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Summary: *Supporters of parallel trade in pharmaceuticals argue that it lower prices, which is popular with consumers and cash-strapped governments. But, in fact, parallel trade reduces safety, since it represents an end-run around domestic inspection procedures. More importantly, re-importation undermines intellectual property protection and hence incentives to invest in research and development of IP-based products; which will have ominous implications for consumers in the long run.*

Parallel Trade in Pharmaceuticals

By Jacob Arfwedson

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

Some argue that parallel trade is a good thing on the grounds that it leads to lower prices for consumers. Others argue that parallel trade in fact adds nothing, except substantial profits to the traders themselves, and that it lowers safety (parallel importers are in many cases not subject to the same regulations as the original manufacturers). More importantly, parallel trade undermines intellectual property protection and thereby undermines the incentives to invest in the research, development and marketing of intellectual property-based products, which may harm the consumer in various ways.

The future of IPRs will largely depend on political decisions governing the tradeoffs between the need to foster innovation by granting just compensation to R&D industries, and the demands for greater access to affordable medicines, both in advanced and developing countries.

This study examines the pros and cons of parallel trade in pharmaceuticals, with special attention to the situation in Europe. But it is of significance in the United States given the probable and impending legalization of re-importation of Canadian drugs into the US.

The study concludes that the net economic effects cannot be established empirically, but that there may be significant long-run harm to innovation if parallel trade grows indefinitely.

Exhaustion of IPRs

The "principle of national exhaustion" means that IPR holders' exclusive rights are extinct upon first sale within national borders. Some have suggested that a global regime of international exhaustion would enhance welfare by enabling consumers everywhere to take advantage of lower prices.

Others have argued that a global regime of international exhaustion would lower welfare for many, especially those in poor countries: it would actually raise prices in those markets to the international average price by hampering firms' ability to "price discriminate." By charging

different prices in different markets, price discrimination enables firms to service people who otherwise could not afford to purchase their products, thus benefiting all.

The ability to price discriminate depends on the ability to preserve market segments as distinct markets. But the threat of parallel imports would undermine the ability to segment markets by country.

The regulation of parallel imports is, moreover, fundamentally a trade-off between short-run static costs (which accrue because IPRs create market power) and long-run dynamic benefits (which include raising the speed of innovation and marketing of new products).

Why Pharmaceuticals?

To understand why parallel trade has particularly affected the pharmaceutical industry, it is necessary first to understand some characteristics of the industry. They are as follows:

An industry protected by patents. Because drug molecules are easy to copy, patents are a necessary and even fundamental condition for the development of new drugs.

A research-intensive industry. Pharmaceutical companies develop and market new products in order to maintain and increase their market share; innovation is accordingly paramount to survival.

A highly regulated industry. The therapeutic nature of pharmaceuticals leads governments to establish strict rules before a new drug is approved for sale. The result is new medicines are delayed in reaching the market and R&D costs increase due to rigorous testing procedures. The flipside of regulations is that healthcare policies in industrialized countries mean that patients only pay a fraction of real drug costs. This does not encourage doctors, hospitals and patients to seek out the most cost-effective drugs.

A competitive industry. Increasingly, brand-name manufacturers have to tackle competition from generic producers once patents expire. Marketing of generic products may in some cases reduce the prices of branded drugs by at least 50 percent.

An industry seeking new markets. Due to saturated and highly regulated markets in the West, the pharmaceutical industry is increasingly searching for new outlets in the newly industrialized countries and in developing countries.

Parallel Trade and the European Union

According to various estimates, more than 10 percent of prescription drugs in Europe are re-imported. The recourse to parallel trade is expected to intensify, as governments and public health services increasingly seek ways to curb health expenditures. The rise in re-imported medicines may to a large extent be attributed to the incentives for their use given to hospitals, physicians, pharmacists and patients.

Parallel trade in Germany is forecast to increase, accounting for $3.6 billion or 9 percent penetration by 2006, despite recent developments where the largest importer Kohl-Pharma was indirectly involved in the illicit re-importation of medicines destined for Africa.

In the UK, market share of parallel traded pharmaceuticals was 17 percent in 2003. France, meanwhile, is essentially a parallel exporter of medicines to other EU countries, due to France's relatively low drug prices.

The inclusion of 10 states in Central and Eastern Europe will provide an additional challenge to the EU single market as the new members offer several conditions for parallel trade: trademark regulations, considerable price differentials and in some cases lack of patent protection in the future member countries.

Share Of Parallel Imports In Total Pharmaceutical Market.

Country	1997 (%)	1999 (%)
Germany	2	2
Sweden	2	8
Norway	0.8	7
United Kingdom	7	7
Denmark	11	10
Netherlands	14	15

Source: Institute for Heath Economics (Sweden)

The USA: A High Potential for Parallel Trade

In July 2002, the US Senate approved a bill that, along with its main provisions dealing with speeding the entry of generic drugs to market, included an amendment to allow pharmacists and wholesalers to re-import prescription drugs from Canada to the US. However, the bill also required the secretary of the Department of Health and Human Services to certify that the legislation would pose no public safety risk in order for it to be implemented. It also required HHS to certify that drug reimportation from Canada would result in "a significant reduction" in the cost of prescription drugs to consumers.

In late April 2004 a bi-partisan group of senators introduced a bill to allow reimportation from Canada and other countries. This would make it legal for wholesalers and pharmacists to import drugs from Food and Drug Administration-approved suppliers 90 days after the law is enacted.

According to newspaper reports, however, FDA opposition to re-imports is unchanged, although the new bill includes new safety features, such as a fee paid by importers which would finance additional hiring of FDA inspectors. The law would also include provisions to restrict market segmentation and supply restrictions currently practiced by pharmaceutical companies.

Authorizing parallel imports may open the door to fake products. In March 2003, a Florida state agency discovered counterfeit drug traffic thought to involve more than 50 wholesalers selling drugs that were either counterfeit or obtained fraudulently. According to its report, the number of criminal wholesale drug cases has increased from practically zero to more than 50 since 1999.

Canada: Exporting Price Controls

In January 2003, GlaxoSmithKline decided to suspend its exports to Canada, a move that drew the ire of US citizens who had grown accustomed to buying drugs cheaply from the 80 online pharmacies in Canada, or by making day-trips across the border. In reaction, they launched a boycott against GSK non-prescription products, "Tums Down to Glaxo."

The following month, Rep. Bernard Sanders (D-Vt.) introduced a bill to preserve the access to Canadian medicine, and Sen. Russ Feingold (D-Wis.) sponsored a bill to deny tax breaks for pharmaceutical companies that reduce their supplies to Canada.

Eli Lilly also notified its Canadian wholesalers that any sales to Canada-based pharmacies reselling to the US would amount to a breach of contract. In April 2003, AstraZeneca followed suit by announcing delivery restrictions to Canada.

The FDA stepped in, warning US companies that they are liable under civil and criminal law for making re-importation of drugs from Canada possible. (Legally, only a drug manufacturer and its wholesalers may import medications.) The FDA has been careful not to target US consumers who still enjoy the right to bring small quantities of medicine into the country for personal use.

The growth of Canadian online pharmacies is believed to produce shortages for Canadian consumers.

Does Parallel Trade Help Consumers?

To the author's knowledge, no expert analysis currently available advances solid proof of the welfare effects of parallel trade in either direction. Although empirical studies have found that drug prices subject to competition from parallel imports tend to increase less than those of other products, the impact of re-importation is not clear cut enough to confidently make policy recommendations on economic grounds.

One econometric analysis study concludes that rents to parallel importers (or adjacent costs) may well exceed the consumer gains in the form of lower prices. Similarly, another study concludes that parallel trade in pharmaceuticals may give an incentive to both price increases and price reductions in different markets, but that on balance consumer benefits (price savings) may well be outweighed in some cases by the extra costs incurred by pharmacies and profits made by parallel importers.

Should bans on parallel imports prove conducive to welfare, this does not per se constitute a policy recommendation; other instruments may prove superior in achieving this goal.

There seems to be a natural coalition of interests forming among governments and providers of generic medicines and parallel importers alike. The latter two enjoy the role of allies to explicit policy concerns (reduced costs) and defenders of the consumer (lower-priced medicines). This is a curious stance, as numerous studies show that increased recourse to both parallel imports and generic products amount not so much to consumer or government savings as to increased profits for pharmacists and producers.

Meanwhile, some have suggested that a global regime of parallel trade would enhance welfare by enabling consumers everywhere to take advantage of lower prices. Others have argued that such a global regime would lower welfare of many, especially those in poor countries, because it would actually raise prices in those markets to the international average price.

Various ways of circumventing IP legislation appeal to the developing world, especially African countries that urgently need affordable AIDS drugs. However, on examination it seems that there is no link between the presence of patents and poor access to antiretroviral drugs. The AIDS crisis could therefore not be resolved by simply disregarding patents or by using compulsory licensing.

Public Choice and Parallel Trade

Public choice provides a model of how the various actors, such as politicians, pressure groups, voters, media and bureaucrats interact. When there are short-run benefits and long-run costs from political decisions, it is likely that those benefiting in the short run will win. And so it appears to be with the debate on parallel trade in most countries.

Cost is the major concern for politicians, insurers and consumers, whatever the evidence saying re-imported medicines can be highly dangerous, and of lower quality than those produced by the research-based industry. Since counterfeiters, legitimate generics manufacturers or other producers not hampered by regulatory constraints (or receiving subsidies) can lower those costs for

importing nations, some politicians in the importing country will always have an incentive to advocate re-importation.

In Europe, assumptions about safety are often secondary. As a result, politicians gain reputation and occasionally more power by pushing re-imports. They argue that pharmaceutical companies have been price gouging and that re-imports increase competition, lower prices and help the poor. So re-importation is an accepted and rapidly growing practice in most EU countries.

In the US by contrast, there has always been opposition to re-importation. Re-importation has been opposed by 10 of the last 11 FDA commissioners since 1969. All cited public safety concerns. Some also expressed concern about the potential for opportunists to manufacture and sell counterfeit drugs.

One reason for the lack of re-importation in the US is the strength of the pharmaceutical industry. It has effectually made the arguments about research and development, safety and the dangers of price controls. The European industry was probably less able to out-battle the combined forces of statist politicians, a dirigiste economy, and centralized publicly funded health authorities.

Over the long run, the US industry has been vindicated by the truth about the research pipeline: European countries did most research and development in the 1960s, but today the lion's share is done in America, which is now the largest market as well. Furthermore, many EU companies have moved their research centers to America.

The European share of the world pharmaceutical market declined from 32 to 22 percent over the past decade; the US share increased from 31 to 43 percent. Similarly, in 1990 major European research-based companies spent 73 percent of their global R&D expenditure in the EU, but only 59 percent in 1999.

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. Due to the system of guaranteed prices, research and development progressively lost its importance, inducing firms to invest more resources into existing products.

In the US, such facts have bolstered the case of the pharmaceutical industry and politicians who are ideologically supportive of free markets. However, the political opposition, especially pressure groups, have grown in strength. Their political and media influence could turn out sufficiently strong to ensure an endorsement of re-importation in the House of Representatives.

Long-run costs of re-importation are easily ignored by politicians (even by those who oppose it), since they are unlikely to be in office when the data prove the opponents correct many years in the future. The opposition to re-importation is aware of this problem and so it is likely that the battleground for debate will be safety, since this is of immediate concern to seniors. There will also be constant reminders that without profits, there are no new drugs.

Conclusion

Parallel trade in pharmaceuticals and its impact on the research-based pharmaceutical industry may or may not have slight short-term benefits for the consumer in terms of increased competition (lower prices) and as a counterweight to monopoly effects in the industry at large. This equilibrium will continue to depend on political decisions worldwide, in particular as the policy discussion evolves around the appropriate tradeoffs between protection of intellectual property rights and the necessary adjustments to accommodate the resolution of healthcare crises such as the HIV/AIDS situation.

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.

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