



EPHA Briefing Note on TRIPs, Access to medicines and the NOVARTIS case

Subject	Briefing on TRIPs, Access to medicines, and the NOVARTIS case
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1. What are TRIPs?

Trade Related aspects of Intellectual Property rights (TRIPs) is a generic term used in international trade rules that refers to the set of rules that govern what can be patent protected, in what circumstances and for what duration. They have a relevance to public health because they govern how Governments can regulate the patenting of medicines. In fact there are two broad categories of TRIPs – rights related to copyright such as literary or artistic works and rights related to industrial property. This second group can be divided between firstly issues surrounding trade marks and brand protection and secondly those protecting innovations and products. It is this second group that has a relevance to access to medicines as patent protection lasts at least twenty years.

See: http://www.wto.org/english/news_e/pres02_e/pr310_e.htm

2. How and when are rules on TRIPs decided?

The World Trade Organisation (WTO see: <http://www.wto.org/index.htm>) is the body that establishes the rules on TRIPs, administers their application, and convenes panels to adjudicate in disputes between Member States over them (TRIPs are administered by the TRIPs panel see: http://www.wto.org/english/tratop_e/trips_e/intel6_e.htm and for the work of the dispute panel see: http://www.wto.org/english/tratop_e/trips_e/intel5_e.htm). Following the introduction of TRIPs with the inception of the WTO in 1995, there was a variety of time-scales given for their full application by countries depending upon their level of economic development. The least developed countries were given the longest transitional period by which to apply all of the TRIPs provisions and for pharmaceutical patents these countries have until 1st January 2016. However, outside of this category are developing countries that were granted a shorter transitional period that expired before the start of 2005. This group of countries include the largest producers of generic pharmaceutical products for sale to the rest of the developing world. Moreover, the approach of a minimum standard to protect intellectual property rights, rather than a



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minimum standard to protect health has meant that the TRIPs agreement was criticized for its “one size fits all” approach as different countries face very different circumstances both in terms of their public health challenges and economic resources.

As a reaction to such criticisms the 142 WTO Member States affirmed in the Doha Declaration of November 2001 that governments were free to give priority to protecting public health rather than TRIPs.

The Ministerial Declaration from Doha affirms that "the TRIPS agreement does not and should not prevent members from taking measures to protect public health". It also adds that it 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".

See: http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm

3. How does Intellectual Property protection deny access to medicines?

Many factors influence access to effective medicines from the quality of diagnosis and the accurate prescription and dispensing of medicines to the quality control of drug production and their distribution. From the capacities and budgets of health systems to the research and development programmes for new treatments. The emphasis on patent protection as a means to secure innovation in treatments and advances in medicine has many problems.

Firstly there has been a historical imbalance in the finance of health related research and development with an overwhelming majority of research and development being concentrated on problems suffered by a minority of people. So wide has this gap been that it is commonly now referred to as the 90/10 gap: 90% of research and development money going to aid 10% of the health burden. Of course for the pharmaceutical industry this business model makes perfect sense- they are after all in business to be profitable and make a return on investment for their shareholders.

The attempt to promote innovation by protecting those who invest in innovation via patents unfortunately ignores the fact that it is not innovation *per se* that drives the business model of pharmaceutical companies, it is returns on investment. Patents therefore have failed to deliver either innovations for many diseases or indeed even treatments to many in low and middle income countries (for an example of the support among the medical science community see the extensively supported open letter to the WHO executive board available at: <http://www.accessmed-msf.org/documents/signon.doc>).

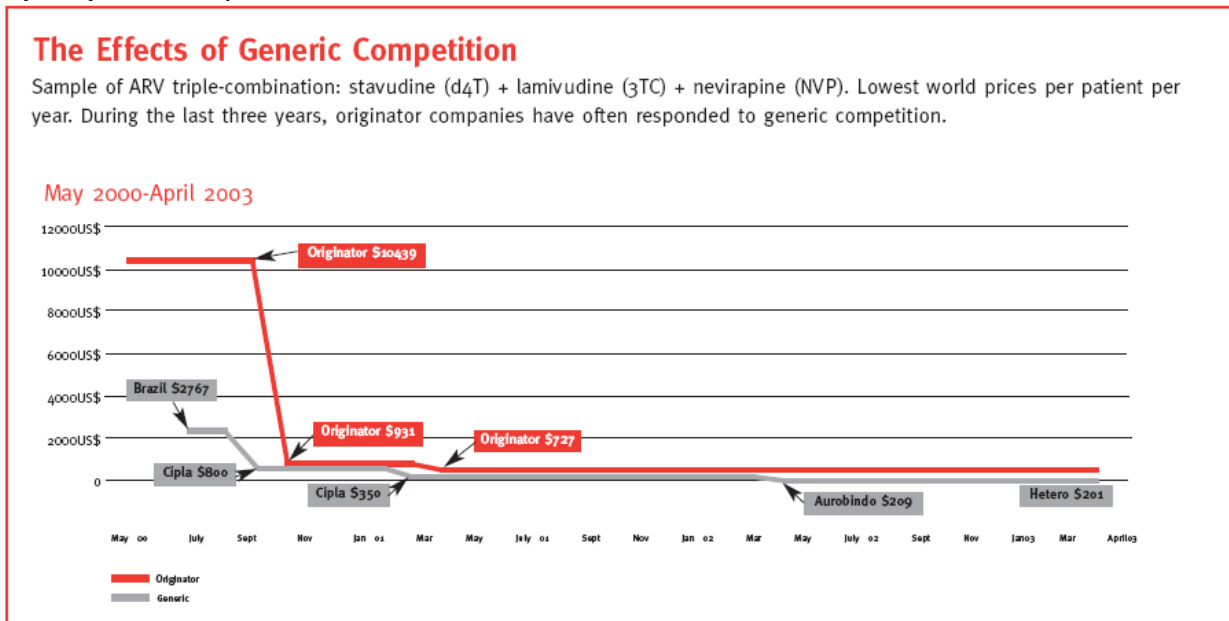
Yet a key feature for many developing countries remains the price of treatments. Drugs with high prices protected by from competition by patents effectively present a barrier to access for the overwhelming majority in developing countries. Furthermore, when



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treatments have been protected with patents their costs have been far higher than when this protection is removed.

By way of example:



Before the Doha round of trade negotiations pressure was brought to bear on all negotiators for a relaxation of the TRIPs provisions to allow greater access to generic drugs in developing countries. Many campaigners were able to demonstrate that far from promoting innovation in beneficial new treatments, patents were preventing access to essential medicines for large and vulnerable populations across the developing world. Nowhere was this more evident than in access to effective treatments for HIV / AIDS patients, where high treatment costs for effective medicines were effectively curtailing the lives of millions in developing countries.

Médecines sans frontières (MSF) have been at the forefront of long running NGO campaigns for improved access to medicines and have been supported by development NGOs such as Action Aid International and Oxfam. MSF estimates that one-third of the world's population lack access to essential medicines and in the poorest parts of Africa and Asia this figure rises to one-half. Since 1999 they have been campaigning to find long-term sustainable solutions to this crisis. They advocate a combination of policies to lower drug prices on a sustainable basis including:

- encouraging generic competition,
- voluntary discounts on branded drugs,
- global procurement, and
- local production.



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It was this NGO pressure that led to the issue being addressed in the Doha Declaration, despite the fact that the Doha trade round ended without a new comprehensive trade accord. However, following the Doha Declaration, and despite its content, there has been strong pressure from some developed nations (such as the USA) to agree so-called bilateral “TRIPs plus” agreements. These have further undermined the ability of developing countries to place public health concerns above trade considerations in defining patent laws. Once again the balance between protecting patent holders and protecting public health is swinging towards protecting patent holders.

See: <http://www.accessmed-msf.org/campaign/faq.shtm>

4. What is the NOVARTIS vs. India case about?

The Indian patent office refused to give a patent to Novartis for their cancer drug imatinib mesylate (brand name Gleevec) and Novartis is challenging this decision in the Indian courts. When Novartis originally filed the application for the patent the Indian cancer patients aid association lodged an opposition against the granting of the patent. Following this opposition the patent office declined the patent request stating that the drug was only a minor modification of a known substance – rather than an entirely new discovery. Novartis is challenging this decision on two counts: firstly that the decision itself is incorrect and that they are entitled to a patent for the drug, and secondly that the provisions of the Indian patent law cited in the refusal for a patent are unconstitutional as they violate the TRIPs agreement.

If the Novartis case is successful it could create obstacles to the provision of many different treatments for developing country patients. Firstly if Novartis successfully argues that drugs such as Gleevec are worthy of an Indian patent, then many of the drugs currently produced by the generic producers in India for export to developing countries may become patent protected and their production halted. Secondly, if Novartis successfully argues that public health provisions are secondary to India's World Trade Organisation TRIPs obligations, regardless of the Doha Declaration, then the very existence of the generics industry is placed in jeopardy. For more information and answers to frequently asked questions upon it see:

http://www.msf.org/msfinternational/invoke.cfm?objectid=A05B02CF-5056-AA77-6CA9A174A5C4E2F7&component=toolkit.article&method=full_html

Novartis has received a petition (supported by Médecins Sans Frontières, Oxfam, and Action Aid International) calling on it to drop this case signed by over a quarter of a million people including numerous world luminaries such as Bishop Tutu. The European Parliament has also let Novartis know of its displeasure with many MEPs supporting a written declaration calling on the EU institutions to support measures for Novartis to drop



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its case. All of this opposition has only produced a public relations backlash from Novartis, rather than a reflection of its actions or a dropping of its legal action. For an Oxfam rebuttal of the Novartis PR campaign against the European Parliaments Declaration see: http://www.maketradeair.com/en/index.php?file=a2m_novartis_12022007.htm

It is hoped that following the decision of the court Novartis will agree to reflect on its attitude and follow a different path, such as accepting any decision against it rather than appealing, that is more supportive of the worlds poorest and most vulnerable patients.

5. Is it just Novartis and why is relevant to Europe?

It is not just Novartis that its pursuing its business in ways that undermine public health provisions allowing access to medicines for the poorest of countries. For example Abbott Laboratories have refused to market the heat-stable version their anti-retroviral drug lopinavir/ritonavir (LPV/r branded as Kaletra) in Thailand because the Thai authorities would apply a compulsory license to the drug allowing its production by all manufacturers for sale in Thailand. It appears as though Abbott laboratories would rather the drug remained unavailable than have it produced and sold by others alongside its own production, a sentiment confirmed by their repeated refusal to meet the Thai authorities to discuss this issue.

Whilst the largest undertakings of the pharmaceutical industry are located across the OECD, many either have a strong European affiliation or have their headquarters in Europe. Given the high profile that these large corporations have, particularly via their strong public relations efforts, their behaviour in developing countries is frequently identified as a reflection of Europe and of the European healthcare / public health community. This is not say that such an identification is sought, rather it is an accidental by-product of their historical roots and current PR and marketing identities. The policies that these corporations follow in poorer countries of the world therefore reflect upon us all in Europe, and those active in the public health sector in particular. Beyond the need to act humanly and defend intrinsic human rights to health and well being, including reasonable access to health care, we also have a right to say “not in our name”.

Moreover the current climate sees public health priorities in Europe driven more and more within a framework of “multi-stakeholder” cooperation and of “public private partnerships”. Those who seek a larger role in European Public health (for example with constructs such as the High Level Pharmaceutical Forum) are often among those seeking to undermine universal access to medicines in poorer countries via application of patent rights. Advocating greater access to affordable essential medicines in poorer countries is, therefore, an element of seeking a better contribution from the private sector to public health protection in general.