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Fair followers: Expanding access to generic pharmaceuticals for low-income populations

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1. From free riders and pirates to fair followers²

Free riders use something they didn't pay for. The term itself calls to mind someone riding a bus without paying the fare. But free riding is not limited to tangible goods and services. With intangible property, free riding is not only possible, but in many ways easier. Downloading music from the Internet is the new paradigm case.

US trade officials employ the rhetoric of free riding when OECD governments use monopsony power to negotiate discounts on patented pharmaceuticals. (US Department of Commerce 2004, Outterson 2004, 2005b) Outside of OECD countries, governments usually lack sufficient market power as a purchaser to negotiate discounts for low-income populations. In these cases, low-income populations may resort to unlicensed generic drugs. In response, US trade officials and intellectual property (IP) owners inflame the rhetoric and label such activity as piracy. (Benson 2005, Drahos with Braithwaite 2002)

Piracy was a crime against humanity. Pirates stole and destroyed wantonly and raped and killed with abandon. Piracy is an inappropriate term for providing essential medicines to the world's poorest people. Heroism would be a better word.

The rhetoric of IP law should consider fundamental distinctions in the economic realities of pharmaceutical knowledge. Unlike tangible property, pharmaceutical knowledge does not suffer from exhaustion or congestion. In economic terms, it is generally *nonrivalrous*. This paper explores the powerful implications of that feature, and concludes that low-income populations should be encouraged to use pharmaceutical knowledge as *fair followers*. In particular, fair followers should use low-cost generic versions of essential patented medicines to maximize access by low-income populations, so long as incentives for innovation are not harmed thereby.

2. Property rights are designed to resolve the problems of rivalry and appropriation

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² I credit Professor Jerome Reichman with this phrase, although I modify its context and meaning. His project was to encourage significant use of flexibilities available under the World Trade Organization TRIPS Agreement. (Reichman 1996) The US government has labored to deny this option to many countries in the past decade. ('t Hoen 2002; Outterson 2005c; Thorpe 2004).

The dominant system of property rights makes eminent sense for traditional categories of tangible goods. Physical things are subject to at least two problems which are addressed by property rules: rivalry and appropriation.

Rivalry

Any item which can suffer exhaustion or congestion is rivalrous. Congestion occurs when too many people attempt simultaneous use: if everyone had equal claims to my car, then I would not find it always available when I wanted it. Ten thousand people cannot simultaneously sleep in the same bed, or farm the same small field, or eat my fig. Exhaustion occurs when multiple users degrade the resource. Classic examples include over-grazed fields and depleted fisheries. (Hardin 1968)

The OECD market-based economy relies on property rights as the primary solution to rivalry. Ownership is entrusted to one person, and that person is given control of the property's use, including the right to exclude others. The owner takes the decisions regarding use of their property, including issues of congestion and exhaustion. But ownership is not absolute. Property owners are also subject to duties, particularly when their actions negatively impact others.³ Property may also be taken for a public use with compensation by the sovereign power of eminent domain.

Globalized legal and moral cultures generally respect private property. If someone takes property without permission, we call them a thief. Moral norms cover similar ground, but an exception might be made for a starving child taking an extra loaf of bread from a wealthy family. In such a case the need is great and the loss is small, so perhaps taking the property is morally justified. Similar moral sentiments have propelled Médecins Sans Frontières (MSF) and their Access to Essential Medicines Campaign. MSF campaigns for significantly lower drug prices for the poor, even when the drugs are unauthorized generics or produced under a compulsory license. (MSF 2005a) The medical need is great and the damage from the taking is miniscule. Action is not only appropriate, but may be a moral necessity. MSF was not arrested as a pirate or a thief; instead they were awarded the Nobel Peace Prize for service to humanity.

Appropriation

The second problem addressed by property rules involves appropriation, or more precisely, the inability to appropriate returns on common pool resources. Absent an appropriation tool,⁴ no single individual retains an economic incentive to invest in common pool resources. Few would purchase or maintain an automobile if they could not control its subsequent use. The orchardist cares for her trees in the spring in anticipation of a harvest in the fall. Property rules permit a person (the 'owner') to appropriate the fruits of their investment. It is thought that society generally benefits when owners invest in their property, particularly if duties are imposed to account for negative externalities like pollution.

³ Economists describe these conditions as negative externalities. Pollution is the classic example.

⁴ Appropriation tools can be legal (property rules and liability rules), consensual (joint contractual management) or unilateral (practical, non-legal barriers to appropriation by strangers). In this discussion of pharmaceutical knowledge, the emphasis is upon property rules.

Intangibles

Now consider the case of property rights for intangibles such as patents, copyrights, trade secrets and the like. Intangibles are even more exposed to appropriation by strangers. Stealing my car requires physical theft; taking my land will lead to adverse physical occupation. Both are relatively easy to identify. Using a patent or trade secret without permission may be easier to accomplish and harder to discover. Music and video files can be copied anonymously over the Internet. Such copying can happen in many locations simultaneously, all over the world. The artist and the distributor may never know. Copying is also possible with pharmaceutical knowledge. For many years, India produced unlicensed generic versions of drugs which were still under patent outside of India. (In many cases, these drugs were the best source for humanitarian programs in Africa and elsewhere).

This type of activity might undermine innovation incentives. Appropriation on IP investments would be much more difficult if many would-be customers did not pay. IP laws hinder free riding by creating temporary legal barriers such as patents and copyrights. But the analogy between tangible and intangible property breaks down on the question of rivalry. Tangible goods are rivalrous. They suffer from exhaustion and congestion. But most intangibles are nonrivalrous,⁵ including the biomedical knowledge which forms the basis of the pharmaceutical industry. Pharmaceutical knowledge is nonrivalrous, and this fact enables a transformation from free riding and piracy to fair following.

3. Reconsidering moral and property rights in nonrivalrous pharmaceutical knowledge

Different property rules might be appropriate for nonrivalrous knowledge. Bread is consumed when eaten, but knowledge may be shared by an infinite number of persons without exhaustion or congestion.⁶ Knowledge may be widely disseminated without creating shortages, a potential boon for humanity.

Nonrivalrous goods may result in different moral rules concerning theft. Return to the example of the starving child. Assume that a loaf of bread was a nonrivalrous good. The Biblical example is Jesus feeding the crowds with miraculous bread and fish: as the contents of the baskets were distributed by the disciples, more food appeared. Although they began with only five loaves and two small fish, thousands were fed and the leftover food filled twelve baskets. (Matthew 14:13-21) In a world of nonrivalrous goods, the moral imperative would require sharing. If the bus ride is truly free, let everyone ride.

⁵ The point is occasionally contested. Landes & Posner (2003) argue that some forms of IP are rivalrous, particularly trademarks and personal likenesses. Trademarks and personal likenesses indicate origin rather than being knowledge per se. Pharmaceutical knowledge is nonrivalrous, although nonrivalrous use may well undercut monopoly pricing and therefore affect appropriation. One category of rivalrous pharmaceutical knowledge would be antibiotics to which bacteria develop resistance. Outterson (2005d).

⁶ Rivalry still afflicts the physical expressions of knowledge, such as books and pills, but the underlying knowledge itself remains nonrivalrous.

Property laws must also be reconsidered. By definition, additional users can be added without exhaustion, congestion, or other costs. If the appropriation (investment) problem can be resolved, then the hegemony of absolutist property rules would crumble.⁷ For example, Lipitor (atorvastatin calcium) is an important lipid-reducing drug, patented by Pfizer. The molecular structure of atorvastatin is well known (thanks to Pfizer). The global medical need for reducing cholesterol is great, in both rich and poor countries. (WHO Global Forum 8, 2004) Generic drug companies could sell much cheaper dosages without congestion or exhaustion, but doing so might diminish appropriation by Pfizer. To be successful, fair following must improve low-income access to generic Lipitor, without undermining optimal innovation incentives for Pfizer.

The pharmaceutical industry frames the issue as intellectual property ‘rights’, with little regard for potential IP ‘duties’. The industry assumes that maximizing IP laws and therefore pharmaceutical appropriation is the best course of action. (PhRMA 2005) But the creation of property rights sometimes creates associated negative externalities, and those negative externalities imply duties. With real property, the negative externality could be pollution, and a possible duty is abatement. With pharmaceutical IP, one prominent negative externality is inadequate access: millions (indeed, billions) of people lack access to patented drugs which would improve health. (Outterson 2005d) The duty could be to permit fair following. Put another way, if appropriation (investment) issues are resolved and the goods are nonrivalrous, then no reason remains to deny access to additional users, especially for low-income populations facing inadequate access to essential patented drugs.

The concept of an IP duty might seem radical, but it is already a prominent feature of US food and drug law. The current US practice of permitting generic drug entry after patent expiration is an imperfect application of this policy, embodied in the Hatch-Waxman Act. Mindless maximization of pharmaceutical IP rights is bad public policy. Taken to its logical conclusion, generic drugs would be abolished entirely. Consumers would pay higher prices and many would suffer adverse health effects from inadequate access. The more reasonable public policy option is to optimize pharmaceutical innovation incentives, balancing access and innovation. (Outterson 2005a, at 217-222)

Whatever one thinks of the balance struck for the US market, we have every reason to suppose that optimization would result in different outcomes in other countries, particularly amongst low-income populations. In such groups, their poverty will limit the effectiveness of appropriation, permitting the relaxation of pharmaceutical IP laws. Poverty also magnifies the damage that high drug prices inflict, strengthening the case for earlier generic entry. But current US policy exports Hatch-Waxman to other countries without appropriate modifications. (Outterson 2005c) The fair followers proposal is an attempt to reverse that policy.

⁷ If the appropriation (investment) issue is resolved, there is no reason to strengthen IP rights further to deny access to additional users, particularly when the users are low-income populations faced with inadequate access to essential medicines.

The following section describes how pharmaceutical knowledge may be shared with low-income populations without damaging optimal innovation incentives. Absent rivalry and appropriation problems, the moral and legal foundations for expanding the global pharmaceutical IP system to low-income populations is undermined.

4. Pharmaceutical rent extraction from low-income populations should be limited

When it comes to the world's low-income populations, pharmaceutical appropriation is nearly irrelevant. Low-income populations cannot contribute much global pharmaceutical rents in any case, and should be exempt from IP property rules based upon appropriation. The economist F.M. Scherer recently described this proposal (Scherer 2004, at 1141), giving economic language to the human rights appeals by essential medicines advocates like Médecins Sans Frontières. Scherer's point is that any pharmaceutical patent rent extraction from low-income populations is likely to be very damaging to people and not very helpful to innovation. In a similar vein, Lanjouw and Jack suggest that poor countries really shouldn't be expected to contribute much towards global pharmaceutical R&D, with the possible exception of locally endemic diseases. (Lanjouw & Jack 2004) Their proposal would effectively exempt low-income countries from most pharmaceutical patent laws, permitting instantaneous generic entry for global pharmaceutical innovation into low-income markets.

Pharmaceutical rent extraction amongst low-income populations is both cruel and unnecessary: cruel because people will die when a life-extending treatment is possible, but unaffordable; unnecessary because low-income populations would never have contributed much towards global pharmaceutical rent extraction in any case. Low-income populations have dramatically higher demand elasticities. Pricing AIDS drugs at US\$10,000 per year might be optimal in the US market, but at that price virtually no one in sub-Saharan Africa can afford them. Moreover, we know that the marginal cost of production of these drugs is less than US\$240 per year. (MSF 2005b) Given these facts, the very poorest cannot be expected to pay top price for AIDS drugs. Indeed, the poorest should not pay any patent appropriation rent for these drugs: the extremely modest contribution from low-income populations is much more valuable to them than it is to the global pharmaceutical industry.

These factors are not limited to AIDS drugs, but are present in many other chronic and infectious conditions. Much of the global burden of disease is from conditions which are truly global in nature: AIDS, cancer, cardiovascular disease, infections, and depression. (WHO Global Forum 8 2004; Outterson 2005a, at 244-46) Global diseases afflict both rich and poor. For global diseases, innovation is assured by demand in wealthy OECD countries. Appropriation from low-income populations is not important for global disease innovation. These drugs could be provided generically to the poorest without undermining optimal innovation.

The same cannot be said for neglected diseases, such as Chagas disease. Neglected diseases are endemic primarily in poor regions of the world. Innovation has lagged because of the poverty of the afflicted. The very poorest are not a good market,

particularly when the wealthy countries have no need for the drug. Several recent proposals attempt to correct this market failure by creating mechanisms such as purchase commitments and prize funds. (Kremer & Glennerster 2004, Hollis 2004) Others rely on non-market incentives such as grants and government-sponsored research. (Love 2003a-b, Hubbard 2003, but see DiMasi & Grabowski 2004) Occasionally proposals are coupled with an expansion of IP rights in poor countries (Sykes 2002), but expanded IP rights are an unnecessary and unwelcome addition. Expansion of IP rights will not create incentives in the absence of money to buy the product. These diseases are neglected due to the poverty of the afflicted, not the lack of IP rights. (Outterson 2005a, at 241-46) The fair follower proposal neither improves nor harms the prospects for neglected disease innovation. Fair following is primarily geared to global diseases such as cancer, cardiovascular disease, diabetes, depression and AIDS.

Pharmaceutical rent extraction is best accomplished in high-income populations, among people who can afford expensive patented drugs. The burden of supporting innovation should rest upon those with the ability to afford expensive medicines. This principle has been embraced by pharmaceutical companies and major Western governments. Price discrimination based upon ability to pay underlies all voluntary differential pricing programs, as well as the recent Canadian legislation to permit export of compulsory licensed pharmaceuticals for low-income populations. In the Canadian program, the royalty varies with the poverty of the target country. (The Jean Chretien Pledge to Africa Act 2004) The United States Department of Commerce followed suit in December 2004 when it calculated pharmaceutical free riding by various OECD countries, with adjustments for per-capita GDP. (US Department of Commerce 2004, fig. 5) High-income individuals typically have low demand elasticities for patented pharmaceuticals, permitting both high prices and relatively modest access externalities. In such situations, both clinical needs and innovation goals can be met simultaneously.

5. Fair following in practice

Several models of fair following are possible. Each one may potentially reach the same end – providing low-income populations with cheap access to essential drugs without harming optimal innovation incentives – but the legal forms differ widely. They also differ wherein the authority lies to make a decision on granting access. The four models discussed herein are: (1) compulsory licensure; (2) voluntary differential pricing; (3) patent buy-outs; and (4) the proposed Global R&D Treaty.

5.1. Streamline and expand compulsory licensure

Compulsory licensure is the sovereign power to use a patent absent permission from the patent owner. Compulsory licensure is often mischaracterized as ‘breaking a patent.’ Compulsory licensure is analogous to the power of eminent domain over real property, with one important caveat: while eminent domain often takes the property completely, compulsory licensure is only a partial taking. The owner retains all rights against all other persons. Under US law, compensation must be paid to the patent owner. Compulsory licensure is fully consistent with the WTO TRIPS Agreement. WTO

Members may compel licensure to protect public health, without limitation concerning the disease or drug at issue. (WTO TRIPS Agreement 1994, at art. 31(f); WTO Doha Declaration 2001, at ¶ 5; 't Hoen 2002 at 40-41)

Royalty rates for compulsory licenses should be modest when the intended recipients are very poor. Canada has proposed royalty rates ranging from 4% down to 0.02% depending upon the importing country's level of poverty. While Canada's law raises many questions,⁸ it is clearly a step in the direction of fair following, recognizing that pharmaceutical patent rent extraction is largely inappropriate from low-income populations.

Sovereign threats of compulsory licensure have led to much lower prices. Prominent examples include Brazil's highly successful anti-retroviral program for AIDS (Bermudez, 2002; U.K. Commission on Intellectual Property Rights, 2002; Reichman with Hasenzahl, 2003; Benson 2005) and the October 2001 threat by the US government to issue a compulsory license for Bayer's Cipro (ciprofloxacin) during the anthrax scare. (Carroll & Winslow 2001).⁹ Most of the affordable AIDS drugs listed in the MSF pricing guide were produced by Indian companies as generics prior to the phase-out of the TRIPS flexibilities afforded to India as a developing country. (MSF 2005b) Even nominally voluntary licenses, such as Merck's grant to South African-Indian company Thembalami Pharmaceuticals (Merck & Co., Inc. 2004) are frequently a responses to litigation and the threat of compulsory licensing. (Outterson, 2005a, at 223-226). Roche's experience with Tamiflu (oseltamivir phosphate) is quite similar: Roche reluctantly agreed to discuss voluntary licenses only when governments began to threaten compulsory licensure. The pressing need to build stockpiles against an influenza epidemic goaded both governments and Roche into action.

The US has consistently opposed compulsory licensure by other countries. In January 2001, the United States requested a WTO panel against Brazil to prevent Brazilian "local manufacture" of AIDS drugs. (WTO 2001) Under international pressure, the United States withdrew the panel request in the months leading up to the Fourth WTO Ministerial Conference in Doha. (Thomas 2001, at 15; 't Hoen 2002, at 38-47) More recently, US groups attacked Brazil in July 2005 over a proposed compulsory license of Kaletra (lopinavir + ritonavir), an AIDS fixed-dose combination drug. The patent owner,

⁸ Canada's use of 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 law 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 (2005a) 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.

⁹ The U.S. compulsory license statutes are 7 U.S.C. § 2404 (2000) (patents necessary for the nation's food supply); 17 U.S.C. § 115 (2000) (copyrights to certain musical works); 28 U.S.C. § 1498 (2000) (patents); 35 U.S.C. § 203 (2000) (patents developed through the use of government research funding under the Bayh-Dole Act); and 42 U.S.C. § 2183 (2000) (atomic energy). The U.S. compulsory license statutes do not contain the restrictions described in Article 31 of TRIPS. For an authoritative review of United States and Canadian experience with compulsory licensure, see Reichman with Hasenzahl (2003), at 19-22.

Abbott Laboratories, reached a voluntary price reduction agreement with Brazil which made the formal compulsory license unnecessary, another demonstration of the power of compulsory licenses to improve access. (Benson 2005)

Compulsory licenses, like any good thing, can become dangerous if used to excess. The power to issue compulsory licenses rests with the government where the patient resides (in the case of an export under special WTO rules, a compulsory license must also be issued by the exporting country). If this decision may be made unilaterally, a collective action problem is possible. Each country could resort to compulsory licensure excessively, depressing global drug sales and retarding optimal innovation. This is unlikely for at least three reasons. First, pressure from the United States Trade Representative's Office has coerced countries to abandon flexibilities inherent in the WTO TRIPS Agreement, including compulsory licensure. (Thorpe 2004) As a result, the empirical use of compulsory licenses has been modest, outside of the examples discussed above. Second, prior to the avian influenza scare, the United States has been the only OECD country to recently display an appetite for compulsory licensure of a patented drug. (Carroll & Winslow 2001) OECD countries would in any case pay royalties to compensate the patent holder for the non-exclusive use. If compulsory licensure is limited to low-income populations, then the damage to optimal innovation incentives will be negligible. Finally, most OECD countries do not need to resort to compulsory licensure at all, but may effectively control costs through the mechanism of government pharmaceutical reimbursement. (US Dept. of Commerce 2004) The TRIPS Agreement does nothing to prevent OECD countries from effectively holding down drug prices (and pharmaceutical rents) through these reimbursement mechanisms. (US Dept. of Commerce 2004; Outterson 2005b) The magnitude of this wealthy country free riding is many times larger than any potential abuse by low-income populations through compulsory licensure. (Outterson 2005b, 2005c)

In short, if compulsory licensure for low-income populations was streamlined and greatly expanded, it would do little or no damage to global pharmaceutical innovation, while greatly improving global access to life-saving medicines.

5.2. Voluntary differential pricing

A second model is voluntary differential pricing. Drug companies suggest that greatly improved generic access is not required because they can engage in voluntary differential pricing programs. The drug companies retain exclusive ownership of the IP, but agree to make the product available at reduced prices for some low-income populations. Voluntary differential pricing could facilitate fair following if adopted for all essential drugs and expanded to guarantee marginal cost pricing for all low-income populations. It is highly unlikely to substantially achieve these goals. Millions have died in Africa while waiting for AIDS drugs to actually reach them under publicly-announced voluntary differential pricing programs. For other drugs and conditions not in the media spotlight, the record of voluntary differential pricing programs is equally dismal.

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 the marginal cost of production. Voluntary differential pricing programs allow the drug companies to retain full control. Countries are not able to act unilaterally, so the collective action problem does not appear, but inadequate access remains. Establishing a few programs may respond to a particularly compelling crisis or a public relations problem, but pharmaceutical companies have no internalized economic incentive to systematically address inadequate access. The empirical track record of voluntary differential pricing programs has proven to be very disappointing as a comprehensive solution. (Outterson 2005a, at 225-228) As discussed above, many notable programs have appeared only as responses to threatened compulsory licensure.

To some extent, fear of pharmaceutical arbitrage from low-income markets to high-income markets has stifled drug company support for voluntary differential pricing. Similar fears could also be raised against expanded use of compulsory licensure. Empirically, such arbitrage is rarely observed, and need not be a significant threat to optimal pharmaceutical innovation when proper tools are utilized to minimize leakage. (Outterson 2005a, at 257-260) For innovation purposes, the most important price discrimination barrier is between OECD markets and the rest of the world. This is exactly the same divide that fair follower models will utilize. Even within a single country, PhRMA has been able to deploy a myriad of legal, contractual, and unilateral mechanisms to price discriminate. Drug prices within the United States vary dramatically between Medicaid, Medicare, 340b, FSS, insurance carriers, institutions (hospitals and nursing homes) and free clinics. (Outterson 2005b) The alleged dangers of pharmaceutical arbitrage are simply overstated. (Outterson 2005a)

5.3. Purchase patents for generic production for low-income populations

A third fair follower model is to leave IP laws undisturbed, but to simply purchase the pharmaceutical patent rights for low-income populations. The purchased patents would then be donated to the public domain, permitting marginal cost production for the world's poorest people. For example, patents could be purchased for the non-OECD world, and left in place for the wealthy OECD countries. The great majority of pharmaceutical appropriation would still flow through the OECD market system; the buy-out would cover only low-income populations and would be a relatively modest part of global pharmaceutical sales. Appropriation would be supported by the combination of the continuing rent extraction (patent laws) in high-income markets and the buy-out prices for low-income markets. This is the patent buy-out model. (Ganslandt, Maskus & Wong 2001; Kremer 1998; Guell 1997; Guell & Fischbaum 1995; Stein & Valery 2004)

5.3.1. Existing buy-out proposals

The common feature of patent buy-out proposals is to separate the market for innovation from the market for drugs, particularly for low-income populations.¹⁰ If patents are purchased and then donated to the public domain, competition will permit the widest

¹⁰ This feature is also shared by the Global R&D Treaty, discussed in section 5.4 below.

possible distribution at the lowest possible market price, freed from the distortions, rent-seeking and inefficiencies inherent in monopolistic pricing through patents. Guell and Fischbaum make this case plainly, although their focus is primarily upon buy-outs for the US market. (Guell & Fischbaum 1995) The access improvements they describe would be even greater amongst low-income populations with higher demand elasticities. Kremer's proposal is primarily an incentive for neglected disease innovation. (Kremer 1998) Kremer would create a market for a neglected disease innovation by making a credible promise to purchase the patent at an attractive price. Purchasing the patent enables generic production, but Kremer's focus is on the innovation side of the problem. Alternatively, Kremer has proposed a commitment to purchase large quantities of the item (such as a drug or vaccine), leaving the patent in place. (Kremer & Glennerster 2004) Stein and Valery reject patent buy-outs as a solution for the US market, and make the case for the federal government entering the drug business as a full competitor. (Stein & Valery 2004, at 153-54) Their only proffered reason for rejecting patent buy-outs is the failure to reduce overall patent rents, completely ignoring the access and allocative efficiency gains described by Guell & Fischbaum. Patent buy-outs should not restrict patent rents (for that would affect innovation), but merely separate innovation from production, and permit the widest possible access to pharmaceutical innovation at generic prices.

5.3.2. Patent buy-outs solely for low-income populations

Three existing proposals could be considered fair following because they focus on low-income populations: the DEFEND proposal by Ganslandt, Maskus & Wong (2001); the patent option proposal by Lanjouw and Jack (2004); and F.M. Scherer's article encouraging poor countries to free ride on pharmaceutical patents. (Scherer 2004) Ganslandt, Maskus & Wong suggest a buy-out of exclusive pharmaceutical licenses for poor countries. The DEFEND proposal and Scherer's article are generally consistent with my own views, with some caveats described below. Lanjouw & Jack do not utilize buy-outs at all, but force pharmaceutical companies to choose between patenting the drug in rich countries or poor countries, but not both. For global diseases, drug companies will always choose to patent in rich countries. In effect, Lanjouw & Jack permits generic production of any global disease drug for poor countries without the expense of a buy-out. This proposal enjoys the virtues of simplicity and economy, but to the extent we are concerned about maintaining optimal innovation incentives, some payment should be considered for market rights in low-income countries. It also ignores the USTR's campaign over the past 15 years to establish a single global standard for pharmaceutical IP.

Patent buy-outs for low-income populations have great potential to improve access to life-saving medicines. In 2004 the global R&D cost recovery from non-OECD markets for all anti-retroviral (ARV) drugs was less than US\$110 million per year. In all of Francophone West Africa, commercial sales of ARVs were only US\$33,000 in 2004, according to IMS data. (IMS Health 2005a) Retail sales of branded NRTI AIDS drugs in Peru have never exceeded US\$19,000 per year. (IMS Health 2005b) In short, the indicated buy-out price for ARVs for these regions of the world is quite modest, cutting

the Gordian knot of the global AIDS patent battles. Anything which lowers treatment costs for effective AIDS drugs should be deployed in the face of this global health catastrophe.

Patent buy-outs are controlled by the wealthy donor (a foundation or government) rather than the country wherein the potential patient resides. The collective action problem is avoided, but the target country lacks control over one important element of the health and safety of its citizens. Unless a global mechanism is created to buy-out all global pharmaceutical IP for low-income populations, then the target countries will be dependent upon continued foreign charity.

5.3.3. Setting the buy-out price

The buy-out price must be set high enough to optimize global pharmaceutical innovation and low enough to be affordable for all global diseases. Lanjouw and Jack effectively set the price at zero by requiring drug companies to choose between patents in rich countries or poor countries. If global pharmaceutical appropriation is already supra-optimal, then zero (or a negative value) is the correct price. (Outterson 2005a, at 220-222). Policymakers should have transparent access to reliable data on global pharmaceutical innovation in order to answer that question.

If the goal of the buy-out price is to mimic what would have happened under best-case competitive market conditions, then the price should be based on expected profits rather than sales or costs. Ganslandt, Maskus & Wong (2001) used cost data to calculate the buy-out, which rewards effort rather than success. Gross sales are certainly an element of pharmaceutical appropriation, but the relevant market metrics are the net present value (NPV) of the cash flow or the NPV of the profit stream. The purpose of the buy-out price should be to restore the expected profits.

Expected future profits will of course be difficult to estimate. The following formula relies to the greatest extent possible on externally generated data, to avoid data manipulation and methodological squabbles, with retrospective experience adjustments:

$$\mathbf{BOP = NPVt \ d (u * m)}$$

BOP is the buy-out price; NPV is the net present value over the patent period t at discount rate d ; u is the number of generic units sold in the target markets by all sellers during t ; and m is the marginal cost of production per unit, estimated as the lowest sustained actual price per unit during t . Estimated payments could be made at buy-out, subject to periodic and retrospective adjustment as actual data developed on u and m , and perhaps for changes in d . The formula avoids any need to know actual costs, profits, or average sales prices. The only data required are actual number of generic unit sales and the lowest sustained price by any generic seller in the target markets. Both are relatively easy to collect and difficult for the patent holder (or anyone else) to manipulate.

This formula aligns incentives against rent-seeking and allocative inefficiency in helpful ways. The buy-out permits any pharmaceutical company to manufacture and sell the drug generically in all target markets. Competition will drive the unit price down towards the actual marginal cost of production. In a competitive market with multiple entrants, no single company controls either u or m , but they each have strong market incentives to maximize u and to minimize m , which translates into the greatest access for a market-determined low price.

5.4. The proposed Global R&D Treaty

The fourth model is both simple and powerful, a global treaty on medical innovation. James Love, Tim Hubbard and a growing chorus of other commentators have discussed a Global R&D Treaty to separate the global market for innovation from the market for drug sales. (Love 2003a-b, Hubbard 2003, DiMasi & Grabowski 2004, Hollis 2004, Baker 2004) The R&D Treaty would serve as a global coordination mechanism to prevent free riding by high-income countries, while clearly specifying the fair following obligations of poorer countries. The Treaty does not commit any country to a particular method of meeting its R&D obligations. Each country retains considerable flexibility. A country could keep (or expand) pharmaceutical patent rent appropriation if it desired, but it could also meet Treaty obligations through government financed R&D, purchase commitments, patent buy-outs, prize funds, or some other mechanism.

One advantage of the Treaty is that many countries could choose to abandon the patent system as the appropriation tool for pharmaceutical innovation. Problems of inadequate access, inefficiency of allocations, counterfeiting and rent-seeking behavior by drug firms could be reduced if innovation was not dependant upon the high retail sales price of patented drugs. Every drug could be a generic, with innovation incentives addressed through the Treaty.

If the Global R&D Treaty were adopted, one could expect quite different drug price levels in various countries, depending upon the Treaty mechanisms chosen for innovation. If so, cross-border pharmaceutical arbitrage would need to be blocked from entering those countries which attempted to support innovation through high retail drug prices. As stated above, empirically, this type of arbitrage has been more limited than often supposed and is susceptible to legal interdiction and control. (Outterson 2005a, at 205, 231-35, 261-67, 275-91)

6. Conclusion

The world is facing a pharmaceutical access crisis. For rivalrous goods like food and cell phones, rationing scarce resources is a necessity. For nonrivalrous intangibles like pharmaceutical knowledge, a different world is possible. We must demand to know why rationing separates most of humanity from effective access to life-saving drugs. The primary answer offered by pharmaceutical companies is innovation. The discussion then descends into name calling: anyone who challenges the dominant IP system is either a

pirate or a free rider. The purpose of this essay is to transcend this impasse, and to offer fair follower alternatives which preserve innovation whilst greatly expanding access.

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