

20

## Intellectual Property and Health in Developing Countries

*Jean Tirole*

### THE DEBATE

Few issues are as controversial as the impact of intellectual property on health in developing countries. Activists and poor countries' governments have, for example, long claimed that patents on antiretroviral (ARV) drugs make AIDS treatments unaffordable in Africa and other low-income areas. Pharmaceutical companies have argued, to the contrary, that the problem is elsewhere, and that rich countries' governments should take the responsibility if vaccines and drugs are to be brought to the poor. Rich countries' governments, unsurprisingly, have not been keen on committing funds to promote health in Third World countries.

Finger-pointing with regard to the AIDS problem is but one of the many symptoms of the overall tension over intellectual property rights (IPRs) between high-income countries, on the one hand, and middle- and low-income ones, on the other hand. More generally, IPRs are the focus of intense interest to developing countries, which express particular concerns for health, plant breeders' rights, traditional knowledge, and education and research.

The WTO TRIPS agreement<sup>1</sup> requires that all WTO members put in place some minimal protection of IPRs by 2006, with a more recent option for the least developed countries to extend the transition period to 2016. Of particular relevance for this chapter, about fifty developing members of WTO that did not provide patent protection for pharmaceutical products will now have to do so, although they will still be able to impose price controls on medicines and in "emergencies" (a concept left broadly undefined at the WTO consultation in Doha in 2001) resort to compulsory licensing.

This essay focuses on the impact of IPRs on low- and middle-income

— -1

— 0

— +1

countries' health care. Many fine contributions have been made to this topic, and the essay aims only at taking stock of where we stand and at listing what we need to give further thought to.

It is widely recognized that there are two different reasons why poor countries may not have access to needed vaccines and drugs.

In the case of *global diseases*, such as diabetes or cancer, patents may hinder the diffusion of pharmaceuticals. IP owners are often reluctant to offer drastically lower prices to poor countries because they fear that rich countries will balk at tiered pricing (witness the shameful statements of some American politicians to the effect that drugs invented in America should not be available at much lower prices elsewhere,<sup>2</sup> and the more insidious use of reference price controls, a benchmarking procedure that ties prices in a rich country to prices abroad, and therefore discourages the use of discounts in poorer countries). Pharmaceutical companies may further be concerned that low prices in poor countries will lead to massive parallel imports in rich countries, their natural income base<sup>3</sup> (although this concern has been partly alleviated by the August 30, 2003, WTO decision on the implementation of Paragraph 6 of the Doha Declaration).

But even if pharmaceutical companies ignore these linkages and, as business judgment would command, practice price discrimination in favor of poor countries, much of the population of these poor countries may still not have access to the drugs for several reasons. First, profit maximization may lead pharmaceutical companies to target the elite and the middle class, not the insolvent poor. Second, and as the rich countries' protagonists (pharmaceutical companies, governments, activists) all agree, patents are at most part of the issue, for two reasons.

First, other costs may be added on top of royalties. Royalties are only part of the financial cost of medicines; manufacturing and monitoring costs may also be significant.

While most medicines' marginal cost is very small, it may be nonnegligible for some. In particular, the lowest cost of ARV triple therapies treatment is often estimated at \$200–\$300 per person per year by producers of cheap copies in India and elsewhere, and used to be much higher. This is still an enormous amount of money for low-income countries with average per capita health expenditures of \$23.<sup>4</sup>

The monitoring of treatments by medical personnel can be extremely important for treatments such as those for ARV, for which a proper monitoring brings the cost to about \$1,100 per capita per year.<sup>5</sup> The medical infrastructure is also crucial for prescriptions; estimates for India indicate a 50% rate of unnecessary or contraindicated drug prescriptions.<sup>6</sup> More generally, the health infrastructure is often so underdeveloped that diseases whose treatment or vaccine is off patent and cheap to produce are still widespread.<sup>7</sup> A related problem is that treatments are not always available in poor countries in which IP owners do not bother to take patents. A widely cited study by Attaran and Gillespie-White (2001) looks at fifteen ARV drugs in

— -1

— 0

— +1

fifty-three countries. Of the resulting 795 potential patents, only 172 (21.6%) actually exist. While the actual picture is more complex<sup>8</sup> (patent owners tend to patent in relatively high-income and populous or highly infected countries, such as South Africa; patents may not reflect IP importance; etc.), this number makes it clear that patents cannot be the end of the story.

Still another reason why royalties are only part of the cost is that some countries impose tariffs and taxes on pharmaceuticals.

Second, populist sentiments may deter politicians in rich and poor countries, as well as multilateral organizations, from trying to find solutions. I have already mentioned the equivocal stance of rich countries, which argue in favor of low prices for poor countries while being unwilling to foot the bill and opposing tiered pricing. Poor countries' leaders sometimes do not help either, as when they express nationalistic preference for locally produced cures, or when President Mbeki of South Africa expresses doubts about the link between HIV and AIDS. Populist sentiments also deter multilateral organizations such as the WHO from recommending vaccines that have not been approved in developed countries because of their side effects; such side effects may be relevant in countries in which the vaccine is of little use, but, for lack of anything better, second-order in others in which the disease is pandemic. Yet health authorities may balk at recommending such vaccines for fear of a (misguided) political backlash.

The second set of issues relates to *neglected or tropical diseases*, such as malaria, tuberculosis, and leishmaniasis, that are of primary concern to developing countries, or more generally to diseases for which revenues from rich countries do not suffice to attract R&D funding. The corresponding vaccines or drugs are not developed because of low profitability due to the poverty of potential customers (perhaps combined with the fear of compulsory licensing). There are several illustrations of the shortage of research in the area: limited work on malaria and tuberculosis, and virtually none on sleeping sickness.<sup>9</sup> A widely circulated statistic is that since 1975, only 11 of 1,300 newly developed drugs relate to developing countries' diseases, and five of them are by-products of veterinary research. The (off-patent) drugs against sleeping sickness date back to 1917, 1939, and 1949 (a dangerous arsenic derivative) and also include an inadvertent by-product of cancer research.<sup>10</sup> More indirect evidence that there is little R&D on poor countries' diseases is the observation that there is much less research on vaccines than on drugs, despite the fact that the former have an important advantage over the latter in poor countries, in that they are much less dependent on a good health care delivery system.<sup>11</sup>

It is of course hard to draw a clear line between global and neglected diseases. AIDS, for instance, stands in between. While it is a global disease, most of the research has focused on the strain that is most common in rich countries. But it is useful to keep in mind this taxonomy, since the solutions for global and neglected diseases are likely to differ.

As might be expected, the wide consensus around the insufficient access

— -1

— 0

— +1

of poor countries to vaccines and drugs disappears when it comes to attributing responsibilities and duties for helping the poor bridge their health gap with the rich world. Candidate policies include

- Donations and acquiescence to low prices in LDCs by the industry;
- Unilateral actions by poor countries' authorities, in the form of compulsory licensing;
- Unilateral actions by rich countries' governments, such as aid to health programs in poor countries; or, in countries with an innovative pharmaceutical industry, tax credits for R&D on neglected diseases or matching programs when the pharmaceutical industry donates or sells vaccines and drugs to nonprofit or multilateral organizations dealing with poor countries;<sup>12</sup> and research on neglected diseases in national laboratories;
- Multilateral efforts by rich countries, including conferring on the WHO a role of certification similar to that of the U.S. Food and Drug Administration;<sup>13</sup> pull and push programs aimed at encouraging research on neglected diseases; or the development by the WTO of a set of precise guidelines for the compulsory licensing of drugs.

#### TOWARD A GLOBAL SOCIAL CONTRACT FOR HEALTH

Intervention in the marketplace always requires a prior analysis of the source of failure and an identification of what goals one is trying to pursue.

In the context of health, one must first understand why health and pharmaceuticals (as opposed to poverty) are such controversial issues. For example, no one would think that the poor's lack of access to Sony's Trinitron tube patented system for color TV is a serious issue (as opposed to the poor's being poor). So why is health different? Curiously, and for all our intuition about the matter, the answer is not completely obvious, and requires some thinking. In the mid-1970s, two economists, Tony Atkinson and Joe Stiglitz, derived a result that still confounds the advocates of targeted policy interventions. They showed that under some conditions,<sup>14</sup> all redistribution among economic agents should operate through a redistribution of income. That is, however redistribution-minded the government is, it should refrain from subsidizing some goods and taxing others. For example, governments should not "force" consumers to consume electricity or local telephone services (often subsidized services) by offering them low prices. The message and logic behind this result are straightforward: make the distribution of income more equal,<sup>15</sup> and let the consumers decide what they want to consume. This result is useful for what it really is: a benchmark that serves as a warning against unmotivated paternalistic preferences of governments, and for which departures are vindicated by well-documented failures of the assumptions. One of the strong assumptions underlying the sufficiency of income taxation is the perfect verifiability of income; in practice, income tax is evaded in legal

— -1

— 0

— +1

(perks, loopholes) and illegal ways, which suggests taxing goods and services mostly demanded by the rich more heavily.

To see why health is different from other goods and services, let us first take a look at rich countries. There are several reasons why using health-related policies to redistribute may actually make sense despite the Atkinson and Stiglitz result (these reasons by and large also apply to education, which may explain why health and education are the two pillars of social democracy). First, health is an input into the production of income (this will be particularly so for poor countries). An alternative to income taxation as a means of redistributing income—and one that is less distortive of labor supply—is to make sure that access to health services is not too unequal. Second, decisions relative to health are, in the case of children, made on behalf of the person, and not by the individual himself/herself; there is thus a concern that some children are denied access to the treatments that they should receive. Third, there are, in the case of vaccines, externalities.

Lo and behold, even the more market-oriented economies heavily regulate health care. Price caps on medicines are widespread (with substantial variations, though; for example, prices of on-patent drugs in the United States are about twice the French or Italian level).

To be certain, the real motivation behind these regulations is often unrelated to the normative considerations just discussed; rather, they reflect two less avowable political economy considerations. First, the pharmaceutical industry has high fixed costs and low marginal costs, a situation that makes expropriation of investment through low prices, once the fixed costs have been sunk, quite tempting. Second, and more specific to the international context, innovations are global public goods, and thus individual countries do not benefit from promising “fair prices” even if they can commit to them. Indeed, each country has a private incentive to free-ride on other countries and pay as little as possible for these global public goods.<sup>16</sup> Price regulation of patented drugs is a simple way to obtain this free ride.

An interesting case in point is the fall 2001 Cipro saga in the United States. In the midst of the anthrax scare, Health and Human Services Secretary Tommy Thompson threatened Cipro manufacturer Bayer with compulsory licensing<sup>17</sup> and forced it to slash prices (ironically, in the same way South Africa forced Merck, Bristol-Myers, and others to cut prices on AIDS treatments, generating a protest from the American government). While everyone will agree that something would have gone wrong if the anthrax threat had proved to be widespread and if Bayer had jacked up prices so as to make Cipro unaffordable to a fraction of the American population, the U.S. government’s intervention raises questions about the pharmaceutical industry’s incentive to develop vaccines and drugs for future bioterrorism attacks. Low-probability events require large rewards to justify R&D expenditures. (To be sure, the problem is not specific to the pharmaceutical industry. Take the power industry, in which prices may, even in the absence of exercise of market power, jump by a factor of 20 or 100 during peak

— -1  
— 0  
— +1

time—a few hours or days during the year. Price caps aimed at limiting economic rents during these peak hours are widely perceived as a disincentive to install or maintain peaking production facilities that operate optimally only a few days a year.)

To sum up:

- There is a legitimate (normative) argument in favor of using the health care system in order to redistribute. And, given limited budgets, there is also a case for regulating drug prices so as to allow a more democratic access to drugs, although it must be recognized that such policies come at the cost of a lower innovation rate.
- While price controls are probably better explained by the unavowable motives of (a) opportunistically expropriating pharmaceuticals once R&D has been sunk and (b) free-riding on other countries, the normative side is still a key ingredient in these positive explanations, to the extent that it can explain why governments are given much larger discretion in the realm of pharmaceuticals than for other products under the TRIPS and other multilateral agreements.

The case for redistribution through health policies is stronger internationally. Income redistribution is less developed across than within countries. This of course is due to the selfishness of rich countries, which redistribute hardly anything to poor countries. Selfishness, to be certain, is only part of the story. First, the fight against poverty is itself a global public good, and so even a country with altruistic preferences may still prefer other countries to provide the global public good. Second, it is by no means easy to ensure that income transfers reach the right people.<sup>18</sup> Third, means-tested aid, like any other form of assistance, creates moral hazard. Yet it is a safe bet that even if a multilateral agreement could be reached concerning rich countries' contributions to world economic development and if solutions to the delivery problem could be found, rich countries' generosity would still show its limits.

Historically, a substantial, although not very visible, share of the redistribution from rich to poor countries has operated through free (or low-price) IP transfers. Technologies developed in rich countries reach poor countries, after a delay, when they go off-patent. And on-patent technologies have in the past not been covered by IP protection, a situation that is modified by the TRIPS agreement, although, as we have noted, countries can still threaten compulsory licensing in order to obtain very favorable deals from IP owners. It is perhaps unsurprising that substantial transfers have occurred in-kind through the IP system while there have been very few in cash. For one thing, knowledge transfers are much less dependent on the cooperation of rich countries' governments. And they don't confront quite the same delivery problems as cash transfers. But the fact that IP transfers are an important source of redistribution to low- and middle-income countries in a world desperately in need of worldwide redistribution does not imply that existing transfers are fair or efficient, as we will observe.

— -1  
— 0  
— +1

A global social contract for global diseases should differentiate prices so as to reflect the health-related needs of countries and, for neglected diseases, design new mechanisms that will boost private incentives to develop vaccines and drugs. The final two sections of the essay accordingly investigate two (complementary) policy interventions: compulsory licensing and health-related aid.

## RULE-BASED COMPULSORY LICENSING

This section argues that compulsory licensing should keep playing an important role for low- and middle-income countries, although definitely not in its current form. Before we take up the argument, let us step back and return to some basic economics of compulsory licensing. (Many of the issues discussed below are also relevant for the discussion of the prize mechanism studied later in this paper, since the issue of the “right prices” arises there as well.)

### General Considerations about Compulsory Licensing

As is well understood in industrial organization, the problem of encouraging innovation is akin to that of regulating a natural monopoly. Both setups involve substantial returns to scale, and thus pricing at marginal cost does not allow firms to cover their total cost. Somehow, fixed costs have to be recouped through sizeable “taxes,” “contributions,” or “markups” above marginal costs.<sup>19</sup>

A “Ramsey social planner” (as it is called in the economics literature) must, in order to maximize social welfare:

- Design an overall reward or price level that allows the firm to receive a fair rate of return on the fixed cost of producing the “facility” or the patent (*price level challenge*)
- Allocate the markups on the different uses made of the “facility” or patent so as to minimize the social deadweight loss (*relative prices challenge*).

The economist’s answer to the latter challenge is the well-known Ramsey rule. Lower markups should be applied to those segments with the highest elasticities of demand (which often coincide with segments populated with low-income consumers), so as to minimize the value loss incurred when high prices deter potential users from consuming. It turns out that this Ramsey principle is in tune with private incentives, since it is also in the interest of a private monopoly to tailor prices across segments as a function of what each market segment can bear; this observation is indeed one of the justifications for price caps, which decentralize the choice of relative prices to the regulated firm in network industries such as the telecommunications, electricity, gas, rail, and postal sectors.<sup>20</sup> (A caveat here: the elasticities of demand reflect not only the consumers’ true demand function and their income, but

— -1  
— 0  
— +1

also the availability of substitute products—the so-called bypass opportunities. Ramsey pricing may be constrained by these bypass options, but ideally would eliminate them so as to achieve unconstrained Ramsey pricing. More on this later.)

The price-level challenge poses more complex issues. To provide the firm with a fair rate of return on investment, the Ramsey social planner must have an estimate of the investment cost. In regulated industries, regulators' permanent and specialized staffs collect substantial amounts of data about the firms' costs in regulated segments and further try to insulate regulated segments from cross-subsidization in favor of unregulated ones. In the case of a patent, the regulator—the authority that orders and monitors the compulsory license—has little knowledge about the actual cost incurred by the pharmaceutical company in developing the particular medicine.

Another informational obstacle in the case of a compulsory license comes from the fact that R&D is a very risky activity. A project that costs \$100 million and has a 10% chance of success should engender \$1 billion in income (ignoring interest and risk premiums) in order for the pharmaceutical company to be willing to undertake it. A regulator's attempt at regulating the rate of return on a medicine must therefore also estimate the ex ante probability that this medicine will succeed. The "fair income" is highly sensitive to the subjective estimate of this probability (for example, it is multiplied by 4 when the probability of success moves from 20% to 5%).

The implications are clear. Even in the simple context envisioned here, a proper implementation of compulsory licensing is no easy task, even for a benevolent regulator. It is no surprise, then, that courts routinely commend "licensing at a fair and reasonable price" when they order compulsory licenses but rarely specify what it means. Things get worse if the regulator behaves opportunistically; in contrast to the case of regulated network industries, in which the firm can appeal what it perceives to be a taking by relying on regulatory evidence on cost data, there is no such natural benchmark to substantiate the appeal in the case of a patent.

### Application to Medicines for Global Diseases

I heartily subscribe to the view that the cost burden of medicines for global diseases should be shared unequally across countries. Low-income countries should pay less than medium-income countries, which in turn should pay less than rich countries. Unfortunately, current practice associated with the threat of compulsory licensing<sup>21</sup> hardly delivers such a Ramsey structure. Until recently, compulsory licensing was credible only if the country had a reasonable domestic capacity for competitive production of copies. With some exceptions (India being the most prominent one), such countries are rarely low-income countries.<sup>22</sup> Sub-Saharan African countries are unlikely to take advantage of compulsory licensing unless they purchase copies from third countries, in contravention of international agreements. Another issue

— -1  
— 0  
— +1



is that compulsory licensing is a unilateral initiative that rewards countries with little (to) fear and penalizes (relatively) those who are afraid of reprisals.

A normatively satisfactory pricing system would not reflect the bargaining positions of the countries (whether they result from bypass opportunities or other considerations), but rather their needs. The current setting certainly does not obey this principle.

A more satisfactory and fairer system would probably reflect the following desiderata:

- Rule-based compulsory licensing rather than unilateral actions by individual countries,
- Expedient procedures administered by a politically independent agency (so as to avoid constant political pressure from influential countries),
- Means-tested conditions,
- Strict prohibition of parallel imports/exports, and
- Some other forms of conditionality.

Let me briefly discuss a few of these desiderata. First, the prohibition of parallel imports or exports is of the utmost importance. The medicines manufactured for Bangladesh or Botswana should not reach the United States, France, or Saudi Arabia, for this would destroy the whole edifice. Developing countries must understand that they have a lot to lose from parallel imports. This is not to say that the system created by the TRIPS agreement, in which compulsory licenses are primarily for domestic production, is a good one. It was motivated partly by the fear that medicines would turn footloose, thereby undermining the tiered-pricing system; but, as we observed, it did not allow the vast majority of poor countries to have access to the needed products.

One should therefore create a monitoring body (to which pharmaceutical companies could be associated, so they would gain some reassurance and would thereby be co-opted into the scheme) in order to license producers of copies and control flows of medicines. Thus, Botswana could procure a medicine from India if it failed to reach a *production* agreement with the patent owner for the supplies needed (it is important to conceptually separate IP ownership and production, even though in practice the patent owner already has facilities and expertise, and is often a serious candidate supplier).

While the principle of means-tested conditions is straightforward, its application is not. Per capita income is certainly a key component, but it is not the only one. One difficult issue, for example, is the treatment of countries with high income inequalities (that is, relatively rich countries with a sizable fraction of destitute inhabitants).

As in the case of other multilateral agreements, the benefits of being part of the scheme could go together with some forms of conditionality regarding minimum standards for health information, tariffs and taxes on pharmaceuticals, and so forth.

— -1  
— 0  
— +1

Probably the thorniest issue concerns the compensation under a compulsory license. One aspect is its structure: Should this be a lump sum paid by the country to the pharmaceutical company for basically unlimited access to the medicine at marginal cost—possibly from producers of copies? Or, as is most often proposed, a royalty of 3% or 4%<sup>23</sup> of the sales price of the medicine?<sup>24</sup>

Still another, more market-oriented scheme that could be considered is the purchase by each country (or an international organization or foundation on its behalf) of an unlimited licensing right for domestic consumption. Although this scheme could be transaction-cost-intensive (but see the discussion below), here is how the mechanism could operate. The pharmaceutical company could be instructed to spin off an entity with the exclusive right to distribute the product in the country (or group of countries) in question. The market price for this entity would presumably be the monopoly profit to be made in the country. The entity could be taken over through a tender process by the buyer (again a foundation, such as the Gates Foundation, a multilateral organization, the country itself, or a combination of the three),<sup>25</sup> which could then sell the medicine at a negligible price or donate it. This procedure would have several benefits:

- The pharmaceutical company would de facto be allowed to keep its profit (the new entity's shareholders would turn down a tender price below this profit).
- At the same time, monopoly prices would not prevail. That is, the medicine would no longer be targeted to the elite of the country.
- Country differentiation would obtain. Richer countries would pay more for control over the medicine.

This mechanism has costs as well. As mentioned above, doing this for all medicines and countries would be infeasible. Grouping countries and/or medicines would be required. On the other hand (and as for compulsory licensing), the procedure could just be a default point on which negotiation would most often converge (and so the procedure itself would rarely be invoked). Another potential difficulty, as in any purchase funding proposal (see below), is the availability of the money. We therefore have in mind that such a scheme would apply primarily to poor countries. For rich countries, the sums at stake might be too large to attract funding.

Little economic research has investigated the trade-offs, and certainly much remains to be done in the area.

#### **PURCHASE FUNDS FOR NEGLECTED DISEASES**

The previous discussion of a market-oriented scheme for the purchase of licenses for global diseases brings us to the purchase fund proposal for neglected diseases. I'll be brief both because many of the difficulties faced by these proposals are similar to those, discussed earlier, faced by compulsory

— -1  
— 0  
— +1

licensing (both approaches involve an ex post purchase, using taxpayer money in the case of aid, and user money under actual compulsory licensing practice, in order to compensate the innovator), and because the benefits of and obstacles faced by purchase funds policies have been discussed with much lucidity by Michael Kremer (2001a, 2001b, 2002).

The prize system, in which the innovator receives a lump sum for delivering an invention with specified characteristics, and thereby forfeits any IPR, has a long history but was not employed much through the nineteenth and twentieth centuries. Lately, though, its principle has made a comeback with proposals by the World Bank, the WHO, and the Clinton administration.

In theory, the prize mechanism is quite appealing since it allows an unlimited diffusion of the knowledge created by the inventive act. In practice, though, it is very difficult to define in advance the characteristics of an innovation, which raises the issue of the ex post assessment of its value. The patent system, for all its flaws, has the major benefit that its market-based reward approach is not subject to the two rocks that bureaucratic procedures usually strike: capture and overpayment, and opportunistic expropriation and underpayment.

Kremer offers the design for a prize mechanism for neglected diseases based on, among other things:

- A list of specifications to be satisfied by the vaccine or drug (efficacy, length of protection, side effects, sensitivity to improper usage, and monitoring . . . )
- A technical approval process by an independent agency (which keeps in mind that the medicine may be the only hope for poor countries)
- A market-based test that uses copayments by countries, which would then supply yet another signal about the medicine's efficacy.

Kremer also discusses the (complex) design of prizes in a world with sequential innovations.

It is clear that this approach is partly dependent on rich countries being willing to contribute to the purchase funds. If experience with international aid in general, and with health-related aid in particular,<sup>26</sup> unfortunately does not invite much optimism, economists and political scientists should nonetheless attempt to design multilateral processes that alleviate the free-rider problem.

In the matter of neglected diseases, as for global diseases, economic research that can help guide policy is scarce, and further research in this area as well is most welcome.

## NOTES

1. Agreement on Trade Related Aspects of Intellectual Property (1994). The TRIPS agreement has homogenized the (minimum standard for) protection of novel, non-obvious, and useful inventions, including pharmaceuticals, to twenty years for all members of the WTO. The protection of IPRs should naturally be defined broadly,

— -1  
— 0  
— +1

not solely through the lens of formal laws but also considering the extent of their enforcement (see, e.g., Combe and Pfister 2002, for survey evidence of corporate perceptions of the relative importance of the legal IP framework and its enforcement).

2. Kettler and Collins (2002), 6.
3. This fear has been growing with the development of the Internet (Lanjouw 2001, pp. 6–7). Much of the parallel importation at this stage occurs between developed countries (e.g., Canada and the United States).
4. Commission on Intellectual Property Rights (2002), 31.
5. Kremer (2002), 80.
6. Phadke (1998).
7. For example, WHO's Expanded Programme of Immunization, while a clear success, still fails to reach many children despite the low cost of vaccines—less than \$1 for a polyvalent vaccine (Commission on Intellectual Property Rights 2002, p. 35).
8. Lybecker (2003).
9. Médecins Sans Frontières (2001), 12.
10. Moran, in Session 6 (2002).
11. Kremer (2001a, 2001b). Note that this argument differs from the standard one (unrelated to the quality of the health infrastructure), according to which vaccines are undersupplied in a market economy because people don't internalize the reduced risk of contagion for others when they choose whether to be inoculated. See Kremer and Snyder (2003) for an interesting analysis of comparative biases in the provision of vaccine and drug research.
12. The United States has such a tax deduction for donations, but it is rather small because it is computed on the basis of the medicine's production cost.
13. Kremer (2002), 86.
14. For the technically minded reader, these conditions are (1) economic agents differ in their ability to earn money (say, their hourly wage); (2) their incomes (but not their ability to earn money) are perfectly verifiable by tax authorities; (3) their preferences are perfectly separable between their labor input, on the one side, and a basket of consumption goods and services, on the other side (that is, their relative preference for two goods is independent of the amount of their labor); and (4) there are no consumption externalities.
15. How much more equal depends on both the government's preference for equality and the incentive effect of income taxation on the supply of production factors such as labor.
16. Under the constraint linked to the fact that manufacturers can threaten not to market the drug in the national market in question.
17. There are other motivations than emergencies for compulsory licensing in the United States and other developed countries. First, competition authorities and courts may order licensing because they deem that a piece of IP is a "unique path" that cannot be bypassed by producers of follow-up innovations or of downstream products, and that the piece of IP allows its owner to command a rent incommensurate with the investment cost. A special case of this situation may arise when a patented technology becomes a standard, and thereby an "essential facility" for the industry. Second, compulsory licenses are often requested when a merger reduces competition. For instance, in the Ciba-Geigy-Sandoz 1997 merger into Novartis (which also controlled Chiron), the U.S. Federal Trade Commission required the merged entity to license a number of products to Rhône Poulenc Rorer and to offer nonexclusive licenses of Cytokine (at, at most, 3% of the net sale prices) to all requesters.

— -1

— 0

— +1

Last, there are a number of exemptions to the free exercise of ownership of IP, as when other inventors are entitled to a free use of patented IP for experimental purposes.

18. The World Bank and other multilateral organizations increasingly resort to NGOs in the delivery of services to poor countries, in an effort to bypass potentially corrupt national and local governments. While this policy is to be applauded, one should also recognize its limits, both in terms of the need to enlist the cooperation of local officials for the provision of complementary services, and of the observation that NGOs, as they secure bigger and bigger budgets and become (unelected) governments, will attract more opportunistic (and less idealistic) types.

19. See Crampes and Hollander (2003) and Jack and Lanjouw (2003) for Ramsey theoretic frameworks of pharmaceuticals' pricing. Crampes and Hollander develop a detailed analysis of the impact of parallel imports on the world price structure of pharmaceuticals.

20. Roughly, price caps impose an average-price-level constraint. For the link between price caps and Ramsey pricing, see Laffont and Tirole (2000), chap. 2.

21. Under Article 31(f) of the TRIPS agreement, a licensee under a compulsory license must produce primarily for the domestic market of the member granting the license. (There are a number of other conditions, such as the necessity of prior negotiations with the patent owner and the subjection to independent review. See Scherer and Watal 2001.) Article 31(h) of the TRIPS agreement, provides that "the rights holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization." See Abbott (2002), 35, for an interpretation of this article.

22. Brazil and India are the best-known producers of copies. For data on India, see Lanjouw (1998), and on Brazil, Commission on Intellectual Property Rights (2002), 43. Other countries with competitive producers of copies include Argentina, Chile, Italy, Turkey, South Korea, Egypt, and Lebanon. See Maskus (2000) for more details.

23. From 1923 through 1992, Canada had an extensive compulsory license policy. In the 1970s and 1980s, it mostly employed a royalty rate of 4% of the licensee's price.

24. The choice between these two policies probably would not affect the final price much, especially for those medicines with low production costs; 4% on a competitive price (competition among licensees bringing prices close to marginal cost) would not have much impact on the diffusion. The benefit of a lump-sum payment is that it allows for more differentiation between low-income countries (which presumably would pay a very low amount) and medium-income countries; on the other hand, the royalties could be differentiated according to income, but with the drawback that medicine prices would depart much more from marginal cost for middle-income countries. Other relevant considerations are that proportional (price-based) payments better reflect the "size of the market" for a particular pharmaceutical (for example, how widespread the disease is in the country), but are too sensitive to the magnitude of marginal production costs (which may differ widely across medicines).

25. The standard free-riding problem would not occur because it would be as if the entity were taken private. The idea of a takeover was first proposed by Cohen (2000), who suggests a takeover of the firm, followed by a spin-off of unwanted entities.

26. For example, the U.S. National Institutes of Health spent only 0.8% of its

— -1  
— 0  
— +1

1999 budget on tropical diseases (Lanjouw 2001, p. 23). Similar figures apply to European countries.

#### BIBLIOGRAPHY

- Abbott, Frederick. "WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries." In Study Paper 2b, Commission on Intellectual Property Rights, London, U.K., 2002.
- Atkinson, Anthony Barnes, and Joseph Stiglitz. "The Design of Tax Structure: Direct and Indirect Taxation." *Journal of Public Economics* 6 (1976): 55–75.
- Attaran, A., and L. Gillespie-White. "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?" *Journal of the American Medical Association* 15 (2001): 1886–1892.
- Cohen, Daniel. "Sida et médicaments: Que faire?" Mimeo, CEPREMAP, Paris, 2000.
- Combe, Emmanuel, and Etienne Pfister. "The Effectiveness of Intellectual Property Rights: An Analysis on French Survey Data." In *Multinational Firms and Impacts on Employment, Trade and Technologies: New Perspectives for a New Century*, edited by R. Lipsey and J. L. Mucchielli. London: Routledge, 2002.
- Commission on Intellectual Property Rights. "Health." In *Integrating Intellectual Property Rights and Development Policy*. London: Commission on Intellectual Property Rights, 2002.
- Crampes, Claude, and Abraham Hollander. "The Pricing of Pharmaceuticals Facing Parallel Imports." Mimeo, IDEI and University of Montreal, 2003.
- Jack, William, and Jean Lanjouw. "Financing Pharmaceutical Innovation: How Much Should Poor Countries Contribute?" Mimeo, Georgetown University and Brookings Institution, 2003.
- Kettler, Hannah, and Chris Collins. "Using Innovative Action to Meet Global Health Needs Through Existing Intellectual Property Regimes." In Study Paper 2b, Commission on Intellectual Property Rights, London, 2002.
- Kremer, Michael. "Creating Markets for New Vaccines. Part 1: Rationale." In *Innovation Policy and the Economy*. Vol. 1. edited by A. Jaffe, J. Lerner, and S. Stern. Cambridge, Mass.: MIT Press, 2001a.
- Kremer, Michael. "Creating Markets for New Vaccines. Part 2: Design Issues." In *Innovation Policy and the Economy*. Vol. 1. Edited by A. Jaffe, J. Lerner, and S. Stern. Cambridge, Mass.: MIT Press, 2001b.
- Kremer, Michael. "Pharmaceuticals and the Developing World." *Journal of Economic Perspectives* 16 (4) (2002): 67–90.
- Kremer, Michael, and Christopher Snyder. "Why Are Drugs More Profitable Than Vaccines?" NBER working paper 9833, 2003.
- Laffont, Jean-Jaques, and Jean Tirole. *A Theory of Incentives in Procurement and Regulation*. Cambridge, Mass.: MIT Press, 1993.
- Laffont, Jean-Jacques, and Jean Tirole. *Competition in Telecommunications*. Cambridge, Mass.: MIT Press, 2000.
- Lanjouw, Jean. "The Introduction of Pharmaceutical Product Patents in India: 'Heartless Exploitation of the Poor and Suffering?'" NBER working paper 6366, 1998.
- Lanjouw, Jean. "A Patent Policy Proposal for Global Diseases." Mimeo, Yale University, 2001.
- Lanjouw, Jean. "Intellectual Property and the Availability of Pharmaceuticals in Poor Countries." *Innovation Policy and the Economy*. Vol. 2. Edited by A. Jaffe, J. Lerner, and S. Stern. Cambridge, Mass.: MIT Press, 2002.

— —1  
— — 0  
— —+1

## Intellectual Property and Health in Developing Countries

317

- Lybecker, Kristina. Review of "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?" by A. Attaran and L. Gillepsie-White, 2003. Available online at <http://www.researchoninnovation.org/tiip/>.
- Maskus, Keith. *Intellectual Property Rights in the Global Economy*. Washington, D.C.: Institute for International Economics, 2000.
- Médecins sans Frontières. "Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases." Brussels: MSF, 2001. Available online at <http://www.msf.org/source/access/2001/fatal/fatal.pdf>.
- Phadke, Anant. *Drug Supply and Use: Towards a Rational Policy in India*. New Delhi: Sage, 1998.
- Scherer, Mike, and Jayashree Watal. "Post-TRIPS Options for Access to Patented Medicines in Developing Countries." Commission on Macroeconomics and Health Working paper W64, Harvard University, 2001.
- "Session 6: Medicines and Vaccines." Conference "How Intellectual Property Rights Could Work Better for Developing Countries and Poor People." Royal Society of London, Feb. 21–22, 2002. Transcript.

— -1  
— 0  
— +1