



# Optimal intellectual property rights protection during an international health emergency

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## ABSTRACT

We analyze policy options during an international health emergency to provide consumers in least developed countries access to patented life-extending pharmaceuticals. Reliance on property rights exhaustion is shown to be insufficiently flexible and costly to implement. By contrast, the optimal degree of price discrimination can always be achieved with a properly specified tariff. We identify a trade-off between patent length and the relevant optimal tariff rate. If the patent length is too short (too long) there must be an offsetting higher (lower) than socially optimal tariff rate. When patent length can be manipulated as an explicit policy tool we identify a clear policy assignment. The tariff rate should be set to achieve social welfare objectives while the patent length can be used to control the resource cost of innovation.

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## 1. Introduction<sup>1</sup>

The creation of the World Trade Organization (WTO) in 1995 established an international system of intellectual property rights protection as articulated by the Trade Related Intellectual Property Rights (TRIPS) Agreement. The TRIPS Agreement required WTO member states to legislate a domestic TRIPS-compliant intellectual property rights structure by 2005.<sup>2</sup> Yet, before the TRIPS Agreement was fully implemented, significant tensions developed between intellectual property rights protections and the ongoing worldwide AIDS epidemic.

The AIDS-attendant humanitarian crisis prompted some significant changes to the TRIPS Agreement in 2001 and 2003.<sup>3</sup> During negotiations over amending the TRIPS Agreement concerning intellectual property rights over essential medicines, several strategies for expanding developing country access to these medicines were proposed. The ultimate objective of all proposals was to find some mechanism for

reducing the price of patented essential medicines in developing countries during a health emergency.

The potential to engage in price discrimination internationally depends fundamentally on the extent to which national markets are segmented. From a legal perspective, market segmentation is exercised through statutes regulating intellectual property rights exhaustion. Under a regime in which the principle of *national* exhaustion prevails, the patent holder cannot control secondary commercial exploitation within a national market but can oppose the reimportation of goods originally sold in a foreign market.<sup>4</sup> Thus, the holder of a property right can legally eliminate 'grey market' transactions and can set a profit-maximizing price for each market.<sup>5,6</sup>

However, even though most industrialized countries adopted the principal of national or regional exhaustion of intellectual property

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<sup>2</sup> Implementation deadlines of some provisions of the TRIPS Agreement were delayed until 2017 for members categorized as least developed.

<sup>3</sup> See Maskus (2001) for an extensive discussion of global intellectual property rights.

<sup>4</sup> [http://www.wipo.int/sme/en/ip\\_business/export/international\\_exhaustion.htm](http://www.wipo.int/sme/en/ip_business/export/international_exhaustion.htm).

<sup>5</sup> See Grossman and Lai (2008) for analysis of the welfare properties of national and international exhaustion.

<sup>6</sup> Richardson (2002) has demonstrated that in a system in which countries are free to set their own rules by which property rights are exhausted, parallel imports are permitted into all relevant foreign markets in a Nash equilibrium. Countries charged a higher-than-average price by virtue of a relatively low demand elasticity will find it welfare-maximizing to promote parallel imports by adopting the principle of *international* exhaustion. As a consequence, even in the case where international price discrimination is globally welfare improving, it is unlikely to emerge in the absence of an agreement establishing national exhaustion as an international norm.

rights, patent-holders of antiretrovirals (ARVs) did not typically engage in price discrimination between industrialized and developing country markets in the early stages of the AIDS humanitarian crisis. To the extent that ARV patent holders initially provided medicines to low-income consumers in developing countries, the deliveries were characterized as humanitarian donations and made available at a zero price.

AIDS activists gained leverage against patent holders following the 2001 Doha Ministerial and the 2003 Amendment to TRIPS Article 31. During the fourth WTO Ministerial (Doha, November 2001), members of the World Trade Organization (WTO) endorsed the use of TRIPS Article 31(b) which permits compulsory licensing of essential medicines for domestic purposes in the event of a national health emergency. Subsequently, prior to the Cancun Ministerial (2003), WTO members agreed to amend Article 31 to allow for the export of essential medicines produced under a compulsory license to other developing country trade partners.<sup>7</sup> In the wake of revisions to the TRIPS Agreement, developing country governments could compel the patent holders of essential medicines to permit the reverse engineering and marketing of generic versions of ARVs.

Thus, in essence, the WTO resolved the conflict between intellectual property rights protection and the AIDS driven humanitarian crisis by allowing developing countries to break the patent on ARVs. This raises the natural question, addressed in our analysis below, as to whether a market segmentation enforcement mechanism other than national exhaustion might have induced the ARV patent holders to supply developed and developing country markets.

From the perspective of the patent holder, protecting price discrimination opportunities created through national exhaustion is costly. Pharmaceutical firms seeking to enforce market segmentation must exercise discipline over the supply chain through the use of batch numbers, bar coding, dating methods, differential packaging and litigation against patent violations by importers. The cost of policing international grey markets may not be offset by the small potential profits available in developing-country markets. Further, differential pricing in which the price paid in developing countries is publicly disclosed, reveals information to all customers concerning the firm's marginal cost and, thus, may adversely affect the outcome of bargaining between the patent-holder and customers in industrialized markets.

From an economic efficiency perspective, an intellectual property rights regime of national exhaustion, which completely separates all national markets, might lead to more price discrimination than is socially optimal. Exhaustion is a binary policy tool. Therefore, the choice of exhaustion regime can facilitate a uniform international price or complete separation of markets. Intermediate results in which there is some international price dispersion but not profit-maximizing price discrimination cannot be supported by any exhaustion regime.<sup>8</sup>

This debate necessarily raises the question concerning how much price variation across countries is socially optimal and which policy tools can most efficiently facilitate optimal price dispersion. More precisely, can policy tools other than national exhaustion achieve efficiency-enhancing market separation?

In light of the fact that intellectual property-rights protection is at least a second-best tool for promoting innovation (Deardorff, 1992), it is likely that some degree of tariff protection is socially optimal in the presence of global patent protection. This consideration leads us to investigate whether a tariff that separates national markets by

penalizing re-exported products can be used to facilitate socially optimal price dispersion.<sup>9</sup> We find that a tariff dominates national exhaustion for achieving optimal price dispersion and improves the efficiency properties of a patent for covering product development cost.

The remainder of the paper is structured as follows. In Section 2 we briefly review the theoretical literature on the efficiency properties of international price dispersion. In Section 3, we consider the optimal tariff without development cost. In Section 4, we introduce the cost of R&D and jointly determine the optimal tariff regime and patent duration. Caveats and conclusions follow in Section 5.

## 2. Literature review

Varian (1986) established the necessary and sufficient conditions under which third-degree price discrimination is welfare improving. He showed that the welfare impact of an increase in price dispersion depends on the convexity of demand in each market. Malueg and Schwartz (1994) analyze the issue of socially optimal international price dispersion in the context of linear demands. Even though linear demands do not have the convexity characteristics identified by Varian (1986), the opportunity to price discriminate across national markets may still be welfare improving. This will be the case if the dispersion in market size is so great that some smaller markets would otherwise not be served under a uniform international price.

Danzon (1997) lends further support for welfare-enhancing price discrimination in the case where additional profits finance R&D expenditures. Following Ramsey (1927), Danzon finds that the socially optimal mark-up of price over marginal cost is inversely proportional to the elasticity of demand in each market when firm profits are constrained to cover the cost of product development. She argues further that if the pharmaceutical industry is monopolistically competitive, implying that profits equal product development cost, profit-maximizing price discrimination will approximate Ramsey pricing.

Based on their analyses, both Malueg and Schwartz and Danzon favor a principle of national exhaustion provided the pharmaceutical industry is sufficiently competitive. However, in the case analyzed by Malueg and Schwartz, while it is welfare improving to allow enough price dispersion to draw unserved consumers into the market, any further price discrimination beyond that critical point, as would be possible with national property-rights exhaustion, reduces world welfare. Similarly, while Danzon finds that the Ramsey and profit-maximizing pricing rules bear a nominal resemblance, in fact as we will see below, the two are not approximately equal even if profits are zero.

## 3. The optimal tariff without innovation

We first consider the welfare-improving role of a tariff against re-exports in a static market without innovation. Consider two regions, with region  $E$  in a national health emergency that can be ameliorated only with a drug  $X$  which is produced at constant marginal cost,  $c$ , solely in another location,  $N$ . Drug  $X$  is covered by a patent that is also owned in  $N$ . Inverse demands for  $X$  in each region are given by  $P_N(X_N)$  and  $P_E(X_E)$ . The only restriction we place on these inverse demands is the natural one that marginal revenue is non-increasing in output:

**Assumption 1.**  $P'_i(X_i)X_i + 2P_i(X_i) \leq 0$  ( $i = N, E$ ).

The patent holder is assumed to maximize profits from sales of  $X$  in  $N$  and  $E$  subject to a constraint on the maximum degree of price

<sup>7</sup> On September 1, 2003, agreement was reached in the TRIPS Council to provide for the export of essential medicines produced under a compulsory license to developing countries with inadequate production capacity. Text of the agreement can be found at [http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm).

<sup>8</sup> Malueg and Schwartz (1994) explore the possibility of varying the degree of price dispersion that emerges by strategically grouping countries. By mixing countries with high and low demand elasticities into groups in which regional exhaustion applies, they can produce a smaller degree of price dispersion, which may be more efficient than grouping like countries together.

<sup>9</sup> This relates to one approach suggested by Watal (2001), of "establishing the right conditions and leaving (the implementation of differential pricing) to the market" (p. 13) while simultaneously putting in place mechanisms that prevent diversion of low-priced products to the developed country markets.

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