Say no to Novartis!

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The Treatment Action Campaign (TAC) supports the Union of India, Cancer Patients Aid Association & others in the case brought against them by the Swiss pharmaceutical company Novartis in relation to the interpretation of Section 3(d) of the Indian Patent Act.

A ruling in favour of Novartis will have devastating consequences for the affordability of essential medicines in developing countries.

For background on the case see the Médecins Sans Frontières (MSF) Access Campaign?s page at http://www.msfaccess.org/content/what-future-india%E2%80%99s-patent-act-novartis-vs-union-.

The summary below of the case was published last week by the MSF Access Campaign. The case is being heard today.

What future for India?s Patent Act?

Update on Novartis vs. Union of India, Cancer Patients Aid Association & others in relation to the interpretation of Section 3(d) of the Indian Patent Act:

Swiss pharmaceutical company Novartis took the Indian government to court five years ago, in an effort to overturn Section 3(d) of the country?s Patent Act that was designed to prevent the patenting of new uses and new forms of known medicines. Now Novartis is up to it again and is targeting Section 3(d) once more. The latest legal challenge in the Supreme Court brought by Novartis against the Indian government has the potential to severely affect access to affordable essential medicines for millions of people across the developing world.

The final arguments have started - and the next date of hearing is set for next week, on Tuesday 6 September 2011 - in a case that will prove determinant in how public health safeguards enshrined in India?s Patent Act?s Section 3(d) can continue to ensure that patents should only be granted on medicines that are truly new and inventive.

If Novartis succeeds in changing the interpretation of section 3(d) for the purpose of obtaining a patent on imatinib mesylate, India may apply the same standards of intellectual property protection as wealthier countries like the US, granting far more patents than required under international trade rules or envisioned by India?s lawmakers. This could lead to generic competition on many essential drugs ending entirely and prices for these in both India and developing countries increasing. This would have a devastating impact on people the world over who rely on affordable medicines manufactured in India.

The Supreme Court case is the final act in a legal battle that stretches back over six years over India?s future capacity to act as the pharmacy of the developing world. In 2006, the Indian patent office rejected Swiss pharmaceutical company Novartis?s patent application for the anti-cancer drug imatinib mesylate - a beta crystalline salt form of imatinib. The application was rejected on the grounds that it lacked novelty, was obvious, and was un-patentable under Section 3(d)

of India?s Patent Act.

After Novartis mounted a legal challenge to have Section 3(d) declared unconstitutional, Médecins Sans Frontières (MSF) launched an international campaign calling on the company to DROP THE CASE, attracting close to half a million signatures. In 2007, the Madras High Court rejected Novartis?s plea and in 2009 the Indian Patents Appellate Board rejected its patent application on imatinib mesylate once again.

But the company is not backing down. After failing to have Section 3(d) struck down, they are now again seeking to limit its effect. In 2009, Novartis filed a special leave petition in the Supreme Court against India in relation to the patentability criteria to be applied to imatinib mesylate.

It is this case that is now before the Supreme Court. Its outcome has wide ramifications for generic production and access to medicines across the developing world. MSF purchases over 80% of the medicines it uses across the developing world to treat HIV/AIDS from India, and international donors rely on affordable Indian generic medicines in similar proportions for their aid programmes.

But if Novartis is successful and the requirements to deserve a patent are lowered, many more medicines ? even those that show no increased therapeutic efficacy will be patentable in India, and the source of affordable medicines will be threatened. If the substance is taken out of Section 3(d), abusive ?evergreening? practices - where drug companies maintain artificially high prices on medicines for longer by ever-extending patent protection thanks to minor modifications to existing drugs ? will be much easier in the future.

If, by contrast, the high threshold for patentability is upheld, generic production will continue to drive the price of life-saving medicines down.

Multinational pharmaceutical companies like Novartis will find it difficult to argue that routine improvements - such as new forms of existing medicines that result in improved stability, enhanced bioavailability, increased solubility, improved flow properties and lower hygroscopicity - meet the efficacy requirements of Section 3(d).

In addition, the improved therapeutic efficacy would have to be supported with actual clinical data that demonstrate this effect.

What is Novartis challenging?

Under Section 3(d) of India?s Patent Act, new forms of already known substances cannot be patented if they fail to demonstrate the required degree of efficacy. The interpretation of the definition of ?efficacy? is therefore central to this case, and to the future of India?s role as pharmacy of the developing world.

What does ?efficacy? mean?

Section 3(d) requires demonstration of increased efficacy for a medicine to deserve a patent. In 2007 in its constitutional challenge against Section 3(d) before the Madras High Court, Novartis also argued that increased bioavailability of the salt form of imatinib meant increased efficacy, entitling it to a patent on imatinib mesylate. But at the time, Madras High Court clarified efficacy to mean "therapeutic effect in healing a disease".

The Indian Patent Appellate Board (IPAB) ? where appeals for unsuccessful patent applications are heard subsequently applied this interpretation, and held that the salt form of imatinib mesylate did not meet the test of therapeutic efficacy, and therefore confirmed the rejection of Novartis?s patent application. Unhappy with this standard, Novartis is now before the Supreme Court to argue against the interpretation of efficacy by the Madras High Court and IPAB.

On what basis is Novartis claiming a patent on imatinib mesylate?

Novartis is basing its claim for a patent on the salt of imatinib based on the fact there is a 30% increase in the bioavailability of the drug in this new form. But according to the Guidelines for the examination of pharmaceutical patents developed by the World Health Organization and ICTSD, the selection of a salt of the active ingredient with the purpose to improve bioavailability is known in pharmaceutical art. It is common knowledge in the pharmaceutical field that salts result in different solubility and, therefore, in different bioavailability.

Does India not grant patents on medicines at all?

In 2005, India was obliged to change its patent law in order to comply with its obligations as member of the World Trade Organization and respect the TRIPS Agreement. The most significant change was the introduction of product patents for medicines.

This is already beginning to have a significant impact on access to affordable medicines, both in India and beyond, as newer medicines (invented after 1995) are highly likely to be product patent protected in India ? and many such as raltegravir (HIV), peg-interferon (Hepatitis C) already are.

The production of more affordable generic versions ? which has been so instrumental in driving down the price of older AIDS medicines by 99% in the past ten years - will therefore have to wait until the patents expire or a country issues a compulsory licence in order to overcome the patent. In the meantime, patients who cannot afford the high prices must simply go without.

How does Section 3(d) safeguard access to medicines?

When framing its new patent legislation in 2005, the Indian Parliament sought to ensure that not only the requirement under TRIPS were met but also provisions to protect public health and access to medicines were taken into account. It therefore included explicit legal safeguards and guidance on how the patentability requirements should be applied.

In particular, evergreening, a well-known abuse of the patent system where companies seek to extend a monopoly by seeking to patent minor changes that do not have a therapeutic effect such as new uses, new forms and other routine improvements of known medicines was addressed.

Section 3(d) of the Indian Patent Act explicitly allows the broad exclusion from patentability of new uses and new forms of known medicines. In sum, the Indian Parliament by introducing Section 3(d) chose to give explicit guidance as to how to apply the 'inventive step' test.

Setting high standards for the various tests in the patent legislation, particularly the 'efficacy' test of Section 3(d) and the inventive step requirement, leading to fewer patents on new forms of known medicines, is key to safeguarding access to affordable generic medicines from India.

What is MSF?s position?

MSF supports the Cancer Patients Aid Association (CPAA) in its battle against Novartis. The CPAA is a party to this case and will be arguing for a strict interpretation of ?efficacy? so that patents on new forms of known medicines ? such as the one on the cancer drug imatinib mesylate - are not granted routinely by Indian patent offices. Given the potential huge ramifications on generic production and the availability of affordable medicines from India, MSF, along with many other treatment providers, patient groups and affected communities is watching carefully the outcome of this case. Support the CPAA and the Lawyers Collective HIV/AIDS Unit, representing the CPAA in its battle to save section 3(d) and access to medicines across the developing world.