright law the opposite occurred when national exhaustion was opened up to at least modified international exhaustion.

The above two cases are meant to illustrate the current differing opinions in US intellectual property law on exhaustion. While the trademark cases will be discussed in more detail below, they also fall into different categories, and for purposes of exhaustion, it has been said that the United States trademark exhaustion system is a hybrid of national and international exhaustion.[137]

It is important to note that the Court is very aware of the different standards for different IPRs when it comes to exhaustion principles. The Court does not operate in a vacuum and will use principles in other matters. This was seen in the Quality King decision where the K Mart decision was cited, but the opinion was distinguished. Depending on the political landscape, the Court may rely more heavily on one principle rather than an other.

4.2.2 Trademark Discussion in the context of parallel trade

Although the US does not allow parallel imports of pharmaceuticals, comparisons can be made to analogous situations of parallel imports of other goods. Generally speaking, parallel imports are allowed from abroad when there is common control of the US and foreign trademark and the products are not materially different. If the mark is under common control, it is generally thought to share the same good will, and therefore will not be denied entry into the US unless it is materially different.[138] The US cases that most closely align with the repackaging cases in the EU are the cases based on the material difference standard.

US litigation regarding parallel imports generally involves sections of the Lanham Act and the Tariff Act, and US Customs regulations. The Tariff Act is not technically a part of the trademark statute, but it is used in halting shipments of goods that don't comply with the applicable laws. A thorough

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[136] Id.

[137] Kimberly Reed, *Levi Strauss v. Tesco and EU Trademark Exhaustion: A Proposal for Change*, Northwestern Journal of International Law and Business, Fall 2002, 23 NWJILB 139 at 159.

[138] Theodore H. Davis, Jr., *Territoriality and Exhaustion of Trademark Rights Under the Laws of the North Atlantic Nations*, The Trademark Reporter, July/ August 1999 89 TMARKR 657 at 675-678.

analysis of the relationship between the Lanaham Act and the Custom's statutes is a thesis in and of it self and will not be discussed here.[139]

Similar to the EU, the US trademark is for the benefit of consumers. It is used to minimize consumer search costs, by providing an indication of source and consistent quality.

K Mart v Cartier[140]is a landmark Supreme Court case that defines the gray market. The Court sets out three different scenarios for parallel trade and discusses under which scenarios parallel trade is allowed and when it would violate the statute. While it is considered a landmark case, K Mart does not really address the material difference standard, so it will not be discussed in detail.

In the US, a trademark is historically associated with providing a consumer identification of a source. The trademark acts as a guarantee of origin and quality, and thereby prevents consumer confusion.[141] Consumer confusion is an important element in presenting trademark infringement. In a parallel import situation, the material difference standard is used as a proxy for the likelihood of consumer confusion test.[142]

Parallel imports are allowed in the US unless the goods are materially different.[143] Some American Courts have held that the difference between foreign trademarked goods and US trademarked goods is enough to render them "non genuine" and prohibit their parallel import into the US as they may confuse consumers and degrade the value of the US trademark.[144] The criteria required to establish such a material difference has been applied in different ways in different circuits.[145]

Essentially, in parallel import situations, it has been held that a material difference is one that the consumer would notice and considers relevant in

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[139] Relevant sections § 1526 Tariff Act, §§ 32 and 42, 43 Lanham Act.

[140]K Mart supra note 134.

[141] See discussion on trademark supra note 120; also see INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE supra note 114.

[142] Swanson, supra note 9 at 334.

[143] Id., 334

[144] See Reed note supra 137 at 166-170.

[145] The Circuit Courts of Appeal are the highest level of Federal Courts under the Supreme Court. They are divided by region, and sometimes apply different standards to similar cases. Generally unless there is a direct split, i.e., where two circuits have reached opposite conclusions, the US Supreme Court will let the decisions stand.

purchasing a good.[146] The following are a few examples of the different views among the circuit courts.

The Second Circuit held in the Cabbage Patch Kid Case, that "the packaging and literature of the gray market dolls produced substantial confusion among domestic customers."[147] In this case, the American trademark holder of Cabbage Patch Kids tried to prevent the importation of its dolls that were intended for a Spanish speaking market. All dolls came with adoption certificates and could be registered with adoption centers. Spanish dolls did not have the same paperwork and it was in Spanish.[148] The Court found that there was a material difference between the Spanish version and the English version, and that consumers were confused. The parallel imports were not allowed.

The First Circuit required relatively marginal differences that could be linked to the consumers' likelihood of confusion to sufficiently satisfy the material difference test.[149] In Societe Des Prouit Nestle, S.A. v. Casa Helvetia, Inc[150]they held that there was a difference between chocolate from Venezuela and chocolate from Italy. Although both parties were authorized users of the same trademark, the Court held the Venezuelan product was material different from the Italian product. The Court found that the Venezuelan goods were not subject to the same quality control, had different ingredients, came in a different number configurations, had different packaging and a lower price.[151]

In Martin's Herend Imports v. Diamond & Gem Trading USA, Co.,[152] the Fifth Circuit found that a material difference existed when a US exclusive distributor of Hungarian porcelain figurines sued to enjoin the parallel import of genuine goods. The parallel imports were genuine goods, but of a different color and design than the ones that the exclusive distributor had chosen to import. This difference was held to be a material difference.

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[146] In the News ,Parallel Imports, 01 Jan 2003, Cooley Godward LLP, Available at http://www.cooley.com/news/inthenews.aspx?id=37515720 last viewed 20 May 2004.

[147] Davis supra note 138 at 679-680 Original Appalachian Artworks, Inc. v. Granada Electronics Inc., 816 F2d 70.

[148] Id.,

[149] Davis supra note 138.

[150] Societe Des Prouit Nestle, S.A. v. Casa Helvetia, Inc 982 F2d 633

[151] Davis supra note 138.

[152] Martin's Herend Imports Inc. v. Diamond & Gem Trading USA, Co. 112 F3d 1296

The Ninth Circuit seems to have a more difficult standard and has held that even repackaging without notice will not be considered a material difference of confusion.[153]

Overall, the material difference standard is low, if the parallel import smells different, creates soapsuds[154] in a different way, and even costs less it could be considered materially different and blocked from the US market. However, if the goods are the same, a trademark holder would not be able to block their import by claiming infringement. If there is a material difference the good is no longer considered a genuine good, and therefore will not be allowed in as an import. The different circuits have set a variety of tests determining what constitutes material difference. In general it is a fairly low standard, with perhaps the fifth circuit being the lowest.

Consumer confusion is a key factor in all of the above cases. The material difference standard has been used as a proxy for consumer confusion, so if there is a difference, there is likely to be consumer confusion and the goods will not be allowed in to the US market. If the US allowed parallel imports of pharmaceuticals, in theory according to this case law, it is likely that they would be considered materially different from the original and not allowed because they would cause consumer confusion, and consumer confusion regarding pharmaceuticals has the potential to be dangerous.

4.3 Safety in the Structure of Pharmaceutical Regulation

As discussed above, the protection of the American consumer in an important factor in the regulation of all parallel imports. Protection from confusion and poor quality goods is taken to a higher level in regulating pharmaceutical products. The United States arguably has the most comprehensive and rigorous government system for regulating and approving medicines in the world.[155] Pharmaceutical products are regulated by the Federal Food and Drug Administration (FDA).

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[153] Enesco Corp. v. Price/ Costco Inc., 143 F3d 1083, see Davis supra note 138 at 684-685

[154] Another US case Lever Brothers, dealt with parallel imports of dish detergent originally meant for the UK. In the UK the mineral composite of the water is different and the detergent was formulated for this water. When used in the US the soap did not suds in the same was and it was held to be a material difference. Lever Bros. Co. v U.S. 981 F2d 1330 (D.C. Cir 1993). See also Reed supra note 137.

[155] Dan Kidd, *The International Conference on Harmonization of Pharmaceutical Regulations, The European Medicines Evaluation Agency and the FDA, Who's Zooming Who?,* Indiana Journal of Global Legal Studies, Fall 1996 4 INJGLS 183 at 196. Donald E. deKieffer, Esq., *The Mexican Drug Connection: How Trade in Pharmaceuticals has Wrecked the FDA*, Southwestern Journal of Law and Trade in the Americas 2002-2003, 9 SWJLTA 321 at 324-325.

The FDA comes under the supervision of the Department of Health and Human Services an administrative agency reporting to the executive branch. FDA's mission is:

> To promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use.[156]

It regulates every step of the manufacturing and marketing of prescription drugs,[157]and its regulations stretch beyond the US borders by regulating the production, storage, testing, transportation, and labeling of every ingredient used in the manufacturing of a domestic pharmaceutical.[158]

Partially due to the comprehensive domestic standards, fear of unregulated and unsafe foreign drugs is common. Passage of the Prescription Drug Marketing Act of 1987 [159]was prompted by evidence that the integrity of reimported drugs to the US had been compromised.[160]

Since 1987, only the original manufacturers have been allowed to reimport a prescription drug to the US. This ban on parallel imports, along with other protections in the "closed" distribution system protects the American drug supply from unsafe, ineffective, and poor quality drugs.[161] There are many layers of protection in this "closed" system. First, all US drugs must be approved by the FDA regulatory process mentioned above. Second, after a drug is approved, it must continue to comply with the FDA standards and is subject to ongoing inspections. Third, pharmacists and wholesalers are licensed by the states where they provide pharmaceuticals. Since there are very few points of entry into the system, it is easy to regulate.[162]

Since 1987, the cost of prescription drugs has skyrocketed[163]and the ability for consumers without prescription drug insurance, typically the elderly,[164]

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[156] FDA Website http://www.fda.gov/oc/opacom/fda101/fda101text.html last viewed 20 May 2004

[157] deKieffer, supra note 155 at 324.

[158] Kidd supra note 155 at 199.

[159] See PMDA supra note 115.

[160] July 9th letter from Tommy G. Thompson, Secretary, Department of Health and Human Services to Senator James Jeffords re MEDS Act. Available at http://www.fda.gov/oc/po/thompson/medsact.html Last viewed 19 May 2004.

[161] Id.,

[162] Id.

[163] myriad of sources – a glance at any major US newspaper will contain an article on the costs of prescription drugs.

to afford their medicines is limited. Busloads of American senior citizens traveling to Canada to purchase pharmaceuticals at a significant discount from American prices, makes for good political capital. So in 2000 Congress passed the Medicine Equity and Drug Safety Act (MEDSA).[165]

This law removed the reimportation monopoly from the manufacturers, and allows pharmacists and wholesalers to reimport FDA approved American manufactured drugs back to the US from countries approved by the Secretary of Health and Human Services. Before the law could take effect the Secretary of HHS needed to certify to Congress that the reimportation could be done safely and at a cost savings for Americans. As mentioned above, neither Donna E. Shalala, former Secretary of HHS nor Tommy G. Thompson the current Secretary of HHS could implement the regulations in a way that would ensure safety and cost savings.[166]

However, in the face of increasing political pressure from Congress, state governments and constituents, there is growing support for allowing the reimportation of pharmaceuticals from at least Canada. At the beginning of May, Secretary Thompson was reported as saying "he would advise President George W. Bush not to stand in the way of legislation to make it legal for drugs to be imported from abroad. 'I think it's coming,'"referring to legislation allowing reimportation.[167]

In summary, US law puts the protection of American consumers, and protection of intellectual property rights above free market access for parallel importers.

US law **currently** bans parallel imports of pharmaceuticals due to safety reasons. Only the manufacturers are allowed to reimport pharmaceuticals because it keeps the pharmaceutical distribution system closed, which makes it easier to regulate and theoretically guarantees a higher level of safety for the products.

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[164] Under the US Social Security system, health insurance is provided for by the government program Medicare after your 65th birthday. However there is no insurance coverage for prescription drugs under this program. Prescription costs are considered an out of pocket expense. Additional insurance policies are available, but they are often prohibitively expensive and are generally only purchased if the cost of the insurance policy is lower than the cost of the prescription drugs. The "elderly" comprise a demographic that is generally on a fixed income, does not have automatic prescription insurance coverage, statistically takes a higher number of prescription drugs, and VOTES!

[165] 21 USC § 384 (2000).

[166] See Thompson letter supra note 160.

[167] Globeandmail.com Breaking News, Posted at 8:50 PM EDT Tuesday, May. 4, 2004 www.globeandmail.com,

The US views towards other forms of parallel trade are mixed. Generally the US promotes a culture of innovation by actively protecting intellectual property rights. US views on exhaustion are mixed, the case law seems to support a hybrid approach depending on the circumstances and intellectual property right in question. The prevention of consumer confusion factors into the trademark cases along with the protection of the trademark holder's goodwill.

The US does not have the same positive feelings towards parallel trade as the EU. The terms most often used to describe parallel imports in the US are gray market goods, a term with slightly negative undertones due to the association with the black market.

This section has identified the underlying rationale of safety as the force regulating parallel imports of pharmaceuticals in the United States. Although political pressures in the US may force safety to give way to lower prices by way of import. The US will need to protect innovation by protecting its IPRs, as the protection of an innovative society goes hand in hand with a high level of intellectual property protection.

The next section will contrast the differing rationales regulating the parallel imports of pharmaceuticals in the European Union and the United States. It will contrast how safety and intellectual property are viewed and treated.

5 Comparative Analysis

The purpose of this paper was to explore whether the rules pertaining to the regulation of parallel trade of pharmaceuticals in the EU considered the safety of consumers, with respect to repackaging, and to compare those rules with those in the US.

Because the different regulatory systems were not compared, it may be that this paper is comparing apples and pears. However, the following discussion is still useful because it identifies the different underlying values in the regulation of parallel imports.

The European consumer is subject to as many safety regulations impacting the pharmaceuticals as their US counterpart; however by allowing a third party parallel importer to interfere with the trademark holder's rights, the ECJ case law has opened the chain of distribution. The more points of entry in the distribution system the greater the chance for safety to be compromised.

However, does this mean that the European consumer is at a possible disadvantage with regards to safety when compared to their American counterpart? Yes, there is a possible disadvantage, but in reality, I do not think it is a serious issue.[168]

As discussed above, if the requirements for repackaging as set out in the European case law are met, then the safety of consumers is most likely protected. The high level of requirements placed upon parallel importers requires that a legitimate business must be involved, not a fly by night operation.

The ability for a third party parallel importer to repackage a pharmaceutical product in Europe is very different from the closed distribution system in the US. However, the European parallel importer has a vested interest in protecting the quality of the parallel import and making sure that the safety of the European consumer is protected, because if he doesn't his livelihood may be jeopardized. If the Member States are faced with tragedy due to the unsafe parallel importation of pharmaceuticals, I suspect that they would rely on the derogations provided for in Article 30 to protect life and health.

It is also perhaps a bit unfair to make such a sweeping statement regarding the low status of safety in the EU. The focus of this analysis was the parallel import of pharmaceuticals with regard to repackaging, perhaps a more evenly balanced analysis would be to compare the FDA regulations

[168] Donald deKieffer argued the FDA bureaucracy could not enforce its own laws, particulary in preventing illegal parallel imports from coming across the NAFTA borders See deKieffer supra note 155 at 325.

with the EMEA regulations. To look at the regulatory approval process and the safeguards inherent in the market authorization case law which was not analyzed here.

As a side note, the issue of liability, of both the trademark holder, and the parallel importer, may also be worth studying in terms of a safety analysis. In the US fear of liability, and a very litigious society, often prompts more self-regulation and sometimes defensive warning tactics. While in Europe the culture is not litigious, and the court systems are not used to enforce or create policy. Punitive damages are not an effective regulatory tool in Europe.

This paper set out to investigate whether the goals behind the European free market jeopardized the safety of European consumers by encouraging parallel imports, especially by allowing for the repackaging of pharmaceuticals contrary to national trademark rights.

Again, I do not think that there are significant safety issues, but the likelihood of consumer confusion is higher in the EU than in the US. To the extent that this causes safety issues, the EU consumer is at a disadvantage compared to their American counterpart.

If for purposes of analysis, the US did allow parallel trade in pharmaceuticals, it is likely that under US trademark law, the safety of consumers is still protected at a higher level than in the EU. In the US the likelihood of confusion, or its proxy the material difference standard, can prevent a parallel import from reaching the market.

As discussed above in the US section, American trademarks holders may block the parallel import of a product that is material different from the one in circulation on the US market. The bar for material difference is set low.

In comparing the EU laws regarding repackaging with the US laws regarding material difference, it is clear that there are different underlying goals between the two systems. In the EU, the free movement of goods drives the law, while in the US, protection of intellectual property rights and preventing consumer confusion are behind the case law. The following few points offer a comparison:

In a case analogous to the a repackaging of pharmaceuticals, the First Circuit court held that parallel imports of chocolates that were sold in different number configurations from that of the trademark holder's configurations would be enough to create a material difference and block the product. This can be likened to a parallel importer repackaging two boxes of five into one box of ten. Under the material difference test the trademark owner could block the parallel import.

Another analogous case could occur where a pharmaceutical is distributed in a very specific shape and color, e.g., an inhaler. Under the Fifth Circuits'

holding, a parallel importer could be barred from brining in a different colored and shaped, although equally effective, inhaler. For purposes of this example, the delivery method and all functional aspects would be the same, merely a distinctive or fanciful embellishment to the shape. This was essentially the situation where the Fifth Circuit held that the trademark holder's choice of shape and color of figurines was enough to create a material difference from a parallel importer who was importing genuine authentic goods from the same place, but because he had chosen different colors and shapes, his product was considered materially different and therefore barred by the trademark right.

However the Ninth Circuit's holding requiring notice of repackaging is similar to the notice requirements as originally set out in Hoffmann La Roche[169] and recently updated in Boehringer.[170]

Finally, I set out to discuss whether, as the political pressure for access to affordable pharmaceuticals grows in the US, the US should look to the EU as a model to follow or as an example to be avoided?

When, as it inevitably will, the US begins to allow the parallel imports of pharmaceuticals as a short term fix to a problem that needs a long term solution, the US could follow the EU's model of active promotion of parallel imports of pharmaceuticals. However, the unique rational behind the EU's promotion of parallel trade, the goal to create an ever closer union among the peoples of Europe and fostering the creation and integration of the Common Market, does not apply to the US. In addition, if the US were to follow the EU's model, it would have to eviscerate the strong intellectual property protection that currently provides the backbone for the US's innovative society and culture. This would be unadvisable.

While it is unadvisable for the US to follow the EU model. The US could learn something from the holding of the DePijper[171] case. The ECJ held in an early case relating to market authorizations, that:

> It ran counter to Article 28* to require a parallel importer to duplicate efforts and provide the Member State with the same information required for a marketing authorization in order to import the same pharmaceutical. The ECJ held that the Member State had already received the information from the original manufacturer, and to require it from the parallel importer ran counter to Article 28* especially when such

[169] Supra note 38.

[170] Supra note 66.

[171] De Peijper Case 104/75 supra note 105.

> information might be difficult and costly for the importer to obtain.[172]

While the US does not have the force of free movement driving its regulatory scheme, it seems contrary to good sense not to incorporate this principle of shared information. Very similar language was removed from MEDSA before it was passed into law.[173]

In summary, pharmaceutical companies are trying to protect their research and development costs in markets where they can set higher prices, but they are competing with parallel importers who are bringing the same drugs in from countries where an artificially low price is set by local governments. Pharmaceutical companies have tried a number of strategies to prevent these parallel imports explicitly forbidding them, choking off supplies, arguing intellectual property rights, and even arguing on behalf of consumer safety.

In the EU parallel imports of pharmaceuticals are supported and protected by the principle of free movement and regional exhaustion. The case law balances free movement of goods with national intellectual property rights by creating a legal fiction. They allow for the existence of the national right, but hold that the exercise of such same right to prevent free movement, or otherwise artificially partition the market, would be considered a measure having an equivalent effect to a quantitative restriction and in violation of the treaties.

The ECJ has enthusiastically supported a parallel importer's right to effective market access. However, this access comes at a cost to a trademark[174] holder's rights, and may also jeopardize the guarantee of origin and possibly the guarantee of safety that is inherent in a trademark.

Free movement is the underlying rationale of the force regulating parallel imports of pharmaceuticals in the European Union. In implementing this regulation and allowing for repackaging, intellectual property rights have been marginalized and safety concerns have not been mentioned.

US law currently bans parallel imports of pharmaceuticals due to safety reasons, and only allows manufacturers to reimport pharmaceuticals. The US views towards other forms of parallel trade are mixed. Generally the US promotes a culture of innovation by actively protecting intellectual property rights. US views on exhaustion are mixed, the case law seems to support a hybrid approach depending on the circumstances and intellectual property right in question. The US does not have the same positive feelings towards

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[172] De Peijper Case 104/75, Similar to language that was taken out of US law, to be discussed in further detail below. Also discussed in PARALLEL TRADE IN EUROPE, Supra note 8 at 69.

[173] See Creech Supra note 21.

[174] Or any IPR holder.

parallel trade as the EU. The terms most often used to describe parallel imports in the US are gray market goods, a term with slightly negative undertones due to the association with the black market.

Safety is the underlying rationale as the force regulating parallel imports of pharmaceuticals in the United States. Although political pressures in the US may force safety to give way to lower prices by way of import. The US will need to protect innovation by protecting its IPRs, as the protection of an innovative society goes hand in hand with a high level of intellectual property protection.

6 Conclusion

I originally set out to investigate how European consumer safety was protected in the repackaging cases, and I was surprised by what I found. That the free movement of goods was such an over arching principle to the internal market and the structure of the EU as a whole, that consumer safety was not really discussed in this context at all. This may be partially due to the choice of repackaging, a subject that has fewer consumer safeguards than a topic such as the market authorization process.

I was surprised at the paucity of safety regulations, within the repackaging law. I had initially assumed that there would be more safety procedures in allowing a third party to take a packaged trademarked pharmaceutical product and allowing them to dissect the package, add safety and dosage information in another language, perhaps create a different size, and then repackage such a product. That would then be sold to a person in need of a potentially life saving medicine.

However it was an interesting note. Perhaps because the EU case law sets out such clear standards of what a parallel importer must do when repackaging pharmaceuticals, the issues of safety are not really an issue. As I stated above, if a parallel importer complies with the all of the rules laid out in the EU case law, consumer safety is probably ok.

The European Union has specific goals of market integration that make parallel imports attractive. However, somewhere in the future the EU may regret subjugating national intellectual property rights in order to let free movement reign free.

Long term I do not think that parallel imports of pharmaceuticals will be a successful regulatory tool used to control price. Especially in the United States where the running of such a system that incorporates at least a few safety measures (at least enough to avoid liability) will come at such cost, the system will possibly collapse under its own weight.

At this time, US law puts the protection of American consumers and protection of intellectual property rights above free market access for parallel importers, while EU law promotes free movement of goods above safety and certainly above national intellectual property rights. However despite the differences in the safety regulation, both EU and US consumers have access to safe pharmaceuticals. The bigger issue uncovered in the above analysis is the role of innovation and the relative importance of intellectual property rights in both systems. Safety aside, the role of intellectual property rights will present bigger ongoing challenges as the political pressure for affordable medicines continues in both systems.

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