

# Intellectual Property and Pharmaceutical Drugs: An Ethical Analysis

---

*Richard T. De George*

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.

## THE MORAL JUSTIFICATION OF INTELLECTUAL PROPERTY

Because intellectual property is significantly different from other kinds of property,<sup>1</sup> the ethical defenses of intellectual property differ from the defenses—such as the Lockean—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 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 economist 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 giveaway 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.

## THE LIMITS OF THE STANDARD ARGUMENT

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.

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. 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. . . .

## 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 challenge 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 lifesaving drugs; 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 lifesaving 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.

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.

Although there are a number of different rights included in this sentence, for our purposes two are central. One is the right to health; the other is the right to medical or health care. 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. 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 caregivers, 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. 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. 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.

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. . . .

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 lifesaving 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. . . .

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."

## 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.

### 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 lifesaving 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 lifethreatening 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 7 years of exclusivity (after FDA approval) to encourage drug makers to develop drugs that affect fewer than 200,000 people and are generally unprofitable. The result has been, on the whole, positive, despite abuses. . . .

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 worldwide is a topic that urgently needs addressing. 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 result 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.), that the amount may even be less than the amount it spends on lobbying government officials; 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. 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 3 years of market exclusivity) and 11 percent were identical to existing drugs.<sup>2</sup> 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 lifesaving drugs seriously, then one might

consider changes in the status quo with respect to IP. Essential, lifesaving 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. . . .

### 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 lifesaving 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 lifesaving 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 lifesaving drugs is maximizing corporate profit.

- (a) Let us look at the poor countries first. The question of access to many 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. 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 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. 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 40 companies filed suit. After much adverse publicity, the charges and the suit were withdrawn. 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 needed 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. 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. . . .

- (b) As opposed to poor countries that cannot afford drugs, the United States can afford to pay for drugs. In fact the United States both pays more for drugs and contributes more to the profit of the pharmaceutical companies than any other nation. 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, 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 United States 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. . . .

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. 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.<sup>3</sup> The lack of adequate transparency exacerbates the communication gap and hinders fruitful dialogue. Abuses and attempts at gaming the system further erode trust. . . .

*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. 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. . . .

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. . . .

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 guaranteeing 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. . . .

## 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. NIHCM, "Changing Patterns of Pharmaceutical Innovation," p. 3 at <http://www.nihem.org/innovations.pdf>.
3. 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 10 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](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](http://www.citizen.org/congress/reform/drug_industry/r_d/articles.cfm?ID=9923)).