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Global Pharmaceutical Markets

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Abstract:

The high price of patented drugs lies at the heart of a major global public health crisis: the global poor are often denied access to lifesaving drugs due to high cost. Do global drug companies owe ethical or legal duties to make their drug patents available for the world's low- and medium-income populations? We suggest that they do, through an exploration of the exceptions surrounding the "duty of rescue" - more precisely, the doctrine in US tort law that does not impose a duty to rescue absent special circumstances such as having contributed to the risk and enjoying special relationships to the endangered person. We find that these special circumstances are surprisingly applicable to global pharmaceutical markets, with both legal and ethical implications for global intellectual property law.

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I. Introduction

We live in a world of both abundance and scarcity. Global pharmaceutical markets share this pattern. Abundance and wealth demonstrates what medicines are possible, especially for the billion people who enjoy high incomes. Scarcity and poverty interject reality for most of the rest of humanity, with devastating effect on health. The high price of patented drugs lies at the heart of a major global public health crisis: the global poor are often denied access to life-saving drugs due to high cost. Paul Hunt, the United Nations Special Rapporteur on the right to health, clearly describes the problem:

> "Almost 2 billion people lack access to essential medicines. Improving access to existing medicines could save 10 million lives each year, 4 million of them in Africa and South-East Asia. Access to medicines is characterised by profound global inequity. 15% of the world's population consumes over 90% of the world's pharmaceuticals." (Hunt 2007).

Pricing policies are a major contributor to this situation. Oxfam estimates that 85% of the world is effectively excluded from the market for medicines due to price. (Oxfam 2007) The World Health Organization estimates that 10 million people die each year due to lack of access to existing medicines and vaccines. (WHO 2004) The human and economic costs of inadequate access are staggering. Estimates of the financial cost of inadequate access to drugs

range in the tens of billions in high-income countries and much worse, as a percentage of gross domestic product, in low- and medium-income countries. (WHO 2006; DFID 2004)

Global access to essential medicines involves both ethical and legal issues. This essay uses the language and forms of the law in order to make ethical observations on the structure and functioning of the global intellectual property system. Law is a socially created institution, with local and global effects. We need an accurate picture of the impact of global intellectual property law in order to evaluate the choices we have made and the alternatives that are available.

For better or for worse, the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is the global legal nexus for access to medicine. In TRIPS-related discussions, two sets of arguments are usually forwarded. Some argue that pharmaceutical prices are necessarily high because innovation requires it. Pharmaceutical companies demand patents as an incentive for future innovation. They posit that the research and development enterprise must be nurtured by high prices in order to yield the next generation of breakthrough therapies. Patent-based drug companies have steadfastly opposed involuntary access initiatives and claim that market-based pricing is generally both legal and ethical. (Bale 2002)

Others counter that much of the profits going to pharmaceutical companies are used for marketing and other expenses rather than for research and development (Angell 2004; Avorn 2004; Goozner 2004; Barton & Emanuel 2005) and that without affordable access, innovation is a cruel taunt for the poor. New wonder drugs will not improve health unless patients are actually able to use them. A pill you cannot afford isn't effective. Medicines, according to this argument, are not normal market goods to be distributed primarily to the wealthy. Health

and human rights activists, among others, seek to reduce financial barriers to access to patented medications. Some argue that is ethical to intervene in public health emergencies, even if patent laws must be modified (Oxfam 2007; Hunt 2007; 't Hoen 2002; MSF 2004); indeed it may be unethical to stand by and not act (Singer 1972; Unger 1996).

Some scholars address both problems simultaneously, looking for ways to provide lost-cost generic medicines without undermining optimal innovation incentives. (Love & Hubbard 2007; Outterson & Kesselheim 2008; Outterson 2005; Hollis 2005; Pogge 2005b; Pogge 2005c; Fisher & Syed 2008; Finkelstein & Temin 2008) One such proposal is differential or equity pricing. A prominent example is the AIDS treatment crisis. Differential pricing permits antiretroviral drugs for AIDS to be sold cheaply or donated in low- and medium-income populations, while maintaining high prices in high-income markets like the United States. In theory, high prices in high-income markets support innovation, while lower prices in low- and medium-income markets improve access. (WHO 2001) Actual implementation of differential pricing has been disappointingly limited, with companies unwilling to undertake it on a sufficient scale. (Oxfam 2007).

Patent law also provides a safety valve for access while supporting innovation. Under the laws of many countries, patent rights may be modified to support other important goals, such as public health, government use, or to enhance competition. *Compulsory licenses* are one important process of modulating patent rights in light of these other objectives. Several countries have used compulsory licenses for public health purposes, most notably Thailand and Brazil, including drugs other than AIDS antiretrovirals. The patent-based drug companies have vigorously opposed these efforts, despite unequivocal support for the practice in the TRIPS Agreement. (Outterson & Kesselheim 2008)

One of the most innovative ideas in this field is generally attributed to James Love and Tim Hubbard. They propose decoupling markets for medicine from markets for innovation, using huge prize funds to stimulate innovation. The patent system remains untouched, but the prize funds purchase drug patents according to their health impact. These drugs essentially become generic immediately after the patent is purchased. Global and local coordination functions are supported through a global research and development treaty and patent pools. (Love & Hubbard 2007; KEI 2007) Three other research groups have subsequently proposed other decoupling mechanisms. Aidan Hollis and Thomas Pogge are working on a health care innovation prize fund project to link the market for medicines more efficiently to health needs. (Hollis 2005; Pogge 2007b) Two Harvard researchers propose a global credit-trading system based on actual health needs rather than merely ability to pay. (Fisher & Syed 2008) Two MIT researchers propose separating drug discovery from drug marketing, with public funding of the research and development phase. (Finkelstein & Temin 2008). These major reforms are the subject of intense discussion at the present time in various international organizations such as the WHO and WTO.

One important normative assumption in these approaches is that if we can promote access without harming innovation, then we should do so. In the language of a legal analogy, it assumes that we have an ethical duty to rescue people who need essential medicines, especially when the rescue can be accomplished with minimal risk and cost. In the next section, we examine a modest duty to rescue in the context of global intellectual property rights in medicines.

II. The Shipwreck of *The Richmond* and the Duty to Rescue

On August 2, 1849, the whaling vessel *Richmond* ran aground in the Bering Straits, near present-day Alaska. The *Richmond* was hunting whales during the brief weeks that those waters were navigable in the mid-19th century. The crew could not repair the ship. The advancing polar ice was expected to arrive before the end of August. If the ship became icebound, both the crew and the valuable cargo would be lost. (With today's global warming, the *Richmond* would not be in immediate danger, as the Bering Straits no longer become icebound in September.)

Two days later, other whaling ships found the *Richmond* and rescued the crew. The masters of the *Panama* and the *Elizabeth Firth* purchased the oil and whalebone at a very low price, and then began the long voyage home to New York City via Cape Horn. Upon arrival in New York, the owners of the *Richmond* sued to set aside the sales contracts. They argued that the situation was one of extreme duress – stranded in the Artic while the sea ice closed in – and they should not be held to the "hard bargain" struck in such dire circumstances. Eventually, the US Supreme Court agreed in *The Richmond v. Jones*.[1]

The facts of this case raise interesting ethical questions that can shed light on the debate over access to essential medicines. Did the masters of the *Panama* and the *Elizabeth Firth* have any duty to come to the aid of the *Richmond*? Can a rescuer take advantage of very desperate circumstances to negotiate a tough contract? Put another way, does a rescuer have some duty to act fairly during an emergency? (Lifshitz 2008)

The Supreme Court noted that the salvage "was effected in a couple of days, with some trouble and labor, but little or no risk or danger…" In such circumstances, the Court did not permit the rescuer to "take advantage of his situation, and avail himself of the calamities of

[1] 60 U.S. 150 (19 How.150) (1856).

others to drive a bargain; nor will they permit the performance of a public duty to be turned into a traffic of profit."

In *The Richmond* the risk to cargo and crew was grave and immediate; the whaling vessels *Panama* and *Elizabeth Firth* were well positioned to salvage; the risk and cost of salvage were modest; but there was no suggestion that either ship had contributed to the *Richmond's* accident. Some of the facts were peculiar, to be sure. The masters of the *Richmond* and the *Elizabeth Firth* were brothers. The owners of the *Richmond* argued that the brothers may have colluded in the bargain sale, but the Supreme Court did not decide this issue, relying instead on the "public duty" of ships to avoid hard bargains in desperate circumstances. According to the Court, the *Panama* and the *Elizabeth Firth* should be content with generous but not extortionate payment for their services. (Lifshitz 2008)

It should be noted that the common law of the United States does not recognize a general legal duty to rescue. In most circumstances, the law will permit an innocent bystander to remain aloof and refuse to offer life-saving aid. This case focuses on the compensation due from a voluntary salvage operation; neither ship was obliged to attempt a rescue. This principle is well established in U.S. common law. One classic problem for first year law students is the person on a bridge who could save a drowning child by simply throwing a rope. The common law is clear: a duty to rescue is not imposed, even if the rescue could be done easily with no risk. (Weinrib 1980; Heyman 1994; Volokh 1999; Hyman 2006; Romohr 2006; Lifshitz 2008)

Two exceptions to this rule are worth mentioning. First, if the bystander enjoys some special relationship, then a legal duty to rescue might be imposed. Examples include a shopkeeper who must assist an endangered customer in their store, or a therapist who must warn foreseen

victims that their client plans a violent act. In both cases, the special relationship entails a modest legal duty. Second, if the bystander was in some way responsible for the situation, or was impeding rescue by others, then a court might categorize the incident as misfeasance rather than nonfeasance, even absent any fault on the part of the bystander. For example, if your car breaks down on a dark road -- through no fault of your own -- the law may impose a duty to take steps to minimize the dangers created for other drivers. You cannot just leave the unlit car on the dark road, and claim innocent bystander status when an accident occurs. You must take some steps to minimize the risk you created: pull the car off the road, light a warning flare, or call the police. Likewise, you may be liable if you volunteer to rescue and do so negligently, or actively prevent others from undertaking a rescue. These exceptions are important analogies for the ethical case for global access, as we describe in the next section.

III. The Ethics of Global Access to Essential Medicines

Suppose we examine global intellectual property law and the access to medicines crisis through the lens of the *The Richmond* and the duty to rescue. Global pharmaceutical companies resist the notion that they are ethically compelled to rescue others by providing their drugs equitably to the poor. If they have no global corporate social responsibility in this area, the companies are free to remain disinterested bystanders, and sell their products at high prices in hard bargains with the world's poor. We seem untroubled that the poor cannot afford Rolex watches or fly first class. If medicines are an ordinary market good, then perhaps the same result should hold here.

In 1972, Peter Singer wrote a seminal essay on our utilitarian obligations to the distant poor and victims of tragedies, such as the millions destitute in East Bengal in 1971 (Singer 1972). If

we walk by a shallow pond, see a child drowning, and believe we should wade in and rescue her, even though we will get wet and muddy, Singer argued, then "It makes no moral difference whether the person I can help is a neighbor's child ten yards from me or a Bengali whose name I shall never know, ten thousand miles away." Secondly, Singer's principle makes no distinction between cases in which I am the only person who could possibly do anything and cases in which I am just one among millions in the same position." The principle is that "if it is in our power to prevent something bad happening, without thereby sacrificing anything of comparable moral importance, we ought, morally, to do it." This principle, "requires us only to prevent what is bad, and not promote what is good…" In the global access to medicines crisis, some individuals have acted with charity in order to provide needed medicines to the poor. These piecemeal efforts, while individually significant, do not recognize the institutional issues relating to health care systems in general and global pharmaceutical markets in particular. Significant change requires something beyond individual responses. Institutions, policies, laws, and markets must be revised if patented medicines are to be provided on a globally equitable basis.

In *Living High and Letting Die*, Peter Unger (1996) extends and refines Singer's original work through a series of test cases, like the man with a very nice car who sees a person lying by the road with a gash in his leg, waving for help as he bleeds profusely. Should you take the time and trouble to drive him to the hospital and have the inside of your nice car get soaked with blood? Even more disturbing is the man who leaves his priceless vintage Bugatti on a railroad siding, when he sees a runaway empty train barreling towards a child playing on the tracks. The man could run and throw the switch so the train would avert the child but destroy his Bugatti. Should he save the child? Most people think he should. Leaving aside fine points, responses indicate that people should be ready not only to help those in need but also make material sacrifices.

Approaches not grounded in utilitarianism also describe a duty to rescue. In telling the parable of the Good Samaritan, Jesus of Nazareth didn't make the rescue effortless. The Good Samaritan expended time, effort, and money in a potentially risky situation to care for a stranger in need. Jesus blessed this example, telling his listeners to "Go and do likewise." (Luke 10:25-37, NIV).

Some, however, remain unconvinced. Responding to Singer, Jan Narveson (2003) writes, "I have seen no plausible argument that we *owe* something, as a matter of general duty, to those to whom we have done nothing wrong." Others, including libertarians, will have more difficulty defending this position in the context of global intellectual property rights, since those rights are state-created positive law.

Thomas Pogge (2002; 2005c) argues for a special moral imperative to rescue those who are dying or seriously suffering when we have participated in the situation through legal, institutional, or economic practices. A prominent proposal with similar aims is the draft *Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines*, prepared by Paul Hunt, the United Nations Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. (Hunt 2007) The *Human Rights Guidelines* articulate principles of ethical corporate social responsibility in the realm of access to medicines; our project complements the *Guidelines* by exploring the ethical justifications for requiring corporate action and institutional reform. Oxfam's briefing paper *Investing For Life: Meeting Poor People's Needs for Access to Medicines Through Responsible Business Practices* reaches broadly similar conclusions. (Oxfam 2007) At the core, both claim a special status for medicines, calling for ethical responses above and beyond ordinary market goods.

In the following sections, we apply five elements of the duty to rescue to the global access to medicines problem. In short, we develop the ethical justifications for proposals to provide generic-priced drugs to the world's poorest people. Singer and Unger find positive moral duties on the rich to care for the needy. Our aim is much narrower: we argue that global intellectual property law should be modified to *permit rescue by others*, especially when the patent-based drug companies are not disadvantaged.

5 Elements	**Application**
Importance of the rescue	**WHO estimates 10 million lives are lost annually from lack of access to essential medications.**
Capacity of the bystander to rescue	**The relevant medicines are already invented.**
Role of the bystander in contributing to the risk	**Patent-based drug companies created the global intellectual property regime that delays low-cost generics and have encouraged poor countries to raise higher barriers to low-cost drugs. They are both creators of the institutional system and also actively prevent rescue by others through their control of the drug patents.**
Special relationship of the bystander	**Patent-based drug companies receive billions of dollars in tax subsidies. For most products, important early research was performed in government labs or in university labs with government funding.**
Risk or cost to the	**Some access proposals do not impose any significant**

bystander	**risk or cost on patent-based pharmaceutical companies.**

1. The importance of rescue: the global need for essential medicines is great.

Pharmaceutical companies tout the life-saving power of their products to transform human health. Denying these drugs to the poor on the basis of patent-based and market-based pricing is a major public health disaster, leading to perhaps 10 million deaths per year. While many other factors certainly disadvantage the global poor, access to medicines is clearly among the important ones. (WHO 2004).

People living with AIDS in resource-poor settings have waited for a decade for access to life-saving anti-retrovirals. Almost six million people in low- and middle-income populations are dying for anti-retrovirals today; despite a multitude of programs, access continues to be inadequate today. (WHO 2005; PEPFAR 2008) Just as treatment in low-income countries is scaling up, biological resistance to first-line AIDS therapy is increasing. Second-line anti-retrovirals including protease inhibitors are not generally available at generic prices. Manufacturers of patented second-line therapies are pricing them at U.S. levels in low-income countries. Even with voluntary discount programs, second-line therapies cost much more than the first-line drugs. (MSF 2005; Chase 2008)

Nor is this problem limited to AIDS. Many anti-malarial drugs are no longer effective after decades of use. According to the American Enterprise Institute, ineffective off-patent malaria drugs (such as chloroquine) were routinely provided to developing countries by global donors, while a more expensive patented drug combination was underutilized. (AEI 2003) Best

practices for global control of malaria will require extensive subsidies in poorer regions of the world. (IOM 2005) Extensively drug-resistant tuberculosis is a growing threat, especially when the poor receive substandard therapy. Annual deaths from tuberculosis exceed 1.6 million people. (Pillay & Sturm 2007) Tuberculosis is treatable in rich countries but is often a death sentence in the developing world when the poor are denied the proper drug regimen. (Farmer 1999)

We should also not make the mistake of assuming that only AIDS, malaria and tuberculosis plague the developing world. The diseases of the rich and poor are converging, and include cardiovascular disease, stroke, mental illness, diabetes, cancer, and arthritis. Equitable access to medicines should include all medicines that can improve the health of the world's poor. (Outterson 2008)

2. Capacity of the bystander to rescue: the medicines are available today.

For the most significant diseases in the developing world, good therapies are already at hand, invented to serve markets in high-income countries. While additional research is always desired for neglected diseases, the pharmaceutical tools required to treat significant global diseases are already invented and in production.

The World Health Organization sorts diseases into three categories. (WHO 2006) The first category includes diseases that occur throughout the world; examples include cancer, heart disease, diabetes, depression, and other familiar conditions. Wealthy country markets stimulate innovation for Type I diseases. Type II diseases are endemic primarily in low- and medium-income countries, but enough cases are still present in wealthy countries (or in wealth-country tourists or soldiers) to create an attractive market. AIDS and malaria could be

considered Type II diseases. The third category includes the truly neglected diseases of the tropics, including diseases lacking any viable commercial market: such as leishmaniasis, lymphatic filariasis, onchocerciasis, and schistosomiasis.

Type I and Type II diseases cause most of the disease burden in the world, including developing countries. Markets in wealthy countries will continue to stimulate innovation in these diseases. As a result, the most straightforward solution is to simply make these medicines available to the world's poor at competitive generic prices. These drugs are already discovered and in the absence of intellectual property rights in these markets, generic firms could produce the drugs for low- and medium-income country populations. For example, relatively modest numbers of cervical cancer deaths in high-income countries were sufficient incentive to prompt the creation of novel HPV vaccines to prevent most cases of cervical cancer. But HPV vaccines are the most expensive vaccines in history, and are not affordable by the women who represent 93% of the global mortality burden. (Outterson & Kesselheim 2008)

Type III diseases require different solutions. Most neglected disease conditions lack a market not because of the absence of intellectual property rights in low-income countries but because of the poverty of the afflicted. Perhaps the best description of a neglected disease drug is that market-based innovation is unlikely because the target population will require the drug or vaccine to be distributed at or below the lowest possible marginal cost of production. Any such drug will require non-market funding for innovation and distribution, with or without intellectual property regimes. Many public-private product development partnerships have been founded in recent years to address the need for neglected disease innovation. These are important and high profile projects, but we do not have to wait decades for success in neglected disease research: the heaviest burdens of disease in the developing world are Type I

and II diseases and those drugs are already discovered. In short, it is the poor themselves who are being neglected, not just their diseases.

3. Role of bystander in contributing to the risk: the patent-based drug companies created the global intellectual property system and are actively preventing rescue by others.

A small number of global companies crafted the TRIPS Agreement, ending a long tradition around the world of exempting medicines from patent laws. Among the companies were Bristol-Meyer-Squibb, Johnson & Johnson, Merck, and Pfizer, but all of the patent-based drug companies benefit from the system thus created. The explicit goal was to prohibit free trade of low-priced generics from the emerging pharmaceutical industries in developing countries. The TRIPS Agreement globalized intellectual property law on the United States model, together with bilateral trade agreements including TRIPS + provisions. (Sell 1998, 2003; Drahos & Braithwaite 2002; Helfer 2004; Correa 2000)

Therefore, the patent-based drug companies are not strangers to the global access to medicines problem; nor are they innocent bystanders who happen upon a tragedy by chance. They cannot rely on libertarian arguments to absolve themselves of responsibility. They created the global system of intellectual property law that stands as a barrier to generic production for the poor. They applied for the patents in developing country markets to block generic production. In the past decade they have pressed hard on the U.S. Department of Commerce to include in their bilateral Free Trade Agreements requirements that trading partners of various income levels add to 20-year patents prohibitions against free trade of patented or copyrighted products, thus extending high prices in their domestic markets as well as in other markets. At the behest of industry leaders, the United States Trade Representative's Office has vigorously

opposed compulsory licensure and pressured poorer countries not to use TRIPS flexibilities in order to get affordable medicines to their patients. (GAO 2007) The patent-based drug companies are among the chief architects and beneficiaries of this global system, and thus bear enhanced responsibility for its effects on the poor (Pogge 2005a), even in the absence of fault or negligence. They are active participants in the creation of the problem rather than innocent bystanders. (Weinrib 1980) Were it not for this expansion of global intellectual property law, charities such as Médecins Sans Frontières and generic drug companies such as Cipla, Ltd. of India could provide these drugs at affordable prices.

The patent-based drug companies actively work to prevent rescue by others, through generic production of patented drugs for low- and medium-income country populations. They use patent law to block generic production of the best available medicines and to drive "hard bargains" on pricing. The Supreme Court found the latter practice objectionable in *The Richmond*. As for blocking generic production, patent law appears to give them exactly that right, but exercising it transforms the companies from innocent bystanders into someone claiming the legal right to prevent rescue.

4. Special relationships of the bystander: patent-based drug companies receive public R&D funds and government-issued patents

Approximately half of effective global R&D for medicines is supported by public funds, and 84 percent of all global funds to discover new medicines come directly or indirectly from public sources. (Light 2006; Outterson 2008) Much of this research occurs in government and nonprofit university labs, which profess allegiance to a broader social mission. The duty to rescue is more salient when the bystander has received public support for the task at hand. A hospital receiving U.S. public funds is obligated to offer emergency treatment to anyone who

comes through their doors, without regard for ability to pay. A captain of a ship can no longer ignore the passenger who falls off the ship, even when the accident occurs through no fault of the captain. (Weinrib 1980) Pharmaceutical research programs that received public support should be under a similar duty. Billions of dollars of public funds have been expended to create these drugs; some duty is appropriate in these circumstances. (Chaifetz et al. 2007)

The drug company's status is also unique due to the patent law's ability to block the activities of others. Return to the paradigm case of the bystander on the bridge as the child drowns. The common law does not impose a legal duty to throw the rope. But what if the bystander actively prevented others from throwing the rope? The legal result would be quite different; vigorous actions to prevent or block a rescue may violate both tort and criminal law. As Ernest Weinrib stated in the *Yale Law Journal*, "[a]lthough it may be nonfeasance to refuse to rescue a drowning person whose predicament arose independently, it is misfeasance to hide the rope that others might toss out to him." (1980)

5. Risk or cost to bystander: some access proposals do not impose any significant risk or cost on patent-based drug companies.

Peter Singer argues for an ethical duty on behalf of the poor. This duty entails obligations upon the wealthy, to divert some of their resources to help improve conditions for the poor. (Singer 2002) Paul Farmer reaches similar conclusions when he advocates for a preferential option for the poor, particularly in health. (Farmer 1999) While some find their accounts persuasive, the wealthy have not adequately responded to the pressing need. (Pogge 2005a) One major stumbling block is pharmaceutical companies' perception of their economic self-

interest: companies are not in the business of giving away their products as charity, and vigorously defend their intellectual property rights.

Economic theory seems to support these companies in their perceptions. Consider the economic concept of rivalry. A service or good is *rivalrous* in an economic sense if multiple or simultaneous users degrade its value. While a number of people can admire my apple, if I eat it, I have denied it to all others. Even admiring the apple is rivalrous at some point: a million people cannot admire it in person; neither can thousands share a house, or a car, or a farm at the same moment. Most forms of property are therefore rivalrous, and this makes donations of property rivalrous as well. If a pharmaceutical company donates drugs that cost $1,000,000 to produce, then the pills become the property of the recipients and are lost to the donor. (Plahte 2005) We should not expect pharmaceutical company donations to meet the medical needs of the world's poor in this way. These pills are not costless to produce and their consumption is rivalrous. Any involuntary mandate would operate as a tax on these firms and their shareholders. The companies are conducting a business, not a charity.

But perhaps this account of rivalry is mistaken. What if you could give a gift that didn't cost anything? Imagine if pharmaceutical companies could make a donation for the world's poor that didn't diminish their wealth in any way. If some property was *non-rivalrous*, then something of great benefit to the world's poor could be made available at no cost to the donor. While this might sound almost magical, in fact most pharmaceutical knowledge is non-rivalrous and can be shared without diminishing anyone else's knowledge. (Outterson 2005)

The primary reason drug companies don't openly share pharmaceutical knowledge is to safeguard their profits in the marketplace. The global system of intellectual property law creates an artificial scarcity in knowledge, making knowledge rivalrous by law rather than by

necessity. Public policy accedes to this unnatural scarcity in order to promote future innovation. But we don't have to be forced into an unfortunate choice between access and innovation. Some equitable access proposals aim to retain the sharing benefits of non-rivalrous knowledge while retaining optimal innovation incentives. All such proposals share a common insight: the poor are very modest markets for global patent-based drug companies; so forgoing these markets will not harm innovation to a significant degree. Concerns about diversion of equitably-priced medicines into wealth country markets have been overstated in the past, and simply haven't materialized. Donors have distributed billions of dollars of AIDS drugs in very poor countries without observable diversion in commercial quantities to wealthy country markets. (Outterson & Kesselheim 2008) Free riding by the world's poorest citizens is not only possible, but may be entirely appropriate for essential medicines. (Scherer 2004)

One example is a patent buy-out for the developing world. Generic companies would have the ability to purchase particular pharmaceutical patent rights for low- and medium-income countries. Generic competition would stimulate production at the lowest sustainable cost, which would maximize equitable access. Optimal innovation would be supported by the combination of buy-out royalties and continuing rent extraction (patent profits) in high-income markets. This is the voluntary "patent buy-out" model. (Ganslandt, Maskus & Wong 2001; Stein & Valery 2004; Outterson 2006; Outterson & Kessleheim 2008) Involuntary versions of this proposal would utilize compulsory licenses, as permitted under TRIPS. Other variants utilize prize funds, as discussed earlier in this essay.

These proposals are made more plausible by a realistic account of the net costs to companies for R&D to innovate. While the industry claims that it costs more than $1 billion on average to develop a new drug, it issues little verifiable and transparent data on this issue, and independent sources suggest the actual costs are much lower. A recent review points out that

corporate tax returns have itemized the costs for clinical trials as a fraction of the costs used to generate high estimates (Light 2007; Love 2003). The size and length of trials are both reported as much smaller by the FDA and the NIH. About half of industry estimates consists of a built-in high estimate for profits not made on the money invested in research. Figures from the National Science Foundation survey of basic and applied research have led one policy research team to conclude that only 1.3 percent of pharmaceutical revenues, after taking into account tax subsidies, are devoted to discovering new molecules (Light & Lexchin 2005). Thus a fair price for patent rights for lower- and middle-income countries should be relatively modest. More importantly, if access proposals impose a very modest or perhaps zero risk or cost to the patent-based drug companies, then modifications are indicated to global intellectual property law to permit rescue by others.

IV. Conclusion

Global pharmaceutical markets distribute medicines based on ability to pay rather than medical need. As a result, billions of people are inappropriately priced out of the market through a global system of intellectual property rules created by and for pharmaceutical companies. Many others are locked into "hard bargains," paying inappropriately high prices akin to the shipwreck of *The Richmond*. As creators and active participants in global pharmaceutical markets, the patent-based drug companies may be subject to an ethical duty to permit an easy rescue, which in this case include opportunities to expand equitable access while preserving optimal innovation. At the very least, they should not actively hinder the rescue efforts of others and permit generic licensing for those unable to pay wealthy country market prices.

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