Stop Novartis's attempt to block Indian generic medicines

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The Treatment Action Campaign (TAC) calls on the drug company Novartis to drop its challenge to Indian patent law. The next court hearing in this critical case will take place on Monday 29 January in Chennai High Court in India.

We call on everyone to sign the Medecins Sans Frontieres (MSF) petition at:
http://www.msf.org/petition_india/international.html

We also call on the Indian government to stand firm against Novartis's court action. We ask the Indian government to recognize its responsibilities not only to its own population, but to other developing countries that depend on Indian generic medicines.

We ask people in Southern Africa to fax or mail the Indian Ambassador in SA, indicating their support:
Mr R K Bhatia, High Commissioner
Post Box No. 40216
Arcadia - 0007
Pretoria

Fax: (+27) (0) 12 342 5310

AN EXAMPLE LETTER IS PROVIDED BELOW.

Please see these materials:

- MSF press release
- Q&A on the court case by MSF
- Text of the MSF petition
- Example letter you can send to the Indian High Commissioner in South Africa
- Timeline on the court case prepared by MSF

MSF Press Release

MSF URGES NOVARTIS TO DROP ITS CASE AGAINST THE INDIAN GOVERNMENT

Case will negatively impact access to medicines for millions across the world.

New Delhi/Geneva - A legal challenge by Swiss pharmaceutical company Novartis against India's patent law could restrict access to affordable medicines in the developing world, the international medical humanitarian organization Mèdecins Sans Frontières (MSF) said today. The organization is urging Novartis to immediately drop the case.

India has long been an important source of affordable essential medicines because the country did not grant pharmaceutical patents until 2005. Generic antiretroviral medicines produced in India are used to treat over 80% of the 80,000 people that receive treatment today in MSF's AIDS projects in more than 30 countries.

"We rely on less-expensive, good-quality medicines produced in India to treat as many people with AIDS as possible," said Dr. Christophe Fournier, MSF International Council President. "This key source of medicines cannot be allowed to dry up."

Novartis was one of the 39 companies that took the South African government to court over five years ago in an effort to prevent the government from importing cheaper AIDS medicines.

"It feels like we're back in South Africa in 2001," said Dr. Tido von Schoen-Angerer, of MSF's Campaign for Access to Essential Medicines. "Just like five years ago, Novartis with its legal actions is trying to stand in the way of people's right to access the medicines they need."

India's law contains provisions that help put people before patents, but Novartis is taking the Indian government to court to force a change in the law. The company is challenging a key public health safeguard enshrined within India's Patents Act that aims to restrict the granting of trivial patents. If Novartis gets its way, it could mean that essential drugs are more likely to be patented in India, thereby restricting generic production and keeping prices for newer medicines high. p<> A constant flow of affordable newer medicines is particularly important for the treatment of AIDS, as people inevitably become resistant to their medicines and need newer drug combinations. But currently, patent applications on crucial newer generation AIDS medicines await patenting decisions in India.

"For people like me, who live with HIV/AIDS, a win by Novartis will mean a step back in time to the days when we could not afford our medicines," said Loon Gangte of the Delhi Network of Positive People, speaking at a press briefing in New Delhi. "Generic competition is what has made first-line AIDS drugs affordable for people and for governments. Novartis needs to stop standing in the way of our right to access the medicines we need to stay alive."

MSF is launching an international petition today to put pressure on the company.

"We are here today to ask Novartis's CEO Daniel Vasella to immediately stop the legal action in India," said Christian Captier, General Director of MSF in Switzerland. "We are urging Novartis to drop the case and we're asking everyone, everywhere to sign on and support the petition."

Q&A on patents in India and the Novartis case

Reproduced from http://www.msf.org/

Why do millions of people rely on India for affordable medicines? - What is the relationship between patents and affordable medicines? - Why does India grant patents on drugs now? - Why is Novartis suing the Indian Government? - How is it possible for India to reject a patent that is granted in other countries? - Does India have the right to have this particular patent law?

What will happen if Novartis wins the case?

Q: Why do millions of people rely on India for affordable medicines?

A: Drugs produced by companies in India are among the cheapest in the world. That is because until recently, India did not grant patents on medicines. India is one of the few developing countries with production capacity to manufacture quality essential medicines.

By producing cheaper generic versions of drugs that were patented in other countries, India became a key source of affordable essential medicines, such as antiretroviral medicines to treat HIV/AIDS.

Drugs produced in India have been used for the country's domestic market and are also imported by many developing countries that rely on India to provide the medicines needed e.g. to run national AIDS treatment programmes. Over half the medicines currently used for AIDS treatment in developing countries come from India and such medicines are used to treat over 80% of the 80,000 AIDS patients in MÃ©decins Sans FrontiÃ¨res projects today.

Q: What is the relationship between patents and affordable medicines?

A: Patents grant local monopolies to companies who hold them for a certain amount of time. This means that a company that holds a patent on a drug in a particular country can prevent other companies from producing or selling the drug in that country for the duration of the patent's term, which, according to World Trade Organization (WTO) rules is a minimum of 20 years. This in turn allows companies to charge high prices in countries where they hold patents, because there are no competitors in the market.

Competition among producers is the tried and tested way to bring prices down. Competition among generic manufacturers is what helped bring the cost of AIDS treatment down from $10,000 per patient per year in 2000 to $130 per patient per year today.

In the absence of patents, multiple producers compete for a share of the market, driving the price down as low as possible. In addition, having multiple sources helps increase the availability of drugs. Furthermore, the absence of patents in India has helped the development of, for example, three-in-one AIDS medicines and formulations for children.

Q: Why does India grant patents on drugs now?

A: As a WTO member, India has to comply with trade rules set by the WTO. One of these is the Agreement on Trade-related Aspects of Intellectual Property, or TRIPS, which obliges WTO countries to grant patents on technological products, including pharmaceuticals.

To comply with this international obligation, India changed its patent law in 2005 and started to grant patents on medicines. As a result, if patents are granted in the country, Indian generic manufacturers will not be able to produce cheaper generic versions of these medicines, which will have an impact not only in India domestically, but also on other countries that import Indian generics. Only a few new medicines have been patented in India today.

Roche obtained the first pharmaceutical patent in India in March 2006 for a hepatitis C treatment - but this is likely to increase in the future.

Currently, nearly 10,000 medicine patent applications await examination in India. If India begins to grant patents the same way that wealthy countries do - where medicines are routinely protected by several patents covering each small modification - it could mean the end of affordable medicines in developing countries.

Q: Why is Novartis suing the Indian Government?

A: Novartis applied for a patent in India on the cancer drug imatinib mesylate, which the company markets under the

brand name Gleevec/Glivec in many countries. The patent was rejected in India in January 2006 on the grounds that the drug was a new form of an old drug, and therefore was not patentable under Indian law.

In other countries where Novartis has obtained a patent, Gleevec is sold at $2,600 per patient per month. In India, generic versions of Gleevec are available for less than $200 per patient per month. Novartis is therefore trying to have the patent decision overturned so that it can sell Gleevec at the same price in India as in other countries.

Novartis is also trying to challenge the Indian patent law so that patents are as easily granted in India as they are in most other countries.

Q: How is it possible for India to reject a patent that is granted in other countries?

A: There is no such thing as an international or global patent. Patent applications are examined by patent offices in individual countries, and each office deliberates whether a particular drug should be patented or not on the basis of local patent regulations.

Fortunately, India designed its new patent law so that the number of patents granted would be kept to a strict minimum. This was an effort to reward innovation, which is the rationale of the patent system to begin with. The Indian law states that patents should only be granted on medicines that are truly new and innovative.

This means that companies should not be able to obtain patents for drugs that are not really new, such as for combinations or for slightly improved formulations of existing drugs.

This part of the law was specifically targeted at preventing a common practice of drug companies of trying to get patents on insignificant improvements of existing drugs, in order to extend their monopolies on drugs as long as possible.

Novartis is challenging this part of the Indian law, which the company says violates WTO rules.

Q: Does India have the right to have this particular patent law?

A: In 2001, all WTO countries signed the Doha Declaration, which states "that the [TRIPS] 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."

The same declaration allows countries to take measures to protect public health. India's patent law is based on this declaration. India chose to design a patent law that contains a key public health safeguard, namely the provision that only truly new or innovative drugs should be patented.

Q: Aren't patents needed to stimulate innovation for new drugs by pharmaceutical companies?

A: An increasing number of studies are showing that while patent protection has increased over the last 15 years, the innovation rate has been falling, with an increase in the number of 'me-too drugs' of little or no therapeutic gain. A survey published in April 2005 by La Revue Prescrire, concluded that 68 percent of the 3,096 new products approved in France between 1981 and 2004, brought 'nothing new' over previously available preparations.

Similarly, the British Medical Journal published a study rating barely five percent of all newly-patented drugs in Canada as 'breakthrough.'

And a breakdown of over one thousand new drugs approved by the US Food and Drug Administration between 1989 and 2000 revealed that over three quarters have no therapeutic benefit over existing products.

Q: What will happen if Novartis wins the case?

A: If Novartis wins the case and succeeds in getting the provision of Indian law changed to resemble patent laws in wealthy countries, patents may be granted in India as broadly as they are in wealthy countries. This will mean that fewer and possibly no generic versions of newer drugs will be able to be produced by Indian manufacturers during the patent terms of at least 20 years, and India will no longer be able to supply much of the developing world with cheap essential medicines.

The example of HIV/AIDS medicines is a good illustration of the problem. Even though older drugs to treat HIV/AIDS have become affordable thanks to generic competition, the availability of newer and improved drugs is crucial, as people become resistant to the drug combinations they take after a certain amount of time and inevitably need to be switched to newer "second-line" drug regimens.

Data from MSF's project in Khayelitsha, South Africa, illustrates this growing need: 17.4% of people on treatment there for five years have had to switch to a newer drug combination. Yet today, newer drugs are largely still only available from originator companies holding patents, which keeps prices high and availability low.

This is because Indian manufacturers have been reluctant to start producing these newer medicines, as they fear production would have to stop if patents were granted on these drugs in India. This in turn has led to the fact that prices for newer AIDS medicines can be up to 50 times more expensive than older drugs.

[END OF Q&A]

Text of MSF Petition

Sign the petition at: http://www.msf.org/petition_india/international.html

PEOPLE BEFORE PATENTS: THE LIVES OF MILLIONS ARE AT STAKE!!

SIGN-ON TO HELP PROTECT ACCESS TO AFFORDABLE MEDICINES!!

Pharmaceutical company Novartis is taking the Indian government to court. If the company wins, millions of people across the globe could have their sources of affordable medicines dry up.

Novartis was one of the 39 companies that took the South African government to court five years ago, in an effort to overturn the country's medicines act that was designed to bring drug prices down. Now Novartis is up to it again and is targeting India.

India produces affordable medicines that are vital to many people living in developing countries. Over half the medicines currently used for AIDS treatment in developing countries come from India and such medicines are used to treat over 80% of the 80,000 AIDS patients in MÃ©decins Sans FrontiÃ¨res projects.

If Novartis is successful in its challenge against the Indian government and its patent law, more medicines are likely to be patented in India, making it very difficult for generic producers to make affordable versions of them. This could affect millions of people around the world who depend on medicines produced in India.

Tell Novartis it has no business standing in the way of people's right to access the medicines they need. Sign on and urge Novartis to DROP THE CASE against the Indian government.

[END OF PETITION TEXT]

Example letter you can send to the Indian Government

Mr R K Bhatia

Indian High Commissioner to South Africa
Post Box No. 40216
Arcadia - 0007
Pretoria

Fax: (+27) (0) 12 342 5310

Dear Mr Bhatia

STAND FIRM AGAINST NOVARTIS

I/We support the Indian Government in its court case against Novartis. We reject Novartis's attempt to challenge Indian patent law. Many countries, including most Sub-Saharan African ones, import affordable generic medicines from India. Novartis's legal action threatens the sustainability of these life-saving drugs. I/We ask the Indian government to recognise its responsibilities both to its own citizens and the citizens of other developing countries. Stand firm against Novartis.

Regards NAME OF INDIVIDUAL/ORGANISATION

[END OF EXAMPLE LETTER]

Timeline of the Court Case

TIMELINE - Some key dates on the Indian Patent Act and the Novartis Case

1994/1995: Creation of the World Trade Organization & entry into force of the TRIPS Agreement, which obliges developing countries to grant patents on medicines no later than 2005.

2003: Novartis launches Gleevec in the US at $2,600 per patient per month. Generic versions of Gleevec soon become available in India for under $200 per patient per month.

April 2005: Amendment of India's Patents Act: medicines can now be patented in India. However, the law stipulates that only true medical innovations will be protected by patents. Section 3(d) specifies that new forms of known substances do not deserve patents.

Jan. 2006: Novartis' patent application on Gleevec rejected by Indian patent office, on the grounds that it is simply a new form of a known substance.

May 2006: Novartis appeals patent office's decision in High Court in India. Novartis also challenges Section 3(d) of the Indian Patents Acts.

September 2006: First hearing of the appeal and challenge. No decision made, but broader hearing set for later date.

Jan 29 2007: Next scheduled hearing in Chennai High Court in India

[END OF TIMELINE]

- Medicine Access
- Patents

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