

Intellectual Property and Pharmaceutical Drugs: An Ethical Analysis

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The Moral Justification of Intellectual Property

Intellectual property is a contested notion in some parts of the world. Nonetheless, there are sound moral arguments of a general sort that justify legal protection of intellectual property for a limited period of time before it falls into the public domain. This includes patent protection and applies to pharmaceutical drugs as well as to other inventions, processes, etc.

The Standard Argument (SA)

What I shall call the Standard Argument has two parts:

A. Fairness. The fairness argument says that it is unfair for someone to free ride on the work of another. If some company invests time and money in developing a product, then it should have a protected period of time in which it can try to recoup its investment and make a profit. For any other party to copy that product immediately upon its appearance and sell it more cheaply because it has no development costs to recoup is unfair.

B. Encouragement of new products (common good)

This argument gives a utilitarian justification of limited protection of intellectual property. If individuals or companies are not given a period during which they can recoup their investment costs and make a profit without unfair competition from free riders, they will have no incentive to produce new products. Society benefits from new products. Therefore society is justified in providing the incentive that protection of intellectual property provides. Such protection promotes the common good.

The Status Quo Approach (SQA)

The pharmaceutical industry defends its patents and its development and marketing practices by utilizing the Standard Argument. But the SA does not lead to specific patent laws. The industry therefore justifies its practices not by ethical argument but primarily by legal and economic arguments. These set the parameters for its policies and the defense of its practices. To these it adds the notion of social responsibility as a surrogate for ethical responsibility.

The Limits of the Standard Argument

The SA and the SQA are often taken to justify more than they are capable of justifying with respect to pharmaceutical drugs.

Intellectual Property Rights Only a Prima Facie Right

This means that intellectual property rights are to hold sway and be enforced unless they run up against other rights claims that take precedence over them. In general, rights trump interests. In most instances, intellectual property rights hold sway because there are no strong competing rights. For instance, people do not have a right to a better mouse trap or to faster computers, even though they may have an interest in having these.

Other Pertinent Prima Facie Rights: the Right to Adequate Health Care, and the Right to Access to Essential Life-saving Drugs

The situation is different when we come to pharmaceutical drugs, however, because there are other strong competing rights. The issue then becomes whether intellectual property rights trump these or are trumped by them. Different societies weigh and balance these competing rights in different ways, and in differing circumstances one or another of the rights may properly trump the other.

Other Ethical Considerations: the Obligation to Aid Those in Need and Competing Claims Made in the Name of the Common Good

In addition to rights there are other ethical considerations that come into play. Pharmaceutical companies as part of the broader health care industry have some obligation to aid those in need (even if they do not bear that obligation alone, and it is shared by governments and others). There are also claims made on the basis of the common good, which is broader than simply a claim to more goods or drugs.

The SA and SQA, moreover, do not provide any right to price goods at any level a company wishes and they do not guarantee profits. Claims made by pharmaceutical companies with respect to these require arguments other than the SA.

The Communication Gap and the Failure to Communicate

Gaps:

- the pharmaceutical industry and the general public;
- rich countries and poor countries
- within the US, industry and the elderly and poor;
- on national and international level

The pharmaceutical industry has in recent years come in for a lot of criticism and bad press in the U.S. and elsewhere. It has not responded well to its critics, and each side seems to speak past the other. There is little engagement, and each side seems endlessly to repeat its own position. This failure to communicate can be traced, at least in part, to the fact that the two sides couch their arguments and responses in different languages.

***Languages: the Language of Ethics (rights, justice, common good)
the Language of Economics and Law***

Critics put their complaints and criticisms of the industry in terms of the rights listed above, or in terms of justice, or in terms of the common good. This is ethical language. The industry responds in terms of the SQA, which is economic and legal language. For instance, in reply to the high cost of drugs which limits access by the poor, the answer is that the cost is justified because unless the companies make a profit they will not invest in R&D and there will be no new drugs. This argument is repeated in various ways to all criticism raised by critics. The answer does not speak to the ethical dimension of the criticism. Hence there is a failure to communicate. The industry asks what it should do within the legal and economic parameters of the status quo. The critics ask how the status quo might be changed to better respect and recognize the rights of patients and the common good.

The Social Responsibility Shortfall

Despite its stated defense, the industry feels the public pressure to respond in some way to the right to access by the poor to life-saving drugs. Rather than adopt an ethical set of guidelines, it substitutes the notion of social responsibility.

Social Responsibility not the Same as Ethical Responsibility or Obligation

But social responsibility is not the same as ethical responsibility. Social responsibility is whatever a given company wishes to do in the way of what are perceived as good works. What companies do in the name of social responsibility is usually praiseworthy and is rightly encouraged. But an improper use of social responsibility is using it to deflect attention from ethical responsibility or to use it as a substitute for ethical responsibility.

Social Responsibility: Decided by the Industry or Company Ethical Responsibility or obligation: not Determined by Industry or Company

Companies adopt different programs of social responsibility and control what they do and the extent to which they do it. There is no external principle that dictates what their social responsibilities are. They may decide to give drugs away without charge to the poor in one country for a certain disease and not give drugs away in another country for another disease. The decisions are not taken on some stated principle, but frequently in response to public pressure. Ethical obligations, on the other hand, are not decided on by individual companies. External agents can therefore make ethical claims on a company. A response requires the invocation of some ethical principle. But the adoption of ethical principle commits one to certain actions.

Critics rightly claim that the language of social responsibility makes actions, such as donating drugs without charge to the needy poor, an act of charity. The language of rights and justice, however, imposes obligations of justice. Replacing justice with charity produces an ethical shortfall.

Patent Strains and Pharmaceuticals: Not all Intellectual Property is Created Equal

The U.S. patent laws treat all intellectual property covered in a similar manner. The patent for the one-click business method on the Internet gets the same protection as a life-saving drug. Yet the one is claimed by many in computing to be obvious, while the drug takes an enormous investment of time and money to develop, and may receive actual protection for only the ten year period after it is finally approved.

A. Pharmaceutical Products Special

A case can be made that pharmaceutical drugs are special for a number of reasons. One is their importance to the general public. Another is the relatively short time after approval within which to recoup expenses and make a profit. The number of special provisions in law made for drugs indicates that they do not fit comfortably within the patent system. Critics call for a change.

Hatch-Waxman Act

This is one example of special legislation to handle special drug-related issues.

Orphan Drug Act

This is another example. Orphan drugs have increased dramatically in number under this legislation, which has been copied (with some modifications) in Europe and elsewhere. This might serve as a model for how the government can promote life saving drugs.

WTO

Although the U.S. pressed less developed countries such as India to change its patent laws to cover pharmaceutical drugs, it recognized the legitimacy of compulsory licensing under certain conditions. This is an exception to general patent laws and again shows the need for special treatment for drugs.

B. Not All Pharmaceutical Products are Equal

Not only are drugs different from other products or processes covered by patent, but not all drugs are equal. Countries such as Australia recognize this difference. The U. S. would do well to do so as well. Much criticism stems from what are seen as abuses of the system. The complaints are not primarily addressed to new life saving drugs but to others.

Essential and break-through drugs

These drugs deserve protection and the government might consider ways to provide additional incentives to encourage pharmaceutical companies to concentrate on these. Possible approaches include following the model of the Orphan Drug Act or underwriting R&D or providing greater tax advantages for developing these drugs or for in some way guaranteeing profits.

Me-too Drugs

These drugs are clearly in a different class from the break-through drugs. The essential drug is already available. These copycat drugs do not deserve the same protection or the same incentive sets.

Cosmetic Drugs, Patents, Extensions and Trivial Modifications

These come in for the most criticism by critics. The various techniques of attempting to extend patent protection, from the use of Hatch-Waxman to

introducing minor modifications in a drug are either borderline unethical or deserving of much less protection than the essential drugs.

B. Need for Change

All of this reinforces the claim that the present patent system of one-size-fits-all can and should be rethought and present legislation modified with respect to essential drugs.

The Lack of Transparency in Pricing: IP and Patent Rights Do Not Guarantee Freedom in Pricing

The SA and the SQA do not say anything about pricing. The U.S. has not attempted to control prices and has let the market operate freely. But it can be argued that with respect to life-saving drugs there is market failure in the area of essential drugs. The drug industry sets up a false dichotomy: either freedom to set prices or fewer drugs developed.

AIDS Drugs in Africa

All parties admit that although prices are not the only factor making drugs unavailable to many who need them, price is one factor. Some drug companies have programs under which they give away needed drugs. But they have come to this only after much criticism. The give-away programs, as noted above, fall under charity (social responsibility) rather than any response to claims of justice or rights.

Canada, Europe and U.S.

Canada and the EU nations are developed countries. Yet people there pay less for drugs made in the U.S. than do those in the U.S. The reason is that unlike the U.S. government, the other governments negotiate prices. The pharmaceutical industry has spent enormous sums lobbying Congress to prevent legislation that would allow the government to negotiate prices.

U.S.'s Subsidizing the World Requires Justification

The result is that the U.S. subsidizes not only drugs in less developed countries but also drugs in developed countries. This is clearly unjust. It is ironic that U.S. drugs cost more in the U.S. than in almost any other country in the world. The move to import U. S. drugs from Canada follows as a reasonable consequence. If the U.S. did not subsidize drugs in the way it does for other developed countries,

drug companies would have to charge countries like Canada and the EU nations more. These countries would have to bear their fair share. Such countries might well not pay more for me-too and marginally improved drugs. That would be the market at work and would send the proper signals to the industry. They would pay, just as the U.S. would pay, for essential drugs. But all nations might require more in the way of transparency with respect to drug pricing.

The Inadequacy of the Status Quo Approach to the Justification of Profits

Standard Argument only Works as Justification of High Profits if Link is Clear and not Simply Claimed or Inferred

Just as there is a lack of transparency in pricing, there is a lack of transparency with respect to profits. The industry repeats over and over that without large profits there will be fewer needed drugs. But some studies show that the profits do not go primarily to R&D and that more goes to lobbying than to R&D. The justification for the high profits has to be taken on faith. But that faith wears thin in the light of abuses of various kinds and the attempt of some drug companies to keep profits up by questionable means.

Profits Before the WTO Doha Round

The drug companies emphasize the need for profits and strong intellectual property protection in WTO negotiations. But prior to such negotiations, the drug companies showed excellent profits. The industry trades on the general SQA rather than being more forthcoming about its profits and their relation to new drugs. The general link is fairly obvious. But the specific cases are not. That the industry needs to be the most profitable year after year because if it were not people wouldn't buy its stock is a claim that has not been tested. Developing new drugs is costly and there are many drugs that never make it to market. But these general truths do not lead to the strong conclusions made about profits by drug companies.

The Right to Access and IP

We have already noted that the right to intellectual property is only prima facie and comes up against other rights claims. One of these is the right to access. This can be derived from the right to life and the right to adequate health care to preserve life. Part of this is the right to those drugs necessary to preserve life, if they are available.

Right to Adequate Health Care and Concomitant Right to Access to Essential Drugs vs. IP Rights

How the conflict of these rights plays out will vary somewhat according to what the society and its members can afford, as well as what drugs are available. Clearly no one has a right to drugs that are not available. In some cases, when the drug is available but not affordable, then the obligation to aid those in need comes into play.

Obligation of Those Who Can Help to do so

This is a general and widely recognized obligation. When applied to access to needed drugs it places obligations on many parties. Exactly who has what responsibility cannot be answered in a blanket way. But the following have varying degrees of responsibility:

Individuals,
Governments,
NGOs,
International Organizations and the
Pharmaceutical Industry

Conceived in this way, aid and (indirectly) access are matters not of charity but of ethical obligation.

The Common Good and Patents

Considerations of the common good are another source of limitation to intellectual property rights, as we have already seen.

A. Common Good Considerations and Requirements for Patents

Patent law is very complex and is not deducible from any set of ethical principles, even though it does not violate them. Typically patent law in the U.S. is developed in committee with special hearings from what are considered the interested parties. These usually are corporations or industries with various vested interests, and a compromise is worked out. Committee recommendations are then voted on by Congress. Critics raise the question, however, of who

represents the interests of the general public? Who speaks for the people? Is the common good considered explicitly, and if so how? Common good considerations form part of the Constitutional justification for patent protection and yet seem to play no role in what legislation is passed.

B. Common Good Considerations not Equated Simply with the Production of More Inventions

Contrary to the SQA, each society has to decide what it can afford in the way of health care. Even in the U.S. the cost of drugs and of health insurance has become so high as to raise concerns. In less developed countries it is not clear that strong IP protection overrides common good considerations. If it costs \$800,000,000 to bring a new drug to market, that may simply price new drug development (and so the need for strong protection for new drugs) out of reach for such countries. Nor is it the case in any country that patients have a right to drugs no matter how expensive. Although the common good is served by the production of new drugs, that is not the only consideration with respect to the common good.

An International Code for the Pharmaceutical Industry

In seeking a solution to the drug industry/general public gap, I have suggested that the industry start by replying to critics in ethical terms. I believe it can do so in many instances successfully. I have suggested changes in patent laws so as to distinguish essential from me-too drugs. I have suggested more transparency in pricing and in defense of profits. Finally, the industry might consider an international code, similar in some ways to the code adopted by the chemical industry after the criticism it received following the Bophal disaster. Its purpose would be to prevent and address ethical abuses by companies in the industry, and so preclude restrictive legislation. Such a code should be:

Developed and Agreed upon by the Pharmaceutical Industry

The code should not be imposed on the industry but developed by it. Clearly, however, 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.

Monitored by Independent Auditors

To be taken seriously by the public, the companies in the industry should be willing to be monitored by independent auditors as to whether or not 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.

Reestablish Public Trust and Confidence.

The general public has lost confidence in the drug industry. The above suggestions are possible ways for the industry to regain that needed trust.

Conclusion

Intellectual property rights in drugs deserve enough protection to promote the common good. Existing structures are under great strain because system is failing to do this. The structures also do not give enough scope to other rights claims that may in cases override IP rights with respect to essential life-saving drugs. Attempted changes so far within existing structures are insufficient to remedy the deficiencies. The pharmaceutical companies can do only so much individually 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, and in the process to serve the common good. They can also as an industry take positive steps to restore the public trust they have lost.