

The WTO and Pharmaceutical Access in Developing Countries

Rachael Smith

University of Essex

Abstract

The WTO attempts to make pharmaceutical products available to developing countries through the inclusion of specific clauses in Intellectual Property legislation enforced through this international organisation. These agreements allow greater access to pharmaceuticals, as well as actively encouraging developed countries to develop such drugs. However, this legislation is not hugely effective, particularly in countries without the necessary infrastructure to domestically manufacture these drugs. Blame can be laid at the feet of the Multinational Companies which produce these pharmaceuticals and yet they act as any profit maximising firm does in a capitalistic economy. Research and development into pharmaceutical products is a global public good, and it therefore falls to the governments of the developed world, and organisations such as the WTO, to more forcefully legislate in an effort to help developing countries afford vital pharmaceutical products and provide financial incentives to encourage the development of drugs to combat issues specific to poorer countries.

Keywords: WTO; pharmaceutical products; developing countries.

Introduction

Providing developing countries with adequate access to pharmaceutical products is a complex and

controversial issue. Pharmaceutical companies argue that they need to charge high prices and have strict patent protections in order to recoup their research and development costs. Unfortunately, these high prices often result in life saving medicine being unobtainable to developing countries.

This essay is specifically concerned with the World Trade Organisation's (WTO) involvement in this issue. The discussion is set out in 4 sections: the first gives a brief background to the WTO and its Trade Related Intellectual Property Rights (TRIPS) agreement, the second will examine the controversial issues surrounding developing countries' access to medicine and the difficult role facing the WTO, the third discusses how the WTO tackles these issues and their perceived effectiveness. And the final section attempts to conclude whether the WTO is effective in making pharmaceutical products accessible to developing countries and postulates how they might do more.

Background

In the 1994 Uruguay round, the Marrakech agreement established the WTO and charged it with providing "the common institutional framework for the conduct of trade relations among its members in matters for which agreements and associated legal obligations apply" (WTO, 1994). This essay is centred upon Annex 1C of the agreement which created TRIPS.

The TRIPS agreement sets out a framework for protection of patents, copyrights and trademarks. It requires all member countries¹ to implement a set of provisions for this protection; most countries had to implement these provisions by 1995. Arguably the two most important provisions are; ensuring patent protection is provided to any inventor for any field of technology, for products and processes alike; and ensuring no previously patented goods, domestic or foreign, are illegally reproduced. The provisions are enforceable through the dispute settlement body of the WTO.

The TRIPS agreement is generally seen as harmful to developing countries, with a diversion of income from developing countries to developed countries. This is mainly due to the type of goods that the provisions are relevant to, goods that require patenting or copy writing are usually high end goods. These goods tend to originate, and therefore be patented in developed countries, the TRIPS agreement means developing countries cannot buy or reproduce these goods cheaply without

¹There are only 14 states and 2 territories that are not involved with the WTO.

facing action from the WTO. McCalman (2005) estimates that the TRIPS agreement involves a net transfer of around \$8billion from developing countries to OECD countries annually.

The TRIPS agreement is particularly controversial when concerned with pharmaceuticals; under the TRIPS agreement pharmaceutical companies are granted patents lasting for 20 years with no limit on price. This relatively high level of pricing severely impacts the developing country's ability to provide adequate levels of healthcare which in turn restricts the prospects for growth and development.

The Debate

Given the discussed implications of the high prices of pharmaceutical products, the question has to be asked; why doesn't the WTO simply relax the patent laws? This would effectively allow developing countries access to pharmaceuticals by endorsing widespread generic production of them at a fraction of the price.

The marginal cost of producing another unit of a drug is comparatively low, the source of pharmaceutical high prices are twofold: firstly, the patent gives the pharmaceutical company an acting monopoly which allows them to push their prices up; secondly the extremely high cost of research and development (R&D) must be recouped from drug sales. Generic drug firms have incurred no R&D costs, solely the relatively cheap production costs, plus they operate in conditions similar to perfect competition, driving prices down. As an example, "For a hundred units of Ciprofloxacin, a drug that treats multi resistant tuberculosis, Bayer will charge somewhere between \$169 and \$549. The generic version from India is sold for \$10" (Strain, 2007). It is obvious that this dramatic price difference would have a huge impact on people's lives.

The more critical will claim that patent laws remain in place due to pressure from huge multinational pharmaceutical companies greedy to protect their profits. This theory is not without merit. The inclusion of intellectual property in the WTO agenda was a direct result of two large American firms, one of which is Pfizer² (Heywood, 2002). "TRIPS agreement was... expected to bring between \$2.1 and \$14.4 billion in additional profits to pharmaceutical companies in developed

²Pfizer is the 2nd biggest pharmaceutical company in the world.

countries.” (Dawar, 2004). In 2008 the net profit of the top 5 pharmaceutical companies totalled \$44,491 million³, whereas the sum of the GDP’s in 2008 of the 5 poorest countries on the WTO's least developed countries list was \$17,104 million. The source of these criticisms becomes clear.

The issues are, however, complex. The patent laws that allow pharmaceutical companies to charge such high prices also provide them with the incentive to conduct crucial research and development (R&D). These costs account for a huge proportion of pharmaceutical companies’ expenditure, PhRMA's Pharmaceutical Industry Profile 2009 estimated that 17.4% of total revenue is spent on R&D and that it takes 10 – 15 years to develop a new drug, at a cost on average of \$1.318 billion. Also it is an area characterised by high risks, it is estimated that only one in ten thousand chemical compounds discovered by the pharmaceutical industry turn out to be medically effective and safe enough to be approved. Around half of all new medicines fail in the final stages of clinical trials (Davidson and Greblov, 2005). PhRMA's Profile 2009 estimates that only 2 out of 10 drugs developed see returns that equal or exceed their R&D costs. Investments with risks this high must have extremely high returns in order to be economically viable. Clearly vital research would not take place if the resultant products were not adequately protected by patent law. If these expensively developed drugs are too quickly made available for any company to reproduce, the original manufacturer would suffer from the ‘free rider problem’. The free rider problem is a form of market failure, it occurs when there is no barrier to stop a third party from benefiting equally from someone else's investment, meaning that investment does not occur if left to normal market forces. As with any market failure, intervention is needed and in this case the solution is patents. Patents encourage crucial research and development, this advances medical science, without it many diseases would still be untreatable and incurable⁴.

Differential drug pricing would seem an appropriate solution; selling the drugs at a high price in developed countries and a low price in developing countries. It is concurrent with profit maximising theory as it is just a form of price discrimination; two distinct markets, the rich countries and the poor countries and two distinct prices, high and low. Unfortunately, there are two main

³Sum of the profits of the 5 biggest pharmaceutical companies as reported on the Global 500 for 2008 (CNNMoney, 2008)

⁴This may become an increasingly important issue as the global recession forces governments to cut public spending, this is likely to affect public sector medical research budgets putting increasing pressure on the private sector.

problems; firstly the prices don't tend to be low enough, the pharmaceutical companies tend to target the higher income population of the low income country and also do not wish to disenchant their main customer base (developed nations) by charging severely different prices. Secondly, if drugs are priced too low a second hand market could evolve, with the developing countries selling these cheap drugs back to the rich. Geography is all that distinguishes these two markets and with increasing globalisation it becomes increasingly difficult to keep them apart.

The situation is exacerbated by the dangerous lack of R&D into diseases specific to developing countries. The source of this neglect can be determined by briefly looking at the characteristics of the pharmaceutical industry globally. The high risk, high cost of R&D has resulted in huge economies of scale in the industry and therefore the formation of giant corporations. These corporations do not have incentive to invest in diseases specific to developing countries as they are almost guaranteed to get higher returns if they invest in drugs for the more affluent consumers in the developed world. Even though pharmaceutical industries in developing countries are in some cases quite well established, Brazil and India for instance, they still don't generally have the resources for high levels of R&D, so for the most part just produce generic medicines invented by the big corporations of the developed world and tailored for the developed world. In the least developed countries pharmaceutical industries tend to be virtually none existent (Kremer, M. 2002).

How does the WTO 'strike a balance'?

The WTO “attempts to strike a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and creations” (WTO, 2006). Applied to pharmaceuticals this can be interpreted as insuring that pharmaceutical companies have enough incentive to invest in research and development, while attempting to make sure the health of developing countries doesn't suffer at the hands of commercial gain.

To do this the WTO includes a number of articles in the agreement that try to ensure that the TRIPS are flexible enough to be bent for the protection of public health. The 2001 DOHA Declaration on TRIPS and public health was particularly important in addressing many of the concerns raised here.

There are a number of mechanisms written into the TRIPS agreement that allow flexibility within

patent laws; the WTO puts these into four categories (see WTO, 2006):

Compulsory licences, Compulsory licenses can be issued by a government to allow the production of a product without the consent of the patent owner.

'Exhaustion' of rights, this is the principle that once a company has sold a batch of its product to another country its rights then become 'exhausted'. This is particularly relevant when there are different prices across regions. It allows for 'parallel imports', a term best demonstrated rather than explained: country A may sell to country B at price x and country C at the higher price of y, once country A has sold all of a particular batch to country B, country B can then resell to country C, undermining country A's price.

Regulatory exception (sometimes known as "Bolar" provision), this allows limited exceptions to patent laws as long as they don't perversely conflict with the patent owner's legitimate interests. An example of this is that generic producers of a patented drug can use the drug, without permission from the patent holder, in order to seek type approval from the relevant public health authorities, so that they may start selling the drug as soon as the patent is expired.

Anti-competitive practices, The TRIPS agreement says governments can also act to prevent patent owners and other holders of intellectual property rights from abusing intellectual property rights, unreasonably restraining trade, or hampering the international transfer of technology.

The most relevant clause here for providing developing countries access to pharmaceutical products is compulsory licences. Compulsory licenses are allowed under article 31 of the TRIPS agreement. The term compulsory license does not actually appear in the TRIPS agreement but is encapsulated by the phrase "other use without authorization of the right holder" (TRIPS and pharmaceutical patent, WTO fact sheet). The specifications were made vague in an attempt to allow developing countries the greatest freedom of implementation. The clause is subject to a number of conditions: an attempt to gain voluntary licence must have been made first, although in cases of emergencies it is acceptable to waive this as long as the patent holder is notified within a reasonable time frame; adequate compensation must be paid to the patent holder and the scope and duration of the license must be limited to the purpose for which it was authorized.

In the original TRIPS agreement the licence could only be issued for use in the domestic market. This had a fatal flaw. It meant that it was useless to countries without the capacity to produce

pharmaceuticals domestically. This was recognised in the DOHA trade round on public health and in 2003 and a decision to allow countries to import pharmaceuticals made under compulsory licence was implemented.

The clause on 'exhaustion' of rights allows for parallel imports, parallel imports could be raised with the WTO dispute settlement body if this clause was not included. This allows developing countries to import from the country with the cheapest prices; hopefully providing them with a more affordable option.

Regulatory exceptions and rulings against anti-competitive behaviour are less significant to developing countries. Although regulatory exceptions do allow generic versions of drugs to be available on the market much sooner, reducing the time frame in which high prices have to be paid.

Separate to the above considerations, there is also general consideration of developing countries included in the TRIPS agreement. Article 66.2 states developed countries must promote and encourage technological transfer to the least developed countries so that they may “create a sound and viable technological base” (WTO, 2001). Article 67 calls for developed countries to provide assistance to developing countries in areas such as “the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters” (WTO, 2001).

Further to this, the WTO has allowed developing countries extended transition periods. They have longer to implement the provisions of the TRIPS agreement; most did not have to apply the provisions until 2000 with the least developed countries having until 2016 plus the opportunity to extend that deadline if necessary.

From this discussion it can be seen that there are six main ways the WTO attempts to ‘strike a balance’: compulsory licenses; parallel imports; regulatory exceptions; rulings against anti competitive behaviour; general consideration; and extended transition periods. The following section draws on the four most relevant of these, namely, compulsory licenses, parallel imports, general consideration, and extended transition periods and argues their relative effectiveness.

Are these methods effective?

Compulsory licenses

Granting governments the right to issue compulsory licenses could be argued to be the most significant way in which the WTO helps developing countries access pharmaceutical products. It has, in some circumstances, been very successful and greatly increased the availability of affordable medicine. It has mainly been utilised by governments of developing countries in order to issue licences allowing local producers to manufacture drugs such as anti-retrovirals.

Compulsory licenses can also be used as leverage by developing countries to negotiate better import prices. Brazil negotiated a substantially lower price on HIV/AIDS drugs by threatening to issue a compulsory licence for domestic production (Fergusson, 2006). This can only be successful if the threat is legitimate, so, like most of these clauses it is more relevant for countries with pharmaceutical manufacturing capabilities.

The new laws that state compulsory licenses can be granted for export purposes should in theory extend the effectiveness of compulsory licenses to the poorest countries which are without the capacity to produce drugs domestically. Unfortunately, this facility has not been widely used. Only once, in fact, when on 19 July 2007 Rwanda notified the WTO that it expected to import 260,000 packs of TriAvir – an HIV/AIDS drug - over two years from a Canadian company, Apotex, Inc. (Royle & Wessing, 2008).

The main criticism of the provision that allows compulsory licences is that it is too vague. But, as discussed, the WTO left it vague on purpose to try and insure maximum flexibility for developing countries. However, it appears that instead it has left developing countries confused about what they can and cannot do. Another unfortunate problem is that issuing compulsory licenses can put off foreign direct investment (FDI). FDI can be deterred if foreign investors believe that country does not implement market oriented policies. Despite this, the overall use of compulsory license can be a very effective tool in developing countries that have the correct manufacturing capabilities. Unfortunately however, new laws targeted at countries without a manufacturing base are too uncommon to be considered particularly effective at this point. The exact reason behind their limited use is difficult to pinpoint, perhaps there is too much confusion over correct implementation. Hopefully they will be utilised more in the future.

Parallel imports

Parallel imports are a useful mechanism that developing countries can employ. There are still significant price differences in between markets for pharmaceuticals and allowing parallel imports means developing countries can shop around for the best price.

However, further to the above discussion on differential pricing, if pharmaceutical companies feel they are losing profit from parallel imports, particularly if the imports leak on to the developed world market, they are likely to employ more uniform pricing, negating the advantages of parallel imports.

General consideration

Supporting developing countries is advocated by the WTO, but that support is quite vague and mainly concerned with helping them establish the provisions of the TRIPS. Although it is likely to have a positive effect in dispute settlements within the WTO, generally skewing rulings in favour of developing countries.

The issue has certainly attracted much attention from the general public of developed nations. The public backlash over the US's attempted litigation in Brazil stopped the process altogether (Cooper, 2001). Unfortunately such attention does have its downsides. There is already a dangerous lack of R&D into diseases specific to developing countries and if pharmaceutical companies feel that they cannot enforce patents in developing countries without facing public backlash the problem is likely to intensify.

Of course it could be argued that helping developing countries establish the provisions of the TRIPS will in itself aid access to medicine by helping their domestic pharmaceutical companies gain income. Unfortunately, there seems little evidence of such an upside as yet.

Extended transition period

Extended transition periods have proved particularly important for developing countries with established pharmaceutical industries. The most prominent case being India whose thriving generic drug industry (Frederick M. Abbott) has applied downward pressure on global pharmaceutical

products. Unfortunately however, because countries with a notable pharmaceutical market are not the *least* developed the transition deadline for most of them has now past. India had to implement the provisions of the TRIPS in 2005. The overall effects of this have not been immediate due to the fact that it only requires the patenting of new drugs. However, any adverse effects are likely to become more prominent as time goes on.

Allowing the least developed countries until 2016 to implement patent laws is an important provision. Many of the least developed countries do not have the capacity to introduce these measures nor will they have for some time. The 2016 date is, therefore, a reasonable target. In the meantime however, the least developed countries have very small or nonexistent pharmaceutical industries so while they may not have to patent their domestic drugs yet, they do still have to pay the high prices on patented drugs that they import which is the issue most relevant to their circumstances.

Extending transition periods was a useful method for promoting access to medicine in developing countries. Unfortunately, the termination of the facility in the countries most benefiting from its implementation has meant the overall effect is likely now in decline.

Conclusion

The WTO attempts to make pharmaceutical products available to developing countries by including clauses in the TRIPS agreement that allow them greater access as well as actively encouraging developed countries to aid them in their development. However, this is not hugely effective, particularly in countries which have no infrastructure in place to domestically manufacture drugs. Unfortunately, these tend to be the poorest developing countries and therefore the ones most in need of affordable pharmaceutical products.

After analysing the issues surrounding pharmaceutical patents it is clear that effectively providing developing countries with pharmaceutical products is no easy task. Abandoning the system of patents would be infeasible and harm both developed and developing countries. Public pressure on pharmaceutical companies not to pursue law suits against developing countries breaking patent laws is encouraging and does help to a certain extent, but it is in no way a long term solution. Too much pressure on pharmaceutical companies not to enforce patents in developing countries will simply

exacerbate the problem of under investment in conditions specific to those countries.

Multinational Corporations (MNC's) making super normal profits, present an easy target (Strain, 2007), while this essay is not of the opinion that said corporations act in a moral manner and it would advocate a higher level of ethical accountability, MNC's do act as any profit maximising firm does. It is an unfortunate down side of capitalism. Research and development into pharmaceutical products is a global public good⁵, and it therefore falls to the governments of the developed world and organisations such as the WTO to help developing countries afford vital pharmaceutical products and provide financial incentives to encourage the development of drugs to combat issues specific to poorer countries.

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⁵A public good is nonrivalrous (may be consumed by one consumer without diminishing the good/service for another consumer), nonexcludable (it is not possible to prevent consumers who have not paid for it having access to it) and is therefore under provided by market forces. This is particularly true of R&D into pharmaceuticals as it has significant positive externalities.

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