

Nonrival access to pharmaceutical knowledge

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Abstract: On innovation grounds, pharmaceutical patents are unnecessary in low income populations, since such markets cannot do much to support global pharmaceutical profits. The public health needs of low income populations require patented drugs to be made produced at the marginal cost of production, without R&D cost recovery. Nonrival access to pharmaceutical knowledge achieves both goals simultaneously.

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1. The sole justification for pharmaceutical patents is to recoup R&D expenditures, thus stimulating future innovation. Absent IP law, pharmaceutical knowledge would be both inappropriable and nonrival. Absent appropriation, firms investing in R&D cannot extract returns on investment in the marketplace. Patents permit the owners to charge prices above the marginal cost of production, extracting rents to support future R&D.
 2. Appropriation through IP law is not necessarily the most efficient method of supporting pharmaceutical R&D. Only a portion of the rents extracted from consumer surplus are utilized for R&D. The industry self-reports that 17.7% of U.S. sales are spent on R&D, broadly defined. (PhRMA 2005) A recent speculative estimate, based on industry data and calculations by John Vernon, suggests that eliminating OECD price controls on patented drugs would increase revenues by \$17.6 to \$26.7 billion per year, with additional R&D of \$5.3 to \$8 billion per year. (US DoC, at 29). Implicit in this estimate is the assumption that about a third of incremental revenues would be spent on R&D. The bulk of incremental revenues goes to other expenses and profits.
 3. Pharmaceutical rent extraction is best accomplished in high-income populations, among people who can afford expensive patented drugs (ie, who have low demand elasticities). In such situations, both clinical needs and R&D cost recovery goals can be met simultaneously.
 4. Pharmaceutical rent extraction amongst low income populations (ie, persons with high demand elasticities) is both cruel and unnecessary: cruel because people will die because a life-saving treatment is possible, but unaffordable; unnecessary because low income populations would never have contributed much towards global R&D cost recovery in any case.

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5. These access issues are not limited to AIDS drugs, but are present in many other chronic and infectious conditions as well. The human and economic costs of inadequate access are staggering, shattering the fragile economies of many countries and the lives of hundreds of millions of people, affecting a significant percentage of the global population and economy.
6. The “nonrival access” proposal is to permit unrestricted access to pharmaceutical knowledge for low income populations. IP rent extraction to support R&D would be limited solely to high income populations.
 - 6.1. Pharmaceutical goods (pills) are rival. Two people cannot share the same pill. Taking a rival good requires compensation.
 - 6.2. Pharmaceutical knowledge is nonrival, and can be shared without diminishing anyone else’s knowledge. The only reason not to share pharmaceutical knowledge is to promote future innovation. Nonrival access proposals must account for retaining optimal innovation incentives.
 - 6.3. One model of nonrival access would permit marginal cost production (MCP) for low income populations, without patent rent extraction (ie, no royalty).² Appropriation would be supported by rent extraction (patent laws) in high income markets. This is the “compulsory license” model.
 - 6.4. Alternatively, nonrival access could be achieved if all pharmaceutical patent rights for low income populations were purchased and donated to the public domain. Appropriation would be supported by the combination of the buyout prices and continuing rent extraction (patent laws) in high income markets. This is the “patent buy out” model. (Ganslandt, Maskus & Wong 2001)
 - 6.5. For example, based upon industry data, the global R&D cost recovery from non-OECD markets for all ARVs is less than \$110 million per year. The similar figure for Cervarix, GlaxoSmithKline’s new vaccine for cervical cancer is \$31.3 million per year until patent expiration.³ In both cases, the bulk of the patients are in non-OECD countries, while the bulk of the profits are in OECD countries. Non-OECD patent buyouts at these prices, followed by nonrival access, would be a great boon for global health, without harming R&D incentives. (Outterson 2004)
 - 6.6. The models converge when compulsory licenses are purchased by donors or governments for nonrival use.

² In order to optimize clinical access, the drug price for many low income patients should be subsidized below MCP.

³ While Ganslandt, Maskus & Wong (2001) used cost data to calculate the buy out, my calculations are based upon the estimated market sales lost due to the buy out. (Outterson 2004) Estimated market loss is the better metric, as it mimics actual markets and avoids the difficulties of calculating sunk costs.

7. Emerging examples of nonrival access:
 - 7.1. Canada recently published its royalty schedule for compulsory licenses for export under the Doha process. Canada proposes to vary the royalty rate from 4% down to 0.02% depending upon the target country's UNDP human development index. While Canada's proposal raises many questions,⁴ it is clearly a step in the direction of nonrival access, recognizing that pharmaceutical patent rent extraction is inappropriate in the poorest countries.
 - 7.2. The United States Department of Commerce recently published a study of pharmaceutical pricing in high income countries which calls for higher patented drug prices in Canada, Europe, Japan, Australia and other OECD countries. (DOC 2004, fig. 5) The report concludes that these countries have been free riding off American patent rent extraction by setting government reimbursement prices too low. While many aspects of this report may be examined and critiqued, for the present purposes I draw attention to the methodology used by the US government to calculate the amount of alleged free riding: ability to pay, as measured by per-capita GDP. Applying this same methodology to low income populations requires the conclusion that nonrival access is possible, not only for AIDS drugs, but for all patented pharmaceuticals. If the US seeks a treaty-based solution to the OECD free rider problem, nonrival access for low income populations should also be addressed.
 - 7.3. In separately published reports, several economists have embraced proposals which are consistent with nonrival access. The DEFEND Proposal is a patent buy-out of exclusive licenses for poor countries. (Ganslandt, Maskus & Wong 2001). F.M. Scherer suggests that pharmaceutical patent rent extraction is unnecessary and inappropriate for the poorest countries, and that free riding should actually be encouraged. (Scherer 2003). Lanjouw and Jack suggest that poor countries really shouldn't be expected to contribute much to global pharmaceutical R&D, with the possible exception of locally endemic diseases. (Lanjouw & Jack 2004).
8. Voluntary differential pricing is not sufficient.
 - 8.1. Some pharmaceutical companies have established voluntary differential pricing regimes in certain low and middle income populations. Voluntary

⁴ The UNDP rank is a course guide for equity. It is not clear why Malawi should pay a royalty which is 14.5 times larger than Sierra Leone. Nor is it clear that global pharmaceutical innovation requires any patent rent extraction from such countries. The royalty rate for the poorest countries should be zero. Canada's proposal also focuses upon countries rather than populations. In every country, elites can afford to contribute to patent rents; while in some middle income countries, very poor persons should not be expected to contribute at all. See Outterson (2005) at 229-232. Canada's law also unnecessarily restricts the process to listed drugs. The Jean Chretien Pledge to Africa Act (2004). Despite these criticisms, Canada's proposal is a step in the right direction.

differential pricing could be a form of nonrival access, if adopted for all drugs, and expanded to guarantee MCP pricing for all low income populations.

- 8.2. While laudable, these programs are generally limited to particular diseases, drugs or countries. Voluntary differential prices are not nearly low enough, and are not generally priced at MCP. (Otterson 2005, at 225-227). Establishing a few programs may respond to a particularly compelling crisis, but pharmaceutical companies have no internalized economic incentive to systematically address inadequate access.
- 8.3. To some extent, fear of pharmaceutical arbitrage from low income markets to high income markets has stifled drug company support for voluntary differential pricing. Empirically, such arbitrage is rarely observed, and need not be a significant threat to optimal pharmaceutical R&D. (Otterson 2005, at 257-260).

9. Conclusions

- 9.1. Nonrival access would greatly improve global human health, particularly among low income populations.
- 9.2. Nonrival access would not harm global innovation incentives, since patent rent extraction would continue in high income markets.
- 9.3. Several models for nonrival access are possible, but the mechanisms must actually result in pharmaceutical production at MCP in quantities sufficient to meet the clinical needs of low income populations. Anything less might be a step in the right direction, but is not nonrival access.

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