

# Justifying Intellectual Property

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JUSTIFYING  
INTELLECTUAL  
PROPERTY

ROBERT P. MERGES

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*This book is much like me:  
A bit long, a bit wordy,  
And totally dedicated to my family:  
Jo, Robbie, and James*

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## Patents and Drugs for the Developing World

ONE OF THE GREATEST CHALLENGES facing the IP system today is what to do about patents on crucial pharmaceutical products needed in developing countries. For the most part, these patents are held by pharmaceutical companies in the developed world. Many argue that diseases in the developing world are ignored by “big pharma,” that companies skew their research toward diseases or conditions of little relevance to the world’s neediest populations. The same voices say that even when pharmaceutical companies have a drug that the developing world needs, the poor of the world seldom have access to it at a price they might be able to afford.

I believe the ideas I have developed can help us tackle this issue. It is in some ways a perfect test case, presenting a remarkably complex combination of economic and ethical considerations.

Before these issues can be clarified, I need to explain some facts about the developing world, the medicines needed there, and the complicated role patents play in regulating access to these medicines. After that, we return to John Locke for a review of the charity proviso that forms an integral part of his property theory (and that I discussed in Chapter 2). After reviewing how the charity concept applies to patented drugs in the developing world, I also discuss some limits on the idea—in particular, the difficult question of when drugs contribute to quality of life as opposed to strict survival.

Next we move from Locke to Rawls. Part of the Rawlsian understanding of distributive justice is the notion of the “fair savings” principle, one

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way of expressing the more general idea known as “intergenerational equity.” This idea, which requires taking account of future generations when making decisions about resource use, turns out to be crucial to the problem of drug patents and the developing world. The reason is this: a wholesale policy of redistribution *today* carries the distinct risk of dismantling the research infrastructure needed to develop drugs for *tomorrow*. Only a sophisticated understanding of the charity proviso and intergenerational equity, infused with a detailed understanding of the practicalities of pharmaceutical research and the mechanics of drug distribution, can do full justice to the complex problem of fair access to medicines.

### Some Background Facts

Overall health is much better in the developed world than in the developing world. Judging from mortality statistics, the single largest cause seems to be differences in nutrition.<sup>1</sup> But differential rates of disease are also very important, particularly infectious diseases such as malaria.<sup>2</sup> Because pharmaceutical products can effectively treat many of these diseases, and because patents are so important to the pharmaceutical industry, the patent/developing country controversy centers primarily on patents for infectious disease therapies. In particular, the following diseases have drawn most of the attention with respect to this debate: (1) malaria; (2) HIV/AIDS; and (3) tuberculosis.<sup>3</sup>

HIV/AIDS was perhaps the preeminent example of the problem of pharmaceutical patents and the developing world. In the 1990s, when the HIV epidemic was first fully understood, some of the early HIV drug therapies were developed, patented, and diffused rapidly throughout the developed world, despite the high cost. The same was not true, however, in the developing world. Although the issue of differential access was by no means novel at this time, the HIV epidemic brought a new urgency to the issue and was the object of a major policy discussion among health experts and academics.

A compounding factor was that at the same time the HIV epidemic was coming into focus, the global patent regime was changing rapidly. As part of a broader set of reforms, the General Agreement on Tariffs and Trade (GATT) had initiated a new round of negotiations on Trade-Related Aspects of Intellectual Property (TRIPs). The TRIPs accord was signed in 1995; under it, developing countries agreed to phase in minimum protection levels for a number of patentable items, including pharmaceuticals. However, almost as soon as the agreement was signed, it was surrounded by a great

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controversy. The confluence of stronger patent protection and the growing gap in access to patented medicines (most prominently HIV therapies) created enormous strains in global patent policy and world health.

These strains put pressure on certain provisions of the TRIPs accord that had been designed as a compromise between the interests of developing countries and those of the developed world, most importantly the large pharmaceutical companies of the United States, Europe, and Japan. These provisions were designed to serve as “safety valves” in the global IP system. One particularly important measure in the TRIPs treaty provided for nation-by-nation “compulsory licensing” of patents over products crucial to public health, in the event of a grave or serious threat to public health. Pro-access forces in the developing world, and the nongovernmental organizations (NGOs) sympathetic to them, argued that the HIV crisis was just the sort of emergency envisioned by these provisions. Trade negotiators from the developed world, informed and backed by large pharmaceutical companies, resisted these arguments at first. They argued that a lack of access to patented drugs was not the real cause of differential access rates; for them, weak health services and high-risk patient behaviors were the real culprits. Even so, partly in response to the pressure from NGOs and general bad publicity, many pharmaceutical companies ramped up or initiated voluntary pharmaceutical “gifting” programs around this time.<sup>4</sup> Next came a major development, in the form of a formal declaration that the compulsory licensing provisions could be invoked fairly widely to respond to drug access concerns. Even after this “Doha Declaration,” named for the city in which the resolution was adopted, controversy over access to patented drugs continued.

### The Right to Access—And Its Limits

Access to patent-protected pharmaceuticals represents a classic fairness-based challenge to property rights. The exclusionary right of property takes away the lives of disease victims who happen to live in places where the patented medicines are unavailable. Does this situation prove the point of all those who criticize property, especially property conceived of as a right? Or is there a way to reconcile the obvious appeal of fair access here with the overall idea of property, that is, individual control over discrete assets?

The answer is a resounding yes. And the raw material for it was laid out earlier, in Chapters 2 through 4. Each of the foundational normative theories we discussed—the property theories of Locke and Kant, and the distributive justice concerns of John Rawls—quite effectively accommodates the problem of access to patented pharmaceuticals. Although the details of

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any actual access policy would be difficult to discern from these foundational writings, the basic principles can all be found there with little room for doubt. A brief review of the relevant aspects of each theory will show what I mean.

*Locke's Charity Proviso*

As we saw in Chapter 2, John Locke provided both a powerful theory of original acquisition of property *and* a robust set of limitations on that right. In that chapter I described at length some of the controversies surrounding application of the appropriation theory to the case of IP rights. I also went into a good bit of detail in discussing the sufficiency and waste provisos, again with significant attention to how they apply in the case of IP rights. I also mentioned the third major limitation on property rights, the charity proviso. Because this is the aspect of Locke's theory that so closely relates to the problem of access to patented medicines, I saved for this chapter a detailed application of this part of Locke's theory.

Locke states the charity proviso in paragraph 42 of his *First Treatise of Government*:

God the Lord and Father of all, has given no one of his Children such a Property, in his peculiar Portion of the things of this World, but that he has given his needy Brother a Right to the Surplusage of his Goods; so that it cannot be justly denied him, when his pressing Wants call for it. And therefore no Man could ever have a just Power over the life of another, by right of property in Land or Possessions; since 'twould always be a Sin in any Man of Estate, to let his Brother perish for want of affording him Relief out of his Plenty. As Justice gives every Man a Title to the product of his honest Industry, and the fair Acquisitions of his Ancestors descended to him; so Charity gives every Man a Title to so much out of another's Plenty, as will keep him from extreme want, where he has no means to subsist otherwise. . . .<sup>5</sup>

In this passage, Locke is saying two important things: (1) that property does not confer the right to deny relief to those in "pressing want"; and (2) that people in desperate need have an actual, binding *right* to the assets held by legitimate owners, and this right arises from the same source, and carries the same weight, as an initial appropriator's right. I take each of these points in order, and then relate them to the problem of pharmaceutical patents.

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Locke's first point can be stated simply: property is not absolute. It may be a right—as we saw in Chapter 2, for Locke it most certainly is—but it is

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not an *absolute* right. In that same chapter I explained why this is so. Locke says that property furthers the broader purpose of sustaining human survival and flourishing. It is a right that follows from the divine command to grow, multiply, and thrive. Individual ownership is necessary because it is too difficult and costly to coordinate resource use among all of the true initial titleholders of the resources we are given, that is, all humankind. Because survival requires removing some things that are commonly owned out of the original state of common ownership, we have property.

For Locke, it would be absurd to argue that property rights held by person A trump the basic right to survive held by person B. If the entire point of property is to further survival and human flourishing, how can this right be used to deny someone else's very survival? That would make no sense at all.

A little later in this chapter I consider some complexities of the charity proviso as applied to pharmaceutical patents in the developing world. But in a simple case of company A's patents standing clearly and directly in the way of person B's survival, the charity proviso is easy to apply. B wins.

#### TITLE FOR THE DESTITUTE

For Locke, the destitute have title to the goods they need to survive, even when those goods are otherwise legitimately held by others, either through valid original appropriation or a subsequent transfer from an original acquisition. This is a distinctive approach to charity for two primary reasons. First, it is a way of describing charity from the perspective of the recipient, the person in need. And second, it states a particularly strong, and in fact quite novel, version of the traditional view of the duty to show charity.

From very early times, charity was described in the Judeo-Christian tradition as an obligation whose primary function is to improve the spiritual well-being of the *giver*.<sup>6</sup> Indeed, well into the Middle Ages some theologians thought that poverty exists, in part at least, so that charity may be shown.<sup>7</sup> From this perspective, the recipients of charity are important only insofar as they provoke the occasion of generous charity; they are certainly not at the center of the picture. Charity is seen as a virtue that is applied by a righteous person to the whole of what he owns. And it is virtuous precisely because it is not required by positive law or the civil state. Charity dictates that, in the presence of great need, one does the right thing with some of what one owns.

Notice in this formulation that ownership is presumed. Charity is a virtue that operates "on top of" the unquestioned fact of ownership. It modi-

fies ownership in the practical sense that a generous person will part with some of what he owns when the moral duty of charity applies. But that duty is separate from matters of ownership and title. Charitable gifts are a voluntary transfer, willingly made, of some portion of the goods one has unquestioned title over.

Locke intrudes here to shake things up. He places the needy themselves at the center of the picture: it is their need, and not the virtue of the giver, that commands our attention. And in Locke's formulation, charity is not a matter apart from issues of ownership and title. Charity is integral to title, because under this proviso the needy have an actual claim on the goods held and owned by the holder of property rights. Charity is not separate from issues of title; it is integral to them.

Recall Locke's forceful words: "As Justice gives every Man a Title to the product of his honest Industry, and the fair Acquisitions of his Ancestors descended to him; so Charity gives every Man a Title to so much out of another's Plenty, as will keep him from extreme want, where he has no means to subsist otherwise." This sentence presents a powerful set of parallels. Justice and Charity are matching origins of strong property claims, each of which culminates in formal title over assets. Likewise "honest Industry" is paired with the lack of "means to subsist otherwise" as equally valid justifications for the respective property claims. And finally, the "product" of industry is paired with "extreme want" as implied limits on the scope of property claims. Initial appropriation and the charity proviso form a matched pair, with equally valid and effective origins, justifications, and limits. The structure of the sentence discloses the structure of the rights: "As Justice gives, . . . so Charity gives. . . ."

With this formulation, Locke moves the recipient of charity out of the background and into the foreground. The giver's aspirational duty is transformed into the receiver's ineluctable right. In the process, the recipient is shown as deserving of the same dignity as an initial appropriator. The passage thus represents unassailable evidence for an egalitarian reading of Locke as described in Chapter 2. More to the point here, it serves as a solid foundation for the argument that the destitute have a firm claim to patented pharmaceuticals, at least when their very lives are at stake.

### *Kant's Universal Principle*

Under Kant's Universal Principle of Right (UPR), "laws secure our right to external freedom of choice to the extent that this freedom is compatible with everyone else's freedom of choice under a universal law."<sup>8</sup> As I explained in Chapter 3, Kant's theory of property rights expresses a special

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instance of this general principle: property is widely available, yet denied when individual appropriation interferes with the freedom of others. Kant says that although the need for robust property drives the formation of civil society, property rights are nonetheless subject to this “universalizing” principle. Under the operation of the UPR, property rights are constrained: they must not be so broad that they interfere with the freedom of fellow citizens. In a Kantian state, individual property is both necessary—to promote autonomy and self-development; see Chapter 3—and necessarily restricted under the UPR.<sup>9</sup>

Death is the ultimate restraint on autonomy; there is no more “self” to guide after a person dies. So when a claim to property by person A leads to the death of person B, Kant’s Universal Principle would seem to rebut that claim. As with other issues, however, Kant’s views in this regard are not so simple. In particular, he expressed complex views on the legal defense of “necessity,” which bears a close resemblance to the property-limiting principle I am attributing to him here.<sup>10</sup> Kant says, in effect, that in at least one important example of necessity—where A kills B, or at least puts B in immediate grave danger, to save A’s own life—one who commits a necessary act is *culpable* but not *punishable*.<sup>11</sup> As with so much in the Kantian canon, there is a great deal of debate over just what Kant was trying to say about necessity. One view—at least as plausible as most others, and more plausible than some—holds that Kant thought of necessity as something like an excuse or defense: a wrong act is not made right by necessity, but it is insulated from formal legal liability.<sup>12</sup> This view, well described by among others the Kant scholar Arthur Ripstein, depends on the distinction between formal, positive law (“external,” in Kant’s terminology; see Chapter 3) and “internal” morality. Property for Kant is an absolute right, and taking it without permission is always objectively wrong. But at the same time, some takings are not punishable by the state because they fall outside the proper bounds of legitimate lawmaking.

Because Kant did not explicitly discuss the necessity defense as it pertains to property rights, any application of his thinking to the case of pharmaceutical patents can only be speculation. Even so, there is one point to make. As I explained in some detail in Chapter 3, there is generally a high degree of symmetry between Kant’s thinking on law and his theory of property. The UPR is a good example; as I explained in Chapter 3, the idea that property can extend only up to the point that it interferes with the freedom of others is simply one specific application of the general Kantian take on law and freedom. Thus, the analysis of the pharmaceutical patents problem would turn on the issue of property’s effect on the freedom of those suffering from treatable diseases. To put it simply, it is difficult to be

sure of the exact conclusion Kant would reach with regard to the issue, but I *am* sure that the analysis would turn on the freedom-restricting qualities of pharmaceutical patents. It is hard to know the right answer, but not hard to pose the right question: should property extend so far as to cut off or restrain the freedom of those who might be treated?

In my view, the freedom of disease sufferers is so constrained that the property rights in pharmaceutical patents must give way. As I said, this is not the only plausible reading of Kant's Universal Principle with respect to the problem at hand. But I think it is the best reading, and it is certainly the best *I* can do, given Kant's text and the problem of pharmaceutical patents as I understand it.

#### *Distributive Justice and Pharmaceutical Patents*

Of the three major foundational thinkers whose ideas I explore in Part I of this book, the easiest to apply to the problem of this chapter is Rawls. Recall that in Chapter 4 I summarized Rawls's view that property is one among a number of secondary rights that occupy a lower level of priority in his philosophical thinking. It is not, in the Rawlsian lexicon, a "primary good." But food, shelter, and access to basic health care are such goods. For Rawls, then, there would be little doubt that property rights must give way in the face of a claim that they stand in the way of someone's very survival. The entire point of the Rawlsian hierarchy is to render straightforward these sorts of issues. Political systems are supposed to be designed (would be designed, if the veil of ignorance dropped and the concomitant deliberative procedures were implemented) such that primary goods are given priority. The pharmaceutical patent problem is precisely the sort of issue Rawls seems to have had in mind when he constructed his system as he did.

The only possible exception to this is the issue of intergenerational equity—what Rawls called the "fair savings" principle. I discuss this in the context of pharmaceutical patents in the next section.

#### *Pharmaceutical Patents and the Midlevel Principles*

So far I have couched the pharmaceutical patent issue in the language of the various foundational theories examined in Part I of this book: Locke, Kant, and Rawls, as well as utilitarian theory as described in the Introduction. If I am to stay true to the pluralism I espouse in Chapter 5, however, it would seem necessary also to discuss the issue in terms of the midlevel principles of IP law. As I argued there, we need not agree on the ultimate

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foundations of IP law to have a sensible policy discussion about the important details of patent law that affect access to patented pharmaceuticals. That's what the midlevel principles are for.

For the most part the question of destitute people and pharmaceutical patents implicates the principles of efficiency and, to a lesser extent, proportionality. The dignity interest of researchers who develop the drug is not directly at issue, nor is the nonremoval principle. So I will confine myself here to efficiency and proportionality.

How is it possible to talk about efficiency when access to pharmaceuticals seems like such a classic case of a right—a human right, in fact—that conflicts with economic interests (in this case, those of the pharmaceutical companies)? Shouldn't human lives trump mere efficiency? Shouldn't helping people to survive take precedence over the economic well-being of pharmaceutical innovators?

I do not think the issue is that simple. In fact, it is possible to restate the access questions in efficiency terms, and in the process identify the needs of the destitute as an important element of the discussion. Maybe the real question is this: given a large supply of human diseases, and a large population needing treatment for them, what is the best way to maximize the number of effective pharmaceutical products that are brought to bear on these diseases? How do we get the greatest mileage out of all the available resources—products of nature, human skill, scientific knowledge, and so forth—that need to come together to solve the problem of treating diseases worldwide?

When stated this way, the efficiency principle obviously has an important place in the conversation. It leads us to look into whether the total supply of medicine is greater, overall and in the long run, when developed countries devote substantial resources to drug innovation while temporarily putting off access by the poor to a later date. Are more people helped in the long run even though many are clearly excluded from the best treatments in the short run? Put another way, the efficiency principle would guide us to a discussion of whether an open-hearted policy of access to all drugs immediately, by anyone who could benefit from them, would amount to a one-time distributional bonanza at the expense of the long-term viability of the drug innovation infrastructure? I consider these issues in some detail below; at this point, I simply want to state that the efficiency principle provides a helpful and useful terminological frame for addressing this crucial question.

The second midlevel principle that bears discussing in this context is proportionality. Recall that the basic idea behind this principle is that the reward to a creator or innovator ought to be proportional to his contribu-

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tion. This comes into play in an obvious way in the pharmaceutical patent debate, though the ultimate conclusion is by no means straightforward. If the structure of pharmaceutical patent law, together with the entire regulatory and competitive environment of the pharmaceutical industry, leads to excessive rewards in light of the benefits conferred, then the economic power of pharmaceutical patents can be trimmed back so as to restore a better sense of proportion. If even a small portion of the suffering of those who require access to patented drugs is a result of overreward to patentees, the proportionality principle dictates that the state cut back on the reward. Disproportionate reward coupled with grave suffering makes a powerful case for this.

There are, to be sure, grave difficulties in *applying* this principle in the pharmaceutical case. The skewed nature of success in pharmaceuticals—where a few drugs are wildly successful (and profitable) while most languish and do not even recoup the cost of developing them—ensures this. Determining whether a particular patented drug deserves to earn its creators massive rewards requires that we consider how many unsuccessful research projects are funded by each successful drug product. The “deserving” return to a well that is a gusher must take account of all the dry holes that came before, and will come after as well.

Nevertheless, at least in theory, we can be guided by the proportionality principle. If access to medicines is blocked by the exclusionary power of a disproportionately large reward, this principle informs clearly about what to do: scale back the reward.

### *Limits*

So far, then, I have tried to establish that Locke, Kant, and Rawls all support a relaxing of patent rights over life-saving pharmaceuticals. I have also referred back to the midlevel principles to show that they are consistent with this conclusion. The goal in this section is to describe a few limits to the general principle that patents must give way in this area. In particular, I want to emphasize (1) cutting off the “right to access” when the relationship between the pharmaceutical in question and actual survival is too remote or attenuated; and (2) the need to preserve the pharmaceutical industry’s infrastructure so it can be deployed to find cures for as yet untreatable diseases. I take each in turn here.

#### WHEN DOES A PHARMACEUTICAL SAVE LIVES?

In some sense, the problem of pharmaceutical patents is not as difficult as it is conventionally stated. Rather, it seems fairly obvious that where access to

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a specific pharmaceutical at a specific time would clearly and unquestionably save a life, fairness requires that access be granted, notwithstanding the presence of a patent. The problem is that most real-world situations are not as clear-cut. The primary issue is this: access to medicines is part of a much broader array of health-related interventions that are required to lower mortality in many situations involving destitute populations, so much so that it can be difficult to identify the precise contribution to health that is made by the pharmaceutical in isolation. Because of this, it can be difficult to say for sure that access to a pharmaceutical in a given situation would clearly and definitely save a life.

The World Health Organization has studied particularly important health threats in the developing world, including malaria. It is true that (a) not enough resources are devoted to antimalarial treatments, an example of the lack of attention to diseases that disproportionately affect the destitute<sup>13</sup>; and (b) the antimalarials that do exist are often not available in an effective way to those who most need them. Yet despite the truth of these facts, the picture is considerably more complex.

Successful campaigns against infectious diseases such as malaria require a number of simultaneous interventions. The reservoirs in which mosquitoes or other “disease vectors” breed must be treated so that the specific disease factor (the bacterium or virus, for example) does not find its way into the vector. These treatments need to be repeated, and the reservoir conditions monitored, if success is to be achieved. It is true that once a person is infected, pharmaceuticals may save his life. But a program of treating only infected persons, without addressing the reservoirs and vectors, will ultimately make little difference. Individuals will be reinfected, infections will outpace treatments, and eventually a mutation in the disease factor—caused by overexposure to the pharmaceutical treatment—may result, wiping out all chances of long-term success.

To put it simply, a series of interventions are required to save lives in this sort of setting. Permitting infected people to override patent rights may not make that much difference—might not save that many lives. Of course, Locke, Kant, and Rawls may still say that where a single life is at stake, property rights ought not to stand in the way. And that seems true. It’s just that the number of people who will actually be helped by application of this principle may be lower than many expect.

Things become yet more complex when we vary the facts just a bit. If a drug does not cure a disease, but instead extends life or treats a major symptom, what then? In such a case I do not believe Locke and Kant can be read to strictly dictate that access trumps property. In such a scenario, the destitute seem not to meet Locke’s requirements for a claim to title

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over the patent; only matters of absolute life and death meet the test. Kant would seem to offer more support for a right to access in such cases, given that disease conditions may often limit the effective autonomy of the destitute. Yet even for Kant, things may not be quite so straightforward. The very universality of the UPR means that a just principle must take account of the autonomy interests of many people. Because some of these people are as yet unborn, and because major inroads on pharmaceutical patents may reduce the future efficacy of the drug research enterprise, we cannot be too quick to permit access under the UPR where imminent life and death are not at stake.

#### INTERGENERATIONAL CONSIDERATIONS

The paradigm case that concerned Locke and Kant poses a stark yet simple choice. A destitute person needs something to survive, but that need is blocked by the legal rights of another—a property right in the desperately needed thing. Both philosophers reach the same conclusion: the property right must yield.

This story is simple in part because it involves only two actors, the destitute person and the property owner. The situation becomes considerably more complex—and the conclusions less straightforward—when the story is expanded to include other actors as well. One example of this is to consider other citizens who may be affected by a rule relaxing property rights in cases of dire need. Will destitute people overuse the rule, or will the near-destitute try to expand it? Will expectations about stable ownership begin to break down, resulting in greater reliance on self-help (for example, armed defense of an owner's property), and perhaps a reduction in economic activity and ultimately wealth? These are examples of what might be called the dynamic effects of a broad application of Locke's charity proviso and Kant's universal principle.

This expanded range of considerations applies to all types of property. Indeed, it applies to all legal rules; the analysis of dynamic effects, of long-term systematic responses to legal rules, is the hallmark of the law and economics approach to law. Law and economics scholars have long taught that the most important impact of a particular case is not the resolution of a particular dispute involving two discrete actors, but is instead the systematic incentives and payoffs established by the rule in the case.<sup>14</sup> In this view, for every two disputants there are many untold *future* actors who will incorporate the rule established in one case into the payoff matrix they face. The normative thrust of this view is quite clear: the legal system ought not to be overly concerned with the apparent fairness of a particular

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rule in the case where the rule originates, but ought instead to pay close attention to the ex ante incentives the rule creates for future actors.

In the case of pharmaceutical patents, this admonition would mean that, before legal actors permit overriding of property rights, they must account for the effects on other people. Given the nature of pharmaceutical research, it would seem that the most important class of people to consider is the group of all those who will suffer from potentially treatable diseases in the future.<sup>15</sup>

So the question is this: how would overriding patent rights to help today's destitute people affect future generations of people suffering from diseases? The answer depends on three important factors:

1. How much pharmaceutical R&D would take place in the presence of weakened patent rights?
2. Would the resulting level of R&D result in fewer actual new pharmaceutical products for treating diseases?
3. If the level of R&D were reduced, and fewer new drugs were developed, would the reduction in future disease treatments offset the increase in access to currently available pharmaceuticals?

The problem, in other words, is to weigh the intergenerational effects against the immediate benefits of expanded access.

It would of course be incredibly difficult to answer these questions in detail. The key to gaining a foothold on them, however, is to understand how patents on pharmaceuticals affect incentives for drug research, as well as the overall structure of the pharmaceutical R&D infrastructure. So we begin with these topics.

*Pharmaceuticals and Patent Protection.* There are a lot of unknowns in the world of patent scholarship. As I said in the Introduction, the empirical data on the overall effectiveness of patents are surprisingly indeterminate. There is simply a lot we do not know. (That's what drove me to look for normative foundations outside the conventional utilitarian framework, as I explained in the Introduction and elaborated on in Chapters 2 through 4.)

But there is one consistent finding across all the empirical literature on patents, one canonical truth that has been repeatedly established and confirmed beyond a peradventure of doubt: the pharmaceutical industry needs patents to survive.<sup>16</sup> If there is one industry where the conventional "incentive theory" of patents is actually true, it is the pharmaceutical industry. As a result, it is equally well understood that eliminating or weakening patent protection in this industry would significantly reduce the volume of R&D and consequently the supply of new drugs. This is as close as we

have to an established fact, or strict empirical regularity, in the economic literature on patents.

The tricky question of course is this: how *much* would R&D be reduced if patents were weakened; and how weak would patents have to be to reduce pharmaceutical innovation so far as to have serious public health consequences? Unfortunately, this we do not know. But the general consensus is that even a minor reduction in patent protection might—note that word—have a significant effect on ultimate measures of public health.

*Estimating the Impact: The Pharmaceutical R&D Infrastructure.* To understand what would happen if the rewards from R&D were reduced in the pharmaceutical industry, it is helpful to understand some basic information about the industry's research infrastructure.

The overriding fact to keep in mind is that pharmaceutical R&D is enormously expensive. One oft-cited study found that it costs on average \$802 million to go from the initial discovery of a promising molecule to a marketable drug product.<sup>17</sup> These costs are spread over many years: it takes on average 12.8 years to develop a pharmaceutical product from the initial synthesis of a new chemical compound to government approval for a new drug product.<sup>18</sup> The overall expenditure for pharmaceutical R&D in the United States exceeds \$65 billion per year, considerably higher than the expenditure of public funds on medically related scientific research.<sup>19</sup> By any measure, the U.S. pharmaceutical research enterprise is a large, complex, and expensive operation.

This complexity shows itself in a number of ways. For example, the organizational landscape in the industry reveals distinct but important roles for both large and small companies. Traditionally, as the pharmaceutical industry grew from its early origins, a number of large, vertically integrated companies developed in parallel.<sup>20</sup> Economies of scale (pure size) and scope (the range of a company's activities) rewarded large companies and weeded out smaller ones.<sup>21</sup> This dynamic held sway from the early twentieth century until well after World War II. However, the advent of new scientific techniques beginning in the 1970s changed this. The emergence of modern genetic engineering, and biotechnology generally, provided an opening for small, research-intensive start-up companies. Many such companies are based on university research and a good number were founded by individual university scientists from various life sciences departments.<sup>22</sup>

Many scholars have seen the modern biotechnology industry as a fine exemplar of the way small, research-intensive companies can carve out a viable role in industries dominated by large, vertically integrated companies.<sup>23</sup>

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If we look at the pharmaceutical industry from this perspective, we can identify a role for patent protection that goes beyond providing incentives to create and produce saleable drugs. Patents, as I argued in Chapter 7, enable small companies to remain independent. Patent protection makes it possible for a small company to specialize in a technology-intensive field, yet still integrate its product into the overall operations of a much larger company.<sup>24</sup> A small biotechnology company can concentrate on what it does best—research in a highly specialized field—and transfer the results of its work to a large company without the threat that its work will be illicitly copied. Thus patents have a dual function in the industry: they protect overall R&D incentives, but they also influence the way the industry is organized, in particular making it more likely that a small, specialized company can set up shop and remain independent. Again, this theme was developed at length in Chapter 7 as a practical example of what it means to apply the abstract goal of autonomy described by Kant and other theorists.

Let us return to the idea of invading patent rights on pharmaceuticals to help the destitute. I am arguing that we need to gauge the effect of this policy on the long-term viability of the research infrastructure of the pharmaceutical industry. To do so, we need to take into account not only the macro-level or aggregate effects, but also the more subtle or second-order effects. These include reducing the viability of small, research-intensive companies. The paradoxical result of reducing patent protection on pharmaceuticals might well be to cause an *increase* in the average firm size in this industry; pharmaceutical research might become more concentrated. This in turn could have consequences worth considering, including perhaps an ultimate reduction in the innovative capacity of the industry. If small companies disproportionately rely on patent protection, and if small companies also contribute significantly to industry innovation, overriding patents may diminish the innovative capacity of the industry, to the detriment of those who suffer from potentially treatable diseases in the future.

*The Risk of Arbitrage.* This is the really hard question: would reduced pharmaceutical innovation tomorrow be worth it, when compared to the increased access to health care today? This reduces to two related questions: Would uncompensated access to patented drugs by the developing world appreciably reduce pharmaceutical company profits? And if so, would this reduction in profits at some point reduce the number of pharmaceutical innovations these companies would develop?

It might seem at first that market prices for standard pharmaceuticals are in most cases far beyond what citizens of the developing world can afford. This implies that opening access to drugs in these markets will have

little effect on the fortunes of pharmaceutical companies. After all, if a buyer cannot pay the going rate for a seller's product, it may seem hard to argue that the seller loses a sale when the buyer gets hold of the product for free, or at a greatly reduced price. This is true, but misses an important point. The availability of an expensive product at greatly reduced prices invites arbitrage—buying the product at the reduced rate and reselling it to others. If arbitrage is permitted, or difficult to prevent, sales at reduced prices may indeed have an effect on the seller's overall profits.

There is a serious risk of arbitrage in the context of access to pharmaceuticals. Many patented pharmaceuticals come in the form of pills—small, easy to hide, and easy to smuggle. In addition, destitute populations are often found in corrupt or failed states, countries with underdeveloped institutions and sometimes a rapacious governing class. There is a real possibility in this setting that drugs intended for destitute citizens will be commandeered and resold to disease sufferers in more developed countries.<sup>25</sup>

From the standpoint of the theories espoused in this book, the problem with arbitrage is that it complicates the right to access by the destitute. In particular, arbitrage brings the potential for consequences from access that we must consider. From a Lockean perspective, the clear-cut case for the charity proviso is undermined when today's charity runs the risk of harming people in the future. Likewise with Kant's Universal Principle: the freedom of others is affected by limits on property rights today that could impact other people in the future. And Rawls's principle of just savings points in much the same direction. If arbitrage were to undermine pharmaceutical company profits enough, future generations might suffer. If restricting access today is necessary to preserve the research infrastructure that serves as the engine driving pharmaceutical innovation, fair savings would require that this be done.

*Intergenerational Effects and Normative Theories.* The difficult issues we have been exploring here may serve as an excellent reminder of why I threw up my hands over utilitarianism in IP in the first place. The problem seems insoluble when looked at from the perspective of weighing costs and benefits. Furthermore, I think the more deontological approach of Locke and Kant, and to some extent Rawls, does not really resolve the issues any more cleanly. In fact, if we look at Locke's theory of property as a whole, or recall carefully some nuances in Kant's Universal Principle, or take seriously Rawls's principle of fair savings, we arrive at much the same destination as we would if we scrupulously follow the utilitarian pathway through these issues. That is to say, even if we put fairness and justice at the forefront, we have to consider how it would affect future generations

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if we were to advocate the widescale overriding of pharmaceutical patent rights. If we accept the facts I presented earlier about the nature of pharmaceutical research, especially the perhaps irreplaceable nature of the private pharmaceutical R&D infrastructure, there is no escaping the fact that access to current patented medicines entails a trade-off between current and future well-being. With this seemingly inescapable fact in mind, I turn to a few modest thoughts about how we might navigate this trade-off.

### Fairness in Practice: Policies for Access to Patented Pharmaceuticals

The preceding discussion has identified a theoretical, normative basis for a claim by the destitute to desperately needed pharmaceuticals covered by patents. It is quite instructive, in light of this background, to observe the actual policies and practices that have emerged in this area over the past ten or so years. These can be summarized as follows:

1. Most major pharmaceutical companies have undertaken voluntary free drug distribution programs. From the perspective of IP rights, they have selectively waived their rights in countries that have a desperate need.<sup>26</sup>
2. The developing world has pushed back against an international patent regime seen as too restrictive. In the process, the poorest countries have won back the right to declare health-related emergencies that justify overriding patent rights—compulsory licenses for patented drugs.<sup>27</sup>
3. International foundations have stepped onto the scene with innovative programs for developing and distributing drugs aimed specifically at the health problems of the poorest countries. The Gates Foundation has been at the forefront here.<sup>28</sup>

What is most interesting about these developments is that they seem to indicate a shared understanding by many interested parties that property claims in this area must necessarily give way in the face of the more pressing needs of the destitute. It is not too grandiose to put it this way: they show an instinct for charity. From this perspective, the normative theories of Locke, Kant, and Rawls seem not so much to create binding limits on property rights as to reflect shared understandings of what those limits ought to be. As I mentioned, first in Chapter 3 and later in Chapter 8, the ability to waive property rights is a crucial benefit. This charity instinct at work in the patented pharmaceutical area shows this once again. The

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choice to waive property rights is part and parcel of the property system, and owners often exercise this choice so as to reduce the worst potential effects of property rights. Although it would be going too far to say that waiver renders property somehow perfectly self-regulating, it is fair to say—as I have at several points in this book—that an awareness of voluntary waiver can significantly influence our understanding of how property works in practice.