Three Reasons Why a Global Market in Pharmaceutical Products Is Inherently Unjust

Søren Holm

> Ideas and knowledge are an increasingly important part of trade. Most of the value of new medicines and other high technology products lies in the amount of invention, innovation, research, design and testing involved.[1]

> Is it true that the intellectual property (TRIPS) Agreement protects mainly the intellectual property of large multinational firms—the big pharmaceutical companies, firms producing seeds and other agricultural inputs? Will the TRIPS Agreement worsen inequalities? After all, the developing countries did not want to negotiate intellectual property?
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> Developing countries are not only users of foreign intellectual property. They are also producers and could gain from intellectual property protection. Many were already introducing intellectual property protection regimes before the end of the Uruguay Round.
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> Also, it is in the nature of GATT/WTO negotiations that all participants are expected to make contributions. Each country makes concessions in certain areas of the negotiations in order to obtain what it wants in other areas.
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> Developing countries were not demandeurs in the Trade-Related Intellectual Property Rights (TRIPS) negotiations, but their acceptance of the TRIPS agreement was an important contribution to the success of the Uruguay Round and the creation of the WTO—which they clearly consider to be in their interests, given that most either already are full members or are seeking to join."[2]

Introduction

With the establishment of the World Trade Organisation (WTO) and the conclusion of the Trade-Related of Intellectual Property Rights (TRIPS) agreement, the global market for pharmaceutical products is going to undergo fundamental changes between now and 2010. In 2010 all member states of the WTO will have to provide uniform product and process patent regulations for pharmaceutical products, including a minimum of twenty years patent protection (or twenty-five years in cases where the time between patenting and possible marketing is extended), and "national

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treatment" for all patent applications. This will have a limited impact in Europe and North America, where such patents are already recognised, but will have a major impact in the developing countries, many of which have had no patent protection for pharmaceuticals or only process patents.

The TRIPS agreement further lays down stringent limits for compulsory licensing (Article 31). These conditions do, inter alia, specify that patent rights shall be enjoyable without discrimination as to the field of technology and whether products are imported or locally produced (Article 31 in conjunction with Article 27.1). This means that the fairly widespread practice of allowing compulsory licensing if a patent holder does not exhibit local "working" of the patent will be illegal under the TRIPS agreement.[3]

Within the general WTO framework, with its strong emphasis on free trade and the removal of all other trade barriers than tariffs, it will further be the case that all countries will have to open up their markets for import of pharmaceutical products to a larger extent than they do today.

In this paper I will try to analyse this new situation seen from a justice perspective. This will involve giving an answer to three questions:

1. How are benefits and burdens distributed under the new patent system following TRIPS?
2. How will an opening of markets in pharmaceuticals and the abolishment of local working requirements affect the distribution of pharmaceuticals?
3. How will the WTO framework affect attempts at rectifying problems in the distribution of pharmaceuticals?

I am not the first to raise these issues. They have been raised by the World Health Organisation (WHO),[4] by some governments and by many nongovernmental organisations (NGOs),[5] but I think that they nevertheless merit some sustained philosophical attention.[6]

The Purpose and Function of Patents

Patents are a specific form of protection of intellectual property. A patent is in essence a time-limited monopoly right in an invention. Patents were "invented" in the fifteenth century and were introduced into law in most industrialised countries in the eighteenth and nineteenth centuries. For an invention to be patentable it most in general fulfil four requirements:[7]

1. It must be new (novelty) and nonobvious.
2. It must have industrial application.
3. There must be an inventive step.
4. It must not fall under a specific exclusion from patentability.[8]

A patent can cover either a product (in the present context, for instance, a specific molecule with desirable pharmaceutical properties) or a process (for instance, a specific way of producing a given molecule). Product patents give stronger protection than process patents, since they block all

competitive uses of the same product, whereas process patents only block competitors from certain ways of producing the product. When a patent is granted, the holder of the patent is required fully to disclose the content of the patent so that "anybody skilled in the art" can produce the product in question on the basis of the disclosure.

Patents are in general theorised to have a number of beneficial social and economic effects:

1. Patents speed up the rate of invention, by increasing the economic benefit to the inventor, and thereby increasing the incentive to invent.[9]
2. Patents lead to disclosure of knowledge that would otherwise be kept secret, and they thereby ensure that there will be competition when the patent expires.

It is thus theorised that a society with a patent system will have greater economic growth than a similar society without a patent system. This conclusion is supported by economic theory, but it has, like many other large-scale economic hypotheses, been very difficult to substantiate with empirical evidence.

For certain kinds of inventions that involve an extended and costly development period between invention and marketing (as is the case for pharmaceuticals), there is also a plausible argument that inventions will be developed to final products only if there is a reasonable degree of certainty that the costs of development can be recouped and that patents are one way of offering such certainty.

What Are the Effects of Allowing Global Product Patents on Pharmaceutical Products?

The organisation of the present global pharmaceutical industry is not monopolistic (there are no one or two dominant firms in the industry), but it is an industry that is very heavily concentrated in the developed countries. Among the world's twenty largest pharmaceutical companies, nineteen are incorporated in the United States, the European Union, or Switzerland, and one (number 19) is incorporated in Japan.[10] The largest of these twenty firms (Merck) had annual sales of $15.3 billion in 1998, and the smallest had annual sales of "only" $4.6 billion. In comparison, the annual gross national product (GNP) of Zimbabwe was $8.6 billion and the GNP of Kenya $9.3 billion in 1997.

If we use sales as a rough guide to research budgets in the pharmaceutical industry we can safely predict that most pharmaceutical patents taken out by industrial firms will be taken out by firms from the developed countries. Since governmental expenditure on medical research is also much larger in the developed than the developing countries we can also predict that publicly held patents will also primarily be held by institutions in the developed countries. After the full introduction of the TRIPS agreement these patents will be enforceable in most of the world. This is not necessarily a problem if the benefits generated by these patents are distributed in a way that does not primarily benefit the developed countries.

Benefits to developing countries from patents could be of several kinds:

1. Lower drug prices
2. Better access to drugs
3. Development of local pharmaceutical industry and its research and development (R & D) capacity
4. Placement of production plants of multinational firms in developing countries
5. Income from patents
6. More research on tropical and other third-world diseases
7. Other kinds of redistribution of wealth (e.g., "trickle down")

Are these positive effects likely to occur? Some critics clearly say "no." Correa, for instance, concludes that

> [a]lthough patent protection of pharmaceutical products will be enhanced this will not necessarily be to the benefit of all countries; it is likely that local production in developing countries will increasingly be replaced by imports of finished products, i.e. trade in drugs will increasingly replace direct foreign investment and the granting of licences to local companies; an increase in research and development of new drugs will not take place in either developed or developing countries.[11]

What is the basis for this negative assessment of the possible beneficial effects of TRIPS? With regard to drug prices and access to drugs it is highly probable that access will increase in a specific sense because companies will be more willing to market drugs in markets where they have patent protection. More drugs will therefore be marketed, and people, even in the poorest countries, will therefore have "access" to more drugs (and in some cases to more effective drugs) than they had before. But this is not real access if the drugs are still priced so that they are practically unavailable at the average level of income in a given country. That the three drugs that are components of standard HIV triple therapy are marketed in a given country does not, for example, mean that there is real access in that country to HIV triple therapy, if it is only affordable for the country's most wealthy citizens.

The welfare implications of WTO and TRIPS in the pharmaceutical sector have also been analysed from an economic perspective, and a number of authors concur in the conclusion that the total welfare effects are likely to be negative for the inhabitants of developing countries, whereas patent holders are likely to gain.[12] These negative effects are denied both by the pharmaceutical industry and by the WTO itself, which states: "The TRIPS agreement itself will not have a major impact since pharmaceutical patent protection is now standard in most countries and only a few essential drugs will be affected."[13] This defence is, however, rather disingenuous. That most countries have brought their patent legislation in line with TRIPS before it has entered into force does not show that they would have made these changes if TRIPS had not been coming and if acceptance of TRIPS had

not been a prerequisite for WTO membership. It is true that few drugs on the WHO list of essential drugs will be affected, but this is not because only a few important drugs will be affected.[14] For a drug to get on the list of essential drugs, three factors are considered: public health need, therapeutic value, and cost. This simply means that even a moderately expensive drug will not get on the list, even if it is the only drug with therapeutic value against a particular disease that is a recognised public health problem. For this reason there are very few essential drugs still under patent protection, since patented drugs tend to be too expensive.

With regard to development of local research or other positive research developments, the negative assessment also has a number of justifications. First, it is based in an assessment of the current track record of the pharmaceutical industry. Of the 1,223 new pharmaceutical compounds introduced into the market between 1975 and 1997, only eleven were designed for tropical diseases (and these eleven include drugs for malaria, for which there is a substantial tourist market).[15] There are no immediate reasons to believe that this pattern is going to change, since the projectable economic benefits of investing in research directed toward health problems in first-world countries in almost all cases far exceed any alternatives involving research in tropical diseases.

Second, the current local pharmaceutical industry in the developing countries is often geared toward the production of generic copies of patented drugs, and its R&D efforts have traditionally been directed toward finding new processes for the production of known compounds (since most developing countries did not allow product patents but only process patents on pharmaceuticals). It is unlikely that local industry can change R&D focus within a few years and develop the highly specialised and trained research workforce that de novo pharmaceutical research requires. And even if these researchers were trained it is not unlikely that many of them would follow the route of their clinical colleagues and join the mass migration of health professionals from the poor to the rich countries.[16]

Third, there seem already to be moves by the international pharmaceutical industry to attempt to patent the active ingredients in indigenous plant medicines. If these patents are recognised it will immediately raise the price of traditional medicines, which will no longer be able to be sold freely.

TRIPS Article 39: Restrictions on the Use of Commercially Valuable Information

In a previous section it was pointed out that one of the traditional advantages claimed for patents is that because of the disclosure element of a patent, a patent ensures that if an invention is commercially valuable competitors are in a position to market the product, and thereby create true competition, as soon as the patent runs out. Article 39 of the TRIPS agreement may, however, erode this justification for patents as far as pharmaceutical products are concerned. Subsections of this article require member governments to protect undisclosed test data and other data whose submission is required by governments as a condition of approving the marketing

of a pharmaceutical product that uses new chemical entities. The United States has relied on this article to argue that countries are obligated under TRIPS to prevent generic drug companies from relying on data, scientific publications, or foreign government approval obtained or produced by the original patent holder, unless the original patent holder as "owner" of these data gives permission. On this interpretation of Article 39, the original patent holder can force generic drug producers to perform a full toxicological and clinical test program to fulfil registration requirements, and since such a testing program can begin only after the expiration of the patent, this will (1) lead to long delays in registration of generics and the establishment of competition and (2) impose very large costs on producers of generics and thereby raise the costs of pharmaceutical products considerably after the expiration of the patent period. Since both these effects are to the benefit of the original patent holder, it has no incentive to give permission to other firms to rely on any of its data. Article 39 in TRIPS therefore potentially vitiates one of the major justifications for patents.

Bolar Exceptions and Limitations on the Exhaustion of Patents

The literature on the effects of TRIPS on the global trade in pharmaceuticals suggests that two possibilities for national patent legislation open under TRIPS may alleviate some of the negative effects of the agreement in the developing countries. One is the introduction of so-called Bolar exceptions in patent laws; the other is adoption of the principle of "international exhaustion" of patents.

A Bolar exception in national patent legislation excepts from coverage under patent law scientific research and experiments involving the patented invention as well as tests carried out before the expiration of the patent to establish bio-equivalence of a generic drug from patent protection.[17] Bolar exceptions thus allow a national pharmaceutical industry to get ready to produce the product, or some new product developed from the original product, as soon as possible after the patent has expired. It is, however, at present unclear how the restrictions in TRIPS Article 39 discussed above and the possibility of allowing Bolar exceptions according to Article 8, Sections 1 and 2, will be balanced by the WTO. If both articles are interpreted in a way that benefits the developing world, quite wide-ranging Bolar exceptions could be envisaged, but they would in all circumstances only help to reduce the time between the expiration of a patent and the marketing of the first generic version.

The issue of the exhaustion of rights is, according to TRIPS, a matter for national legislation (footnote to Article 28, referring to Article 6). This means that a given country can choose to have either no exhaustion, international exhaustion, or national exhaustion of patent rights.[18] If no exhaustion is applied, it means that the patent holder has a monopoly not only on production, but also on importation or sale. If national exhaustion is applied, the patent holder has a monopoly on production and importation, but not on sale. If international exhaustion is applied, the patent holder has a monopoly only on production and cannot claim any exclusive rights in cases where

the product is imported from a market where it is marketed with the producer's consent. By choosing to apply international exhaustion in its patent laws, a country thereby makes it possible to legally carry out parallel importation from other countries where the drug is cheaper. Initially this may seem like a good strategy, but it may well in the end be self-defeating if applied by any other countries than the poorest. Let us imagine that a given pharmaceutical company for altruistic (or public relations, or self-interested, etc.) reasons has segmented its markets in three segments, with high prices in affluent countries, medium prices in less-affluent countries, and low prices in developing countries. Such a company will get most of its profits on any particular drug in the high- and medium-price segments. If too many countries in these segments introduce international exhaustion clauses in their legislation the firm would for economic reasons have to do one of two things: (1) stop marketing the drug in the lower segment (but this might lead to compulsory licensing) or (2) raise the price in the lower segment to comfortably profitable levels. Applying international exhaustion is thus, in a global liberalised market, not likely in the long run to lead to lower prices. International exhaustion could only work if the richer countries did not apply it.

I thus agree with the authors indirectly quoted in the WHO report *Globalization and Access to Drugs* who conclude: "According to other authors, the effect of international exhaustion of rights would be for right holders to move towards a single worldwide price for their products, which they would be likely to seek to set at the price that the market can bear in the wealthier countries."[19] It is thus highly unlikely that Bolar exceptions and international exhaustion of patent rights will do much to alleviate the general negative effects of TRIPS in the developing countries.

Justice in an Unjust World?

There can be no doubt that the present distribution of wealth in the world is unjust, seen from the perspective of any account of justice that is worth the name. On justice accounts that claim that we can evaluate a given distribution directly, this is uncontroversial. But even on libertarian accounts of "justice," which deny this, a distribution of wealth is legitimate and just only if it has been arrived at via a process involving just or legitimate acquisition and transfer of goods. If there has been illegitimate acquisition or transfer, compensation must be made for these wrongs. Now we may not be able to give a detailed account of the specific illegitimate actions leading to the present skewed distribution of wealth and may therefore not be able to devise a perfect scheme of redistribution, but this does not detract from the conclusion that the present distribution is unjust. Unfortunately we live in a world where many people are willing to accept this conclusion but at the same time willing to live with the consequences. In some cases it is because they genuinely believe that this permanent state of injustice cannot be changed, in other cases because such a belief is in their interest.

With regard to the situation of the trade in pharmaceuticals after the establishment of the WTO and the establishment of the TRIPS agreement

we are therefore in a situation in which developments on the international scene have made (and will continue to make) an already unjust world even more unjust. How should we assess this situation from an ethical point of view?

At the most formal level our rules about justice tell us only to treat similar cases similarly and dissimilar cases dissimilarly, and at this formal level it may initially seem as if the equal recognition of patents in all countries is a victory for equality and justice. For isn't it the case that a patent is a patent no matter where it is issued? On closer analysis this claim does, however, fall through. Patents are socially constructed permissions given to certain persons (in both the natural and the legal sense), because this construction is believed to have positive social benefits. We do not give out patents because there is a natural right to have your inventions protected; we allow them because they are supposed to lead to greater innovation and thereby greater wealth. But with the WTO and the TRIPS agreement we have created a situation where the recognition of patents is highly likely to have exactly the opposite effect in many WTO member states. Equal patent protection is therefore not similar treatment of similar things and not supported by any formal justice considerations.

If we then move to more substantive accounts of justice, we see that no account of justice that is interested in end-states can find a transition in which the gap between those who have and those who do not increases to be a positive transition, unless those who do not have are better off than they were before. On a Rawlsian account of justice, such a transition could be just, if it were to the benefit of the least well off. It is notoriously difficult to define "the least well off" within a Rawlsian framework, but this is not a problem that need delay us here, because it is not very likely that the TRIPS agreement is to the benefit of any of those who could fall in the group of the least well off. All end-state conceptions of justice must therefore condemn the TRIPS agreement for its negative justice effects.

But what about libertarian and other accounts that are not interested in end-states, but only in the processes of acquisition and transfer of wealth? Again it may initially look as if these accounts could justify TRIPS, because as the WTO itself states:

> Also, it is in the nature of GATT/WTO negotiations that all participants are expected to make contributions. Each country makes concessions in certain areas of the negotiations in order to obtain what it wants in other areas.
> Developing countries were not demandeurs in the Trade-Related Intellectual Property Rights (TRIPS) negotiations, but their acceptance of the TRIPS agreement was an important contribution to the success of the Uruguay Round and the creation of the WTO—which they clearly consider to be in their interests, given that most either already are full members or are seeking to join.[20]

It could thus be argued that the developing countries sold certain rights under TRIPS in return for certain rights in other parts of the WTO

framework. The advantages the developed world gains under TRIPS are therefore justly acquired (paid for by other concessions), and the situation after TRIPS therefore perfectly just (or at least not more unjust than before).

But even if this argument is valid, the TRIPS agreement contains elements that are contrary to standard libertarian theory. Here we need to remember that the area covered by patent law is very broad and extends beyond "pure inventions." It is possible to patent inventions that most ordinary people would call discoveries, for instance, substances purified from natural sources. In such cases the correct analysis could be that we are here talking about initial acquisition of wealth from nature. Just as the first farmer or the first miner could only justly acquire land de novo if there was "as much and as good left" for others (the famous Lockean proviso), so the modern exploiter of nature should perhaps be allowed to patent natural substances only if there is as much and as good left for others. This analysis of certain kinds of patents seems to show that at least some kinds of patents amount to unjust acquisition of common goods and that either such patents should be banned, or the patent holders should be forced to pay compensation. Even libertarians therefore have reasons to be sceptical towards TRIPS, and this scepticism should perhaps be even stronger if they consider that most pharmaceutical development in the future will flow from the results of the human genome project, a project analysing a finite resource in which the Lockean proviso is again violated. If after some years international companies hold the patents on most human gene sequences, then there is simply nothing left of this resource to patent or utilize for the researchers in developing countries.[21] We can therefore conclude that the TRIPS agreement is in its present form unjust and thereby unjustifiable with regards to the implications of its provisions on the patenting of pharmaceutical products.

Notes

[1] WTO, *Trading into the Future—WTO: The World Trade Organisation*, 2nd ed. (Geneva: WTO, 1999), p. 25.

[2] Ibid., p. 59.

[3] On local "working" requirements, see W. Lesser, *Equitable Patent Protection in the Developing World—Issues and Approaches* (Christchurch, New Zealand: Eubios Ethics Institute, 1991).

[4] See, for instance, Resolution WHA52.19, "Revised Drug Strategy," adopted at the 52nd World Health Assembly, 1999.

[5] See, for instance, the "Open Letter to the WTO Member Countries on TRIPS and Access to Health Care Technology," sponsored by Health Action International, Médecins Sans Frontières, and the Consumer Project on Technology <http://www.haiweb.org/campaign/novseminar/WTOletter.html>.

[6] For a useful bibliography see G. Velásquez and P. Boulet, *Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement* (Geneva: WHO, 1999).

[7] *Intellectual Property Law*. London: Cavendish, 1999.

[8] For instance, "those which, by publication or exploitation, might result in offensive, immoral or anti-social behaviour"; ibid., p. 27.

[9] However, most patented inventions are never exploited. See C. T. Taylor and Z. A. Silberston, *The Economic Impact of the Patent System* (Cambridge: Cambridge University Press, 1973).

[10] *The Observer*, 14 November 1999, Business, p. 2.

[11] C. M. Correa, "Patenting pharmaceuticals: A new global order," *Essential Drugs Monitor* 22 (1996): 20. A more extended argument can be found in C. M. Correa, *Uruguay Round and Drugs* (Geneva: WHO Task Force on Health Economics/Action Programme on Essential Drugs, 1996).

[12] J. Nogues, "Social costs and benefits of introducing patent protection for pharmaceutical drugs in developing countries," *The Developing Economies* 31, no. 1 (1993): 24–53. A. Subramanian, "Putting Some Numbers on the TRIPS Pharmaceutical Debate." *International Journal of Technology Management* 10, no. 2–3 (1995): 252–68.

[13] WTO, *Trading into the Future*, p. 59.

[14] "Important" here meaning effective against life-threatening, disabling, or extremely unpleasant diseases or conditions.

[15] A. Donald, "Political economy of technology transfer," *British Medical Journal* (1999) (319): 1298.

[16] For the scale of this migration see *World Health Report 1998* (Geneva: WHO, 1998).

[17] Correa, "Patenting pharmaceuticals."
There is a current dispute before the WTO between the European Union and Canada with regard to the second component of the Bolar exception, especially since Canadian law allows manufacturers of generic drugs to manufacture and store their version of the drug before the patent expires.

[18] Regional exhaustion within a free-trade zone is also a possibility.

[19] Velásquez and Boulet, *Globalization and Access to Drugs*, p. 25.

[20] Ibid., p. 59.

[21] This also holds if the patents belong to governments in the developed world.