Intellectual Property and Pharmaceutical Drugs: An Ethical Analysis

Author(s): Richard T. De George

Source: *Business Ethics Quarterly*, Oct., 2005, Vol. 15, No. 4 (Oct., 2005), pp. 549-575

Published by: Cambridge University Press

Stable URL: https://www.jstor.org/stable/3857978

INTELLECTUAL PROPERTY AND PHARMACEUTICAL DRUGS: AN ETHICAL ANALYSIS

Richard T. De George

Abstract: The pharmaceutical industry has in recent years come under attack from an ethical point of view concerning its patents and the non-accessibility of life-saving drugs for many of the poor both in less developed countries and in the United States. The industry has replied with economic and legal justifications for its actions. The result has been a communication gap between the industry on the one hand and poor nations and American critics on the other. This paper attempts to present and evaluate the arguments on all sides and suggests a possible way out of the current impasse. It attempts to determine the ethical responsibility of the drug industry in making drugs available to the needy, while at the same time developing the parallel responsibilities of individuals, governments, and NGOs. It concludes with the suggestion that the industry develop an international code for its self-regulation.

The notion of intellectual property (IP) is contentious. Nonetheless there is justification for granting exclusive rights to some original useful products or processes if the result benefits the common good. This is recognized in article 1, section 8 of the U.S. Constitution, which establishes the power of Congress "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." The length of time is somewhat arbitrary, has varied over the past century, and is vastly different for copyright than for patents, the latter offering much stronger protection for a shorter period of time.

1. The Moral Justification of Intellectual Property.

Because intellectual property is significantly different from other kinds of property,[1] the ethical defenses of intellectual property differ from the defenses—such as the Lockean[2]—of other kinds of property, and traditions in different parts of the world treat intellectual property differently. Nonetheless, there is a two-part argument in defense of the ethical legitimacy of limited intellectual property rights that is intuitively attractive, widely held, and, I believe, sound.

The first part is a fairness, or justice, argument that says that, within the economic system of free enterprise, those who spend time and/or money in developing a product

© 2005. *Business Ethics Quarterly,* Volume 15, Issue 4. ISSN 1052-150X. pp. 549–575

or the expression of an idea deserve a chance to receive recompense if the result they achieve is useful and beneficial to others who are willing to pay for it. It would be unfair or unjust for others to take that result, market it as their own, and profit from it without having expended comparable time or money in development, before the original developer has a chance to recoup his investment and possibly make a profit. Intellectual property protection gives innovators this chance.

The second part of the argument is based on consequences. It states that unless developers are allowed a period during which to recoup their investment and make a profit, the incentive to produce new products beneficial to society will be greatly reduced. Society benefits from new products, both initially and after they are no longer protected and fall into the public domain. Hence, the greatest benefit to the common good or to society is achieved by offering inventors and developers of new products a period during which they can make their profits without the competition of free riders. Both arguments together lead to the conclusion that protection of intellectual property for a limited period of time is just and produces more good for society than an absence of such protection.

I shall call the two arguments together the Standard Argument (SA). For the sake of argument, let us accept SA as a valid moral justification for intellectual property. It is general in form, and applies to pharmaceutical products as well as to inventions, machines, and other types of intellectual property. There have been many studies by economists to support the second part of the Standard Argument. The pharmaceutical industry and some economists[3] have persuasively argued that more new drugs are developed when pharmaceutical companies make sufficient profits to invest in research and development, and the pharmaceutical industry argues that the large profits for which the industry is known are necessary to underwrite both the high cost of developing a new drug and the large number of initial attempts that never turn into successful, marketable drugs.

The industry then builds on the Standard Argument to develop what I shall call the Status Quo Approach (SQA), which is a legal-economic approach, to reply to critics of their policies who adopt not an economic but a moral approach to pharmaceuticals. The Status Quo Approach takes existing intellectual property law, especially patent law, as setting the appropriate parameters within which to view and answer all challenges to the practices of pharmaceutical companies. Taking this approach leads to concentration on using the law to help these companies protect and increase their profits so that they can develop new drugs. Thus they defend their techniques to extend the time before which generic drugs can be introduced, to extend patent protection on an international level through the World Trade Organization (WTO), to produce me-too drugs or drugs that are only marginally different from existing drugs rather than concentrating on breakthrough drugs, and so on. Morally based attacks that make a link between patents and the availability of drugs for the poor are rejected as misconceived. Nonetheless, there is an attempt to diffuse the latter attacks by giving away some drugs in some circumstances. These give-away programs are presented as the industry's or a particular company's living up to its social responsibility. Social responsibility is the surrogate for moral responsibility, is part of the Status Quo Approach, and is seen by the industry as answering morally based criticism.

The SQA is an approach that pharmaceutical companies are comfortable with, as well as one that is widely accepted. It has the benefits of tradition, of requiring no change in current practices or law, and of having produced beneficial results in the past. Hence, one can argue, it is more likely than untried alternative schemes of intellectual property protection to produce beneficial results in the future. The approach thus entrenches and sanctifies the status quo.

Both the Standard Argument and the Status Quo Approach, however, are coming under increased strain and attack, and in this paper I shall attempt to examine the direction of those strains and the validity of these attacks. Only if we fully appreciate the Standard Argument and the Status Quo Approach, and their shortcomings, can we make sense of the continuing charges made by critics and the responses made by the pharmaceutical industry. My aim is to bring some order to a very confused and confusing public discussion on the actions of pharmaceutical companies, the obligations attributed to them, and the claimed right of the public with respect to needed drugs. Although clarifying the discussion is my main purpose, I shall also make some suggestions for improving the situation.

2. The Limits of the Standard Argument and the Communication Gap

Patents, I have argued, can be justified from an ethical point of view. But that justification is limited. Despite the Constitutionally stated basis for patents, neither common good (nor utilitarian) considerations form part of what is required for a patent. Nor have ethical considerations been a dominant consideration in changes that have been made in patent law. Hence the details of how patent protection has developed do not follow from the ethical justification. It is not that the way in which patent law has developed is unethical, but that it is only one of many sets of ethically justifiable ways of protecting pharmaceuticals.

Discussions of intellectual property are very complex and involve knowledge of convoluted laws, legal decisions, and economic and business analyses. Typically, at any negotiation involving intellectual property prior to the drafting of legislation, the parties are government officials, lawyers, and corporate representatives. Thus the best defense of those policies is given not in ethical but in legal and economic terms. This is why the SQA uses these. Critics, however, fail to be convinced by such considerations. It is not clear to them who, if anyone, represents the general public in the general process. It is difficult for any government to represent both the consumer and the industry, and the public's trust in government as representing the public's interest is lessened when the industry present in the negotiations is the pharmaceutical industry, which is known for being one of the most successful lobbying groups and for being among the top spenders of lobbying money.[4]

The complaint about the Standard Argument is not that it is wrong, but that it is taken to prove too much and to respond to all objections. The mantra that is repeated by industry representatives in every context and in reply to every criticism with respect to intellectual property protection, pricing and access is that unless the pharmaceutical companies are profitable enough to have the funds to do so and can expect future profits

from their products, they will not engage in R&D and will not develop new drugs, which, of course, benefit society as a whole. When critics point to the fact that the industry has the highest rate of profit of any industry year after year, this is the primary answer. When critics complain about the high cost of drugs and the fact that the price of drugs increases much faster than the inflation rate, this is their answer. When the critics claim that the developed nations are forcing the less-developed ones to adopt standards of intellectual protection that go against their traditions and may not be in their best interests, this is their answer.[5] When critics say that the reason for intellectual property protection is not private profit but the common good, this is the answer. And all this makes some sense because there is ample evidence that, without profits, there are few new drugs developed. Yet the answer covers over a good deal, as I shall try to show.

A resulting communication gap is found in the United States between the pharmaceutical industry and the general public, especially the elderly and the poor, and between governments of rich countries, which tend to defend intellectual property rights to the fullest extent, and poor countries, which defend the right of their people to access to needed life-saving drugs. Although the gap raises different problems on the national and the international level, the communication gap exists on both levels.

The pharmaceutical industry and the general public (and their self-appointed spokesmen, such as Common Cause and AARP) rarely carry on discussions. Rather, each states and restates its own position. The lack of conversation comes from the fact that they speak different languages. The critics speak the language of ethics—they talk of rights, duties, and the common good, and they tend to raise questions and issues in ethical language. They tend to ask: given the right to life, the right to adequate health care, the right to access to essential life-saving drugs, and the common good as well as the right to intellectual property, what should the law be? The pharmaceutical industry typically replies in terms of law and economics, relying on the SA and the SQA. It tends to focus on: What should pharmaceutical companies do within the existing structures of law and intellectual property protection? Yet the industry's answer to that question is not taken as adequate response by the objectors to the questions they raise. Hence there is no real meeting of the two sides, to the frustration of both.

To some extent the gap represents a tension within the pharmaceutical industry. The tension comes from the fact that on the one hand the pharmaceutical industry is part of the health-care industry, and so has as its primary aim the health of people, which is a morally praiseworthy aim; and yet on the other hand the industry can achieve this aim only if it makes a profit, which becomes its driving concern. The industry almost systematically refuses to speak in moral terms because that possibly opens the floodgates to demands it feels it cannot meet or to arguments it cannot persuasively answer, while it can and has defended its policies in economic and legal terms.

3. The Right-to-Health-Care Argument

Just as the Standard Argument is often assumed by the pharmaceutical industry, the defense of the right to health care is often assumed by its critics. The critics do not deny the overall validity of the SA and the SQA, but at its limits the critics chal-

lenge the application of the argument and the defenses of their practices given by representatives of the pharmaceutical industry. The central claim is that although the Standard Argument justifies the right to intellectual property, the right is only a prima facie and not an absolute right. In many cases the right holds sway and trumps other considerations. But in the case of pharmaceuticals it comes up against other prima facie rights, namely the right to life, the right to adequate health care, and the right to access essential life-saving drugs;[6] it comes up against the obligation to aid those in need; and it comes up against competing claims made in the name of the common good. The right to life, the right to adequate health care, the right to access to essential life-saving drugs and the obligation to aid those in need, critics note, must be given at least as much consideration as intellectual property rights. Not only do IP rights not necessarily trump those other rights, but they are in fact often trumped by them. The pharma industry tends to argue that intellectual property rights are always sacrosanct, when they are not. Although critics sometimes give too little weight to the actual strength of IP rights, the rights to health and to health care raise serious issues in certain circumstances about the pharma industry's claims. Hence the discussion does not end with simply asserting the Standard Argument and the SQA.

What then are the arguments in support of the right to health and health care and the right to access, and how can they be weighed against the right to intellectual property?

There is considerable confusion in the literature, and although the basic ethical claims are usually fairly clear, how they are justified is not.[7]

We can start by distinguishing two different rights that are often confused. They are related but are not identical. One is the right to health; the other is the right to health care. The UN Declaration of Human Rights, Article 25, states

> (1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing, and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age, or other lack of livelihood in circumstances beyond his control.[8]

Although there are a number of different rights included in this sentence, for our purposes two are central. One is the right to health,[9] the other is the right to medical or health care.[10] It is generally agreed that the rights stated in the Declaration are primarily rights that members of a state enjoy vis-à-vis their governments. Thus, the primary obligation that is correlative to the right to health falls on the state. The right to health has perhaps received so little attention in developed nations because in its most plausible sense these nations face no problem with respect to it. Most plausibly the right to health is analogous to the right to life. The state cannot give anyone health. Its obligation, rather, is to ensure that the conditions necessary for maintaining good health are provided and to prevent any party from damaging the health of another. Understood in this way, the state has the obligation to provide those conditions that promote the health of its citizens, such as ensuring clean water and air, providing sewers and sanitation, and taking other basic measures necessary to promote and protect the health of its members. But although states may have that general obligation, their obligation does not exhaust the obligation of others. The rights impose obligations on

business, individuals, and others as well. It is a violation of the human right to health, for instance, for manufacturers to dump toxic waste that will infiltrate a community's water supply and cause people to fall ill. The obligation not to cause harm to people's health and thus not to act in this way is a negative obligation. Positively, companies are bound to provide safe and healthy working conditions for their employees. Providing these conditions is an obligation imposed on them by their employees' right to health, whether or not it is also required by law. And positively, the government has the obligation to pass and enforce such laws.

If one reads the right to health care in the same way, then it is an obligation of states or governments to see that medical care is available to their people, whether or not the governments actually provide it.[11] Although states are generally held responsible for protecting the health of their citizens by providing the common goods of clean drinking water and sewers and other general sanitation facilities, they are not usually held responsible for providing health care in the same way. The reason is that the principle of subsidiarity comes into play. The principle of subsidiarity states that one does not call on a higher level to do a job that can be done at a lower level. With respect to health care, it is usually applied intuitively, even by those who do not use that term. Thus, when children get sick, for instance, it is typical for their parents to care for them, and family members usually are the primary care givers, rather than the state. When a family is unable to adequately care for someone who needs medical care, they might first go to the circle of friends, or to the larger community. When the community cannot handle the need, they go to the city or the state or federal level. Although in a developed society the structures are in place to handle the needs of people at the appropriate level, they are considerably different in a country that has a socialized medicine program than in a country that does not.[12] If a government is unable to handle the need or needs it faces, it might appeal to the international community. Also assumed by this process is that individuals have not only the right to health and health care, but they also have the obligation to do what they can to preserve their health and to care for themselves to the extent they are able to do so. Thus the rights to health and to health care impose correlative obligations on many parties. So far the obligations of pharmaceutical companies are no different from the obligations of other companies. But this is only part of the story.

Another argument comes into play here that develops the obligation to help others in serious need to the extent that one can do so. There are two versions of this. One is a weak version which says that one has the obligation to help others in serious need to the extent that one can do so with little or moderate cost to oneself. A stronger version says that one must do so even at great expense to oneself, although one does not have to make oneself worse off than the person or persons one is helping.[13] The obligation to aid others in serious need can be justified by either a rule-utilitarian approach, which argues that more good is achieved overall if this rule is followed than if it is not; or by a deontological approach, which bases it on the respect due others as persons and beings worthy of respect. The obligation is one that is widely acknowledged. Intuitively, if one sees a child drowning and one can save the child's life by extending a hand, one has the obligation to do so. Not to do so would be characterized by most people as

inhuman or barbaric. The obligation holds even if one will be late to an appointment, or if one will get one's shoes wet in the process of saving the child. The obligation becomes less clear as the cost to oneself increases, and most would agree that one is not obliged to save the child at the risk of one's drowning oneself.

The application of this principle with respect to an individual vis-à-vis a drowning child is straightforward. It becomes more and more problematic as the case becomes more complex. What if the child is drowning in the water of a crowded beach, with a thousand people on it? Is it the obligation of each of the thousand to save the child? Is the obligation greater for those closer? Is it exculpatory for someone who is dressed to say that the obligation falls on those in bathing suits? Would all be equally blameworthy if no one did anything and the child drowned? Now increase the number of children drowning, say from an overturned boat, to twenty. Each person on the beach can save at most one of the children. Is it the obligation of every person on the beach to save all the children, or to save only one, and, if the latter, which one? When we then move to millions of people in danger of death from the lack of medical care in the world and ask what is the obligation of developed countries, of those living in developed countries, of NGOs, and of pharmaceutical companies with respect to the needy, the arguments tend to get more and more tenuous. This is not to say that there is no obligation to help based on the right of the people to health or medical care. But the complexity of the situation suggests the need for action by many parties on many levels.[14]

If one accepts the obligation of aid, then it is not difficult to argue that those in the best position to help have the greatest obligation to do so. Now join that with the fact that those in the health professions have special obligations with respect to health and health care. They have these special obligations because of the field they have freely chosen, because they are related to health care in a way others are not, because they have the expertise that others lack, and because they make their living or profit from health-related activities. A doctor, for instance, has a greater obligation to help an accident victim if other aid is not available, than does someone without medical training. A hospital has a greater obligation to help an accident victim brought through its doors than does a bank or a department store, and people naturally would bring such victims to a hospital rather than to some other kind of enterprise.

Although the obligation to aid is widely held, there is much disagreement about the strength of the obligation. One controversy arises in deciding how much cost any one person or government or firm or industry is obliged to bear. Another controversy is whether one has the obligation to help all whom one can or only those who are in extreme circumstances due to no fault of their own. The latter recognizes the responsibility of each person to take reasonable precautions. One is reckless at one's own peril and people are allowed to suffer the consequences of their actions and choices.

With this background we can develop the right to access to needed medicines. But the argument works differently with respect to life-saving medicines, to those which are necessary for health but which treat non-life-threatening illnesses, and to those that are neither and are simply life-enhancing.

The strongest case can be made for the right to access to those drugs that are essential for the preservation of life. If one has the right to life, then one has the right to

that which is necessary to sustain one's life—be it food and shelter, or medicines and medical care. Medicines, obviously, are included in medical care. The right of access to available life-saving medicine has both a negative and a positive aspect. Negatively, all have the obligation not to prevent anyone from having access to what they need to sustain their lives. The positive obligation to ensure that access is available, as in the earlier case, falls on a variety of parties (applying the principle of subsidiarity) and is practically limited by the goods and resources available in a given situation.

To the extent that life is threatened, then the obligation to aid, as described above, applies, and legitimate demands can be made on all appropriate parties—including pharmaceutical companies, as we shall see.

For drugs that are not essential for preserving life, the argument in defense of the obligation to aid, as we have developed it, does not apply. But the right to access to needed medicines follows from the right to health care.

For life-enhancing drugs, such as Viagra, the argument from the right to health care is certainly weaker, and may not apply at all. In this case, defenders of some weak right to access might fall back on a right to equal treatment, claiming that beneficial medicines should not be restricted only to those rich enough to be able to pay for them. But who should bear the cost in such cases is far from clear and any claimed obligation on the part of pharmaceutical companies is very tenuous and a line of argument that I shall not pursue here.

My main concern is primarily with essential life-preserving drugs, and secondarily with those that are not essential but which treat non-life-threatening illnesses.

There are limitations on the right to access, just as there are limitations on IP rights.

The right to access does not include the right to every treatment available regardless of cost, and the right to life has limits to the amount and kind of aid others are required to supply.[15] Similarly, the right to adequate health care sets a minimum for such care to which one is morally entitled. That minimum is not and should not be equated with the maximum care available anywhere in the world. A much stronger and different argument would be needed to support that claim. At some point even the richest society may have to decide it cannot afford certain drugs. Societies have to decide how much they can afford on health care and on the use of very expensive drugs. Given limited resources, if money spent on very expensive drugs can be more effectively spent on saving more lives if used differently, then the latter is a defensible course of action. In the United States payment for drugs, as well as for other aspects of health care, comes primarily from third parties—Medicare or private health insurance policies. The payment for the latter comes from employers or individuals or both; none of the parties has infinite amounts of money to spend; and money that goes to health care, including medicines, is taken from somewhere. If all life-saving drugs were exorbitantly priced, employers and individuals would have to make hard choices. If the result of doctors not prescribing or of societies not buying drugs that are very expensive is that drug companies have less incentive to develop new breakthroughs that will be extremely expensive, that is arguably a decision a society may see as a less than optimal result, but overall one that it must choose as the lesser of two evils.

I shall call the set of arguments I have sketched out above the Moral Argument.

People typically invoke something like the above general arguments with respect to the drug industry and drug companies. The various claims are that the industry as a whole and the individual companies that make it up have special obligations; that these are related to what they produce, namely pharmaceutical drugs; that they are in a special position to help and that therefore they have the special obligation to do so; and that those in dire need, because of their right to health care, impose obligations on those able to help, including the pharmaceutical industry.

We can apply this claimed right to access both on the international and on the national level in the United States and see how we can weigh it against the right to intellectual property.

We should note that approaching ethical issues relating to the pharmaceutical industry from the perspective of the Moral Right to Access dramatically changes the issues that rise to the surface as opposed to those that arise when taking the Standard Argument and the Status Quo Approach. To see how, we can start with the pharmaceutical companies' use of the term "social responsibility."

4. The Moral Argument and Social Responsibility.

Assurances by pharmaceutical companies that they are socially responsible is not the same as recognizing ethical responsibilities and being willing to be held accountable for living up to them.

To the extent that the pharmaceutical industry attempts to defend its reputation as part of the health care, and so caring, industry, it speaks in the Status Quo Approach terms of social responsibility. Socially responsible action is usually praiseworthy and should be encouraged. But social responsibility is not the same as moral responsibility, although the two may overlap.[16] Social responsibility is a term that companies use to highlight whatever good works they choose to engage in and want to publicize. Since there is no principle from which to mount a claim, no one can say what the social responsibility of any company is, and so it is whatever the company chooses to define it as (or what some other vested interest group wishes the company to do).[17] Social responsibility language for the most part carries with it no non-self imposed obligations and so no broader accountability beyond what the company defines its responsibility to be. On the other hand, ethics or morality provides specific demands that must be met if one wishes to be ethical. The language of ethics is not as ambiguous as the language of social responsibility. The company or industry is in charge of the definition of social responsibility in a way that it is not and cannot be in charge of what is ethical. The attempt by business in general and the pharmaceutical industry in particular to speak in terms of social responsibility and eschew the language of ethics contributes to its failure to adequately respond to its critics. In their various programs, many pharmaceutical companies give a variety of drugs away free to the needy, be they AIDS victims in Africa or poor people in the United States. These are most often presented as meeting part of the company's social responsibility. So framed, it sounds as if these are voluntary, non-obligatory programs that the companies adopt as good citizens or through their philanthropic foundations. They might be considered supererogatory, or good works that

are not required, and ones for which they deserve praise; but failure to engage in them would deserve no blame. This approach puts the actions of pharmaceutical companies in the realm of charity, and portrays them as generous and caring.

One gets a different perspective if one views needs of people for drugs in the light of the Moral Argument. This approach emphasizes a dual distinction: one between charity and obligation, and another between perfect and imperfect duties. The Moral Argument, as we have seen, holds that one has a duty or obligation to help those in great need whom one can help at little (or, on the stronger version of the principle, greater) cost to oneself. The obligation to help is not an act of charity. An act of charity would consist in doing more than one is morally obliged to do. If one has a moral obligation to help a fellow human being in need, fulfilling that obligation is not an act of charity. With respect to obligations, they can be either perfect or imperfect. A perfect duty is one that one is obliged to do in all cases, and the obligation is reasonably specific. The clearest kinds are negative duties. One is obliged (or has the duty) not to kill others, not to steal, and so on. But if there are several people that need aid equally at the same time and one can help only one of them, then, absent any special circumstances or relations, one's obligation is to help one of them but one is not obliged to help any particular one. Hence it is an imperfect obligation. If the help that one supplies is monetary, then the amount that one is obliged to give is related to one's monetary situation and the amount of one's disposable income. A rich person would be obliged to give more than a poor person, especially if the burden of giving the greater amount is less for the rich than for the poor person. If we apply this to the pharmaceutical industry, then the obligation both of the industry as a whole and of individual companies is at least open for debate. There seems to be at least a prima facie case for saying that they have some obligation, even though the extent of that obligation may be difficult to specify, since it is an imperfect obligation. Clearly, however, the discussion changes if one acknowledges an obligation, rather than simply speaking in terms of social responsibility. The fact that pharmaceutical companies have put so much emphasis on their fulfilling their social responsibility by giving away drugs lends credence to those who claim that the companies have and feel moral pressure to aid those in dire need.

Many pharmaceutical companies have truly praiseworthy programs. But these do not satisfy some critics, for three reasons. One is that some of the programs are introduced only after much public pressure has been brought to bear and the programs consequently seem to be done more for public relations purposes than for humanitarian purposes. In addition the fact some such donations under U.S. tax law can be written off for as much as twice the cost of production makes critics doubt that the real reason for the give-aways has anything to do with ethical considerations.

The second (and related) criticism is that most of the programs seem to the public to be ad hoc. It is not clear what ethical criteria, if any, are used in giving away drugs, or in developing some drugs and not others. There is no stated general principle that determines which programs will be instituted, no general commitment of any kind by the various companies or the industry. The lack of any articulated principle means that the companies and the industry do not hold themselves—and imply that

they cannot be held—to any ethical account for their programs or for failure to have other programs. For true communication the ethical dimension should made explicit. The pharmaceutical industry might offset much criticism if it were willing to adopt ethical language and articulate the ethical criteria it uses in its decision making. It can do so without opening itself up to a legal quagmire. It might as a start adopt the first principle of Johnson & Johnson's Credo: "We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services,"[18] and then act in accord with that principle.

The third is that the social responsibility position adopted by many in the industry makes their give-away programs acts of charity. Hence charity replaces any notion of mandatory obligation or response to a right held by the recipients. The ethical critics, however, criticize the industry not for lack of charity but for failing to recognize legitimate demands of justice and the obligations imposed by human rights. The social responsibility claim, including giving needed drugs away free, is seen as a means of avoiding or as an attempt at defusing justice and rights claims.

Hence, despite the fact that it is admirable for companies to act in socially responsible ways, doing so does not imply that they have fulfilled their ethical obligations. Claims made by critics in terms of the obligations that the right to health care imposes on pharmaceutical companies or on the industry as such may be overstated and exaggerated. If so, the way to diffuse such criticism is not to argue that the critics do not understand economics or that the arguments are misplaced, but to engage the arguments as posed and show why they are mistaken in the obligations they claim the industry bears.

5. The Moral Responsibility of Pharmaceutical Companies

With this background, we can now ask: what are the obligations, from an ethical point of view, of the pharmaceutical industry as a whole and of individual pharmaceutical companies? The above discussion forms the background that is generally understood by critics, even though they do not often articulate their arguments very clearly. Can we come up with general obligations that stem from the rights of those in need of medical care? Clearly, pharmaceutical companies are not the only health care providers and the entire obligation to fulfill the rights in question does not fall on them. And clearly if they have special obligations, that does not mean that governments, individuals, families, NGOs, and so on do not also have obligations. Since governments have the primary responsibility to provide for the health care of their citizens, they bear the primary obligation. They may either meet this obligation directly or indirectly by ensuring the needs of the public are met in some other way.

Given present structures, the pharmaceutical industry, as part of the health care system, arguably has two basic ethical obligations. I shall call the first the Production Obligation and the second the Access Obligation. The obligations of the industry with respect to health care are broader and more general than the obligations of any particular pharmaceutical company. The industry's obligations can only be met to the extent that individual companies take the appropriate action. Yet the two levels—industry and company—should be kept distinct, even though many critics conflate the two.

A. The Production Obligation

The Production Obligation consists in the obligation to develop and produce beneficial drugs. This is the area of the industry's expertise and it is that which the companies in the industry can do that others cannot. Moreover, in this regard one can argue that the pharmaceutical industry as well as individual companies have the obligation to pursue needed new life-saving drugs more than to pursue alternatives to drugs that already exist and are effective, namely, so-called me-too drugs. Benefit to the patient, and hence to the public and the common good, should play a greater role in the case of health care than in other industries, just as safety is paramount in the engineering industries, whether it be in airplane or building and bridge safety. This first obligation is not an unjust imposition by society, but simply reflects part of the role of pharmaceutical companies in society. The obligation is one that is arguably shared by governments also. The United States Government funds billions of dollars worth of medical research, and it is appropriate that it does so because of its obligation to fulfill the rights of its citizens to health and to health care. In a free enterprise system governments do not engage directly in production, although they can encourage and promote production through their system of intellectual property protection and their tax system, among others. To the extent that the pharmaceutical industry fails to produce needed drugs, it is up to governments to ensure that they are produced.

Many pharma companies and the industry in general, as well as government sponsored programs, are engaged in the search for cures or remedies for cancer, various kinds of heart disease, new and improved antibiotics to fight infections, and so on. The industry as a whole, therefore, not only is actively engaged in fulfilling this obligation, but individual pharmaceutical companies have an economic interest in pursuing breakthrough and essential new drugs. The market for such drugs, if they treat diseases suffered by large numbers of people in the developed countries, is potentially lucrative.

Nonetheless the market incentive fails with respect to orphan drugs. Diseases which are life-threatening but in which the market is either small or the potential recipients poor, require a different approach.

In the United States the Orphan Drug Act has proven to be a successful marriage of government and pharmaceutical companies. The government provides tax incentives and guarantees seven years of exclusivity (after FDA approval) to encourage drug makers to develop drugs that affect fewer than 200,000 people and are generally unprofitable.[19] The result has been, on the whole, positive, despite abuses.[20]

The U.S. Orphan Drug Act has been copied, with changes, by the EU, Australia, Japan, and other countries. In the EU, unlike in the U.S., if a drug is "extraordinarily profitable," after five years it loses its orphan drug status. The United States, by contrast, not only does not control pricing but it permits "medically plausible subsets" to qualify for orphan drug status, which leads to an abuse called "salami slicing."[21] Nonetheless, whether one follows the U.S. version or some other, the basic concept has been successful in bringing needed drugs to market.

The market similarly fails with respect to the development of drugs for diseases restricted to those living in tropical countries. Although the governments in such countries have the responsibility for providing for the health of their people, they have insufficient funds to promote research and in addition they lack the facilities and the expertise needed. With minimal budgets for health care, they have difficulty providing the bare essentials of clean water and sanitation and developing an adequate delivery system for health care, regardless of the cost of drugs. Under these conditions the obligation of aid comes to the surface. In this case the appropriate aid is the development of drugs for the diseases in question. The obligation does not clearly fall on any particular pharmaceutical company, and how it is to be apportioned among countries and the pharmaceutical industry world-wide is a topic that urgently needs addressing.[22] The first step in any solution, however, is to recognize the obligation. Perhaps something comparable to an international orphan drug act can be agreed upon; perhaps governments can subsidize special research in these areas; perhaps companies can agree to fund joint research for drugs that would not be covered by patents and would be produced and distributed at cost. The actual action taken should be the results of negotiations among all the interested and affected parties. The pharmaceutical industry clearly has an important role to play in any such negotiations. But approaching the problem from the point of view of the Moral Argument brings to the fore obligations in this regard that the Standard Argument and the Status Quo Approach do not.

Although I have indicated the financial incentive that drug companies have to pursue important new drugs, critics of the pharmaceutical industry have concentrated on whether the drug industry is actually doing either all it can and should do, or all it claims to be doing with respect to the development of new drugs. The issue arises in part because of the industry's use of the Standard Argument and the Status Quo Approach. The many tactics used by pharmaceutical companies to produce profits are justified, the SA and SQA claim, because these profits are necessary to fund the research that has led to and will lead to the development of new essential drugs. The industry thus implicitly acknowledges that the production of such drugs is its goal, even if it does not acknowledge that it is also its obligation.

It is in this context that some critics claim that the amount that the industry spends on R&D is less than the amount that it spends on marketing (including advertising, free samples to doctors, etc.),[23] that the amount may even be less than the amount it spends on lobbying government officials;[24] that most of the profits it makes are not in fact plowed back into research but distributed as dividends to shareholders; and that most of the research that leads to new drugs comes from government-funded research, the results of which are appropriated for private gain.[25] All of this may be appropriate. But it is not self-evidently so, and this is what most concerns the critics. The industry in its blanket claims fails to be convincing.

According to a 2002 study of the National Institute for Health Care Management Research and Educational Foundation for the period 1989–2000, only 35 percent of new drug applications contained new active ingredients (of which only 15 percent were considered to provide "significant improvement over existing drugs"), while 54 percent were incremental modifications of existing drugs (and under Hatch-Waxman

get up to three years of market exclusivity) and 11 percent were identical to existing drugs.[26] Although these facts by themselves prove nothing with respect to the obligation to provide new drugs, they are used by critics to offset the image that the pharmaceutical industry suggests by its use of the SA to justify its approach to the development of new drugs.

To be convincing the industry must first acknowledge its obligations; but even more important it must be willing to show why the above activities are necessary to produce new drugs. Simply pointing to new drugs as proof is an instance of a logical fallacy. Simply because new drugs have been produced and the industry has been profitable using its advertising, lobbying, and other techniques, does not show that these techniques are necessary to produce new drugs.

If one takes the obligation to produce new life saving drugs seriously, then one might consider changes in the status quo with respect to IP. Essential, life-saving drugs can and arguably should be distinguished from other drugs for a variety of purposes. Me-too drugs and incremental changes, as well as cosmetic changes, do not clearly deserve the same protection or the same encouragement and inducement on the part of government.

These considerations all suggest considerable and far reaching changes to the status quo. If at least certain drugs that are life saving are treated differently with respect to the protection they are given, they may require a special kind of protection separate from patents, or the patent laws might have to be changed so that they are no longer one-size-fits-all. Governments might guarantee a certain level of profit for companies developing those drugs; governments might give them protection for a longer period of time so that they can recoup their large investments and make a profit, providing that access during that period can be assured to those in need; governments might be the principal buyers and distributors of such drugs, with international and inter-country aid programs worked out as appropriate. The details of the appropriate approach need much informed thought, negotiation by all affected parties, and a willingness to consider changes to the status quo. The Moral Argument does not specify the details of such changes. But it does highlight the obligation of all affected and interested parties to pursue alternatives to the status quo to the extent that the latter prevents rather than promotes the meeting of the obligation to develop new life-saving drugs. The driving impetus should be that of benefiting patients and the common good rather than only protecting intellectual property rights. Moreover, failure on the part of the pharmaceutical industry to live up to the production obligation will trigger the government's obligation to meet or to see that this obligation is met by taking whatever means is necessary.

B. The Access Obligation

The second obligation, the Access Obligation, is the obligation to make the drugs the industry or a company develops available to those who need them. Simply developing them would not serve any purpose otherwise. Fulfilling this obligation may be compatible with the existing structures relating to existing practices concerning intellectual property, pricing, government regulation, charity, and so on. Yet critics

claim that both the industry and the market fail to some extent with regard to this obligation, and they claim that if and when current practices impede the fulfillment of this obligation, then the right to access and the concomitant obligation to provide access take precedence over IP and other rights.

The argument as we have developed it so far imposes a stronger obligation on governments to ensure access than it does on the pharmaceutical industry. As we have developed the argument to aid, it comes into play most clearly in times of dire need. This would apply most clearly with respect to essential life-saving drugs. The obligation to help those in need in less dire circumstances is proportionately weaker. But the obligation of governments is not to ensure access only for life-saving drugs, but for all drugs needed for health. Governments are obliged to ensure their people have access, whether by actually buying and supplying the drugs or by other means—such as making sure the price of drugs makes them accessible. The right to access puts a strain on any strong claim to intellectual property rights in drugs, if what stands in the way of people receiving life saving drugs is maximizing corporate profit.

We should distinguish the right to access to needed medicines in poor countries from the right to access in the United States, and these rights from the right to access in countries with a socialized health system. In those countries with socialized medicine, the government has the responsibility of ensuring access to needed medicines, and it determines which drugs will be made available to all and under what conditions. We have seen that individuals do not have the right to all medicines no matter what their cost, and most government-run systems have limits on what they will pay. They also negotiate with pharmaceutical companies for the amount they will pay for different types of medicines. In Australia, for instance, the government negotiates drug prices on the basis of therapeutic value, paying only a small amount more for drugs that are only slightly more effective than already available drugs.[27] The amount any government is willing and able to pay for health care, and so for medicines, is in part a political decision, best made by a government responsive to the people. I shall not pursue this situation further. This leaves the questions of access in poor counties and in the United States. The ethical issues are different in the two cases.

a) Let us look at the poor countries first. The question of access to any medicines is a pressing need. Although governments have the responsibility to enable or provide access, it is beyond the ability of many of them to do so. Hence the obligation falls on others able to do so. Included in that number are pharmaceutical companies, especially those that manufacture the needed drugs. The issue was brought to global attention by the AIDS epidemic. The drugs in question are very expensive and only a few are on the current WHO list of essential drugs because of that. The most widely used such drug in poor countries is a combination of three generic drugs produced by the Indian pharmaceutical company Cipla.[28] Nonetheless, it is clear from the Moral Argument that when millions of people are dying and can benefit substantially from available medicines, they have a right to access with respect to them. A consensus is emerging that many parties are ethically responsible for access—the patient, the local government, other governments that can help, NGOs, international organizations, and the drug companies. The problem is clearly not only the result of practices of

pharmaceutical companies. Even if the drugs were given away free, access by many of the needy would still be a problem. And a number of pharmaceutical companies have instituted plans to give away antiretroviral drugs, to sell them at cost, or to license them for production by generic manufacturers in less developed countries under certain conditions. Arguably they are at least to some extent meeting their obligation to be part of the solution. (We have already seen the arguments of critics to the industry's approach that it is being socially responsible by its programs.)

Both nations and companies seem to acknowledge in principle the obligation to respond in case of dire need. Thus, for instance, a provision of the TRIPS agreement[29] states that mandatory licensing of necessary medicines is justifiable in times of extreme national emergencies (such as epidemics) as decided by the country in question.[30] Yet despite the Agreement the right to access is not being met and the pharmaceutical industry bears part of the blame. The TRIPS Agreement, despite its recognition of the obligation to aid, has in practice had little effect and has been faulted for a number of reasons. In 2001 PhRMA and a group of pharmaceutical companies charged South Africa with violating the WTO's rules on patents by producing the drugs needed by their people and forty companies filed suit. After much adverse publicity, the charges and the suit were withdrawn.[31] But neither the industry nor the companies involved ever acknowledged the right of the South African government to provide access to the needed life-saving drugs in accord with the spirit of TRIPS, if not with its letter.

The TRIPS Agreement requires that poor countries adopt the type of IP protection found in the developed countries. They must do so whether or not it impedes the government of the country in question from meeting its obligation to provide access to need drugs for its people. In this way it fails to consider the common good of the people of the country in question. For instance, while strong defenses of intellectual property with respect to pharmaceuticals may produce the best results overall for developed countries, they do not seem to do so for poor and developing countries, such as India. If , as drug companies claim, new drugs cost $800,000,000 to develop, then developing countries are probably not able to develop any. They are better served by developing generic drugs or by requiring compulsory licensing of drugs or by some other strategy. Compulsory licensing and parallel importing policies—with measures adopted to prevent the development of a gray market—would arguably benefit poor countries more than present arrangements.[32] The Moral Argument puts these as well as other suggestions on the table for consideration, while the Standard Argument and the Status Quo Approach—used in negotiating TRIPS—in effect prevent their being raised.

Moreover, the pharmaceutical companies of the developed countries made enviable profits and made enough to continue producing new drugs before the Doha round of the WTO, despite the fact that less developed countries did not recognize patents on pharmaceutical drugs. The people of developing countries do not have enough money to pay for the expensive drugs of developed countries, and hence do not contribute to their profits. It also remains problematic why the right to access to essential medicines trumps IP rights only in times of national emergencies. Those suffering and in need of the essential drugs need them no less if there is no epidemic or other national emergency than if there is an epidemic. The TRIPS agreement was

the result of a compromise; but the Standard Argument trumped the Moral Argument for the most part, when it arguably should not have.

The fierce and continuing opposition to any perceived crack in the strongest wall of intellectual property protection thus appears to less developed countries as clearly self-interested and is taken by critics as a lack of any principled ethical criteria other than the SA and the SQA guiding the industry and the governments of the developed nations in negotiations. Economic and business considerations are held to be paramount and to override human rights considerations.

From the point of view of the Moral Argument, the obligation of governments to provide for the needs of their people and the right of the people to access to drugs necessary for life trumps property rights. Taking this right seriously puts on the table for discussion alternatives to the status quo. Mandatory licensing at internationally approved royalty rates might become standard. Gray markets might be eliminated if protections were agreed upon to prevent the sale of drugs that were given away in the form of aid or in a system of tiered pricing or because of mandatory licensing.

Changes in IP protection are only part of the solution to very complicated problems of access to adequate health care in less developed countries. But such changes are an important part of any solution. Both governments and the pharmaceutical industry, according to the Moral Argument as we have developed it, have the obligation not to prevent access and to find ways to increase rather than impede access. This means willingness to take seriously alternatives to the status quo.

b) As opposed to poor countries that cannot afford drugs, the United States can afford to pay for drugs. In fact the United Stated both pays more for drugs and contributes more to the profit of the pharmaceutical companies than any other nation.[33] So the aspect of the right to access that has received the greatest attention is the barrier of high prices to access, even though access and price are not the same thing. Even if drugs were free, access requires that the drugs be transported, distributed and administered to patients. At issue is accessibility, especially of the newer drugs for which no competitive generic drug is available. Although the lack of accessibility for the poor and elderly on restricted incomes gets most publicity, more and more people are complaining that the high cost of drugs is limiting accessibility by putting the cost of insurance out of their reach. As insurance prices rise, employers are less and less willing to pay the escalating costs and are forcing employees to bear a larger and larger portion of the cost. The complaints against the pharmaceutical industry focus especially on two issues that are seen as limiting access. One is the high and ever increasing price of new drugs covered by patents. Not only the poor and elderly, but even middle class families find that the "co-pay" portion of medicines is increasing at a rate so much faster than inflation that they are having a harder time keeping up. The second is what is seen as illegitimate attempts by drug companies to "extend" their patents and to prevent generic drugs from entering the market, thereby keeping prices high and restricting access for those who can afford only the lower cost of the generics.

The Status Quo Approach simply applies market economics, assuming the force of law in protecting intellectual property rights with respect to patents, and adding that the overall result is not only fair but produces the most good for society. A rights

approach to health care yields a different focus. If the right to access to needed drugs is more important than the right to property, then the status quo is up for evaluation and becomes a candidate for change, rather than for passive acceptance. The issue then is not what does market economics prescribe, but how should the status quo be changed to do justice to the right to access to needed drugs. This means once again that intellectual property rights with respect to pharmaceutical drugs should be carefully scrutinized and perhaps changed.

i) Access and the Cost of Drugs

My earlier argument distinguished between those drugs that are necessary for life and those that are important for illnesses that are not life-threatening. In the United States critics of pharmaceutical industry pricing are critical of both, and for the most part insurance plans do not distinguish clearly between the two kinds of drugs. The assumption—and as we have seen a dubious assumption—of most Americans is that they are entitled or have a right to the best drugs available for their condition. The relation between the cost of health insurance and the price of medicines and between the cost of health care and the price of medicines is complicated. But the cost of medicines has increased much faster than the cost of health care generally,[34] and the justification for the increase is not obvious, except if one invokes market economics and produces the not-surprising result that the market has been willing to pay the higher prices.

The right to access argument in the U.S. is joined to a fairness argument. That argument says that fairness involves all parties paying their fair share for medicines, including paying sufficient amounts so that drug companies have a continuing incentive to produce more beneficial drugs. The complaint is not that American consumers are subsidizing drugs for the poor countries, or even that they are subsidizing the pharmaceutical companies' compassionate programs. That would be acceptable, and the better off—such as Americans in general—may well have the obligation to bear this cost. But under the Status Quo Approach, in effect, Americans are subsidizing not only poor countries but also seem to bear a disproportionate load. Japan, Canada and the countries of Europe all negotiate much lower prices than are available in the United States. Americans are increasingly finding it not only ironic but unfair that U.S. drugs cost more in the U.S. than in other developed countries. This leads to such anomalies as the U.S. government presently prohibiting the importation of U.S.-made drugs from Canada for personal use, while various state governments attempt to find ways of making it legal for senior U.S. citizens to buy U.S.-made drugs from Canada, where the government helps keep the price lower than it is in the United States.[35]

Part of the complaint about the recent U.S. legislation on health care is that it precludes negotiation by Medicare on prices and so limits access by those least able to pay. The reason why Medicare is prohibited from negotiating drug prices as almost all other governments of the world do, giving their citizens lower prices, seems to be that the pharmaceutical industry successfully lobbied Congress to protect the vested interests of the industry and the status quo. According to the SQA, any talk of controlling prices or of making them competitive with those in other countries (for

instance by parallel importing) is countered by the need for higher prices to produce the profits necessary to fund the R&D that will lead to new drugs. This, in effect, is to defend the existing practices and legal and insurance structures as necessary for the common good.

An arguably better alternative would be to allow the U.S. government to negotiate prices the way other governments do, or at least to allow Medicare to negotiate prices, just as the large insurance providers do. This would give greater access to the poorer, often uninsured consumers, and keep the cost of drugs affordable by more people. This would at the same time satisfy the justice demands. The aim of the justice argument is not to cut the profit on new drugs and so to cut incentives, but to equalize the ability to negotiate prices and so the cost to consumers among those who can afford it. With similar negotiation, those in the U. S. might pay roughly the same for essential drugs as the other developed countries This would be the market at work and would send the proper signals to the industry.

If the right to health care justifies access to needed drugs, and if price is a barrier, then society must find some way of overcoming that barrier. Pharmaceutical companies are not required by this argument to lower the price on these drugs. But they are part of the nexus involved in pricing and access, and they cannot claim an absolute right to set a profit-maximizing price, or any other that the market will bear, without government intervention if doing so denies access to their drugs by those who have a right to access. Exactly what their obligation is, how much of the burden they should share, how much government must help in one way or another—through subsidizing research or drugs themselves or through paying for drugs for those who have no or limited access—are questions that are complicated and require discussion and negotiation by all affected parties. How prices are determined for the U.S. market is not transparent to consumers,[36] and more transparency in this regard is essential in any meaningful negotiation in which the public has a voice and is adequately represented.

The standard reply to all questions about the high cost of drugs is to appeal to the SA and the SQA and claim that unless there are the profits brought about by high prices, there will be many fewer future drugs. The Status Quo Approach tends to present a questionable dichotomy: either protect drugs and drug pricing to the maximum or face a future with fewer new innovative drugs.[37] The claim is made no matter what the percent of profit, no matter what the prices, no matter how much the industry spends on lobbying and advertising to consumers. The claims are blanket, the justification is blanket, and the public is asked to take the claims on faith. The consuming public must take it on faith that money spent on the recently developed technique of advertising prescription drugs to the general public, for instance, is necessary to produce the profits that will lead to new drugs. They must take it on faith that money spent on researching minor changes in existing drugs is necessary to produce the profits that will lead to new drugs. They must take it on faith that the various tactics that seek loopholes in legislation—whether with respect to the Orphan Drug Act to garner windfall profits or Hatch-Waxman or other legislation to keep competition at bay as long as possible—are necessary to produce the profits that will lead to new drugs.

That faith has been shaken. Because there is very little transparency in drug pricing economics, the claims have worn thin. That the industry needs the highest rate of profit of any industry is not obvious, even for the production of new products.[38] The lack of adequate transparency exacerbates the communication gap and hinders fruitful dialogue. Abuses and attempts at gaming the system further erode trust. In the absence of engagement, it is not surprising that critics make some charges that may be poorly based and therefore unfair. But the appropriate response is not to simply repeat the same economic arguments but to be more willing to raise the curtain at least part way, without revealing trade secrets, and to facilitate rather than impede greater access.

ii) Access and Patents

If there is a difference between different kinds of drugs, and if people have a greater right to access to the more essential drugs than to the less essential ones, then at least it becomes an open question what the best means of protecting the different kinds is. If one takes seriously the Moral Argument, then the assumption of the SQA that all drugs deserve the same length or strength of protection and that they should be treated the same as all other patents in all other areas, is on the table for discussion. Although the laws governing patents are uniform for all products and processes, the range of processes and products is extensive, the differences among them considerable, and so the argument for a one-size-fits-all approach is questionable.[39] Moreover, the pressure on pharmaceutical patents is different from the pressure on patents in general. No one has a right to a better mouse trap, and the market may legitimately determine who gets one; but the right to access to essential medicines places an obligation on all those who can satisfy that right to come up with an equitable means of doing so.

In the United States the view that all patents are equal and deserve equal treatment is being challenged indirectly. Consider special legislation respecting pharmaceutical drugs, such as the Orphan Drug Act and the Hatch-Waxman Act. Thus pharmaceuticals arguably are special and require special kinds of protection, perhaps less broad than protection of other kinds of products, perhaps stronger, but in any event different. Australia, for example, allows a five-year extension of patent protection for certain drugs, and government pays the higher price for the drug for this period.[40]

Since access and price are related, attempts to extend the protected life of a drug by introducing slight modifications to get new patents or to delay the entry of generic competitors—which would lower the price and increase accessibility—are not justified by the Standard Argument and are more appropriately seen as taking advantage of the system.[41] Criticism of these practices by other pharma firms within the industry are rare, which gives rise to often blanket unfair charges against the industry as a whole. If an original drug is available in generic form when its patent expires, then if there is an alternative with some modification that is patented and so more expensive, it is a matter of choice on the part of the doctor and patient which to use. If the modification, for instance, makes it necessary to take the drug only once a day rather than twice a day, but is several times more expensive than the original, there is nothing unethical in making that choice available to those who can afford it. There is no overriding moral

imperative that requires the improved drug to be available to all at the same price as the earlier version. But neither is there any moral obligation on the part of doctors to prescribe the more expensive alternative. The situation is different, however, if the patenting of the modified drug prevents the introduction of the generic equivalent of the original. For in that case a modification which may be valued by some patients is obtained at a cost to all patients, some of whom may be kept from obtaining the drug at all because of the continued patent enforcement.

A Status Quo Approach type argument is sometimes made to defend even this, however. Although some patients may be disadvantaged by the "extension" of the original patent, some claim, the producing company is able to reap profits that it can apply to the research and development of new drugs, which will greatly advantage many future patients. Hence the benefit to the future patients outweighs the harm to the present patients in the form of higher prices and potential lack of access.

The argument, however, is not persuasive. For it violates the spirit, if not the letter, of patents. One can claim, on the other side, that the public and so patients have a right to have the product enter into the public domain once the original patent expires. That right cannot be overridden by some promise of expected benefit for patients in the future. For the right in question is a right of present people, and can only be overridden by a stronger right of such people, not simply by promised benefits. The benefit of the patient—in our present discussion, the patient's right to access—is the crucial ethical component to be considered in any attempt to "extend" patents. In some cases, such extensions may be ethically justifiable. But in such cases it should be possible for the manufacturer to explain the benefit to patients, and it should also be possible to explain why no rights of patients are violated and so why the adopted practice is fair. This could not be done for a drug modification which almost all would acknowledge is trivial or minimal. But the test might be met by some drug modifications that some critics, because of lack of full information, might claim to be unethical extensions of a patent.

The burden of proof is on the manufacturer. To be sure to be able to meet it, drug companies should ask themselves as they consider whether to work on incremental improvement of drugs presently under patent whether the results aimed at truly benefit patients.

Daniel Vasella, chairman and CEO of Novartis, notes, "There have been some legalistic ways of extending patent life, which I don't think are legitimate. One has to accept that patents have an end."[42] Similarly, executives of Merck, Pharmacia, and Eli Lilly "have expressed concern about other companies' aggressive patent extension tactics,"[43] as has the FTC.

The task with respect to pharmaceutical products is to balance claims to intellectual property rights against the rights to access to needed medicines, the common good and the obligation to aid. The economic argument that unless companies can make a profit from their research in discovering, developing and producing drugs, they will not produce them, is only a partial defense of the existing patent system, and one that focuses only on property rights. It is only a partial defense because patent protection is not the only conceivable way of either protecting intellectual property or of guar-

anteeing profits. It does not show that other alternatives—public financing of research and development, cooperation instead of competition on some drug development, government regulation of prices or guarantees of profits at a certain level for certain drugs, and so on, are not viable alternatives. In particular, the SA and SQA do not show that intellectual property rights, no matter how strong and justifiable, trump the right to basic health care and the right of access to needed medicines or that the right to profits trumps these, the common good, or the obligation to aid.

The critics understand the economic argument but are not convinced by it and believe that ethics and not only economic considerations must play a role in health care decisions.

As the above discussion indicates, an alternative approach to the Status Quo Approach is not to accept the existing structures—either legal or economic—as basic and to ask: what does the reality of existing conditions with respect to people's needs demand, and how can the legitimate expectations of pharmaceutical companies be accommodated within that consideration?

6. An International Code for the Pharmaceutical Industry

In seeking a solution to the drug industry/general public communication gap I have suggested that the industry start by replying to its critics in ethical terms. I believe it can do so in many instances successfully. I have emphasized the need for negotiation among all concerned parties, giving due voice to the rights to health, health care and access to needed medicines. I have suggested more transparency in pricing. And I have suggested considering changes in patent laws so as to distinguish essential from me-too and frivolous drugs.

Finally, part of the reason for the communication gap and the basis for much criticism of the pharmaceutical industry is not the legitimacy of patents and intellectual property in pharmaceutical drugs. It is the perceived abuses by some in the pharmaceutical industry—abuses such as gaming the system, everygreening patents, abuse of the Hatch-Waxman Act, excessive lobbying for self-interested purposes, inequitable or unfair or excessive pricing, and so on. These are not issues that any one company can solve, but one that the industry as a whole can address. Some company or group of companies must take the initiative and be the leaders in any such development, if the industry wishes to avoid the less desirable alternative of government action

One possible approach is for the industry to adopt an international code, similar in some ways to the code adopted by the chemical industry after the criticism it received following the Bophal disaster.[44] Its purpose would be to prevent and address ethical abuses by companies in the industry, and so preclude restrictive legislation. The point of any such code is not to regulate prices (it would probably not mention prices), but to help prevent abuses. Self-regulation of industries is an accepted principle (as the many international voluntary codes show) and should not be confused with cartels, collusion, and monopoly practices.

Such a code should be developed and agreed upon by the pharmaceutical industry, not imposed upon it. Clearly, to be effective it cannot be self-serving. It should be

widely publicized and the industry should be willing to be held by the public to the standards stated. To be taken seriously by the public, the companies in the industry should be willing to be monitored by independent auditors as to whether they measure up to the standards set by the code. The sanctions should not be legal but should be public censure and pressure by other members of the industry on the offending party.

The general public has lost confidence in the drug industry. The industry's adoption of such a code would be a good start towards restoring public trust and confidence.

The industry is structured competitively so that each seeks to maximize its profits. This is part of the free enterprise system and in principle acceptable. But this does not mean that the industry as a whole does not have the responsibilities we have discussed above. The burden of meeting these responsibilities does not and cannot fall on any individual company. It is a collective obligation that must be met collectively. How these are met requires thought and negotiation. But adopting a code, which would be enforced by members putting pressure on those who violate it,[45] would be a good start.

Intellectual property rights deserve enough protection to promote the common good. Existing structures are under great strain because the system is failing to do this. The structures also do not give enough scope to other rights claims that may in some cases override intellectual property rights, especially with respect to essential drugs. Attempted changes so far within existing structures are insufficient to remedy the deficiencies. The pharmaceutical companies should move beyond SA and SQA and fill the communication gap. The pharmaceutical companies and the industry as a whole can do only so much within the system and cannot be expected on their own to change the system. They can, however, be expected not to stand in the way of changes that are needed to help them serve the needs of their customers—and so of all the people—better by increasing access to needed drugs, and in the process to help them serve the common good.

Notes

1. Unlike other property, intellectual property is infinitely shareable. It can be stolen, borrowed, copied, and one still has it. Intellectual property refers to some products of the mind. But arguably the most important products—ideas—cannot be claimed as one's property. Only the expressions of ideas or their embodiment in some product or process can with any plausibility be said to constitute property in any sense. Even in these cases, no expression or invention is developed completely independently. In the realm of knowledge one always builds on what has gone and has been developed before and is part of the public domain.

2. See Lawrence C. Becker, *Property Rights: Philosophical Foundations*, Boston: Routledge & Kegan Paul, 1977, for an extended discussion of the foundations of property rights. See also Arthur Kuflik, "Moral Foundations of Intellectual Property Rights," in *Owning Scientific and Technical Information*, ed. Vivian Weil and John W. Snapper, New Brunswick, N.J.: Rutgers University Press, 1989. This is not to deny that some philosophers use a Lockean approach to defend intellectual property.

3. For a sample of the economic arguments, see Frank R. Lichtenberg, "Cipro and the Risks of Violating Pharmaceutical Patents," National Center for Policy Analysis (November 15, 2001), at http://www.ncpa.org/pub/ba/ba380/; and Henry Grabowski, "Patents, Innovation and Access to New Pharmaceuticals," *Journal of International Economic Law* (2002): 849–60.

4. Common Cause, "PhRMA Wins Big After Spending More Than a Half Billion on Contributions, Lobbying and Ad Campaigns" (July 1, 2002), notes that the Pharmaceutical Research and Manufacturers Association (PhRMA) spent at least $558 million in past decade on political contributions and that between 1993 and 2000 it spent over $65 million on ads fighting legislative proposals it dislikes. See also Bill Hogan, "Pulling Strings from Afar," *AARP Bulletin* (February 2003): 3–4, who claims that the pharma industry spends more on direct lobbying and front groups than any other industry.

5. See Peter J. Hammer, "Differential Pricing of Essential AIDS Drugs: Markets, Politics, and Public Health," *Journal of International Economic Law* (2002): 888, on how "the rhetoric of strong intellectual property rights leading to innovation that meets social needs rings particularly hollow in this setting."

6. The World Health Organization publishes an essential drug list (EDL). I do not mean this list when I use the term "essential life-saving drugs," because the EDL does not include new, expensive drugs still covered by patent. It does not include, for instance, many of the AIDS drugs. The criteria for inclusion in the EDL are safety, efficacy, and reasonable price. As a result only a very few drugs that are not generic are included in the list. For information on the EDL, see http://www.twnside.org.sg/title/twr120c.htm.

7. The situation is very similar to the situation in 1948 when the UN Declaration of Human Rights was adopted. Philosophers and others had discussed the philosophical justification for human rights for three years and were unable to find one justification on which they all agreed. They found, however, that they could agree on the set of rights they enumerated in the Declaration, even though different philosophers justified those rights in different ways.

8. We start here because the Declaration is widely accepted worldwide.

9. Most of the philosophical literature is concerned with the right to health care, rather than the right to health. Three exceptions are Tom L. Beauchamp and Ruth R. Faden, "The Right to Health and the Right to Health Care," *The Journal of Medicine and Philosophy* 4(2) (June 1979): 118–31; Nora K. Bell, "The Scarcity of Medical Resources: Are There Rights to Health Care?" *The Journal of Medicine and Philosophy* 4(2) (June 1979): 158–69; and Dan W. Brock, "Broadening the Bioethics Agenda," *Kennedy Institute of Ethics Journal* 10(1) (March 2000): 21–38. But both of the first two articles place their emphasis on the right to health care.

10. Although the right to health care is widely accepted by philosophers as a valid right, there is considerable discussion about the proper way to justify it. John C. Maskop, "Rawlsian Justice and a Human Right to Health Care," *The Journal of Medicine and Philosophy* 8(4) (November 1983): 329–38, considers whether Art. 25 of the UN Universal Declaration of Human Rights can be justified using Rawls's theory. He argues that attempts by others (such as Ronald Green and Norman Daniels) fail, and even if other attempts succeed the defense would only be as strong as Rawls's theory, which has been heavily attacked. Maskop suggests (following Joel Feinberg) considering health care a social ideal. Norman Daniels, "Rights to Health Care and Distributive Justice: Programmatic Worries," *Journal of Medicine and Philosophy* 4 (June 1979): 174–91, argues that the right to health care can only be specified by reference to a general theory of distributive justice. David DeGrazia, "Grounding a Right to Health Care in Self-Respect and Self-Esteem," *Public Affairs Quarterly* 5(4) (October 1991): 301–18, bases the right to health care on self-respect and self-esteem. Amartya Sen, "Elements of a Theory of Human Rights," *Philosophy & Public Affairs* 32(4) (Fall 2004): 315–56, approaches rights from the point of view of capabilities.

11. The literature typically addresses the issues of fair allocation of resources and the obligation of the state towards its people in providing health care. Emphasis is on the system and how it should be changed in the United States rather than on other actors other than the state. See, for example, Norman Daniels, "Health Care Needs and Distributive Justice," *Philosophy and Public Affairs* 10 (Spring 81): 146–79, as well as the articles in note 10.

12. I shall not enter here into a consideration of whether a system of socialized medicine is preferable, from a moral point of view, to a privatized system that relies on insurance. In either system the government bears responsibility for the system and for ensuring that medical care at least at the basic level is available to all its citizens.

13. Perhaps the best known statement and application of the principle with respect to alleviating hunger in the world is Peter Singer, "Famine, Affluence, and Morality," *Philosophy and Public Affairs* 1(3) (Spring 1972): 229–43.

14. See, among others, Virginia Held, "Can a Random Collection of Individuals Be Morally Responsible?," *Journal of Philosophy* 67 (July 23, 1970): 471–80; *Collective Responsibility: Five Decades of Debate in Theoretical and Applied Ethics*, ed. Larry May and Stacey Hoffman, Lanham, Md.: Rowman & Littlefield, 1991; R. S. Downie, "Collective Responsibility in Health Care," *Journal of Medicine and Philosophy* 7 (February 1982): 43–56; Peter French, "Collective Responsibility and the Practice of Medicine," *Journal of Medicine and Philosophy* 7 (February 1982): 65–88.

15. For an extended discussion of limits on health care, see Norman Daniels and James Sabin, *Setting Limits Fairly* (New York: Oxford University Press, 2002), which deals with issues of establishing priorities and rationing care and also with fairness of a system, such as the U.S., that leaves 45 million people uninsured.

16. For a more detailed discussion of the relation of social responsibility, moral responsibility, and legal responsibility, see Richard T. De George, *Business Ethics*, 6th ed., Upper Saddle River, N.J.: Prentice Hall, 2005, 198–206.

17. The pharmaceutical industry has not, on the whole, adopted the position of Milton Friedman that the only social responsibility of corporations is to increase profits for their shareholders (Milton Friedman, "The Social Responsibility of Business is to Increase its Profits," *The New York Times Magazine*, September 13, 1970).

18. Johnson & Johnson: "Our Credo: We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to reduce our costs in order to maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our suppliers and distributors must have an opportunity to make a fair profit." Online at http://www.jnj.com/our_company/our_credo/index.htm. The principle is one worth following, whether or not Johnson & Johnson, or any other particular company, lives up to it in all cases.

19. See the Orphan Drug Act (as Amended) at http://www.fda.gov/orphan/oda.htm. Larry Stevens, "Orphan Drug Act at 20: Big Gains, Some Strains," August 4, 2003, at AMNews (http://www.ama-assn.org/sci-pubs/amnews/pick_03/gvsa0804.htm), notes that the FDA places no control on pricing and provides no incentive to keep prices down or for developing a drug for one disease rather than another.

20. "Health Care and Intellectual Property: The Orphan Drug Act" at http://www.cptech.org/ip/health/orphan/ joins others in citing as a defect of the Orphan Drug Act the fact that companies sometimes use the Orphan Drug Act to keep other companies from bringing drugs to market, that sometimes it is counterproductive and that some companies use the Act to cover a drug previously developed and now used for a new indication. See also "Excerpts from James Love, 'Comments on the Orphan Drug Act and Government Sponsored Monopolies for Marketing Pharmaceutical Drugs'" at http://www.cptech.org/ip/health/orphan/orphan92.html, which argues that the Act needs more targeted incentives and more public accountability.

21. Thomas Maeder, "The Orphan Drug Backlash," *Scientific American* (May 2003): 80–87. He notes that in the decade before the law the U.S. produced thirty-four orphan drugs, while in the two decades since then, American companies have produced 229 orphan drugs, treating 11,000,000 patients. Nonetheless, he is critical of the salami-slicing technique, which results from the FDA permitting "companies to parse diseases into 'medically plausible subsets'" (87).

22. *Developing World Bioethics* 1(1) (2001) carried a "Symposium: Drugs For the Developing World" with essays by David B. Resnik, Norman Daniels, and Dan W. Brock. While Resnik put emphasis on the social responsibility of pharmaceutical companies, Daniels argued for the domestic and international action to address the problem of allocation, and Brock questioned the moral obligation of developing countries to respect patents when violating such patents is the only effective means of making needed medicines available to their people.

23. Public Citizen Congress Watch, "Drug Industry: Prices, Profits and R&D, Campaign Contributions & Lobbying," at http://www.citizen.org/congress/reform/drug_industry/profits.

24. Mitch Miller, AIDSMedsd.com"Forum," Aug 4, 2004, at http://www.aidsmeds.com/Fusetalk/messageview.cfm?catid=5&threadid=14483.

25. Public Citizen, April 18, 2002, "Pharmaceutical Industry Ranks as Most Profitable Industry—Again" at http://www.citizen.org/congress/reform/drug_industry/profits.

26. NIHCM, "Changing Patterns of Pharmaceutical Innovation," p. 3 at http://www.nihcm.org/innovations.pdf.

27. Richard Laing, "Global Issues of Access to Pharmaceuticals and Effects of Patents," pp. 4–5, at http://dcc2.bumc.bu.edu/richard/IH820/GenevaPresentation.

28. MSF Access to Essential Medicines Campaign "An advance for HIV/AIDS treatment access in the developing countries," 2 July 2004 at http://www.accessmed-msf.org/prod/publications.asp?scntid=272004153542&contenttype=PARA&.

29. TRIPS is the Agreement on Trade-Related Aspects of Intellectual Property Rights, and is Annex 1C of the Marrakesh Agreement establishing the World Trade Organization and signed in 1994. The text of the original Agreement is available at http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm. It has been modified and interpreted at subsequent meetings of the WTO.

30. See item 1, 5 (c) of the Doha WTO Ministerial "Declaration on the TRIPS agreement and public health," 20 November 2001 (WT/MIN(01)/DEC/2, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

31. Anup Shah, "Pharmaceutical Corporations and Aids" at http://www.globalissues.org/TradeRelated/Corporations/AIDS.asp#USThreatenedTradeSanctionsonSouthAfricaforTryingtoHelpitsPeople. See Hammer, "Differential Pricing of Essential AIDS Drugs," 883–912, especially 900–03 for details of the about-face by U.S. drug companies in South Africa in 2000–2001.

32. For a discussion of other options, see F. M. Scherer and Jayashree Watal, "Post-TRIPS Options for Access to Patented Medicines in Developing Nations," *Journal of International Economic Law* (2002): 913–39.

33. Among other sources, see CBS News, *60 Minutes*, "Prescriptions and Profits" (August 22, 2004), at http://www.cbsnews.com/stories/2004/03/12/60minutes/main605700.shtml; and Bain & Company, "The Pharma Innovation Divide: The High Cost of Europe's 'Free Ride,'" at http://www.bain.com/bainweb/Consulting_Expertise/hot_topics/detail.asp?id=22.

34. In 2003, the prices of the thirty most-prescribed drugs to senior citizens increased, on average, 4.3 times the rate of inflation, with Combivent (used to treat chronic asthma) rising 13.2 times the rate of inflation, and Diovan (used to treat high blood pressure) rising 8.6 times the rate of inflation, among others, according to a Families USA Report, "Sticker Shock: Rising Prescription Drug Prices for Seniors," at http://www.familiesusa.org/site/PageServer?pagename=Media_Sticker_Shock_Release.

35. Pharmacist.com, "FDA threatens penalties for 'aiding' importation of Canadian drugs," March 13, 2003, at http://www.pharmacist.com/articles/h_ts_0232.cfm; Patricia Barry, "More North Americans Go North for Drugs," *AARP Bulletin* (April 2003): 3–4.

36. See, among other sources, Marcia Angell, *The Truth About the Drug Companies: How They Deceive us and What to Do About It*, New York: Random House, 2004.

37. Ian Maitland, "Priceless Goods: How Should Life-Saving Drugs Be Priced?" *Business Ethics Quarterly* 12(4) (2002): 451–80, presents a good review of the arguments against the pricing of life-saving drugs by pharmaceutical companies. He tends to answer them in terms of the SQA, but he correctly states that "the real moral challenge of pricing medicines . . . is to determine how pricing medicines helps or hinders getting them to people who need them" (470).

38. According to the *Fortune* 500 Report, in 2001, the pharmaceutical industry was the most profitable industry again for several years running. In 2001 the profit of the top ten drug makers increased 33 percent, and drug prices increased 10 percent, even though the rate of inflation was only 1.6 percent. *The Public Citizen* (April 18, 2002, "Pharmaceutical Industry Ranks as Most Profitable Industry—Again" at http://www.citizen.org/congress/reform/drug_industry/profits) notes that "The drug industry maintains that it needs extraordinary profits to fuel risky R&D into new medicines. But companies plow far more into profits than into R&D. Fortune 500 drug companies channeled 18.5 percent of revenue into profits last year. Yet they spent just 12.5 percent of revenue on R&D." It also reports that for 2002 the industry had return on assets of 14.1 percent (compared with a median of 2.3 percent for Fortune 500 companies); that it spent 30.8 percent of its revenue on marketing and administration, but only 14.1 percent on R&D; and that its direct-to-consumer advertising increased from $800 million in 1996 to $2.7 billion in 2001. (Public Citizen, Congress Watch, June 2003, "2002 Drug Industry Profits: Hefty Pharmaceutical Company Margins Dwarf Other Industries," at http://www.citizen.org/congress/reform/drug_industry/r_d/articles.cfm?ID=9923).

39. Consider the difference between a method of doing business (such as Amazon.com's one-click patent) and a life-saving drug, both of which are covered by the same patent law.

40. "Australian Pharmaceutical Patent Term Extension Database," at http://www.drugterm.com/help.htm.

41. In July 2002 the FTC study "Generic Drug Entry Prior to Patent Expiration" recommended changes to the provisions of the Hatch-Waxman Act governing generic drug approval prior to patent expiration. The Report is available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

42. Julie Appleby and Jayne O'Donnell, *USA Today*, "Consumers Pay as Drug Firms Fight Over Generics," June 6, 2002.

43. Chris Adams and Gardiner Harris, "Drug Firms Face Growing Pressure Over Extensions of Their Patents," *Wall Street Journal* (online), March 19, 2002, available at http://www.chelationtherapyonline.com/technical/p15.htm.

44. In 1988, over 170 members of the Chemical Manufacturers Association of the United States adopted industry wide Guiding Principles of a "Responsible Care" program. They were published in full-page ads in the *New York Times* and the *Wall Street Journal* on April 11, 1990. Since then companies in other countries have adopted the code. See De George, *Business Ethics*, 527.

45. Amir Attaran and Lee Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?" *Journal of the American Medical Association* 286(15): 1886–92 (October 17, 2001) (at http:/mail.iipi.org/db/news/detail.asp?itemID=45), suggest that "Brand-name pharmaceutical companies might also consider adhering to a code of practice, in which they agree to voluntarily license patents for important medicines (antiretroviral drugs and others) to high-quality generic manufacturers willing to supply at low prices" (1891).