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# Parallel Trade in Trademarked Pharmaceuticals in Europe

Finding a solution for China

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# Summary

Parallel trade in the pharmaceutical industry is a complicated issue because it has connections with competition law, trade law, and intellectual property law. International exhaustion benefits consumers by promoting price competition. This is an extremely attractive argument. For several years, the parallel trade in pharmaceutical products has been an important issue for the European pharmaceutical industry and numerous EU (European Union) institutions, including the European Commission, the ECJ (European Court of Justice) and the Member States of the EU. Much of the debate now raging about parallel trade is centred on precisely this question of international exhaustion; this concerns manufacturers, parallel traders, retailers, consumers and national governments.

In China there is still no clear law regulating this area. Despite being regarded as one of the world's strategic potential markets for drugs and despite pharmaceuticals being classified as one of the key strategic industries along with oil and gas, iron and steel by China's government, there has been little comprehensive investigation into the effects of parallel imports on the Chinese pharmaceutical industry.

In this paper, I discuss several aspects of the parallel trade problem. In the first part I give an overview of the current debate, then in the second section try to find a global standard for the treatment of such trade on the international law level. The global IPR system allows each country to provide its own legal regime. After investigating the European case law, I found I still needed to discuss the economic theories of parallel trade in order to give the whole picture. I provide concluding remarks in the final section, recommending international exhaustion in the short term and national exhaustion as the long term policy for China.

# Preface

This is my final work as a Master in European law student at Lund University. First, I very much appreciate that I had the chance to take this great programme; I received warm support and friendship from the Professors and my classmates here. I would like to say that my valuable study in Lund gave some assets that I will be able to use in my future life.

The writing process involves great pressure, and is limited in time, but I learned much from doing the investigation. Here, I want to take this opportunity to express my sincere thanks to my supervisor, Professor *Hans Henrik Lidgard*, a very special person in my life. To me, he is not only an excellent, impassioned and inspirational professor, but also a warm and kind father figure and friend. He is a person who opened doors and gave me strong support. That is why I want to thank him very much. I will also keep good memories of the other professors and administrative staff here especially *Sandra Forsen*.

And very special thanks goes to Bettina, my best German friend....without whom I would probably still be struggling to find articles. Of course, without the constant help and support of my husband Yunlong Xia back home and my friends Spring, Alisa, Hongtu, Martin here, and Min and Mingming in China, I would never have finished this paper on time. Finally thanks to Philip Horowitz, who helped by proofreading my paper. All of you mean a great deal to me.

Ling Fan  
May 10, 2006 in Lund

# Abbreviations

C.M.L.R	Common Market Law Review
CTMR	Community Trade Mark Regulation
E.C.L.R	European Competition Law Review
E.I.P.R	European Intellectual Property Review
EC	European Community
EC Treaty	Treaty Establishing the European Community (consolidated version in accordance with the Treaty of Nice)
ECJ	European Court of Justice
EEA	European Economic Area
EFPIA	The European Federation of Pharmaceutical Industries' Associations
EFTA	The European Free Trade Association
GATT	The General Agreement on Tariffs and Trade
IP	Intellectual Property
IPR	Intellectual Property Right
IMS	Institute of Mathematical Statistics
MFN	Most Favored Nation
NERA	National Economic Research Associates
NHS	The National Health System
OTC	Over-the-counter drug available without a prescription
PRC	People's Republic of China
PI	Parallel Imports
R&D	Research and Development
TRIPS	The Agreement on Trade Related Aspects on Intellectual Property Rights
WTO	World Trade Organization

# 1 Introduction

## 1.1 Purpose and Delimitations

The main objective of this paper is to study parallel trade in the Chinese pharmaceutical industry. Which exhaustion principle should China choose: international exhaustion or national exhaustion? What is a good commercial policy for China? What development strategy should the Chinese pharmaceutical industry pursue after accession to the WTO? I chose Europe as a model and I address the following issues. First it is appropriate to define the term “parallel trade”, and then I examine its impact in the pharmaceutical area and its relationship with the principle of trademark exhaustion. Then I go on to assess how it is treated in the European Community and review the development of the European legal position with a view to finding a solution or recommendation for a Chinese policy. The question is whether, from the economics and law perspective and under the current international legal system, China should adopt a policy of admitting parallel imports.

Due to time constraints and limitation of resources, I have only focused on trade marked parallel imports in the pharmaceutical industry. Other issues of intellectual property law such as patent rights or copyright are not covered. Geographically, the area of interests are the European Union and the mainland of China. I also did not look at the link with competition law. I regret that many equally significant issues had to be omitted from this study or were given less attention than merited.

## 1.2 Methodology

The method used in this thesis is a traditional one for legal research, combining a descriptive and analytical study of the legal sources as follows:

- a) Identification of sources and specialist centres where parallel trade related research is being conducted.
- b) Review of primary material in the form of legislation (EU law, Chinese law and the TRIPS agreement) and case law.
- c) Analyzing the recent literatures in academic journals, or by professional bodies to identify trends and predict possible future recommendations.

I have also searched the internet, trying to find and use objective and reliable sources.

## 1.3 Outline

This paper consists of seven parts; it starts by describing what parallel trade is and deals with some issues and theories relating to such trade.

In part two, I want to make clear what the legal situation is under WTO and the TRIPS agreement. The result of this overview is that the principle of exhaustion to be adopted is for the Member States to decide.

Part three is dedicated to the case law in the European Union and the EU Trade Mark Directive; its focus is on the principle of community exhaustion for parallel trade which is what is applied in Europe.

Part four describes the current situation in China; where there are two totally conflicting cases on parallel imports by the Chinese Courts - due to the lack of regulation of this issue.

After the investigation of the European and Chinese situations, it is still difficult to decide which principle China should apply: the international exhaustion principle or national exhaustion? In parts five and six, I analyze the relationships between parallel imports, R&D and welfare, the objective being to consider the issue from an economic perspective with a view to giving a natural recommendation for China.

In the end, it is my conclusion, that for the short term, China can allow parallel imports, while in the long term it should oppose them.



# 2 What is Parallel Trade?

## 2.1 The Definition of Parallel Trade

Parallel trade refers to the practice of buying branded products which have been put on the market at a relatively low price with the consent of the brand owner in one country and then subsequently, without the brand owner's consent, importing these products into another country where the brand owner can also in principle claim protection and where these same products are normally sold at a higher price.<sup>1</sup> The trade is sometimes referred to as constituting a 'grey market'. In contrast to a criminal black market, genuine goods are acquired, if indirectly, via authorized channels. The key reason for this trade is different prices between countries.<sup>2</sup>

There are many forms and channels for parallel trade; here I illustrate three main types. One is that the manufacturer sells his goods both in the local market and in foreign markets through authorized channels. The local or foreign grey market channel buys goods from the manufacturer or the authorized dealer in the local market, and sells in the foreign market without the consent of the trademark owner. This situation would occur if the price in the foreign market is higher than the local one. The second case occurs when the price in the foreign market is lower than the local market. So the grey marketer buys from the authorized channel in the foreign market and sells back into the market where the goods are originally from. The third case is where the original market is not the source market for the parallel trade. This happens between two foreign markets if the former's price is lower than the latter one's price. If the same goods are sold in various markets with different prices, parallel trade is likely; but there are also other conditions which create parallel trade including ex factory price differences between source and target country, exchange rate, product quality differences and over-production in the source country.<sup>3</sup>

The legal background for the right-holder to prevent such trade is the doctrine of exhaustion of intellectual property rights. We will discuss this topic further below. A regime of national exhaustion allows the right owner to ban parallel imports, while the international exhaustion principle makes such imports legal.<sup>4</sup>

To narrow the analysis, this paper does not cover the undermining of quality medicine, counterfeit drugs or pirate goods - as stated parallel trade only

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<sup>1</sup> Kuilwijk, 'Parallel Imports and WTO law: Some Thoughts After Silhouette', 1999 E.C.L.R., pages 292-297, at page 292.

<sup>2</sup> Ganslandt and Maskus, 'Parallel Imports of Pharmaceutical Products in the European Union', Working Paper No. 546, 2001, The Research Institute of Industrial Economics, page 2.

<sup>3</sup> NERA, SJ Berwin & Co and IFF Research, 'The Economic Consequences of the Choice of Regime of Exhaustion in the Area of Trademarks, Final Report for DG XV of the European Commission', 1999, pages 7-11.

<sup>4</sup> Maskus, 'Parallel Imports', 2000 World Economy (23), pages 1269-1284, at page 1269.

involves genuine products.. It also focuses on parallel imports as the export side of the matter is generally uncontentious (except where producers try to impose export bans or otherwise limit exports).

## 2.2 The Reasons for Price Differences

As mentioned above, due to profitable arbitrage conditions, parallel trade occurs between different markets where the equivalent goods are offered at a different price. Once the price gap exceeds the costs of transporting and selling goods across border, the basic motivation for parallel trade exists. Keith E Maskus<sup>5</sup> provides an extensive study of the reasons why such gaps exist. His arguments may be summarized as follows:

**Retail Price Discrimination** is the way by which the producer can maximize profit in segmented markets by relying on local demand.<sup>6</sup>

**Vertical Price Control:** It is usual for pharmaceutical companies to keep an eye on marketing efforts and enforce product quality by way of exclusive distribution systems. However, it might be illegal to have contractual provisions restricting sales outside the authorized distribution chain in the foreign markets. So prohibitions against parallel imports are a necessary match to exclusive territorial rights. The problem here is collusive behavior among exclusive dealers, especially in the least-developed countries where the distribution system is highly concentrated. This is another reason for the high price trend in some developing countries.<sup>7</sup>

**Free Riding on Fixed Marketing Costs:** Authorized distributors make investments in quality control, consumer service, brand-awareness, protection from counterfeit, marketing, discounting, pre-sale information and after-sales service and promotional efforts, which allow them to charge a higher price markup. Grey traders may not pay these costs, and can thus supply at a lower price than the authorized dealer.<sup>8</sup>

**Differential Price Regulations:** Many nations have drug price regulations to limit consumer cost or public health budgets, all of which is perhaps the major reason for price variability.<sup>9</sup>

**Various IPR Protections** in different jurisdiction means the product may have longer or shorter patent protection time, which means the generic drug can drive down the price of the branded medicine.<sup>10</sup>

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<sup>5</sup> Maskus, 'Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries', 2001, Final Report to World Intellectual Property Organization, pages 12-22.

<sup>6</sup> Ibid.

<sup>7</sup> Ibid, page 20.

<sup>8</sup> Ibid, page 21.

<sup>9</sup> Ibid, page 22.

<sup>10</sup> Arfwedson, 'Re-importation (Parallel Trade) in Pharmaceuticals', 2004, Institute For Policy Innovation, page 5.

**Differing Inflation Rates**, which account for exchange rate differences, can lead to differences in retail price.<sup>11</sup>

**Variations in Purchasing Power:** Consumers in low income countries are more price-sensitive so demand and market size are lower than in higher income countries. Also, discounts negotiated by government or donations of medicines can lead to substantial price differences.<sup>12</sup>

**Diverse Tax Rates** are another important reason for international price differences.

## 2.3 Parallel Trade in Practice

To understand parallel trade even better, we need to learn more about how it is effected. From the exporting country where the drug price is lower than in the importing country, the parallel trader chooses a product, which is new and innovative and offers a high price differential and profit above 15%, repackages and replaces or adds mandatory product information in the language of the importing country.<sup>13</sup> According to EU regulations, the trader has to obey the rules of the country of import, such as obtaining a product license, meeting the standards for pharmaceutical companies, obtaining a license for parallel trade, and showing documents proving the quality of products.

There are some other actors indirectly involved, for example physicians may have the right to choose or not to choose re-imported products when they make the prescriptions, pharmacists could promote the imported drug and, finally, consumers have their own choices to make. Any insurer is also motivated to guide consumers towards cheaper alternatives when these are available.<sup>14</sup>

## 2.4 The Debate on Parallel Trade

There are arguments for and against parallel trade. For a positive attitude to parallel trade, there are three main areas of concern about the restrictive territorial application of intellectual property rights. First, parallel trade assure price competitions at the international level and may thus achieve efficiency gains. The European Union allowing free parallel trade in the internal market is an example of a policy which assures a competitive supply of goods and services from internal EU resources. Second: parallel trade is in the interests of developing countries which can take advantages of their own lower-priced manufactured goods. The third reason is that restraints against parallel trade may constitute non-tariff barriers to trade and

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<sup>11</sup> Ibid.

<sup>12</sup> Ibid.

<sup>13</sup> Arfwedson, 'Re-importation (Parallel Trade) in Pharmaceuticals', 2004, Institute For Policy Innovation, page 8.

<sup>14</sup> Ibid.

are inconsistent with the fundamental principles of the WTO. Under Article XI of GATT, restrictions on imports other than tariffs and taxes are forbidden, including quotas or other measures. Article III prohibits internal measures to discriminate against the importation and to be in favor of the domestic good. Above all, any restriction of parallel imports constitutes a discriminatory measure. Parallel imports undermine such discrimination<sup>15</sup>

A global ban for parallel imports is a natural wish for the IPR owner who wants to control international distribution, engage in price discrimination and get the maximum profit.<sup>16</sup> The other argument against parallel imports came from distributors, including retailers, who purchased the trade mark owner's authorization in the high price country and then invest and develop that market by advertising and by providing after sales service. Consequently, opponents argue that free riding by parallel traders disrupts a supplier's overall marketing plan, discourages various investments and is generally inefficient.<sup>17</sup> They claim that parallel trade "benefits neither social security nor patients but deprives the industry from additional resources to fund R&D".<sup>18</sup>

## 2.5 Parallel Trade and the Principle of Exhaustion

Parallel imports relate to the issue of exhaustion of rights because the competing interests and policy concerns are linked with these two concepts.<sup>19</sup> The principle of exhaustion of the rights conferred by a trade mark is a part of most countries' trade mark law. It means that the trade mark owners' rights cease to exist once the product bearing the trade mark has been put on the market by him or by a third party acting with his consent (for example, affiliate, licensee, distributor, agent). After the product has been put on the market, the trade mark owner cannot prevent the resale of the product or indeed in any way control the 'movement' of the product within the area which is governed by the trade mark legislation recognizing this principle.<sup>20</sup>

The scope of this rights exhaustion can be divided into three categories: the national exhaustion of trade mark rights; the regional exhaustion of trade mark rights; and the international exhaustion of trade mark rights.<sup>21</sup>

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<sup>15</sup> Bale, 'The conflicts between parallel trade and product access and innovation: the case of pharmaceuticals', 1998 *Journal of International Economic Law*, pages 637-653, at pages 644-646.

<sup>16</sup> Maskus, 'Parallel Imports', 2000 *World Economy* (23), pages 1269-1284, at page 1271.

<sup>17</sup> Malueg and Schwartz, 'Parallel imports, demand dispersion, and international price discrimination,' 1994 *Journal of International Economics* 37, pages 167-195, at page 172.

<sup>18</sup> European Federation of Pharmaceutical Industries and Associations, 'The pharmaceutical industry in figures', 2000.

<sup>19</sup> Gangjee, 'The Rise of the ©. A Scoping Study of global Trademark Law', 2002.

<sup>20</sup> Rasmussen, 'The Principle of Exhaustion of Trade Mark Rights Pursuant to Directive 89/104', 1995 *E.I.P.R.*, pages 174-179, at page 174.

<sup>21</sup> Trogh, 'The International Exhaustion of Trade Mark Rights after Silhouette: the End of Parallel Imports?', Master Thesis, 2002, at page 13 to page 15.

Under the national exhaustion of trade mark rights, the exclusive rights of trade marks exhaust following the first sale within a particular country but the owners of intellectual property rights may exclude parallel imports from other countries.<sup>22</sup> Under the regional exhaustion of trade mark rights, the rights end on the original sale within a group of countries or regions, thereby allowing parallel trade among them, but are not ended by first sale outside the region. The EU market is the example of regional exhaustion. Parallel imports are allowed in the EU circular, but not allowed from outside.

The concept of the international exhaustion means once the owner of trade mark put the products on the market anywhere or with his consent, he has no right to prohibit the parallel imports. The proprietor's right was exhausted worldwide, no matter whether the products exist in the domestic or foreign markets.<sup>23</sup>

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<sup>22</sup> Zhang Hui, 'Comparative Study on Parallel Imports in Trade Marks', 2002, page 10.

<sup>23</sup> Ibid.

# 3 Are Barriers to Parallel Trade Inconsistent with WTO Law?

## 3.1 GATT

The goal of the WTO is to encourage economic growth and to expand production and trade in goods and services in accordance with the objective of sustainable development. The way to achieve this is a substantial reduction of tariffs and other barriers to trade and the elimination of discriminatory treatment in international commerce<sup>24</sup>. This means that barriers to parallel trade are inconsistent with the spirit of WTO and GATT. Specifically Article XI: 1 of GATT 1994 provides for the general elimination of all quantitative restrictions:

*No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licenses or other measures, shall be instituted or maintained by a contracting party on the importation of any product of the territory of any other contracting party....*

The restriction of parallel trade may also breach GATT Article III: 4 which stipulates that imported goods must be given the same IP protection as domestic goods. In other words, it prohibits discrimination in favor of domestically produced goods. The above two articles provide the general foundation for eliminating rules against parallel imports in the WTO framework.<sup>25</sup>

However, GATT Article XX (d) explicitly permits member states to protect IP rights as one of the exceptions that justify measures which derogate from GATT obligations. This provision states that, subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination, or a disguised restriction on international trade, members are permitted to adopt measures which are necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of GATT. A WTO Member that does not recognize international exhaustion could probably only justify the consequent import prohibitions on the basis of Article XX (d) of the GATT. To persuade a country to accept the principle of international exhaustion, the principle of proportionality plays a significant role under article XX. The protection of specific intellectual property rights and the free flow of international trade need to be properly balance<sup>26</sup>.

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<sup>24</sup> See 1947, GATT (The General Agreement on Tariffs and Trade), preamble.

<sup>25</sup> Abbott, 'First Report (final ) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation', 1998 Journal of International Economic Law, pages 607-636, at page 632.

<sup>26</sup> Kuilwijk, 'Parallel Imports and WTO law: Some Thoughts After Silhouette', 1999 E.C.L.R., pages 292-297, at page 297.

## 3.2 TRIPS Agreement

Generally, modern patent protection laws allow intellectual property rights holders to restrict or bar parallel trade, but this has been the subject of international policy debate in recent years. It was a major subject of negotiation in the Uruguay Round of multilateral trade negotiations, and resulted in a major new international agreement protecting intellectual property rights - the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) <sup>27</sup>. But, sadly, the movement toward effective harmonization of national legislation in Article 6 of the TRIPS agreement failed to achieve consensus and excluded the topic of international exhaustion from its coverage. Article 6 states: For the purposes of dispute settlement under this agreement, subject to the provisions of Article 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property. In this context, the effect would be that Members would be entitled to determine their own parallel import policies.

## 3.3 The Doha Declaration<sup>28</sup>

Paragraph 5(d) of the Doha Declaration provides:

“The effect of the provision in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Article 3 and 4”.

The international policy structure regarding parallel imports is currently as follows:

Japan, for example, has followed a more open policy with respect to parallel imports in trademarked goods than has the United States (as evidenced by the recent Supreme Court decision in the Aluminium Wheels Case<sup>29</sup> . Section 301 of the US Trade Act of 1974 was amended during the Uruguay Round implementation process to authorize the US Trade Representative to impose sanctions on countries that fail adequately to protect IPRs<sup>30</sup>. In principle, intellectual property developers in the United States generally preferred a global rule restricting parallel imports. Australia, New Zealand and the developing countries tended to choose international exhaustion. The

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<sup>27</sup> Bale, ‘The conflicts between parallel trade and product access and innovation: the case of pharmaceuticals’, 1998 *Journal of International Economic Law*, pages 637 – 653, at page 638.

<sup>28</sup> 2001 DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH, Adopted on 14 November 2001

<sup>29</sup> NERA, SJ Berwin & Co and IFF Research, ‘The Economic Consequences of the Choice of Regime of Exhaustion in the Area of Trademarks, Final Report for DG XV of the European Commission’, 1999, page 23.

BBS is a German Company and held a patent for an aluminum wheel in both Germany and Japan. A Japanese company imported the wheels from Germany into Japan at a lower price, and began re-selling them. BBS sued the Japanese company for infringement of its patent in Japan and, the Supreme Court supported the Japanese Company. This is a new precedent in Japanese law on the doctrine of international exhaustion.

<sup>30</sup> Abbott, ‘First Report (final ) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation’, 1998 *Journal of International Economic Law*, pages 607-636, at page 632.

European Union wished to preserve its special internal exhaustion principle regarding the relationship between member state IPRs laws and the free movement of goods.<sup>31</sup>

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<sup>31</sup> Maskus and Chen, 'Vertical price control and parallel imports: theory and evidence', 2000, page 8.



## 4 The European Perspective

### 4.1 A Brief Review of the Pharmaceutical Industry in Europe

Until 1990, Europe was the world leader in terms of pharmaceutical R&D and innovation, but it has gradually lost that position. Compared to the US, Europe is seen as a less attractive R&D investment location in terms of market size because of the highly fragmented market and lack of incentives for the creation of new innovative biotech companies. In 1997, the US industry for the first time surpassed its European counterparts in terms of the total amount of R&D expenditure. R&D investment in Europe from 1990 to 1998 doubled, while in the United States it grew by 3.5 times.<sup>32</sup>

The Europe's pharmaceutical companies have to widen their operations under the new globalized market. They face stiffer competition, particularly from the USA and from Japan. In order to make sufficient income to fund their R&D and keep their competitive position on the world market, the research-based pharmaceutical companies have to consolidate their positions on their home market. The current situation in the major European drug markets is unhelpful and rather fragmented. On the other hand, their American and Japanese competitors can easily launch into new market as they are backed by vast, non-fragmented home markets. Leading American and Japanese companies make 66% and 82% of their sales on their respective home markets, against 42% for their European counterparts.<sup>33</sup>

### 4.2 The Impact of Parallel Trade in Medicines within the EU

The pharmaceutical market in Europe is not a free market because the manufacturers and distributors of pharmaceuticals are not free to set their own prices in the majority of European Member States.<sup>34</sup> In the meantime, they have to comply with the principle of the free movement of goods. The situation is different in other industries. For example, perfume companies could change their prices if they face competition from the parallel imports of substitute. They might choose to supply more cheaply elsewhere in Europe. Therefore it is understandable that the companies wish to stop the movement of pharmaceuticals from the cheaper countries of Europe to the more expensive one.<sup>35</sup>

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<sup>32</sup> European Federation of Pharmaceutical Industries and Associations, 'The Pharmaceutical Industry in Figures', 2000.

<sup>33</sup> Ibid.

<sup>34</sup> Mutimear, 'Parallel Wars Rage on in Europe', *Managing Intellectual Property*; December 1999/January 2000.

<sup>35</sup> Ibid.

**Germany:** Parallel trade's prime target is Germany since it is the biggest pharmaceutical market in the European Union and the third largest worldwide. The market share of such trade increased from 1.8% in 1998 to 5.8% in January 2002 due to a law enacted in 2000 which requires pharmacists to replace brand names with re-imported drugs when the latter are at least 10% cheaper. And a law in 2001 makes it mandatory for pharmacists to supply low-priced alternatives (re-imported products or generics) whenever possible. A series of government decisions favouring parallel trade obviously makes it increase, accounting for \$3.6 billion or 9% penetration by 2006.<sup>36</sup>

**The UK** is a major parallel importer of cheaper medicines due to having higher prices than most of the other states. It is estimated that 90% of UK pharmacists source products through parallel trade, which leads to savings of £ 80 million a year for the National Health System (NHS). There is no direct pricing control for pharmaceuticals, but the UK government has introduced several measures to cut prices. One peculiar feature is that the cheaper the price of the product the greater the profit for the pharmacist. Another reason for re-importation is that the UK remains outside of the Euro zone.<sup>37</sup>

**Sweden:** In 1996, Sweden granted the first re-import license and early in 1997 the first parallel traded product appeared. There were 137 products from parallel importation, accounting for 8.6% of the total pharmaceutical sales in 2000. There are 10 main parallel import companies in Sweden. In some cases, the original manufacturer has lost almost all of its sales due to parallel imports.<sup>38</sup>

**The Netherlands** probably has the highest figure of parallel imports in the EU in 2001: 15% of the total market and 16% forecast in 2006.<sup>39</sup>

**In France,** drug prices are comparatively low and that is why parallel exportation to other EU countries takes place from there. The French pharmaceutical industry has lost its competitive edge in terms of innovation. It went from number two worldwide in 1970 to number seven in 1995. The government is planning to curb such parallel exports by fixing prices closer to the European average price level for new products, which is 15% higher than the current French drug price.<sup>40</sup>

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<sup>36</sup> Arfwedson, 'Re-importation (Parallel Trade) in Pharmaceuticals', 2004, Institute for Policy Innovation, page 11.

<sup>37</sup> Ibid, page 13.

<sup>38</sup> Ibid, page 13.

<sup>39</sup> Ibid, page 14.

<sup>40</sup> Ibid, pages 14 - 15.

## 4.3 The European Legal Framework

Prior to the Community's program of harmonization of national intellectual property rights under Article 95 EC, the principles governing when an intellectual property owner is deemed to have exhausted the relevant right were developed by the ECJ over a 30-year period. Exhaustion of rights can be seen primarily as a balance between the concept of the single market in free movement of goods and the territorial nature of intellectual property rights.<sup>41</sup>

### 4.3.1 Primary Law

The first legal foundation of parallel trade is Article 28 and 30 of the EC Treaty, which authorize free movement of goods and lay down conditions for restrictions of trade established by the Member States.

Article 28 prohibits quantitative restrictions and other measures of similar effect on imports and trade between Member States.

Article 30 states that the provision of Article 28 shall not preclude prohibitions or restrictions justified on grounds of public morality, public policy or the protection of industrial and commercial property. Further, it provides that such prohibitions or restrictions must not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

### 4.3.2 The European Trade Mark Directive<sup>42</sup>

The second important framework is the Trade Mark Directive (1989) which upholds the principle of community exhaustion of intellectual property rights.

The Trade Mark Directive was adopted under Article 95 of the EC Treaty. Its aim was not to undertake full scale approximation of the trade mark laws of the Member States but simply to approximate 'those national provisions of law which most directly affect the functioning of the internal market'.<sup>43</sup>

The first recital in the preamble to the Directive notes that the trade mark laws applicable in the Member States contain disparities which may impede the free movement of goods and the freedom to provide services and may distort competition within the Common Market, so it was adopted with a view to approximating the trade mark laws of the Member States. The ninth recital emphasizes that, in order to facilitate the free movement of goods and services, it is fundamental to ensure that registered trade marks enjoy the

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<sup>41</sup> Norman, 'Parallel Imports from non EEA Member States: The Vision Remains Unclear', 2000 E.I.P.R., pages 159-170, at page 159.

<sup>42</sup> First Council Directive 89/104 of December 21, 1988 to approximate the laws of the Member States relating to trade marks (89/104/EEC).

<sup>43</sup> Third recital of the preamble to the Directive.

same protection under the legal systems of all the Member States Generally, its purpose is to reduce or eliminate the substantive differences that exist in the national law throughout the European Union and expressly incorporates the Community doctrine of exhaustion or rights.

It is to be noted at the outset that Article 7 of the Trade Mark Directive deals with exhaustion of trade mark rights and was at the centre of debate in the *Silhouette*<sup>44</sup> case. It provides:

“The trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent.

Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialization of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market.”

In other words, Article 7 states that the exclusive rights conferred by the trade mark are exhausted under certain circumstances, with the result that the proprietor is no longer entitled to prohibit use of the trade mark. Exhaustion is subject first of all to the condition that the goods have been put on the market by the proprietor or with his consent. According to the text of the Directive itself, exhaustion occurs only where the products have been put on the market in the Community (in the EEA since the EEA Agreement entered into force).<sup>45</sup>

According to the agreement on the European Economic Area (EEA), Annex point 4, the Directive (and Regulation 40/94) is to be extended to the EFTA<sup>46</sup> countries joining the EEA. The exhaustion principle in the Directive will therefore cover the whole EEA territory. In the EFTA / EEA countries the Directive should have been implemented on 1 January 1994 with the coming into force of the EEA Agreement.

### **4.3.3 The Community Trade Mark Regulation<sup>47</sup>**

Further guidance on the interpretation of the Directive is provided by the Community Trade Mark Regulation. The Regulation, which provides for a single Community trade mark valid throughout the Community, was drafted concurrently with the Directive and it contains a virtually identical provision on exhaustion. Article 1(2) provides that a Community Trade Mark has “a unitary character” and that:

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<sup>44</sup> Case C-355/96, *Silhouette International Schmied GmbH & Co. KG v Hartlauer Handelsgesellschaft mbH*, 1998 ECR I-4799.

<sup>45</sup> Case C-355/96, para. 18.

<sup>46</sup> The EFTA countries in the EEA are Iceland, Liechtenstein, and Norway. Switzerland, following the negative referendum, did not join the EEA. Liechtenstein cannot join before its customs arrangements with Switzerland has been modified.

<sup>47</sup> Council Regulation (EC) No 40/94 of 20 December 1993 on the Community Trade Mark, OJ 1994 L11,p.1.

“It shall have equal effect throughout the Community: it shall not be registered, transferred or surrendered or be the subject of a decision revoking the rights of the proprietor or declaring it invalid, nor shall its use be prohibited, save in respect of the whole Community. This principle shall apply unless otherwise provided in this Regulation.”

Article 13, entitled “Exhaustion of the rights conferred by a Community trade mark”, provides as follows:

“1. A Community trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent.  
2. Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialization of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market.”

Thus, except for the reference to the “Community Trade Mark”, Article 13 of the Regulation is in identical terms to Article 7 of the Directive. In the case of the Regulation, however, it seems scarcely possible to contend that the Member States have discretion. Whereas the Directive, as has been seen, is a partial measure of harmonization of national laws, the Regulation comprehensively governs the incidents and effects of a Community trade mark. Moreover Article 14(1) provides that: “The effects of Community trade marks shall be governed solely by the provisions of this Regulation”; leaving only infringement actions to be governed by national law in accordance with Title X of the Regulation, which is concerned only with jurisdiction and procedure in legal actions relating to Community trade mark. It therefore seems impossible to contend that the Trade Mark Regulation confers any discretion on Member States to opt for full world-wide international exhaustion.

The question then is whether the provisions on exhaustion in the Regulation and Directive, notwithstanding their common origin and their identical wording, can be construed differently. In the present case however the context is, both for the Regulation and for the Directive, the Community's internal market. Although an argument can be advanced that the objectives of the two instruments are different, since the Directive only aims to achieve a limited measure of harmonization, it must be accepted that the Regulation provides at least some further support for the view that the Directive precludes international exhaustion. Regard to the wording and purpose of the Directive, its legislative history, the identical wording in the Trade Mark Regulation, and the undesirable effects of leaving the question to the discretion of the Member States, Thus, Article 7 (1) of the Directive is to be interpreted as meaning that the proprietor of a trade mark is entitled to prevent a third party from using the mark for goods which have been put on the market under mark outside the territory of the EEA. Member States are

accordingly precluded from adopting the principle of international exhaustion.<sup>48</sup>

It is necessary to review some cases on community exhaustion to get a deeper understanding of these points:

## 4.4 Case Law

One of the first major inroads into the Community doctrine of exhaustion of rights, established by cases such as *Deutsche Grammophon Gesellschaft mbH v Metro- SB-Großmarkte GmbH & Co.KG*<sup>49</sup> and *Centrafarm BV v Winthrop BV*<sup>50</sup>, was made in the case *EMI Records Ltd v CBS United Kingdom Ltd*.<sup>51</sup> Here the court ruled that what is now Article 28 EC had no application when goods which were the subject of intellectual property rights entered the Community from a third country. The Court emphasized that the treatment accorded to third-country goods under the Customs Union rules in Article 23 EC should not be extended to the free movement of goods provision, at least when intellectual property rights were in issue. Since 1976, the only qualification added to the EMI ruling was that in *Phytheron International SA v Fean Bourdon SA*<sup>52</sup>, to the effect that if goods have been manufactured outside the Community but then marketed in a Member State with the trade mark owner's consent, they are subject to Community-wide exhaustion with all the consequences which that entails.<sup>53</sup> The European Court of Justice (ECJ) developed case law and established a principle of "Community exhaustion", but rejected the idea of international exhaustion.

### 4.4.1 The *Silhouette Case*<sup>54</sup>

#### 4.4.1.1 Facts

This case was raised in proceedings between two Austrian companies. Silhouette, an Austrian company, produces high-priced fashionable spectacles under its Silhouette brand name, which was registered as a trade mark in many countries around the world. In order to protect the image of the spectacles, the company refused to supply Hartlauer with these spectacles. Hartlauer is a retailer, whose chain of retail stores was known for its cut-price goods and was not included in Silhouette's selective distribution network, also based in Austria. The case came about because Silhouette had 21,000 pairs of spectacles which it no longer required as they

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<sup>48</sup> Opinion of Advocate General Jacobs, Case C-355/ 96, *Silhouette International Schmied GmbH & Co. KG v Hartlauer Handelsgesellschaft mbH*, 1998 ECR I-4799, paras. 55 to 63.

<sup>49</sup> Case 78/70, 1971 ECR 487, 1971 C.M.L.R. 631.

<sup>50</sup> Case 16/74, 1974 ECR 1183, 1974 2 C.M.L.R. 480.

<sup>51</sup> Case 51/75, 1976 ECR 811, 1976 2 C.M.L.R. 235.

<sup>52</sup> Case C-352/95, 1997 ECR I-1729, 3 C.M.L.R. 199.

<sup>53</sup> Norman, 'Parallel Imports from non EEA Member States: The Vision Remains Unclear', 2000 E.I.P.R., pages 159-170, at page 159.

<sup>54</sup> Case C-355/96, *Silhouette International Schmied GmbH & Co. KG v Hartlauer Handelsgesellschaft mbH*, 1998 ECR I-4799.

were, in terms of fashion, out of date. In October 1995 (some nine months after Austria's accession to the EC) a transaction was arranged whereby the goods were sold through Silhouette's sales representative in the Middle East to a firm called Union Trading, the sales representative being under strict instruction to require the purchaser to sell the frames only in Bulgaria or the states of former Soviet Union and not to export them to other countries. Subsequently, Hartlauer managed to sell the spectacles in Austria from abroad. Silhouette brought an action for trade mark infringement and unfair competition against Hartlauer. In Silhouette's view, this constituted a violation of their EC trade mark for these goods, because they had not agreed to sales in Austria or elsewhere in the EEA. Hartlauer, however, maintained that Silhouette's trade mark had been exhausted as soon as it had marketed the goods outside the EEA. This was indeed the position on international trade mark exhaustion under Austrian law prior to its implementation of the Directive.

Silhouette's action for trade mark infringement having failed before both the Steyr Regional Court and the Linz Higher Regional Court, it appealed to the Austrian Supreme court. The referral to the ECJ asked whether Austria was obliged, in the light of Article 7 of the Trade Mark Directives, to reverse its previous policy of permitting international exhaustion of rights. A further question was also put to the Court concerning the remedies available to the trade mark owner, which need not concern us. So the crucial question which the ECJ had to answer concerned the interpretation of Article 7(1) of the 1989 EC Trademark directive.<sup>55</sup>

#### **4.4.1.2 Advocate General's Opinion**

In January 1998, Advocate General Jacobs delivered his opinion in the case based on three interdependent arguments. One was based on the language and structure of the Directive in the light of its legislative history, the second was based on the objectives of the single market and the last on the need to achieve conformity with the Community trade mark. Article 13 of the Community Trade Mark Regulation had the identical wording to Article 7 of the Directive, so that it would be quite illogical to have Community-wide exhaustion under the former but international exhaustion, at the discretion of Member States, under the latter. He argued that if the Trademark Directive had been intended to allow for international exhaustion, or to give Member States any discretion in this matter, it would have stated so explicitly. Since this was not the case and the Directive only referred to the principle of Community exhaustion, it would have to follow that the principle of Community exhaustion applied to the exclusion of other exhaustion principles and therefore the rights of brand owners were only exhausted when their branded products were marketed with their consent in the Community. The interesting thing here is that AG Jacobs also appears to agree with some points of international exhaustion. He also shows his concern for free international trade. But the wording of the Trademark

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<sup>55</sup> Norman, 'Parallel Imports from non EEA Member States: The Vision Remains Unclear', 2000 E.I.P.R., pages 159-170, at page 161.

Directive did not leave him any other choice than to argue for Community exhaustion.<sup>56</sup>

#### 4.4.1.3 The Court's Decision

The ECJ delivered its judgment on July 16, 1998. If the way in which the Advocate General dealt with the arguments of those in favor of international exhaustion seems far too brief, then the ruling handed down by the court must be considered even more disappointing. Basically, the Court uses only one argument, the one based on the integrity of the single market, with a brief comment in passing as to whether Article 95 EC can be used to regulate external trade. By resorting to the Directive's recitals, in particular the ninth Recital, which speaks of the need to ensure that trade marks receive the same level of protection in all Member States, the Court concluded that Article 5 had to be construed as embodying total harmonization of the rights conferred by a trade mark. Although the Article permitted Member States to bestow a higher level of protection, they were not at liberty to reduce the right by recognizing international exhaustion. This interpretation was the only one which would guarantee the objectives of the Directive, namely safeguarding the functioning of the internal market. To allow some Member States to provide for international exhaustion while others provided for Community-wide exhaustion would give rise to barriers to the free movement of goods.<sup>57</sup> The Court attached great importance to the principle of uniform application of the law through out the Community.

The arguments of the Swedish Government were dismissed by stating that Article 7 of the Directive was not intended to regulate relations between Member States and third countries, only to define the rights of the proprietors of trade marks within the Community. In any event, it was always open to the Community to negotiate bilateral agreements providing for international exhaustion, just as had been done with the EEA Agreement.<sup>58</sup>

#### 4.4.1.4 Comment

The Court's judgment seems more concerned with protecting the sanctity of the internal market than with the doctrinal principle of the original function of trade marks. The Court addresses neither the question of shared competence nor the question of the economic consequences of its "fortress Europe" approach. A further point which deserves mention is the difference in application of Article 7 of the Trade Marks Directive within the Community and within the EEA. The EFTA Court ruled in *Mag Instrument Inc. v California Trading Company Norway*<sup>59</sup> that EFTA Member States (at present, Norway, Liechtenstein and Iceland) are free to recognize international exhaustion of rights. EC Member States are not. This difference may be supportable on the basis that the purpose and scope of the

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<sup>56</sup> Kuilwijk, 'Parallel Imports and WTO law: Some Thoughts After Silhouette', 1999 E.C.L.R., pages 292-297, at page 294.

<sup>57</sup> Case C-355/96, *Silhouette International Schmied GmbH & Co. KG v Hartlauer Handelsgesellschaft mbH*, 1998 ECR I-4799, paras. 23-27.

<sup>58</sup> *Ibid*, paras. 28-30.

<sup>59</sup> Case E-2797 Advisory Opinion of December 3, 1997; (1998) O.J. C20/17; (1998) 1 C.M.L.R 331.



EC Treaty and the EEA Agreement are dissimilar<sup>60</sup>. However, when viewed in the light of both the origin function of trade marks and the shared competence of Member States and the Community under the WTO agreement, the two-tier approach to exhaustion may seem illogical.<sup>61</sup>

A fundamental principle in Article 4 EC Treaty provides that “the activities of the Member States and the Community shall include the adoption of an economic policy which is based on the close coordination of Member State’s economic policies, on the internal market and on the definition of common objectives, and conducted in accordance with principle of an open market economy with free competition”. Article 131 EC Treaty states that, “By establishing a customs union between themselves Member States aim to contribute, in the common interest, to the harmonious development of world trade, the progressive abolition of restrictions interest, to the harmonious development of world trade, the progressive abolition of restrictions on international trade and the lowering of customs barriers.” The ECJ’s decision in *Silhouette* cannot be said to be conducive to the attainment of these fundamental goals of the European Community.<sup>62</sup>

#### 4.4.2 The *Sebago* Case<sup>63</sup>

It is clear from *Silhouette*, that the Member States cannot apply the principle of international exhaustion of trademark rights. There are, however, a number of other issues which should be considered by the ECJ. The ruling does not mean that trade marked goods imported from outside the EU can always be stopped by the trade mark owner. If as a matter of fact the owner consented (whether expressly or by implication) to the importation, then the defendant can defeat the action. In the *Sebago* case, the rule of consent was considered, where the Brussels Court of Appeal asked the ECJ to clarify whether a trademark owner can resist the sale of shoes imported from outside the EU when the trademark owner is selling identical products within the EU.<sup>64</sup>

The facts of *Sebago* were that GB-Unic had advertised for sale some 2,561 pairs of Dockside Sebago shoes for sale in its Belgian hypermarkets. The shoes were genuine goods, manufactured in El Salvador and acquired by an intermediary specializing in parallel imports. Sebago, a U.S. company, and its exclusive distributor sued for trade mark infringement under the

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<sup>60</sup> See Opinion 1/91 of the Court of Justice concerning the Draft Agreement between the Community and the countries of the European Free Trade Association, relating to the creation of the European Economic Area (1991) E.C.R. 1-6079. The same holds true of any Association Agreements entered into by the Community with individual States: see case 270/80 Polydor Ltd v Harlequin Records (1982) E.C.R. 329; (1982) 1 C.M.L.R. 677

<sup>61</sup> Norman, ‘Parallel Imports from non EEA Member States: The Vision Remains Unclear’, 2000 EIPR, pages 159 – 170, at page 164.

<sup>62</sup> Kuilwijk, ‘Parallel Imports and WTO law: Some Thoughts After *Silhouette*’, 1999 ECLR, pages 292 – 297, at page 295.

<sup>63</sup> Case C-173/98, *Sebago Inc. and Ancienne Maison Dubois et Fils SA*, (OJ 1989 L40, p.1)

<sup>64</sup> NERA, SJ Berwin & Co and IFF Research, ‘The Economic Consequences of the Choice of Regime of Exhaustion in the Area of Trademarks, Final Report for DG XV of the European Commission’, 1999, page 21.

provisions of Article 13A (8) of the Uniform Benelux law on Trade Marks, as amended, which is in similar terms to Article 7 (1) of the Directive. Two questions were referred to the ECJ, namely, whether Article 7 (1) of the Trade Mark Directive contemplated international exhaustion (a matter already resolved by the Court in *Silhouette*) and how the word “consent” in that provision was to be interpreted. As in *Silhouette*, the ruling of the court in *Sebago* is brief and to the point, concerned only with the issue of implied consent. The court took GB-Unic’s argument to be, simply, that by not imposing an export ban on its licensee in El Salvador, Sebago had given its consent to sale within the Community.

The *Sebago* case thus confirmed that national rules that provide for international exhaustion of trade mark rights are precluded, and at the same time it made clear that the legal consequence of exhaustion can arise only if consent extends to every individual item in respect of which exhaustion is claimed. To open the door to free trade within the EEA, importers must establish such consent to exhaust the trade mark holder’s rights.

#### **4.4.3 *Davidoff (and Levi) Case*<sup>65</sup>**

It is this issue of consent around which the *Davidoff* and *Levi Strauss* joined cases revolved. The judgment is important because it clarified the determination of consent. In so doing, the ECJ strengthened the internal market and consequently the external position of the EEA<sup>66</sup>.

##### **4.4.3.1 Facts**

In *Davidoff*, the plaintiff’s business concerned high-cost luxury products, cosmetics and toiletries with the trade marks “COOL WATER” and “DAVIDOFF COOL WATER” in the United Kingdom. The products are manufactured for Davidoff under license and are sold by it or on its behalf both within and outside the EEA. The products, their packaging and marking are identical wherever in the world they are sold.

The defendant (A & G) acquired stocks of products bearing the trade marks which had originally been placed on the market in Singapore by Davidoff or with its consent. The defendant imported those stocks into the Community, into England, and sold them there. The products, packaging and marking were identical to those marketed in the EEA by Davidoff, except that the batch code numbers had been removed or obliterated at some stage.

Levi Strauss & Co., a Delaware corporation, is the holder of the trade marks “Levi’s” and “501” registered in the United Kingdom; Levi Strauss (UK) Ltd is the holder in the United Kingdom of a trade mark license granted by Levi Strauss & Co. for the manufacture, sale and distribution of Levi’s 501 jeans. The defendants (Tesco, a supermarket company and Costco, a

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<sup>65</sup> Joined Cases C-414/99 to C-416/99, *Zino Davidoff SA v A& G Imports Ltd, Levi Strauss & Co., Levi Strauss (UK) Ltd v Tesco Stores and Tesco plc, Levi Strauss & Co., Levi Strauss (UK) Ltd v Costco Wholesale UK Ltd*, 2002 C.M.L.R. 591.

<sup>66</sup> *Ibid.*

wholesale clothing company) acquired stocks of products bearing the trade marks marketed by or with the consent of Levi Strauss in the United States, Mexico or Canada. The jeans were identical to those marketed in the United Kingdom. The contracts pursuant to which they acquired those products contained no restrictive covenants to the effect that the goods were, or were not, to be sold in a particular territory. Levi Strauss claimed trade mark infringement by importation and sale, which the defendants denied.

In its referrals to the ECJ, the High Court asked in essence what constitutes consent and whether it can be implied directly or indirectly. Specifically the High Court asked whether consent was a Community or national concept. Finally the High Court asked whether the removal of batch codes placed in compliance with the Cosmetic Directive, amounted to a legitimate reason under Article 7(2) of the Trade Marks Directive for a trade mark holder to prevent the import of the goods into the EEA.

#### 4.4.3.2 Advocate General's Opinion

In her introductory remarks, AG Stix-Hackl gave a brief confirmation of the ruling in cases *Silhouette* and *Sebago*, which means the Community exhaustion principle. She states that there is a close link between the concept of consent and the scope of EEA-wide exhaustion.<sup>67</sup> On addressing the issue of consent, the Advocate General rejected the argument that consent is a national concept on the ground that it would be contrary to the objective of the Trade Marks Directive to harmonize the scope of protection for trade marks within the EEA. Instead consent must be interpreted in the light of Article 7(1) of the Trade Marks Directive. The Advocate General explored the origin of the concept, finding that the relevant feature was whether the placement of the goods on the market for the first time in the EEA could be *attributed* to the trade mark proprietor. Citing the *Sebago* judgment, the Advocate General stated that where the trade mark holder did not avail of an opportunity to exercise his exclusive rights through means of sales bans and territorial restrictions, the trade mark holder could be deemed as having waived his exclusive rights. Ultimately the national courts would have to look at all factors to determine whether the conduct of the IPR holder constitutes a waiver and amounted to the exhaustion of the trade mark holder's right.<sup>68</sup>

With regard to the question whether the removal or obliteration of batch codes constituted a "legitimate reason" under Article 7(2) of the Trade Marks Directive to oppose the commercialization of goods bearing trade marks in the EEA, the Advocate General, following the ruling in *Parfums Christian Dior*<sup>69</sup>, stated that a trade mark holder can object to the further

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<sup>67</sup> Opinion of Advocate General Stix-Hackl, Joined Cases C-414/99 to C-416/99, Zino Davidoff SA v A& G Imports Ltd, Levi Strauss & Co., Levi Strauss (UK) Ltd v Tesco Stores and Tesco plc, Levi Strauss & Co., Levi Strauss (UK) Ltd v Costco Wholesale UK Ltd, ECR 2001 page I-08691, paras. 3-4.

<sup>68</sup> Joined Cases C-414/99 to C-416/99, Zino Davidoff SA v A& G Imports Ltd, Levi Strauss & Co., Levi Strauss (UK) Ltd v Tesco Stores and Tesco plc, Levi Strauss & Co., Levi Strauss (UK) Ltd v Costco Wholesale UK Ltd, 2002, C.M.L.R. 596.

<sup>69</sup> Case C-337/95, Parfums Christian Dior SA and Parfums Christian Dior BV v Evora BV, 1997 ECR

commercialization of his own market goods when the actions of third parties “affect the value, allure or image of the trade mark” – but only if such damage is “serious”. Under the judgment in *Loendersloot*<sup>70</sup>, it was for the national courts to determine whether the removal of the batch code was disproportionately adverse to the reputation of the trade mark to amount to a legitimate reason to remove the goods from the market. Accordingly the Advocate General concluded that unless a trade mark holder has protected his goods at the first available opportunity, legitimate expectations arise in the parallel importers’ favor to consider the waiver of the trade mark holder’s consent.<sup>71</sup>

#### 4.4.3.3 The ECJ's Decision

To answer the question whether consent must be express or whether it may also be implied, the Court first had to determine whether the term “consent” used in Article 5 and 7(1) of the Trade Marks Directive is a Community concept to be applied uniformly throughout the Community legal order or whether it may vary depending on the differing national laws and principles. The ECJ noted that if the concept of consent were a matter for the national laws of the Member States, then the consequence for trade mark proprietors would “vary according to the legal system concerned”. Such a situation would be contrary to the fundamental objectives of the Directive outlined in the ninth recital of the Trade Marks Directive to provide the same protection to trade mark proprietors under the legal systems of all Member States.<sup>72</sup> Consent is therefore a Community concept; it falls to the Court to supply a uniform interpretation of the concept of consent to the placing of goods on the market within the EEA as referred to in Article 7 (1) of the Directive.<sup>73</sup>

It follows from the answer to the first question, the ECJ stated that consent must be “expressed positively” and “the factors taken into account in finding implied consent must demonstrate unequivocally that the trade mark proprietor has renounced any intention to enforce his exclusive rights”<sup>74</sup>. The burden of proof is on the trader alleging consent; the trade mark proprietor is not required to demonstrate its absence.<sup>75</sup> Consequently implied consent could not be inferred from the mere silence of the trade mark holder.<sup>76</sup> Likewise consent could not be implied merely because the trade mark holder had not communicated his opposition to the marketing of the goods into the EEA to the buyer of the goods or from the fact that the goods did not carry a warning of that nature.<sup>77</sup> Finally such consent cannot be inferred from the fact that the trade mark proprietor transferred ownership of the goods bearing the mark without imposing contractual reservations or from the fact that, according to the law governing the

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I-6013.

<sup>70</sup> Case C-349/95, *Loendersloot v. Ballentine & Son Ltd.*, 1997 ECR I-6227.

<sup>71</sup> *Ibid.*

<sup>72</sup> Joined Cases C-414/99 to C-416/99, para. 42.

<sup>73</sup> *Ibid.*, para. 43

<sup>74</sup> *Ibid.*, para. 53.

<sup>75</sup> *Ibid.*, para. 54.

<sup>76</sup> *Ibid.*, para. 55.

<sup>77</sup> *Ibid.*, para. 56

contract, the property right transferred includes, in the absence of such reservations, an unlimited right of resale or, at the very least, a right to market the goods subsequently within the EEA.<sup>78</sup>

#### 4.4.3.4 Comment

The key to exhaustion is consent. In *Sebago* the ECJ held that consent could not be implied merely because the products being imported were identical to those marketed in the EEA, as otherwise the ruling in *Silhouette* “would be devoid of substance”. In *Davidoff*, if the trade mark holder had not required restrictions on a good, according to English law the trade mark holder could not be regarded as having any rights over the goods. The suggestions put forward by the Advocate General attempt to strike a compromise between rights of the trade mark holder and the parallel importer. Her suggestion was that unless the trade mark holder gains his rights through sales bans and territorial restrictions, the importer had a legitimate expectation that the owner had consented to the placement of the goods into the EEA. Even though it has some attraction, this view creates legal uncertainty. There is also a danger of defeating the ruling in *Silhouette* and opening the door to international exhaustion.

The *Davidoff* judgment brings this argument to an end. The ruling is a clear victory for the trade mark holders, having wide implications for the future conduct of parallel importers and retailers in Europe. The ECJ has unified the concept of consent for the EEA. Further, the Court has created a test for the determination of consent at the highest possible standard. Consent, whether implied or express, must be demonstrated positively and unequivocally. The burden of proof is now on the traders importing goods from outside the EEA for resale in the EEA to make sure that they have the unequivocal consent of the trademark owner for such resale.

Indeed, the ECJ in coming to its judgment, made no distinction between the facts of the *Levi Strauss* case, where there was no prohibition on the importation of the goods into the EEA, from those in the *Davidoff* case where there was a prohibition on sales outside the agreed territory. In other words, in the absence of explicit consent, the trader must prove it has received implied consent. The ECJ has clearly and quite intentionally made the possibility of implied consent being inferred almost non-existent. The back door to international exhaustion has been firmly shut.<sup>79</sup>

The effect of the ruling is to allow brand owners to use their trade marks to control distribution prices in Europe, maintaining price differentials throughout the world and keeping prices high in Europe as they wish. This right of the trade mark owner to use its trade mark to control the distribution of its goods into Europe is an extension of the more usual function of a

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<sup>78</sup> Ibid, para. 57.

<sup>79</sup> Joined Cases C-414/99 to C-416/99, *Zino Davidoff SA v A & G Imports Ltd, Levi Strauss & Co., Levi Strauss (UK) Ltd v Tesco Stores and Tesco plc, Levi Strauss & Co., Levi Strauss (UK) Ltd v Costco Wholesale UK Ltd*, 2002, C.M.L.R., 39: 591-607, page 601.

trademark, that being to identify the origin and guarantee the quality of goods.<sup>80</sup> Above all, the decisions of the ECJ on international exhaustion are rooted in the basic aim of the Internal Market, which is to create a unified, single market.

#### **4.4.4 Van Doren Case<sup>81</sup>**

The burden of proof no longer falls squarely on the shoulders of importers and retailers in parallel import disputes: In cases where there was a risk of blocking the free movement of goods the brand owners must first prove that the goods were put on the market outside the EEA. In the Van Doren case, the court had to decide whether its previous ruling on consent, as defined in the Davidoff and Levis cases, applied in all circumstances.

##### **4.4.4.1 Facts**

Stussy is an American company and the proprietor of the trade mark Stüssy. The trade marked goods are marketed worldwide without any particular characteristics that would enable them to be recognised as being allocated to a specific sales territory. The plaintiff in the main proceeding, van Doren + Q. GmbH, distributes products from the Stussy Inc. exclusively within Germany. The defendants Lifestyle sell genuine "Stussy" clothes on the German market, which they do not obtain directly from the plaintiff. Van Doren brought proceedings against Lifestyle for trade mark infringement alleging that the clothes they sell came from the United States and were imported into the EEA without the trade mark owner's consent. The defendants alleged exhaustion of the trade mark. They alleged purchasing the goods within the European Community and claimed they had been put on the market there by the proprietor of the trade mark or with his consent.

##### **4.4.4.2 Advocate General's Opinion**

In the Advocate General's opinion, the Trade Marks Directive does not have an effect on national rules of procedure, including those on the burden of proof. However, the national autonomy of procedural rules cannot challenge the harmonising effect of the Trade Marks Directive.<sup>82</sup> In other words, it was for the Member States to lay down the necessary rules of evidence in accordance with Community law.<sup>83</sup>

Recalling the Dassonville<sup>84</sup> formula, the Advocate General stated that the German rule could be considered as a restriction of trade between Member States. She pointed out that the entire burden of evidence on the defendant would be a disproportionate measure. It would force the alleged infringer to show the sources of the retailed goods and enable the proprietor to discover

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<sup>80</sup> 'Davidoff and Levi Strauss, Addleshaw Booth & Co, Sovereign House, LS1 1HQ, ©Copyright Addleshaw & Booth & Co 2001, <http://www.les-bi.org/news/83.htm#3>

<sup>81</sup> Case C-244/00, Van Doren + Q GmbH v Lifestyle Sports + Sportswear Handelsgesellschaft mbH, ECR 2003 Page I-03051

<sup>82</sup> Rosner, 'Trade Mark Exhaustion', 2002 E.I.P.R., pages 604- 607, at page 606.

<sup>83</sup> Dyrberg, 'For EEA Exhaustion to apply, who has to prove the marketing of the trade marked goods in the EEA – the trade mark owner or the defendant', 2004 E.I.P.R., pages 81-84, at page 83.

<sup>84</sup> Case C-8/74, Procureur du Roi v. Dassonville, 1974 ECR 837.

the unsealed holes and take steps to block them.<sup>85</sup> This restriction could not be justified according to Article 30 of the E.C. Treaty. Therefore the trade mark owner cannot apply the rule to divide national markets and thus keep price differences between Member States.<sup>86</sup> In her opinion, the Advocate General argued that labelling could not discharge the plaintiff's burden for practical reasons, although labels are the clearest indications on the market. Brand owners still need to keep an eye on what is going on in their distribution system. They cannot be blind to resellers and distributors putting their goods on the grey market.

#### **4.4.4.3 The ECJ's Decision**

The ECJ changed its mind within a year of its Davidoff judgment on dealing with the question in Van Doren. By imposing some legal burden on the trademark owner, the ECJ could boost free movement of goods within the Common Market using case law. Article 7 (1) of the Directive not only widens the trade mark owner's ability to sustain its international pricing differentials and selective distribution. It also makes clear that parallel importing within the EEA is legal. If the Court kept firmly to its judgement of the Davidoff case, legal parallel trade freely in the single market could be seriously harmed. It is a suitable solution that the proprietor needs to adduce some evidence by showing that the goods themselves carry a restriction on where they might be marketed. A label on them should suffice.<sup>87</sup>

#### **4.4.4.4 Comment**

In its decision in the Davidoff case, the Court was very concerned about the uniform application of the Directive. The notion of consent was a Community concept and the Court allocated the burden of proving consent.<sup>88</sup> In Van Doren, the Court did not require that the provision of the burden of proof be a matter of Community law. There is, not even, the slightest mention of the need to preserve uniformity. Thus, the Court trusts that, in principle, the subject matter of Van Doren maybe left to the national legal orders. In other words, the national legal orders are free to operate with other rules of evidence. With regard to the principle of exhaustion, it is reasonable for the trademark owner to have to prove first marketing outside the EEA. If he can prove this, then the defendant has to prove the owner's consent to further commercialisation within the EEA.<sup>89</sup>

## **4.5 Conclusion**

To summarize, the EU system essentially mandates free parallel imports within its territory, despite the existence of national intellectual property regimes and price controls. This is the European Union's internal

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<sup>85</sup> Dyrberg, 'For EEA Exhaustion to apply, who has to prove the marketing of the trade marked goods in the EEA – the trade mark owner or the defendant', 2004 E.I.P.R., pages 81-84, at page 83.

<sup>86</sup> Ibid.

<sup>87</sup> Rosner, 'Trade Mark Exhaustion', 2002 E.I.P.R., pages 604-607, at page 607.

<sup>88</sup> Dyrberg, 'For EEA Exhaustion to apply, who has to prove the marketing of the trade marked goods in the EEA – the trade mark owner or the defendant', 2004 E.I.P.R., pages 81-84, at page 83.

<sup>89</sup> Ibid.

mechanism for policing against potential abuses of vertical territorial restraints by trademark holders.<sup>90</sup>

In Harvey's analysis, the parallel trade practice in the European Union might be a bad example for other countries reviewing international exhaustion. In his opinion, parallel trade is a policy not based upon efficiency or other economic grounds, but rather on internal EU 'Single Market' politics. EU policy-makers are not affected by the economic logic of parallel trade. If they really wished to increase domestic competitiveness and consumer welfare, they would not stop goods from outside EEA at applying parallel trade. EU policy-makers and courts maintain a distinction between internal and external EU trade. It is Community exhaustion in the EU. In effect, internal EU trade can be defined as domestic trade. "*It is a case which actually reinforces the principle of IPR territoriality and distinction between 'national' (in this case, a building of the 'nation of Europe')* and international exhaustion of IPR."<sup>91</sup>

Harvey claims that this EU policy is misread by many, including developing country officials, as a good reason for adopting the strong parallel trade rule. In fact, it is an example of what not to do: force parallel trade for a sector (pharmaceuticals) on a system of existing national price controls and the continuation of gross differences in IPR protection. It is a burden on R&D in the pharmaceutical industry and it is a case of victory of European-unification politics over sound economics and law. This policy has also led to attempts to develop mechanisms to address the distortions arising from this odd and harmful mix of 'free movement of goods' (parallel trade) and price controls. In 1996 and 1997, European Union Commissioner Martin Bangemann organized high level meetings in Europe to try to resolve the divergence between price controls and the free movements of goods. From the long term perspective, the price liberalization could be possible in Europe.<sup>92</sup>

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<sup>90</sup> Abbott, 'First Report (final ) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation', 1998 Journal of International Economic Law, pages 607 - 636, at page 630.

<sup>91</sup> Bale, 'The conflicts between parallel trade and product access and innovation: the case of pharmaceuticals', 1998 Journal of International Economic Law, pages 637 – 653, at page 647.

<sup>92</sup> Ibid.



# 5 The Chinese Perspective

According to IMS Health's report, 88% of the audited prescription drug sales market jointly belongs to North America, Europe and Japan which reached US\$ 466 billion in 2003. There is serious pressure on the pharmaceutical industry's main markets. Only North America experienced double-digit growth; sales rose a respectable 11% last year, compared with just 8% in the European Union (EU) and 3% in Japan.<sup>93</sup>

China has two key attractions for those who treat this market as an essential part of their global business strategies. One is a huge population with urbanization increasing; another is the developing biopharmaceuticals sector.<sup>94</sup>

The question of parallel import in China is still not a clear one, while the issue needs more attention since trade marked goods are becoming more and more common in China.

## 5.1 The Chinese Drug Market

Economic growth in China has been about 8% per year for the past five years<sup>95</sup> and, despite the SARS epidemic, the momentum continues. Real GDP growth is expected to be about 9.5% in 2006.<sup>96</sup>

China's pharmaceutical's market, including ethical and over-the-counter (OTC) drugs, also increases healthily. It already ranks in the top ten. According to the Boston Consulting Group's prediction, it will rise to \$24 billion by 2010-making it the fifth-largest market in the world. In the long run, it could be better. The Economist Intelligence Unit estimates that drug sales in China will exceed those in every other region.<sup>97</sup>

With such predictions, it is no surprise that the foreign drug markets show great interest in this area. There are currently about 1,700 Sino-foreign joint ventures in the pharmaceuticals sector, again according to IMS Health. Most of the industry giants have some sort of marketing presence; indeed, the local subsidiaries set up by Roche, Novartis, GlaxoSmithKline and Pfizer rank among the top 10 marketing companies in the country, measured by sales. To get more market share, many of the multinationals plans to enlarge their Chinese operations according to recent announcement.<sup>98</sup>

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<sup>93</sup> Price Waterhouse Coopers, 'China Prescription for growth', page 1.

<http://www.pwc.com/extweb/pwcpublishations.nsf/docid/2992C71A5CA9BE1285256F5000662664>

<sup>94</sup> Ibid.

<sup>95</sup> Ibid.

<sup>96</sup> Forbes, 'World Bank China 2006 GDP growth forecast raised to 9.5 pct from 9.2-UPDATE'.

<sup>97</sup> Price Waterhouse Coopers, 'China prescription for growth', page 2.

<sup>98</sup> Ibid.

## 5.2 China's Drug-Pricing Policies

Moreover, the Chinese government's main interests are to cut down the drug price. The local governments take the responsibility of managing reimbursement schedules and continued to keep retail prices of a number of popular drugs reduced by between 5% and 70%.<sup>99</sup>

Drug-pricing policies are not the only issue. At present, Chinese hospitals control almost 80% of the drug sales. They prefer generic drugs produced by the local factory and there is some corruption even though drug procurement is nominally a fair-bidding process. To break the hospital sector's strong hold on supply, the central government has therefore actively encouraged retail pharmacies and permitted foreign investment in pharmacies since the start of 2003.<sup>100</sup>

OTC products are very welcome under the present policy. It is a good time for multinationals to build up well-known brands in China although in a short period it is difficult to get revenues. China's OTC market is almost the fastest growing market in the world; in 2003, sales were an estimated \$3.6 billion and some forecasts suggest that they could reach as much as \$7 billion by 2007. But the prices of OTC products made by foreign pharmaceutical companies are three or four times higher than domestic substitutes. So the true market could be smaller than the above figures. There are two reasons for the foreign brand's higher prices. One is the import tariffs; the second is the distribution system which is operated by the middlemen. The inefficient distribution system triples drug prices.<sup>101</sup>

After signing the WTO agreement, the central government has now reduced the average import tariff on pharmaceutical goods to 4.2%. Imported drugs and multinational products made by Sino-foreign companies have the same treatment as local drugs in terms of registration, reimbursement and pricing after December 2004. Foreign drug makers will also be free to import and distribute products in any part of China after that time. Ultimately, China's distribution channels need to improve and compete with the foreign giants.<sup>102</sup>

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<sup>99</sup> Ibid, page 6.

<sup>100</sup> Ibid.

<sup>101</sup> Ibid.

<sup>102</sup> Ibid.

## 5.3 The Current Situation in China Regarding Parallel Import

### 5.3.1 Different Systems

At present, China has different legal and economic systems in the mainland, Hong Kong, Macao and Taiwan. Trade has become more and more common between the four regions, while there is no harmonization of law between them. The four parts have enacted their own trade mark laws. Under the new Hong Kong trade mark law,<sup>103</sup> there exist ambiguous rules relating to parallel imports. With some exceptions and limitations, parallel imports may now freely enter Hong Kong. A registered trademark is not been infringed by the use of the trademark on goods that have been put on the market anywhere in the world by the proprietor or with his consent, be it express, implied, conditional or unconditional. Consent is a question of fact in each case. The reference to conditional or unconditional consent suggests that contractual restraints or the placement of prohibitive labels on products will not necessarily need as non-consent.<sup>104</sup>

But here I only focus on mainland China (hereinafter China), and I pay particular attention to the question whether China should apply national or international exhaustion.

China acceded to the World Trade Organization (WTO) in 2001, and promised to uphold the Trade-Related Aspects of Intellectual Property Rights (TRIPS). There are several laws and regulations concerning trade mark protection and importation. The Trade Mark Law<sup>105</sup> and the Anti-unfair Competition law<sup>106</sup> are the most relevant laws dealing with trade mark infringement issues. Unfortunately, there is nothing on parallel trade or exhaustion in these two statutes.

According to the Foreign Trade law<sup>107</sup> (2004) article 4, the State shall pursue a uniform foreign trade regime, encourage the development of foreign trade and maintain fair and free foreign trade order on the principle of equality and mutual benefit. Still no words addressing parallel trade.<sup>108</sup>

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<sup>103</sup> In force since April, 2003.

<sup>104</sup> Mathew Laight and Sofia Chen, 'Recent Developments in Intellectual Property' Bird & Bird, Hongkong and Beijing. [http://www.buildingipvalue.com/05\\_AP/312\\_315.htm](http://www.buildingipvalue.com/05_AP/312_315.htm)

<sup>105</sup> In force since March 1, 1983, amended on Feb 22, 1993, and Oct, 27, 2001.

<sup>106</sup> In force since Dec 1, 1993.

<sup>107</sup> In force since July 1, 2004.

<sup>108</sup> Zhang Hui, 'Comparative Study on Parallel Imports in Trade Marks', 2002, page.

## 5.3.2 Two Conflicting Judgments about Parallel Trade

There are less few connected to trade marked parallel trade in China; prior to the new PRC Trademark Law promulgated in 2001 the first parallel import case decided in the PRC found Thai-made LUX soaps to be in breach of the local trademark. However, the correctness and applicability of this case is questionable.

### 5.3.2.1 The LUX Case<sup>109</sup>

In the LUX case, Unilever set up its first joint venture (Shanghai Lever) to make bar and liquid soap. The Shanghai Lever Co. was the exclusive licensee to use and sell the soap branded “LUX” in the mainland of People’s Republic of China. In the financial crisis of south-east Asia, the LUX products were much cheaper in China’s neighboring countries than inside China.

The defendant, a trade company located in Guangzhou Province, imported 895 boxes of cheap LUX soap from Thailand and sold it to Chinese consumers. The plaintiff argued that the defendant had no right to sell the soap there and infringed its exclusive trade mark right to use the LUX brand. The defendant claimed that the products were genuine goods and it was legal to import the goods since there is no prohibition about the parallel trade. The court took a different view and held that the plaintiff was the legal user who had the exclusive right to use the LUX trade mark in China and that this right should be protected. According to Article 4, 5 and 7 of the civil law<sup>110</sup> and the trade mark law, the court ruled that the defendant’s products were counterfeit since there was no evidence proving permission from the brand owner. The import and sale of the branded LUX constituted trade mark infringement. The defendant had to pay a fine of 50,000 RMB and had to publish an apology to the plaintiff in a newspaper.

The defendant did not appeal. The effect of this is that China has begun to prohibit trade mark parallel imports. The court held that the plaintiff has the exclusive rights granted by a trade mark and that includes the exclusive right of import into China. Therefore, by importing goods with the same trade mark but without a license, the defendant infringed the trade mark right. But the question arises whether a trade mark right necessarily includes an import right. The court did not establish any legal basis for this, and generally did not give any explanation of its jurisprudence. In fact, the court evaded the key issue of whether or not the trade mark right includes the exclusive right

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<sup>109</sup> Yuan Xiao Dong, ‘Balance required in approaching parallel battle’, 2002, *Managing Intellectual Property*, pages 36-40.

<sup>110</sup> Article 4: In civil activities, the principles of voluntariness, fairness, making compensation for equal value, honesty and credibility shall be observed.

Article 5: The lawful civil rights and interests of citizens and legal persons shall be protected by law; no organization or individual may infringe upon them.

Article 7: Civil activities shall have respect for social ethics and shall not harm the public interest, undermine state economic plans or disrupt social economic order.

of import, as well as whether or not the trade mark right could exhaust internationally. In this case, the court fudged the issue of parallel trade.<sup>111</sup>

### **5.3.2.2 The AN GE Case<sup>112</sup>**

The second case also deals with parallel trade, but resulted in a totally opposite ruling. Beijing Trade Company A entered an exclusive distribution contract with the French Company AN GE to sell branded “AN GE” dresses within a defined territory in the mainland of China, comprising several cities only, such as Beijing and Chongqing. The first defendant Beijing Trade Company B acquired dresses from a Hong Kong trader, which is the licensee of the AN GE French Company and had the right to sell clothing with the AN GE trade mark in Hong Kong, and sold the products in the second defendant C’s hypermarket in Chongqing City. Company A brought proceedings against B and C, alleging that the action of the defendants infringed the plaintiff’s exclusive right of selling the clothing with the AN GE trade mark and asked the court to stop the defendant’s unfair competition. In the first instance, the Court said that the exclusive right could not ban a third party from selling the same products acquired legally in the same market. Therefore the court rejected the plaintiff’s claim. In the second trial, The Court supported the plaintiff’s part of argument and ruled that its exclusive trademark contract was valid. On the other hand, the court also said that this did not mean that the exclusive right allows the vendor to impose restrictions on the further marketing because the clothing was legally imported from Hong Kong and the products were real AN GE goods. Therefore, the third party has a right to market the goods in the same area. There is no confusion for the consumer since the goods are not counterfeit goods. Finally, the court holds the adjudication in the first trial and said the claim of the appellant was short of legal and factual evidence.<sup>113</sup> This is a typical parallel trade case although the plaintiff’s claim was based on the unfair competition. From the court result, it can be concluded that it was permitted for the parallel imports of trade market goods if the goods are genuine. There is no unfair competition in this kind of situation; there is no prohibition on the third party marketing the products within the stipulated territory. Due to the lack of regulation on this issue, different courts have now given differing judgment.

### **5.3.2.3 Comment**

From the above cases, the attitude of the Chinese court seems to be to evade the parallel import issue instead of facing it and giving clear guidelines. Historically, parallel importation has been less of a problem in China because of the low manufacturing and cheap labour costs in the mainland. However, this issue may now be brought to the forefront with recent changes, which allow goods of Hong Kong origin to be imported to China at zero tariffs.<sup>114</sup> The financial crisis in southeastern Asia made parallel import

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<sup>111</sup> Yuan Xiao Dong, ‘Balance required in approaching parallel battle’, 2002, *Managing Intellectual Property*, pages 36-40.

<sup>112</sup> Xiang Yu, ‘The Regime of Exhaustion and Parallel Imports in China: A Study Based on the Newly Amended Chinese Laws and Related Cases’, 2004 *E.I.P.R.*, pages 105-112, at page 108.

<sup>113</sup> *Ibid*, page 108.

<sup>114</sup> Mathew Laight and Sofia Chen, ‘Recent Developments in Intellectual Property’, *Bird & Bird*,

become more and more common in China because prices there are even lower than in China. With the speedy expansion of the Chinese economy and with the gradual reduction of tariffs since China joined the WTO, the issue of parallel imports cannot be avoided and is likely to become more problematic. Compared with the cases in other jurisdictions, Chinese parallel trade cases tend to be related to well-known brands of foreign companies, as China does not yet have any famous own brands. I am sure there will be more Chinese world wide trade marks on the market soon. The courts have to face the challenge.

# 6 Parallel Imports and R&D Performance

## 6.1 The Chinese R&D Perspective

The Chinese government recognizes that only by supporting R&D in the pharmaceutical sector can it have a 'strategic industry' competing in the international market. China's goal is to be "one of the world's pharmaceutical giants by the middle of the next century".<sup>115</sup>

The fact is that Chinese pharmaceutical R&D capability is far behind the global giants. Between 1985 and 1998, only 62 out of 1,500 new medicines developed in China met international standards and only *two* were original products with a unique chemical structure.<sup>116</sup> There is no single Chinese chemical drug that has achieved an international patent. For chemical drugs, the fact is that the R&D budget of the whole Chinese pharmaceutical industry is lower than that of an ordinary Japanese company. For instance, the whole Chinese pharmaceutical industry spent US\$121 million on R&D in 1998, which is even lower than the US\$134 million spent by Ono Pharmaceutical (Japan), which ranked 74th in the international R&D league. The R&D expenditure of the entire Chinese pharmaceutical industry is about 3.4% of that of Aventis and 4.8% of Merck's.<sup>117</sup>

Taking all this into account, it is not surprising that there is no international chemical drug patent that belongs to China. The weak R&D capability makes parallel imports and violation of intellectual property rights common in China. The image of the Chinese pharmaceutical industry is one of low value-added generic drugs and low profit-margins due to the big R&D gap between the west and China<sup>118</sup>. The question about the impact of parallel trade on R&D incentives and development of new drugs is an extremely difficult one to answer. Unfortunately there is no data or materials to analyze the impact of parallel trade on the Chinese pharmaceutical industry. Here we can look at Keith's<sup>119</sup> analysis on this issue, summarized as follows: From the point of view of the manufacturers, parallel imports will interfere with their discriminatory price setting and vertical control and will limit their licensing revenues. The result is that the original rights-holders may find their profits diminished. The decrease in profits would reduce the incentives for further innovation, slowing down the pace of technical change and product development. Thus, the regulation of parallel imports, like that

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<sup>115</sup> Yeung, 'The implications of WTO Accession on the Pharmaceutical Industry in China', 2002 Journal of Contemporary China, 11(32), pages 473-293, at page 482.

<sup>116</sup> Ibid.

<sup>117</sup> Ibid., page 483.

<sup>118</sup> Ibid., pages 482-484.

<sup>119</sup> Maskus, 'Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries', 2001, Final Report to World Intellectual Property Organization, pages 23-27.

of IPR generally, involves a tension between short-run static costs of market power and long-run dynamic benefits of faster product introduction.

## 6.2 General Observations

Letting patients have access to existing pharmaceutical drugs at a reasonable cost is a key health-policy objective. From a welfare point of view, if existing drugs are provided at a price equal to, or in some cases below, the marginal cost of production, total welfare is maximized in the short-run. The problem, however, is that developing new drugs typically involves substantial investments in R&D which accounts for perhaps 30% of total costs for U.S. pharmaceutical firms.<sup>120</sup> The pharmaceutical companies would not be able to get back their investments if prices were set equal to, or even below, marginal cost of production. The result is that the economic motivation for research and development would disappear. The long-run consequence of marginal-cost-pricing is, therefore, that too little investment in R&D takes place and too few drugs are developed. To correct for this market deficiency, patents exist to reduce competition and allow pharmaceutical companies to exercise some market power in order to recover their investments in R&D.<sup>121</sup>

When choosing a welfare policy, each country has to balance two basic interests: First, giving patients access to existing drugs at reasonable costs, and second, ensuring profits for pharmaceutical companies. In this choice, they also have to take into account the impact of tradeoffs across borders. The first and best solution from a welfare perspective is to reward new innovations with a fixed lump-sum transfer to the innovating firm and to distribute existing drugs at competitive prices or even below competitive prices given their additional social value. While this policy might be unworkable or even impossible to execute in most cases, it can be useful in particular situations. More precisely, cost-based pricing and lump-sum payments for innovations could be the only way to achieve both current and future health objectives in the poorest countries of the world. It is, however, important to recognize the international aspects of this issue. First of all, the different trade-off between diverse objectives means that the optimal policy necessarily differs across nations. Moreover, health-care policy in one country has important implications for policy in other countries due to the international trade in pharmaceutical products.<sup>122</sup>

Due to the different objectives in industrialized and developing countries, their policies depend on different factors when they come to choose short-run and long-run objectives. Because of different levels of income, the optimum is likely to vary across nations. Countries with high average income are likely to put more attention on new and progressed drugs comparing with the low income countries. They would like to pay for the

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<sup>120</sup> Ibid, page 23.

<sup>121</sup> Ibid.

<sup>122</sup> Ibid, page 24



R&D during the long process when the new drug becomes to the normal drug. These rich countries willing to accept high profits in the pharmaceutical industry to promote future innovations and improved drugs, while governments in developing countries prefer low costs for patients access to existing drugs. The latter approach keeps prices down by way of weak or non-existent patent rights and generic imitation. These different interests have the unfortunate result that R&D expenditures are rarely aimed at developing treatments for the endemic diseases of poor counties, such as tuberculosis and malaria.<sup>123</sup>

### 6.3 The Impact of Parallel Imports on R&D

It is extremely difficult to assess the potential impacts of parallel imports on R&D incentives and on the development of new drugs because there are no available studies based on actual data. I would like to draw the reader's attention briefly to three aspects: First, the particular structure of competition has a high weight on the precise effects of profits on original manufacturers. Second, a small volume of parallel imports do not imply small price and profit effects. It is difficult to compare price changes with profitability. Third, even if we could calculate the impacts on expected profits, we still do not have enough information to know the relationship between the long-run sensitivity of R&D spending and the declines of profitability.<sup>124</sup> For example, it could be linear, in which case any threat of parallel imports would reduce R&D. However, the relationship could be non-linear, and then the impact of parallel imports on R&D could be insensitive until the reduction of market size lead to the decline of expected profits.<sup>125</sup>

Another significant observation is that the motivations for parallel imports appear primarily on economically successful, or "blockbuster" drugs. The parallel trader would concentrate on such drugs, which typically make up an important share of the profits earned by research-intensive pharmaceutical firms. The impact on overall profitability could be substantial even if only a small number of drugs were the target. From a dynamic point of view, this character of parallel imports could entail almost perverse consequences. First, parallel imports firms have no intention of undertaking the significant R&D costs of developing new drugs and therefore contribute little to dynamic drug introduction. Moreover, they do not have to worry about the substantial uncertainty implicit in attempting to develop a successful new drug. What they will do is to focus on their competitive efforts on the price markups in blockbuster drugs.<sup>126</sup> Rather, their direct aim is on the drugs which have already been successful. From the above, parallel imports have at least two harmful effects on R&D programs: First, reducing the R&D spending. Second, the pharmaceutical firms do not want to devote more

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<sup>123</sup> Ibid, page 23 to 24

<sup>124</sup> Ibid, page 25.

<sup>125</sup> Ibid, page 25.

<sup>126</sup> Ibid, page 26.

resources on smaller drugs which have lower average profit margins and market sizes if the profitability of blockbuster drugs reduced.<sup>127</sup>

There are four major reasons for impeding the expansion of Parallel imports. First, manufacturers and some hospitals, and pharmacists dislike parallel imports because they thought parallel imports is only a form of commercial behavior while providing no added value or technology to the drugs market. Second, the differences in packaging, labeling, and information inserts, raise the cost for manufacturers do business across borders. So there is a need to limit its growth. Third, distributors implicitly collude in refusing to supply parallel traders in those countries with concentrated wholesale distribution systems. Fourth, Government regulations also discourage parallel imports. Such regulations include licensing and approval delays and price "claw-backs" from pharmacists. At the same time, in some countries, encouraging purchases from original manufacturers is supported by financial incentives which aim to supplant parallel imports.<sup>128</sup>

There is a positive argument for restraining parallel trade on the ground of motivating R&D: the theory is that segmentation of the drug market would enhance the efficiency with which drug research is financed.<sup>129</sup> However, in the international context each national government would have different preferences between access to medicines and contributing to R&D. In the short run, if prices can exceed marginal cost and contribute to R&D costs, rational pharmaceutical firms would be willing to supply such drugs at near-marginal cost. Health authorities may not be concerned about the long-term impact on drug development when making their price regulation because they believe that the market is too small to have effects on R&D. Finally, whether the true demand elasticity is revealed by market volumes is doubtful in an environment of extensive price controls.<sup>130</sup>

Overall, it is hard to get a clear picture of the relationship between R&D in the pharmaceuticals industry and the allowing or extent of parallel imports, at least on a per country basis. So there is little reason to say that parallel imports clearly decrease R&D expenditures in pharmaceuticals because there are so many complicated relationships concerning its price impact on global sales and profits, product by product, and the R&D performance of pharmaceutical firms, research spending and so on<sup>131</sup>.

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<sup>127</sup> Ibid, page 26.

<sup>128</sup> Ibid, page 35.

<sup>129</sup> Ibid, page 27.

<sup>130</sup> Ibid, page 27

<sup>131</sup> Ibid, page 41

# 7 Does Parallel Trade Help Consumers?

## 7.1 Competing Interests

Parallel import of trade marked goods is the point connecting many different interests, such as that of the trade mark owner, the trader, the consumer and the marketplace in the country where the importing occurs. When trying to forecast future legislative policy in China, these diverse economic interests need to be taken into account.

**The Interest of the Trade Mark Proprietor:** Multinational enterprises construct markets through establishing exclusive dealership rights in various territories. Exclusive rights make it easier to monitor marketing efforts and enforce product quality, which may be a significant issue in pharmaceuticals. Restrictions against parallel import are a necessary complement to exclusive territorial rights. If such trade were widely allowed, it would reduce profits in the research-intensive pharmaceutical sector and finally slow down innovation of new drugs<sup>132</sup>. As a developing country, China has few well-known trade marks. Parallel imports have more impact on Chinese exclusive distributors or on foreign companies with well-known brands, which have subsidiaries or joint ventures in China.

**The Interests of the Parallel Traders:** Price difference is the main reason allowing the parallel trader to make a profit. Authorized dealers make investments in good will such as customer service, quality control and investing in marketing. The grey trader does not need to incur these costs and benefits from the reputation of the brand and the goods.

**The Consumer's Interest:** The general benefit to the consumer is lower price. Further, there is no clear evidence that parallel imports could bring a lower level of service by the dealer. In the short term, consumers may gain by the free riding on the authorized distributor.

**The Market Order:** Almost all countries admit the principle of national exhaustion of trade marks for the free circulation of goods. Parallel import is not only a legal question but also a commercial issue for States. As a developing country, the Chinese government wants to attract more international investment. Parallel imports with some conditions would be a good choice to make in order to balance the interests of foreign IPR rights and consumer welfare.

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<sup>132</sup> Maskus, 'Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries', 2001, Final Report to World Intellectual Property Organization, pages 2, 20.

## 7.2 Public Choice and Parallel Trade

According to Jacob Arfwedson's article, no experts have seriously analyzed the effects of parallel trade on welfare with convincing proof. There are empirical studies that show that the price of drugs increases less than the prices of other product when there is competition from parallel imports. However, the impact of parallel trade is not clear enough to confidently make policy recommendations on economic grounds.<sup>133</sup>

Even though bans on parallel imports might have a favorable effect on welfare, this does not per se constitute a policy recommendation. There is a natural coalition of interests among governments and providers of generic medicines and parallel importers alike. The latter two argue that their business activities mean that costs are reduced, which is the main goal of policy, and that they supply lower price medicines to consumers.<sup>134</sup> The truth is that the money goes much more into the parallel trader's pocket than for the benefit of consumers, or to government savings, or to increase profits for pharmacists and producers. Some suggest that the international exhaustion principle would enhance welfare for consumers because it gives them the possibility of buying drugs at low prices all over the world. Others have argued that such a global regime would decrease the welfare of many, especially those in poor countries, because price convergence would in fact raise prices in those markets. When policy makers are faced with the short run benefits and long run costs, the short run will probably win. So the debate on parallel trade appears in most countries.<sup>135</sup>

Cost is the main concern for politicians, insurers and consumers. Politicians in Europe push parallel imports and argue that pharmaceutical companies have been price gouging, and that parallel imports can raise competition, decrease prices and help the poor. Parallel imports are an acceptable concept and rapidly growing in most EU countries.<sup>136</sup>

In the 1960s, the European countries had the leading rank in the pharmaceutical industry and a strong R&D background, but today the position belongs to America, which is now the largest market as well. Furthermore, many EU companies have moved their research centers to America. Pharmacia (Sweden) moved its headquarters from London to the U.S. in 1995. This was followed by a similar move by French-German Aventis in 1999. GlaxoSmithKline (UK) moved its operational headquarters to the United States in 2000. Novartis, the Swiss pharmaceutical company, also moved its headquarters to USA in May 2002.<sup>137</sup> The strength of the pharmaceutical industry is one of the reasons for the lack of parallel imports

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<sup>133</sup> Arfwedson, 'Parallel Trade in Pharmaceuticals', IPI Center for Technology Freedom, 2004, page 3.

<sup>134</sup> Ibid.

<sup>135</sup> Ibid.

<sup>136</sup> Arfwedson, 'Re-importation (Parallel Trade) in Pharmaceuticals', 2004, Institute For Policy Innovation, pages 24 to 25.

<sup>137</sup> Ibid, page 25.

in the US. Over the long run, the US industry has been vindicated by the strength of its research pipeline.

Despite the above facts relating to the pharmaceutical industry, the free market views supported by some politicians, who claim that poor people cannot afford the high price fixed by the research-based industry, are more likely to find favor. The long-term effects on innovation should be the strongest arguments against it. More importantly, the argument for and against can never end. Any argument in favor can be ignored by politicians because they will have left office before data has proved that the opponent was right. On the other hand, the opposition will constantly remind the public of the truth which can be summarized in the catch phrase “no profit no new drugs”.<sup>138</sup>

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<sup>138</sup> Ibid.

# 8 Conclusions and Policy Recommendations

## 8.1 General Conclusions

It is really hard to reach a conclusion on the issue of parallel trade as discussed in this paper because there are such strong views on both sides of the policy debate. On balance, a regime of intellectual property rights contributes to economic growth and international trade, provided that certain basic legal institutions (rule of law, respect for basic property rights, and freedom of information) are equally respected and enforced. The strong IPR view against parallel imports is a natural expansion of the trademark holder's rights to market goods globally without interference. According to Jacob Arfwedson, *"it should be remembered that, wherever other interests are at work, intellectual property rights will always be viewed as essentially a utilitarian instrument that may at any moment be modified to suit other interests on the political agenda."*<sup>139</sup>

On the other hand, supporters of international exhaustion point out that they expect consumer benefits from the integrated markets. In terms of increased competition, the impact of parallel trade on the research-based pharmaceutical industry may or may not have slight short-term benefits for the consumer through lower prices and act as a counterbalance to monopoly effects in the industry at large. Parallel imports were seen as a valuable method for restraining collusive behavior among IPR owners. As already analyzed above, there are four factors that fundamentally stimulate PI: retail price discrimination, vertical price control, free riding on the costs of marketing, and national price regulations. However, recommendations for an optimal policy depend on the source of PI and whether a country is a net importer or net exporter of intellectual property<sup>140</sup>. In other words, this balance will continue to depend on the tradeoffs between protection of IPR and necessary amendments to accommodate, for example, the resolution of healthcare crises such as the HIV/AIDS situation.

The developing countries, especially those that are at present switching from imitator industries to research-based innovation (e.g. China) are the key points for future IPR protection. Awareness of the importance of IPR protection systems in China is increasing, and its capability for enforcing IPR protection has also improved. However, it is hard to give a positive policy recommendation for parallel imports. *"It is impossible to support on economic grounds either a global policy to ban parallel imports or a mandate that there be a free international exhaustion in parallel trade. The*

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<sup>139</sup> Ibid, page 26.

<sup>140</sup> Maskus, 'Parallel Imports', 2000 World Economy (23), pages 1269 – 1284, at page 1283.

*best advice is simply to permit each country or region selecting its own policy.*<sup>141</sup>

## 8.2 Policy Recommendations for China

Turning to the Chinese pharmaceutical industry perspective, the policy on parallel imports would have to change in accordance with the development of the Chinese economy.

At present, the market for pharmaceuticals is characterized by weak R&D capacity, limited global distribution channels, and not well-known trade mark drugs. That is why it is extremely difficult for the Chinese pharmaceutical industry to compete with the western giants in the international market level of prescription drugs. The globally strongest pharmaceutical companies can easily penetrate the Chinese drug market with all their available weapons. In the short run, China, as a low-income country, should permit parallel importation. This would help to avoid problems of high prices charged by the western giants and thus use competition to decrease drug prices for consumers. Which means the Chinese pharmaceutical company could buy the drugs globally at a reasonable price and can use the market power to negotiate with the suppliers and get the same drugs from a cheaper market. If the parallel imports were prohibited, then the drug sources in Chinese market are from the IPR owner or its authorized distributor. They could easily charge the drugs at high or monopoly price.<sup>142</sup> At the same time, parallel exports should be banned, because low price medicine from China might disturb the market strategy of major players in the pharmaceutical industry in high price countries. The sustainable supply of drugs in China must be ensured, and the country needs to attract the western giants to invest in its market. If China followed a different policy, i.e. if parallel exports were allowed, foreign undertakings will have no interest to invest there since there is no sufficient protection for their intellectual property. This would also be a danger for the constant and reliable supply of drugs in China.

In the future, things might look a lot different, requiring a new policy approach. In the long run China has its own goal of being the world's pharmaceutical giant by the middle of the next century. Once this level is reached, China's interests will have changed: The country will have a strong pharmaceutical industry of its own, people's income will have increased, and companies will have both the desire and the ability to focus on R&D. At that point, China's policy will have to be similar to what Europe and the United States are doing right now. Parallel imports should be banned: The price for pharmaceuticals might be higher in China than in foreign markets where Chinese companies are active, and parallel imports would disturb the pricing policy made by the Chinese pharmaceutical

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<sup>141</sup> Ibid, page 1283.

<sup>142</sup> Xiang Yu, 'The Regime of Exhaustion and Parallel Imports in China: A Study Based on the Newly Amended Chinese Laws and Related Cases', 2004 E.I.P.R., pages 105-112, at page 111.

industry. Parallel imports would negatively affect their natural interest to make profits, and consequently, their investment in R&D. Of course, parallel export would be very welcome for them, because they can charge different prices in different foreign markets. Thus, the best long-term advice is to encourage the prohibition of parallel imports in pharmaceuticals and permit parallel exports to the international drug market. In this case, there will be the need for negotiations and multilateral agreements. In all this process, it is essential to maintain R&D incentives.



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