Does the new WTO drugs deal really benefit developing countries?

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On the 30th of August, just before the negotiating teams at the WTO in Geneva went back to their countries to prepare for the ministerial meeting at Cancun, the deadlock over intellectual property and public health was finally broken. The TRIPs Council agreed on legal changes that are officially supposed to make it easier for poorer countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves.

The decision settled the one remaining piece of unfinished business on intellectual property and health that was left over from the WTO Ministerial Conference in Doha in November 2001, and which had been hanging for the previous months because of fierce resistance from the US government and the multinational lobby.

The decision was immediately hailed by some and described as a great a victory for developing countries, and indeed for the people of the world. "This is a historic agreement for the WTO," said the WTO Director-General Supachai Panitchpakdi. "The final piece of the jigsaw has fallen into place, allowing poorer countries to make full use of the flexibilities in the WTO's intellectual property rules in order to deal with the diseases that ravage their people. It proves once and for all that the organisation can handle humanitarian as well as trade concerns."

However, the actual details of the agreement suggest that such extravagant and fulsome praise may be uncalled for. In fact, many independent analysts, along with the NGOs and civil society groups that had been fighting for an agreement on this issue, feel betrayed by the final character of the resolution, and have argued that it will do little or nothing to improve the situation for people in developing countries in terms of accessing cheaper life-saving drugs.

Thus, James Love of the Consumer Project on Technology has written that "the persons who have negotiated this agreement have given the world a new model for explicitly endorsing protectionism." Oxfam and Medecin sans Frontieres, two groups who have closely followed the negotiations, have called the solution "unworkable" saying the "deal was designed to offer comfort to the US and the Western pharmaceutical industry" and that "global patent rules will continue to drive up the price of medicines."

It is even possible to argue that the final form of the resolution is actually a step backwards compared to the flexibilities that already existed in the original TRIPS agreement, and that the entrenched position of the large international drug monopolies is further legalised by the recent statement. However, to understand this, it is necessary to provide some background on both the international pharmaceuticals industry and the TRIPs agreement and the controversies that have surrounded it.

The international pharma industry

Pharmaceutical markets differ from markets for most other commodities, since drugs are rather special commodities. Private drug markets typically suffer from a number of forms of market failure. These include (a) informational imbalances - thus, for example, consumers are not in a position to judge the quality and efficacy of drugs, which creates the need for a social monitoring and surveillance system ; (b) monopoly and lack of competition created by patent protection, brand loyalty and market segmentation ; (c) externalities in the form of social benefits of drug consumption. Drugs play a significant social role in that they are an integral part of the realisation of the fundamental human right to health. For these reasons, pharmaceutical products are classified as essential goods, with the understanding that they have to be accessible to all people.

Obviously, access to the latest available technology in this sphere is crucially important for the health and welfare of children, not only in terms of the availability to all children but also the access of mothers. There is clear need for some social control over investment in technology relating to drug production, and the subsequent prices and distribution, not only because of the market failures described above, but also since unregulated drug markets tend to create substantial inequity, particularly in terms of access to drugs.

The world market for drugs is a huge one, but it is dominated by only three countries - the United States, Japan and Germany - which make up more than two-thirds of total sales. In fact, only 15 per cent of the world's population accounts for 86 per cent of drug spending, while the remaining 85 per cent of the world's population get only 14 per cent share.

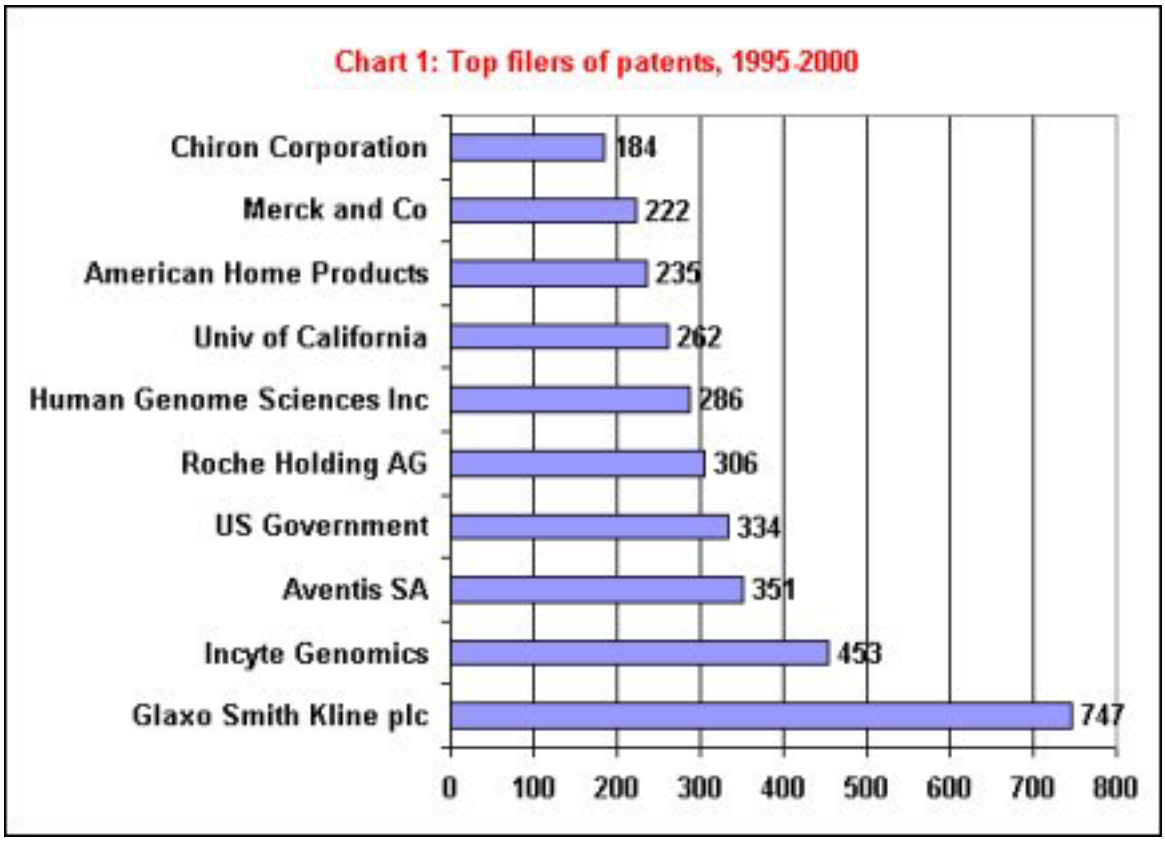
The difficulty of ensuring even a minimum degree of democratic access to life-saving drugs is compounded by the high degree of concentration in the international drug industry. Table 1 describes the situation in 1998, when the top ten companies controlled 36 per cent of the market and the top twenty companies controlled 57 per cent of world sales.

Top Ten Pharma compnaies in 1998

Company	Sales, US $ bn	% of global sales	% growth p.a.
Novartis	10.6	4.2	5
Merck	10.6	4.2	8
Glaxo Wellcome	10.5	4.2	88
Pfizer	9.9	3.9	21
Bristol Myers Squibb	9.8	3.9	11
Johnson & Johnson	9	3.6	8
American Home Products	7.8	3.1	1
Roche	7.6	3	6
Lily	7.4	2.9	17
Smith Kline Beecham	7.3	2.9	6
Leading 10 companies	90.5	35.9	8
Leading 20 companies	143.8	57.2	9

Since then there have been more mega-mergers which have made the industry even more concentrated. Thus, Glaxo Wellcome has merged with SmithKline Beecham, Pfizer merged with Warner Lambert, and the companies Hoechst-Marion, Merrell and Rhone-Poulenc merged to form Aventis. Currently the top ten companies are estimated to control more than half of the world market, and the top twenty companies more than two-thirds of the world market.

Apart from mergers, there is growing evidence that drug companies are using the patent system to establish monopoly control. Often patents are filed for products or chemical substances or now even genes, whose attributes are not fully known, simply to pre-empt the competition and allow for monopoly rents once further research - possibly by others including public agencies - reveals the uses. As Table 2 shows, the top ten filers of patents have included 6 drug companies and two companies specialising in genetic research.



Such monopoly allows drug companies to charge prices which are as high as they feel the market will bear, without reference to or well in excess of the actual costs of R&D that they may have borne. Thus there is wide variation in prices of the same drug charged not only by different companies but even by the same company in different markets. As Charts 2a, 2b, and 2c, show, the prices of branded or patented products are often far higher than the prices of similar medicines produced by alternative or generic sources.

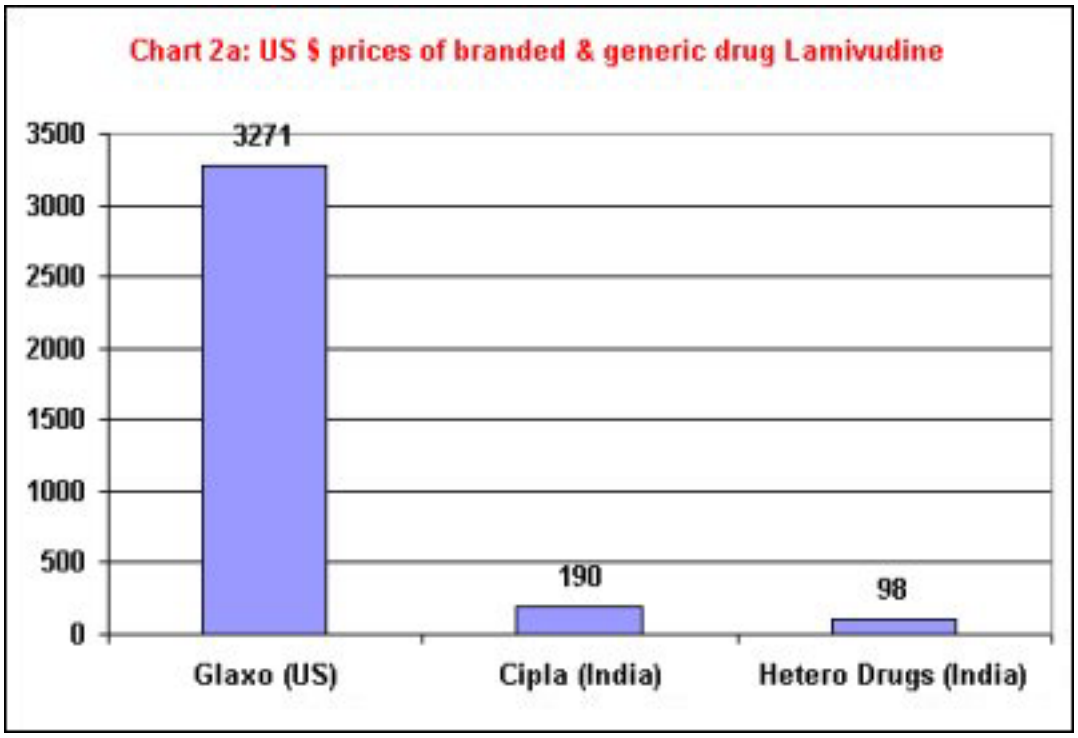


Chart 2a: US $ prices of branded & generic drug Lamivudine
3500
3000
2500
2000
1500
1000
500
0
3271
190
98
Glaxo (US)
Cipla (India)
Hetero Drugs (India)

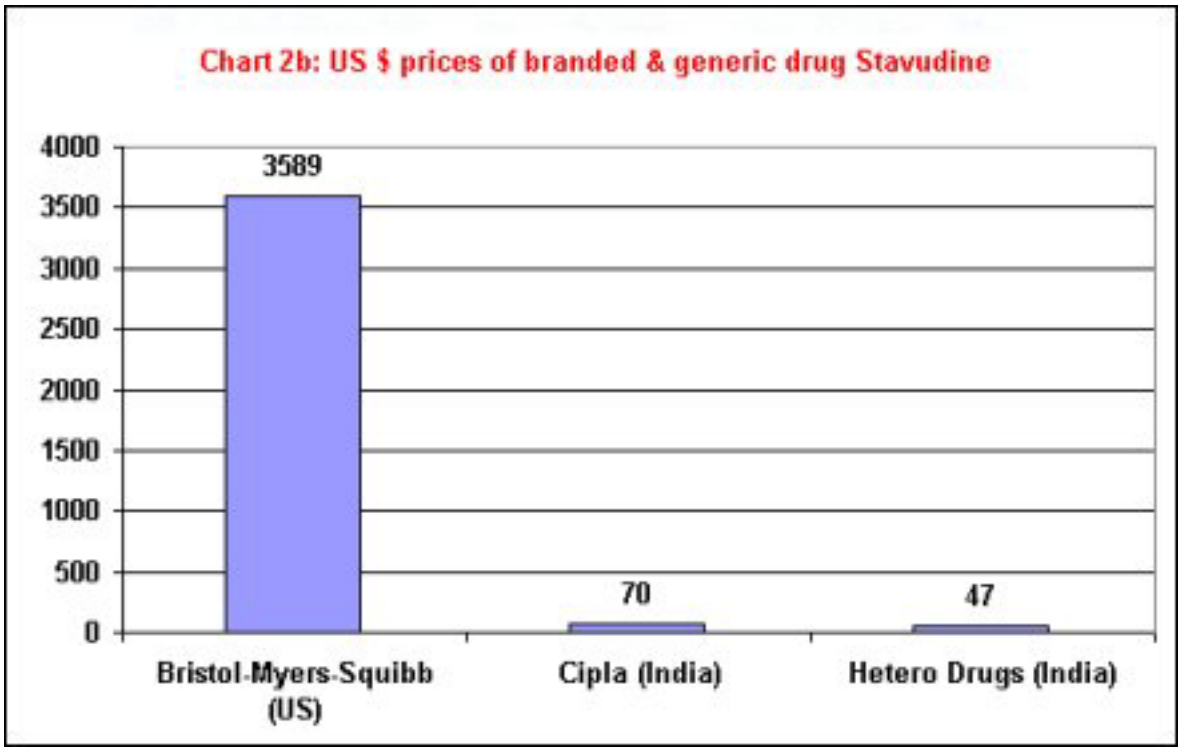
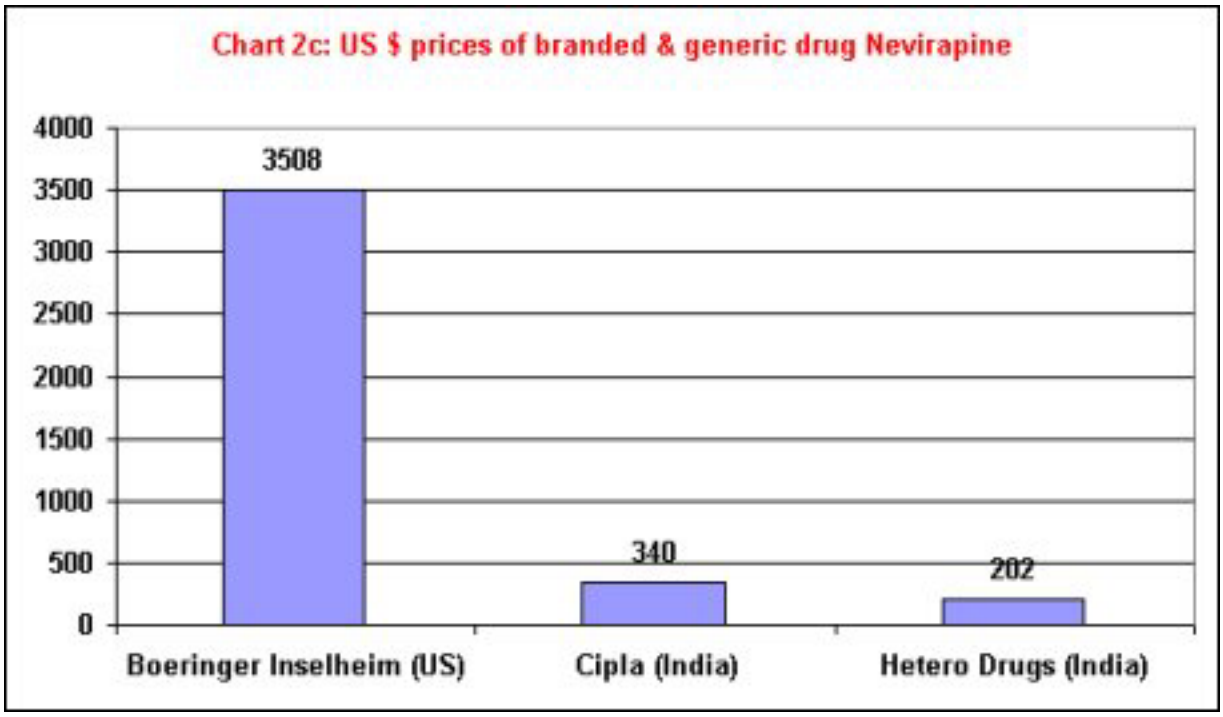


Chart 2b: US $ prices of branded & generic drug Stavudine
4000
3500
3000
2500
2000
1500
1000
500
0
3589
70
47
Bristol-Myers-Squibb (US)
Cipla (India)
Hetero Drugs (India)



The use of market segmentation to earn monopoly profits is obviously constrained by the possibility of undercutting by competitors producing generic substitutes. This possibility, and the opposition of multinational drug companies to allowing it, was dramatically illustrated by the battle between the Indian drug company Cipla and major MNC players over providing cheaper drugs for AIDS patients in Africa.

The fact that competition from generic producers will result in the lowering and levelling of prices of medicines is very clear even from the pricing behaviour of large multinational drug companies in different markets. Not only do MNCs price differently in different markets, but they tend to charge much less when generic drug substitutes are available.

This is sharply evident from Chart 3, which shows prices of flucanazole in different markets, and Chart 4, which indicates the different prices charged by Glaxo for its anti-ulcer drug Zantac. Such pricing bears little relation to per capita income in the country concerned, but is much more dependent upon the existence of generic substitutes like ranitidine, which is why the drug is cheapest in India.

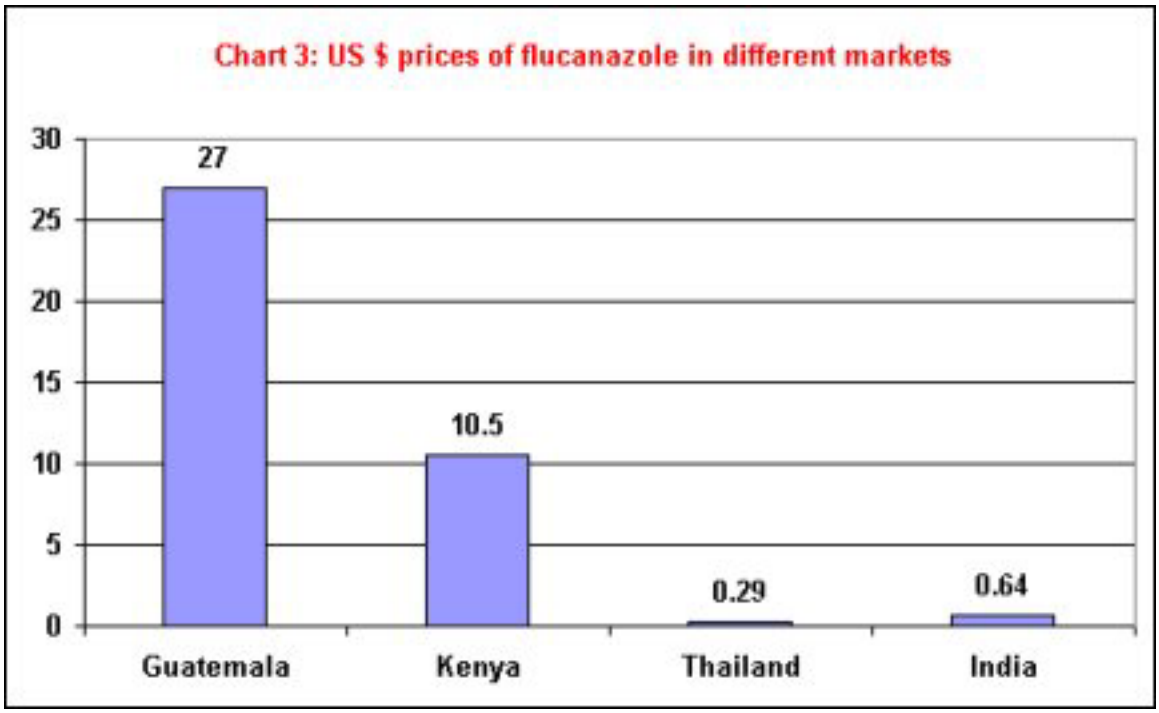
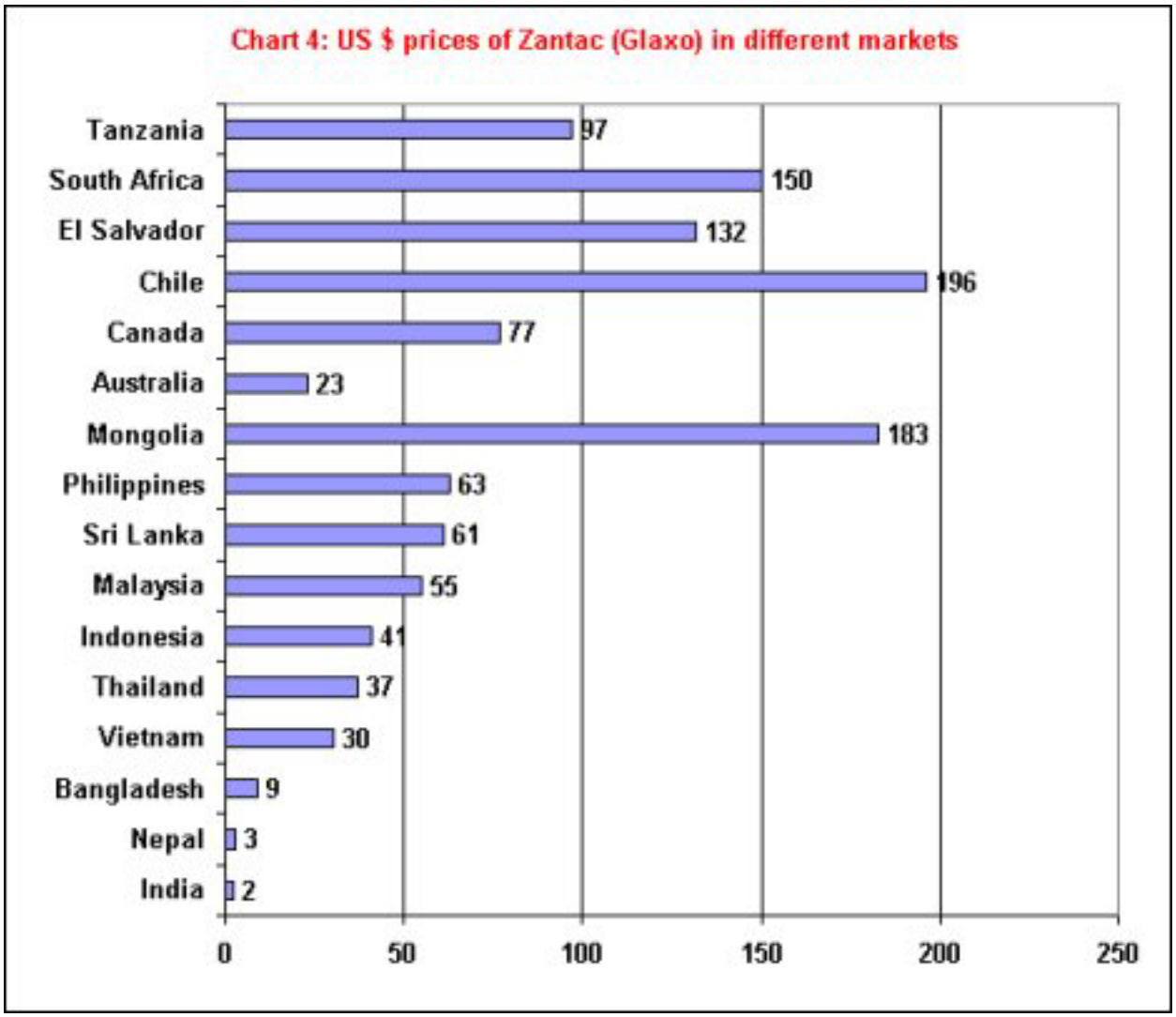


Chart 3: US $ prices of flucanazole in different markets
30
25
20
15
10
5
0
27
10.5
0.29
0.64
Guatemala
Kenya
Thailand
India



The TRIPS Agreement

This context explains why there have been major concerns about the enforcement of the TRIPS agreement particularly with reference to health conditions in developing countries, since the agreement is seen as increasing the power of large corporations who may be in a position to capture patents, vis-à-vis state regulatory authorities.

The Agreement requires all WTO Member States to grant patents for pharmaceutical products or process inventions for a minimum of 20 years. The major shift for countries like India was that the TRIPS agreement forces upon member countries, a patent regime that recognises product patents for chemicals and pharmaceuticals. The earlier Indian Patent Act allowed for only process patents in these areas, which created the possibility of reverse engineering especially for

drugs, a factor that was crucial in the rapid development of the generic drug industry in India.

Some of the most frequently expressed concerns about the adverse implications of TRIPS for public health have included the following:

- Increased patent protection leads to higher drug prices, while the number of patented drugs of importance from a public-health point of view is likely to increase in the coming years.
- The access gap between developed and developing countries, and between rich and poor in all countries, will continue to increase, especially as producers in developing countries have to wait for 20 years before they can have access to innovations.
- Enforcement of the WTO regulations has an effect on local manufacturing capacity and removes a source of generic innovative quality drugs on which the poorer countries depend.
- While technology transfer is actually be discouraged, there are no incentives or provisions to ensure that increased revenues will go towards the development of essential medical technologies.

It is now much more widely recognised that there is no necessary correlation between socially desirable and necessary R&D in drug development, and a tight patent regime. Indeed, much of the major research in pharmaceuticals and medicine, both in the past and currently, is under the aegis of publicly funded institutions across the world. Table 2 indicates that R7D expenditure forms a relatively small part of the total revenues for large pharma companies, and is significantly less than marketing expenses. It is also worth noting that even in many western countries, pharmaceutical products remained unpatentable until the 1980s or even the 1990s, with no adverse implications for research.

Financial data for top Pharma companies in 2000

Company	Revenue	Percent of Revenue Allocated to:		
	(Net Sales in millions of dollars)	Profit	Marketing/	R & D
		(Net Income)	Advertising/	
			Administration	
Merck and Co. Inc	40,363	17%	15%	6%
Pfizer Inc	29,574	13%	39%	15%
Bristol Myers Squibb Co.	18,216	26%	30%	11%
Pharmacia Corp.	18,144	4%	37%	15%
Abbott Laboratories	13,746	20%	21%	10%
American Home Products Corp.	13,263	-18%	38%	13%
Eli Lilly and Co.	10,862	28%	30%	19%
Schering-Plough Corp.	9,815	25%	36%	14%
Allergan Inc.	1,563	14%	42%	13%

However, even this restrictive Agreement did leave Member States a certain amount of freedom in modifying their regulations. For example, the terms *invention* and *discovery* are not defined in the Agreement, yet how they are defined could have important implications, especially in the biotechnological field. The Agreement says that Member States may provide limited exceptions to the patent holder's exclusive rights in their laws.

National public authorities may be allowed, within the conditions laid down in the Agreement, to issue compulsory licences against the patent owner's will when justified by the public interest. The Agreement does not prohibit parallel imports. These restore price competition for patented products by allowing the importation (without the holder's consent) of identical patented products which have been manufactured for a lower price in another country.

Table 3: Explanation of Article 27.1 of TRIPS

Article 27.1 **Patentable subject matter**	**Comments**
patents shall be available for any inventions, whether products or processes,	Some countries only made available process patents for pharmaceutical inventions. Under TRIPS, product patents must also be available; the protection of rights on a product is much broader in scope.
in all fields of technology	Some countries, unable to invest in R&D, have been excluding pharmaceuticals from patentability so as to allow the possibility for copies of patented drugs to be produced locally or imported - from other countries which also do not respect pharmaceutical patents - without the authorization of the company that invented the drug.
provided that they are new, involve an inventive step and are capable of industrial application.	Usual definition of the conditions of patentability of an invention.
patents shall be available and patent rights enjoyable without discrimination as to the place of invention	No discrimination between national and foreign inventions, or between foreign inventions
the field of technology	No discrimination between types of products - pharmaceutical or other.
provided that they are new, involve an inventive step and are capable of industrial application.	Usual definition of the conditions of patentability of an invention.
and whether products are imported or locally produced	Some countries have been issuing compulsory licences for lack of exploitation of patents. This type of

	obligation was intended to require foreign companies to set up on the national territory in order to exploit their patents, with resultant transfers of technology. The Agreement would here appear to allow these companies to import their patented product without having to transfer the related technology.

Source : Germán Velásquez and Pascale Boulet, Globalisation and access to drugs: Implications of the WTO/TRIPS Agreement, WHO Geneva, 1999

Thus, compulsory licensing and parallel importing policies are two policy tools which can still play an important role in helping developing country governments make essential medicines more affordable to their citizens, although their use is being sought to be restricted by drug MNCs and their home country governments.

Compulsory licensing

Compulsory licensing may occur as follows: when reasons of general interest justify it, national public authorities may allow the exploitation of a patent by a third person without the owner's consent. This involves a government giving a manufacturer - which could be a company, government agency, or other party - a licence to produce a drug for which another company holds a patent, in exchange for the payment of a reasonable royalty to the patent holder. The effect is to introduce generic competition and drive prices down, as has occurred in India. Compulsory licensing can lower the price of medicines by 75% or more. Zimbabwe, for example, could issue a license to a local company for an HIV/AIDS drug manufactured by Bristol-Myers Squibb. The Zimbabwean firm would then manufacture the drug for sale in Zimbabwe under a generic name, and it would pay a reasonable royalty to Bristol-Myers Squibb on each sale.

Five kinds of use without authorisation of the right holder are expressly envisaged by the Agreement [Correa 1999, 2000]:

- licences for public non-commercial use by the Government;

- licences granted to third parties authorised by the Government for public non-commercial use;
- licences granted in conditions of emergency or extreme urgency;
- licences granted to remedy a practice determined after administrative or judicial process to be anti-competitive;
- licences arising from a dependent patent.

In addition, since the Agreement does not state that these are the only cases authorised, member states are not limited in regard to the grounds on which they may decide to grant a licence without the authorisation of the patent holder. They are in practice only limited in regard to the procedure and conditions to be followed. Thus, in principle, compulsory licences can be issued for considerations of public health as well as to prevent anti-competitive practices and possible uses connected with monopoly.

Parallel imports

Another strategy for lowering drug prices is by parallel imports. Parallel importing involves a government or another importer shopping in the world market for the lowest priced version of a drug rather than accept the price at which it is sold in their country. In the pharmaceutical market, as has been shown, prices tend to vary dramatically. Since parallel imports involve imports of a product from one country and resale, without authorisation of the original seller, in another, thereby allowing the buyer to search for the lowest world price, they also can be a tool to enable developing countries to lower prices for consumers.

Both the promotion and the transfer of technology, as well as public health or nutrition could justify derogation of the patentee's exclusive rights. Scrutiny of the exceptions existing in much national legislation gives an idea of the different possibilities [Correa, 1999]:

- parallel importation of the protected product;
- acts carried out on a private basis and for non-commercial purposes;
- scientific research and experiments involving the patented invention;
- preparation of drugs by unit and on medical prescription in pharmacy dispensaries;

- a person being, in good faith, already in possession of the invention covered by the patent;
- tests carried out before the expiry of the patent to establish the bio-equivalence of a generic drug.

In addition to these measures, as pointed by Correa [2000] there is scope within the TRIPS Agreement (under Article 30) for a number of exceptions to exclusive patent rights. Such exceptions must of course meet certain conditions, that is they must be limited, they should not unreasonably conflict with the normal exploitation of the patent, and exceptions should not unreasonably prejudice the legitimate interests of the patent owner. Given these conditions, there is a wide range of exceptions that an be provided that are within the scope of Article 30, such as:

- acts done privately and/or on a non-commercial scale, or for a non-commercial purpose
- use of the invention for research
- use of the invention for teaching purposes
- experimentation for teaching purposes
- preparation of medicines under individual prescriptions
- experiments made for the purpose of seeking regulatory approval for marketing of a product after the expiry of a patent
- use of the invention by a third party that had used it bona fide before the date of application of the patent.

As can be seen, even though the TRIPS provisions were restrictive, government that were anxious to ensure drug development for public health purposes could still endeavour to push for more flexible patent regimes, if they were not prevented from doing so by other forces. The problem was, of course, that many developing country governments have found it difficult to implement the more flexible provisions because of other kinds of external pressure.

The US government and other developed country governments, in particular, because of their own large drug lobbies like phaRMa, have been aggressively restricting governments that have or had intellectual property rules such as compulsory licensing and parallel imports, that are designed to make essential medicines more affordable to their citizens.

This is why developing countries were keen on explicit recognition in the WTO that public health requirements could permit the legal implementation of loopholes that already existed in the TRIPS document. All the subsequent activity has been devoted to nothing more ambitious than a restatement of that basic right.

Developing countries were essentially seeking a declaration recognizing their right to implement certain pro-competitive measures, notably compulsory licences and parallel imports, as needed to enhance access to health care. They were frustrated by the opposition and pressure exerted on some countries by the pharmaceutical industry and governments.

Moreover, some felt that the final proviso in Article 8.1 establishing that any measures adopted, *inter alia*, to protect public health should be consistent with the provisions of the TRIPS Agreement, provided *less* protection for public health than under the corresponding exceptions of Article XX (b) of GATT and the Sanitary and Phytosanitary Measures and Technical Barriers to Trade agreements.

For information, TRIPS Article 8.1 states that: "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement." The GATT Article XX: "Nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures necessary to protect human, animal or plant life or health."

The Doha declaration on TRIPS and public health was the first step towards the restatement of such rights. It stated that "Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted", and that "Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including

those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."

However, the agreement did not specify conditions for parallel imports, instead providing the now-infamous Paragraph 6, which ran as follows: 'We recognise that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."

If the WTO establishment had been serious about fulfilling this promise, the most straightforward way would have been for the exporting country to make a limited exception from the patent privilege under Article 30. It is noteworthy that so far the developed countries have succeeded in forcing the discussion in the TRIPS Council away from the possibilities inherent in Article 30 of the TRIPS Agreement, which were discussed above. Instead they have focussed on Article 31, which is much more limited, constraining and cumbersome.

The basic statement which was finally cleared on August 30, had actually been formulated in 2001, but was held up by the US government on behalf of its Big PhRMA lobby (which incidentally had generously funded the Bush and Republican election campaigns). The modified version which is now cleared, has put in many more restrictions, which drastically limit the ability of importing countries to access cheaper generic substitutes, and therefore contain the ability of such generic manufacturers to benefit from economies of scale and emerge as real competitors of the large drug companies.

All that the new statement does is waive the obligations of the exporting country under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to a company, which was supposed to be for the domestic market only. Export can be permitted to importing countries that fulfill the following conditions:

First, the eligible importing Member can only be a Least Developed Country or a developing country that does not have adequate facilities to produce the drug in question. This importing country has to make a notification to the TRIPS Council that:

- specifies the names and expected quantities of the products needed;
- confirms that the eligible importing Member in question, (other than a least developed country Member) has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the products in question in one of various ways are which specified; and
- confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this decision.

Importing countries also have to ensure legal administrative means of preventing re-exportation of any such drugs.

Similarly, the compulsory licence issued by the exporting member has to contain the following conditions:

- only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;
- products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and
- before shipment begins, the licensee shall post on a website information relating to the quantities being supplied to each destination and the distinguishing features of the products;
- (c) the exporting Member has to notify the TRIPS Council of the grant of the licence, including the conditions attached to it. The information provided has to include the name and address of the licensee, the products for which the licence has been granted, the quantities for which it has been granted, the countries to which the products are to be supplied and the duration of the licence, and the address of the relevant website.

It is amazing that the same developing countries which had been clamouring for a quick and fair resolution of the problem, have agreed to a decision which is so patently imbalanced in favour of large multinational patent holders, so restrictive and so unworkable for exporters and importers of generic drugs. The suspicion must be that this agreement, which had been held up for so long by the developed countries (especially US) and the multinational drug lobby, has now been hammered down the throats of the unfortunate developing country negotiators, simply in order to show some results before the Cancun meeting. If this is so, it certainly augurs badly for the outcome of other trade negotiations in Cancun.