

Parallel Trade of Pharmaceuticals: A Review of Legal, Economic, and Political Aspects

Thomas N. Bart, MD, MPH, MBA

Medical Coordination, Swiss Blood Stem Cells, Bern, Switzerland

ABSTRACT

Objectives: An overview of the status quo of parallel trade of pharmaceuticals (pharmaceutical parallel trade [PPT]) was performed. The different economic, political, and legal viewpoints as well as the public health perspective are being taken into consideration. Analysis is being undertaken on a worldwide level, focusing on the situation of Switzerland in the context of current developments in the United States as well as in the European Union (EU).

Methods: Desktop analysis using publicly available information (e.g., scientific literature, congress reports, official statistical databases) was performed during the years 2006 through 2007. Such gathered information was compiled and systematically structured to allow a crude overview of the development of intellectual property law in the last 100 years (as a prerequisite under which PPT legally can exist) as well as a description of the health economic and political context in which PPT is set currently.

Results: It could be shown that PPT is an ubiquitous phenomenon, appearing in industrialized countries as well as in the developing world. Economically, it has gained a

significant weight in substantial parts of the EU in the last decade. This has to be seen in the context of EU efforts of enhanced economic and political integration. The worldwide constant growth of health-care expenditures, with its strain on national health-care budgets, has led to increased discussions about the necessity and consequences including possible dangers of PPT, namely, in the United States and in Switzerland, where up to now PPT has been only of marginal importance.

Conclusions: The analysis of the value of PPT depends strongly on the importance that is given to different perspectives by the individual analyst. It is clear that an item-centered view of PPT is not able to analyze this phenomenon in an equitable way. Further attempts have to be made to standardize evaluation as well as to increase available information to empower science and decision-makers to perform objective analyses and informed decisions.

Keywords: comparative study, health economics, multi-country economic evaluation, pharmaceutical pricing, Switzerland.

Introduction

This article tries to give an overview of the current international situation of pharmaceutical parallel trade (PPT). Parallel trade is not limited to pharmaceutical products (see later in the article, but because of the special nature of pharmaceuticals, which differentiate them from “normal” consumer goods, there are not only economical facts to be given, but legal considerations and political implications to be remembered. This becomes clear—among others—when analyses of the same phenomenon come to completely different, sometimes even contradictory results, as it is the case with the recent economic studies on this subject, which will be shown next. Part of the reason for such

different results could lie in some shortcomings in economic theory as well as in the limited availability of appropriate data.

By giving an economic, legal, and political outline, the reader of this article should be enabled to understand the international status quo of PPT as well as the different interests, policies, and aims of the individual market participants.

Definition of PPT

Parallel trade is a phenomenon well known internationally: A common definition is worded in the fundamental work of Arfwedson [1] as follows:

Re-importation (or parallel trade as it is known in Europe) occurs when products protected by patent, trademark or copyright are first placed into circulation on one market, then (re-) imported into a second market without the authorization of the original owner of the intellectual property rights (IPRs).

Arfwedson concludes his definition with the remark that “Myriad products are re-imported, including

Address correspondence to: Thomas N. Bart, Medical Coordination, Swiss Blood Stem Cells, Laupenstrasse 37, Bern 3008, Switzerland. E-mail: thomas.bart@bloodstemcells.ch
10.1111/j.1524-4733.2008.00339.x

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Table 1 International comparison of average per dosage ex-manufacturer's prices, common drugs, 1998 (US\$)

Country	Number of drugs	Average price (US\$)	Average price relative to the USA
USA	19	2.72	1
Brazil	19	2.03	0.81
Mexico	18	2.02	0.76
Japan	8	1.33	0.74
Sweden	16	1.79	0.73
UK	20	1.85	0.7
Canada	19	1.63	0.63
South Africa	19	1.37	0.58
Czech Republic	17	1.18	0.56
Italy	20	1.39	0.55
Korea	18	1.35	0.54
Spain	17	1.35	0.52
Thailand	17	1.12	0.41
India	7	0.14	0.08

Source: IMS data, in Maskus [3].

automobiles, clothing, perfume and other consumer goods." This shows to us that parallel trade is an almost ubiquitous phenomenon (at the end of the last decade, it was estimated, for instance, that up to 20% of the market for Coca-Cola in the UK was served by parallel imports coming from wholesalers in other European countries [2]).

Price Differentials As Driving Forces

What are the reasons of this situation? Apparently, there must be a strong driver for the international, almost ubiquitous appearance of parallel trade: profit, or better said, price differences allowing firms to make profits in exploiting the possibility of arbitrage if transaction costs are low enough. Wherever there are sufficient price differentials to make movement of goods economically viable, and a regulatory framework, which permits it, parallel trade comes into action. In the case of pharmaceuticals, Maskus [3] obtained international ex-manufacturer's prices and sales data for major molecules (20 brand-name drugs) in 14 countries, for which he calculated average per dosage prices (see Table 1). In the same study, he used data from the Swedish Medical Products Agency for a basket of 90 brand-name drugs (see Table 2) to make a European price comparison.

Maskus [3] identified the price differentials on the international as well as on the European level, with low-price countries like Greece and Spain, and high-price countries like the UK or Switzerland. Maskus found that prices in many drugs were relatively low in numerous developed countries, e.g., Canada, Italy, and Spain, whereas in other less developed countries, e.g., Mexico, Brazil, and South Africa, they were relatively high, which he explained mainly with the existence of significant price controls in countries with low prices.

Costs of marketing pharmaceutical parallel imports (PPIs) are high—it is a tightly regulated industry with

rigorous standards and regulatory requirements, but there are still enough margins to make it worthwhile, and parallel trade in pharmaceuticals has grown consistently in Europe. The market size has been estimated at a value of EUR 4.2 billion in 2004 [4], a development of between EUR 2.6 billion in 2001 and EUR 5.8 billion in 2006 [5], respectively.

Legal Background

Exhaustion and Its Different Forms

The definition of parallel import in Deardorff's Glossary of International Economics [6] is as follows:

Trade that is made possible when the owner of intellectual property causes the same product to be sold in different countries for different prices. If someone else imports the low-price good into the high-price country, that is a parallel import.

The legal basis of parallel import lies in the European principle of exhaustion and the American "first-sale doctrine," which are explained in the following: Exhaustion was developed in Germany in the early 20th century by the pioneering work of Josef Kohler [7]. Its American equivalent, the "first-sale doctrine," was established at roughly the same time by a decision of the US Supreme Court in 1908 [8].

Exhaustion is one of the basic principles of intellectual property (IP) law worldwide. The concept of exhaustion can be explained in the following: Once trademarked goods are put on the market by the trademark owner or with his consent, the trademark owner is no longer allowed further to control the distribution of those goods. He has "exhausted" his distribution right by the first sale of the goods. There are basically three different forms and concepts of exhaustion:

1. National exhaustion means that the trademark right (or patent or copyright) is exhausted only

Table 2 Average percent deviation from European mean prices in pharmaceutical products, 1998

Country	All 90 products	Products in all 15 countries
Greece	-28	-16
Spain	-20	-12
Portugal	-13	-4
Italy	-13	-4
France	-10	-1
Finland	-2	-2
Austria	-2	+0
Norway	-1	-5
Sweden	-1	-1
Belgium	-1	+0
The Netherlands	+2	+3
Denmark	+3	+3
Germany	+11	+8
UK	+19	+12
Switzerland	+25	+17

Source: Calculations by Mattias Ganslandt with data from Swedish Medical Products Authority, in Maskus [3].

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