Patents on medical products constitute one of the chief impediments to people in developing countries receiving access to vital medication. They cause prices to skyrocket and inhibit low-priced production.

WTO arrangements on patent protection for medical products are set out in the TRIPS Agreement. The TRIPS Agreement primarily safeguards the interests of pharmaceutical companies by guaranteeing high sales prices for years.

At the same time, TRIPS provides for several possibilities to ensure access to essential medication and circumvent the patent system. Instead of abolishing TRIPS, pressure should be applied to use and magnify these possibilities in a purposeful manner.
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In a market economy, patents serve the purpose of providing their holders ownership: whereas the postulate of free competition otherwise applies generally, patents are especially designed to prevent competition for a certain period, as they grant monopolies for a period of time; holders of patents have the exclusive right for a certain period of time to produce and sell the patented product. Holders of patents can therefore determine the price virtually as they see fit in a monopoly situation (Barton 2005: 2075 et seqq.).

This has a major impact on all areas of the international economy. The consequences of the patent system are especially pronounced, however, in those sectors which directly affect people’s basic needs such as, for instance, in the area of healthcare. Here monopolies on medication mean that a large portion of the sales price is tantamount to a “patent rent”. Take for instance the cancer medication Sorafenib Tonsylat: the patent holder, Bayer, charges 500 US dollars for 120 original tablets. A competing company, Cipla, has been offering this important medication for less than one-tenth of this price in India since 2010. The Indian government has now for the first time issued a compulsory license to a company called Natco, which is expected to lead to a drop in price to 178 US dollars, i.e. 3 per cent of the price charged by Bayer. The price is thus only based to a limited extent on actual production costs. Most of it is reaped as profit by the patent holder. Huge price savings can hence be attained by fostering competition between original providers and manufacturers of generic drugs (IP – watch 2012).

Proponents of the existing patent system forward as their main argument that higher profits encourage companies to engage in research and development of important new medication, which benefits society (vfa 2009, vfa 2007). This positive impact on innovative activities of companies and thus public health is conspicuously absent in developing countries, however. Patent protection on medication became possible in the European market for the first time at the end of the 1960s. Before this, research was conducted on new medication without this being afforded any patent protection; many of today’s most important medical discoveries date back to the period preceding the introduction of patent protection.

1,556 new chemical substances were developed as medications between 1975 in 2004. Only 20 of these substances (1.3 per cent) were suited for treating so-called neglected diseases including tuberculosis, which altogether cause 12 per cent of diseases throughout the world (Reichmann 2009, 247 et seqq.). Over the same period of time, the number of true innovations declined massively to only 10 per cent of substances developed. Patents apparently create skewed incentives here, as they redirect research activities towards innovations that sell well especially in industrialised countries. Medical needs and requirements, on the other hand, suffer as a result (Barton 2005:2075 et seqq.). More than one thousand of the medications researched during this same period were either lifestyle medications or pseudo-innovations.

1. The TRIPS Agreement

The Agreement on Trade Related Issues of Intellectual Property Rights (TRIPS) is one of the binding agreements of the World Trade Organization (WTO), founded in 1994. TRIPS sets out a minimum standard to protect intellectual property, which all WTO member states have to transpose into national law. This minimum standard includes patent protection lasting at least 20 years on all products which can be industrially manufactured and are new and innovative – including pharmaceuticals (WTO 1994). States are allowed to require stricter patent protection than the TRIPS minimum standard, but not less protection. It is up to the individual states to implement patent laws.

The TRIPS Agreement was designed by leading pharmaceutical enterprises in order to integrate protection of intellectual property in international trade law. Down to the present day this linkage has served to monetise and monopolize innovative medications while constricting supply and boosting prices.

TRIPS sets out protective clauses to harmonise the rights of patent holders with the human right of access to essential medication and the results of research. Whether individual members transpose these protective clauses into national law or introduce additional provisions (TRIPS plus) that TRIPS does not require (data exclusivity, patent linkages1) is left up to these states, how-

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1. Data exclusivity: clinical data is kept secret for a certain period of time independent of patent status and is thus not available to manufacturers of generic drugs in order to review licensing of needed bioequivalence for the market. This can lead to a longer period of monopoly. Patent linkage: licensing is linked to the patent status.
ever. Business and industrialised countries frequently attempt to pressure poor countries to institute such TRIPS plus clauses and/or wave protective clauses, as is demonstrated by ongoing negotiations over the Indian free-trade agreement with the EU.

2. Compulsory Licenses

One of the most important of these TRIPS protective clauses is compulsory licenses. When a compulsory license is issued, a government produces a patented product or a process protected by patent without the consent of the patent holder at a government-owned production site itself or awards a license for public use (government use licenses) (WTO 1994, WTO 2006). This allows medication protected by patents to be produced at lower prices; it can also be made available to other countries at lower prices. For many developing countries this offers an important option to ease access to vital medication (t’Hoen 2009).

The Doha Declaration issued upon the occasion of the WTO’s 2001 conference affirmed not only the right of governments to issue compulsory licenses. It was also stipulated that governments could determine the reasons for issuing these compulsory licenses themselves. A health emergency is by the same token only one reason among many for awarding compulsory licenses.2 »We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health… We affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all« (WTO 2001).

2.1 Consequences for Development Policy

The instrument of compulsory licenses is of tremendous importance to developing countries and contributes to an improvement in access to vital medications protected by patent. The effectiveness of the instrument highly depends on whether countries are able to import and export vital medication with compulsory licenses protected by patent, however. Especially small countries have scarcely made any use of compulsory licenses to date, nor do they produce vital medication, as the markets in which they could sell products with compulsory licenses are too small and thus not profitable. Article 31f of the TRIPS Agreement stipulates, however, that medication has to be produced especially for the domestic market with compulsory licenses. For poor countries with insufficient production capacities this leads to problems using compulsory licenses in the first place. Article 6 of the Doha Declaration recognises this. The WTO discussion process led to a compromise on 30 August 2003 which theoretically allowed countries with insufficient production capacities to import products with compulsory licenses (WTO 2003). Since then, however, only one country, Rwanda, has been successful in actually applying this compromise option and importing products with a compulsory license. Médicins Sans Frontières and other civil society actors are therefore contending that bureaucratic barriers and red tape are excessive and that the compromise does not work in actual practice.

What effect does the Doha Declaration have on the award of compulsory licenses as a whole? 24 compulsory licenses have being issued in sum total by the larger developing countries, most of them in countries with medium-level incomes. HIV medication constitutes the largest share by far with 16 compulsory licenses. Other diseases such as cancer, erectile dysfunction, anthrax and influenza only play a secondary role, while neglected diseases play no role at all. Aside from HIV, compulsory licenses thus do not appear to be the best tool with which to achieve lower prices in spite of the possibilities associated with this instrument (Beall 2012).

There are 2 reasons for this:

- Compulsory licenses must also be judged in terms of their effectiveness in a market economy. In lieu of sufficient demand, production is not worthwhile; prices do not decline without competition (O’Dowd2012).
- Compulsory licenses do not offer small, poor countries any alternatives as a result of woefully insufficient production capacities.

2. Countries are required to negotiate over a voluntary license before awarding a compulsory license. Whether they are obligated to do this or not is a source of ongoing debate. At any case they have to pay a royalty to the patent holder.
2.2 Recommendations for Action

Restrictions on use of products with compulsory licenses to the domestic market must be abolished. Article 27 of the TRIPS Agreement could make lack of domestic production a legitimate reason for a compulsory license. This issue has not yet been resolved in legal terms, however (Sionina 2003:29).

At the same time, developing countries must not continue to be put under pressure to refrain from exercising their rights, i.e. issuing compulsory licenses. Because pharmaceutical manufacturers and the industrialised nations are unlikely to stop applying pressure here, a redoubled commitment is needed on the part of civil society to step up media and public-relations work while encouraging targeted advocacy work with political decision-makers.

3. Parallel Imports

The TRIPS Agreement provides a second possibility for developing countries to reduce costs of vital medications. Pharmaceutical companies sell identical pharmaceutical products at different prices in different countries. This differentiated pricing policy allows them to maximise their profits. Parallel import is the term used to describe when governments purchase medication in another country where the medication is priced lower than if they bought it directly from the manufacturer. If a manufacturer has already exercised its patent rights in selling products, it is not allowed to block further sale of the medication to another government, the reason being that under article 8 of the TRIPS Agreement intellectual property rights are completely exhausted upon sale in one country (WTO 1994). Parallel imports are thus legal under the TRIPS Agreement – re-imports, on the other hand, are not. TRIPS explicitly prohibits medication produced in other countries without patents from being imported if such medication is still protected by patent in the importing country.

3.1 Consequences for Development Policy

Parallel imports are hence an instrument used to trigger price competition between the original manufacturer and the reseller. Access of the poor to medication protected by patent can improve as a result (HAI 2009). It is left up to the WTO member states to implement parallel imports in national law and stipulate in what geographic territory these are to be allowed (WTO 2006). Parallel imports have been successfully used by Médicins Sans Frontières and later by the public sector in Kenya as well (Lewis-Lettington 2004). Aside from these isolated examples, however, price reductions through parallel imports have for the most part remained hypothetical. If original manufacturers fear an erosion of profits, they have the option of raising the price of medical products in a country where it is resold or, if it is a less important country in economic terms, to simply stop supplying this country. For these reasons as well, parallel imports are scarcely used in developing countries such as the sub-Saharan states and therefore only play a marginal role in improving access to vital medication protected by patent (Sibanda 2009:183 et seq.).

Why do parallel imports not constitute any real alternative to the attainment of price reductions? Parallel imports fail to succeed as a tool because of a systemic internal contradiction. From a company perspective it generally makes sense to offer medication at lower prices in poorer countries in order to penetrate new markets. At the same time, all poor countries have a need to acquire medication as cheaply as possible. Hence parallel imports under TRIPS set a downward spiral in motion which companies opt out of by not offering medication at lower prices in the first place. The WTO principle of linked markets and parallel imports under TRIPS are mutually exclusive in this case (Reichmann 2009).

3.2 Recommendations for Action

In addition to these systemic barriers, pharmaceutical companies do not hesitate to fiddle with terms and definitions. They frequently denounce counterfeit pharmaceuticals, be it in legal trade in generic drugs or legal and legitimate parallel imports. Even if there are no legal means to counter such trade, such allegations generate enormous pressure on poor countries dependent on supplies from pharmaceutical companies. The fact of the matter is that developing countries have in the past been prevented from including parallel imports in their bodies of patent law. The confusion over terms has moreover led to a fatal situation in which medication has been repeatedly confiscated at European airports over the last few years – drugs which were merely in transit, to take one example, on the route from India to Brazil. They were not protected by patent in either country (Pharma-Brief 2009: 1 et seq.).
This has to change: even if parallel imports are no panacea, the advantages of this instrument must be upheld and preserved. The expressions »counterfeit medication« and generic products must be strictly separated in order to avoid confusion that legitimises the confiscation of drugs and prevents parallel imports.

4. Restrictions on Patentability

One crucial problem faced by patent arrangements for medication is the enormous number of new patents awarded each year. Each country has to award one patent for one product (or one process) which »is new, can be produced industrially and constitutes an innovative step« (WTO 1994). TRIPS does not specify, however, what an innovative step is supposed to mean. This makes it possible for countries to avoid patents on products which are not considered to be innovative enough (Amin 2011). Because patents on vital drugs restrict its availability by reducing the quantity produced, hence raising the price, this TRIPS flexibility is very important in providing access to new, improved vital medication.

Indian patent law takes advantage of this. Under section 3 (d) »discoveries of a new form of a known substance« are not eligible for patenting because they are not able to demonstrate any »enhancement of the known efficacy« (Ministry of Law and Justice 2005). This relative exception in patentability reduces the number of patents issued and protects public health by not affording patent protection to new medications that are beneficial to patients but only marginally innovative and can therefore be inexpensively reproduced as generic products (Khader 2008: 424 et seq.). Patents have accordingly been rejected for the merely marginally innovative Tenofovir Disoproxil Fumerate (TDF) or the heat-stable form of Lopinavir / Ritonavir (LPV/R) for not being innovative enough. Prices subsequently dropped due to a surge in competition from generic drugs.

The right to pre- and post-grant opposition has a similar thrust. It stipulates that the validity of a patent before and after its issue can be contested by individuals and/or groups. This enables experts to supply patent authorities with important information which they would otherwise have difficulty obtaining (Amin 2011). Thus pre- and post-grant opposition offers governments an additional means with which to restrict the patentability of products based on marginal innovations.

4.1 Consequences for Development Policy

The restriction on patentability is viewed to be the most important flexibility offered under TRIPS for the protection of public health: excluding products which are not innovative enough from patent protection has a positive impact on access to vital medication, as the example of India shows:

- Access to affordable, vital new medication is fostered by price reductions and production of greater amounts of generic drugs.
- Patents having a negative impact are discouraged by setting high standards for therapeutic progress.

4.2 Recommendations for Action

Pharmaceutical companies attack protective clauses based on the Indian model again and again both politically and by taking legal action. Novartis repeatedly argues – even though it should know better – that Section 3 (d) is not compatible with TRIPS or the Indian Constitution. The strategy of discrediting Indian patent law as unlawful has not worked to date. The courts rejected the action, although a new ruling is pending (Mudur 2007: 273). If such an action were successful, it would have a devastating impact. The crucial factor will be to demonstrate political support for the Indian position and not allow comparable legal actions to succeed.

While Indian patent law is of key importance to the export of vital generic drugs, access to this medication also depends on the patent laws of developing countries importing these drugs. At present we are seeing a paradoxical situation in which products without any patent protection are being produced in India and exported while not, however, being allowed to be imported by other developing countries. It is for this reason important to support developing countries in the formulation and implementation of patent rights compatible with TRIPS in order to take advantage of existing possibilities. Marginal innovations must remain ineligible for patent-
ing, or better yet: only if it is clearly demonstrated that there are considerable therapeutic benefits may a medication be patented.

5. Preserve or Abolish TRIPS?

Everyone has the right of access to vital medication and research results. This is stipulated in § 12 and § 15 of the UN International Covenant on Economic, Social and Cultural Rights (UN 1966). Withholding drugs and medication from people in developing countries that are vital to their survival is not only unethical – it also constitutes a violation of human rights. Governments are hence obligated to allow access to innovative medication at a reasonable price (Grover 2009). If this is in conflict with the profit motives of pharmaceutical companies, governments have to act in the interest of human beings. The TRIPS Agreement has fundamentally recognised this exigency and set out a host of escape clauses if patent rights prevent access to important medication.

Is the TRIPS Agreement for this reasons capable or incapable of providing access? This question defies any clear answer: As a result of the TRIPS Agreement, all WTO member states are forced to implement patent laws compatible with TRIPS and grant patents on new medication. The opportunity for pharmaceutical companies to profit from this is promoted by research on medication and a type of production that caters to Western sales markets. A departure from the principle of universal patentability would be advantageous to research on innovative medications, especially for neglected diseases.

The question is, however, what alternatives there are to the TRIPS arrangements? Because revocation of the Agreement would probably lead to each state which has a strong pharmaceutical industry to seek bilateral patent protection treaties, it would probably spawn a plethora of bilateral and regional trade agreements. Whether the developing countries would profit from this or not is more than doubtful.

It would appear to make more sense to expand on the existing protective clauses of the TRIPS Agreement. Compulsory licenses must be awarded in a more consistent manner. Parallel imports should be optimised within the realm of the possible. Above all, however, there needs to be a global campaign to establish more stringent requirements for patenting. If only medication for which real therapeutic progress is demonstrated is eligible for patenting, a large portion of patents would be eliminated. People in the developing countries would profit directly from this. This narrow definition of innovation would preclude the need to abrogate TRIPS and avoid the danger that the TRIPS Agreement could be replaced by even worse »TRIPS plus« agreements.

Another approach would be to supplement the TRIPS Agreement with socially just, non-exclusive licenses. In the past patents have almost always translated into exclusive rights to production and sales. This monopolisation could be broken by non-exclusive licenses, but these have been unimportant in the research community so far. The »Med for all« project especially fosters and promotes these ideas (med4all 2012). This is the right strategy.

Should TRIPS be preserved? Yes, but...
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About the author

Dr. Christiane Fischer has been managing director of the BUKO Pharma Campaign since 1999. The focal point of her work is on the impact of pharmaceutical patents on access to vital medication for people from poorer countries.

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Friedrich-Ebert-Stiftung | Global Policy and Development
Hiroshimastr. 28 | 10785 Berlin | Germany

Responsible:
Henrik Meyer | Social Responsibility

Phone: +49-30-26935-7462 | Fax: +49-30-26935-9246
http://www.fes.de/GPol/en

To order publications:
Sandra.Richter@fes.de

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