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**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 Médecins Sans Frontières 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.

Petition text

Millions of people around the world today rely on affordable medicines produced in India. India's law contains elements that help put people before patents, but Novartis is taking the Indian government to court to force a change in the law. Neither Novartis, nor any company, should stand in the way of people's right to access the medicines they need. We urge Novartis to **DROP THE CASE** now against the Indian government.

People before Patents: The lives of millions of people are at stake!

PEOPLE BEFORE PATENTS: THE LIVES OF MILLIONS ARE AT STAKE - More Info

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 is a major source of affordable medicines, such as antiretrovirals to treat HIV/AIDS. Until 2005, the country did not grant patents on medicines, allowing Indian companies to freely produce cheap generic versions of medicines patented in other countries. These were used both domestically and in other 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 Médecins Sans Frontières projects. But World Trade Organization rules now require India to grant drug patents, which could lead to India drying up as a source of affordable medicines.

Fortunately, India designed a patent law that aims to protect public health by stating that patents should only be granted on medicines that are truly innovative. This 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. Indian law is strict about which drugs should and shouldn't be patented. One provision of the law that is unique to India says that no patent should be granted on a merely minor adjustment of an existing drug or molecule. This means that companies should not be able to patent drugs that aren't really new, such as combinations or slightly improved formulations of existing drugs.

Based on this part of the law, India for the first time ever decided to reject a drug patent in January 2006, on the cancer drug imatinib mesylate, marketed by Novartis as Gleevec.

Now Novartis is taking the Indian government to court, challenging this safeguard of India's law. If Novartis gets its way and the law is changed there is likely to be more patenting of medicines in India, which will in turn restrict the availability of affordable generic versions of essential drugs produced in India. And this would be detrimental for the millions of people worldwide who depend on them.

Q&A ON PATENTS IN INDIA AND THE NOVARTIS 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 Médecins Sans Frontières 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. Further, the absence of patents in India has helped the development of e.g. three-in-one AIDS medicines and formulations for children.

Q: Why does India grant patents on drugs now?

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?

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?

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?

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 preparations¹. Similarly, the British Medical Journal published a study rating barely five percent of all newly-patented drugs in Canada as ‘breakthrough.’² And a breakdown of over one thousand new drugs approved by the US Food and Drug Administration between 1989

¹ “A review of new drugs in 2004: Floundering innovation and increased risk-taking.”, Prescrire International, April 2005, vol.14, n. 76 pp. 68-73.

² “Breakthrough drugs and growth in expenditure on prescription drugs in Canada”, Morris L Barer, Patricia A Caetano and Charlyn D Black, Steven G Morgan, Kenneth L Bassett, James M Wright, Robert G Evans, British Medical Journal, 2nd September 2005, 331:815-6.

and 2000 revealed that over three quarters have no therapeutic benefit over existing products³.

Q: What will happen if Novartis wins the case?

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.

³ “Changing Patterns of Pharmaceutical Innovation”, The National Institute for Health Care Management Research and Educational Foundation,. Washington, DC, NIHCM Foundation, May 2002, <http://www.nihcm.org/innovations.pdf>

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.

29 Jan. 2007 – Next scheduled hearing in Chennai High Court in India

A KEY SOURCE OF AFFORDABLE MEDICINES IS AT RISK OF DRYING UP

– THE CASE OF NOVARTIS’S CHALLENGE AGAINST THE INDIAN GOVERNMENT AND WHAT IT COULD MEAN FOR MILLIONS OF PEOPLE ACROSS THE GLOBE –

Médecins Sans Frontières Briefing Note – December 2006

Swiss pharmaceutical company 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. An ongoing legal challenge 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. Novartis is challenging a public health safeguard enshrined within India’s Patents Act. If the company is successful, the era of India being a producer of affordable generic medicines for much of the world could be coming to an end with regard to newer and future medicines. This would have a devastating impact on people the world over who rely on affordable medicines manufactured in India.

PATENTS IN INDIA THREATEN A KEY SOURCE OF AFFORDABLE MEDICINES

India produces affordable medicines that are vital to many people living in developing countries. As an example, 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 Médecins Sans Frontières (MSF) projects today.

That is because until recently, India did not grant patents on medicines, which allowed Indian generic manufacturers to compete with patent holders and amongst each other to produce lower-priced generic versions of drugs patented in other countries. This sort of generic competition among multiple producers is what made the cost of AIDS medicines fall dramatically and helped facilitate global AIDS treatment scale-up thus far.

However, India is drying up as a source of affordable versions of newer and future medicines. This is due to changes made to India’s patent law in 2005, when the country was required to begin reviewing pharmaceutical patents according to its international obligations under the World Trade Organization (WTO) Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS).

Widespread medicines patenting in India could mean that cheaper versions of newer medicines will no longer be able to be produced by Indian manufacturers. Precisely such newer drugs are crucial e.g. for the treatment of HIV/AIDS.

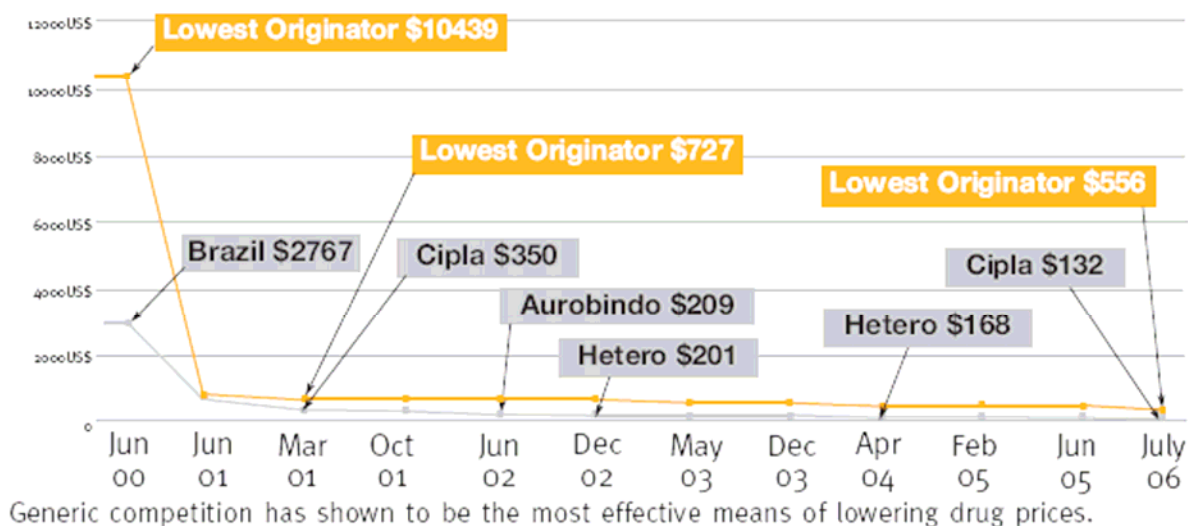
Fortunately, when the Indian government designed its patent law, an effort was made to find a balance between the intellectual property rights of pharmaceutical companies and the need to make drugs as affordable as possible. However, with this legal challenge brought by Novartis, access to newer affordable medicines produced in India could further worsen.

GENERIC COMPETITION NEEDED TO DRIVE PRICES DOWN: THE EXAMPLE OF AIDS MEDICINES

Thanks to competition among generic manufacturers since 2000, which was strongly encouraged by civil society pressure in countries such as India, Thailand and Brazil, the price of first-line antiretroviral drug regimens has fallen by 99% from an average of US \$10,000 to the current price of US \$132 per patient per year (see graph 1).⁴

Graph 1: Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices per patient per year.

The Effects of Generic Competition June 2000-June 2006



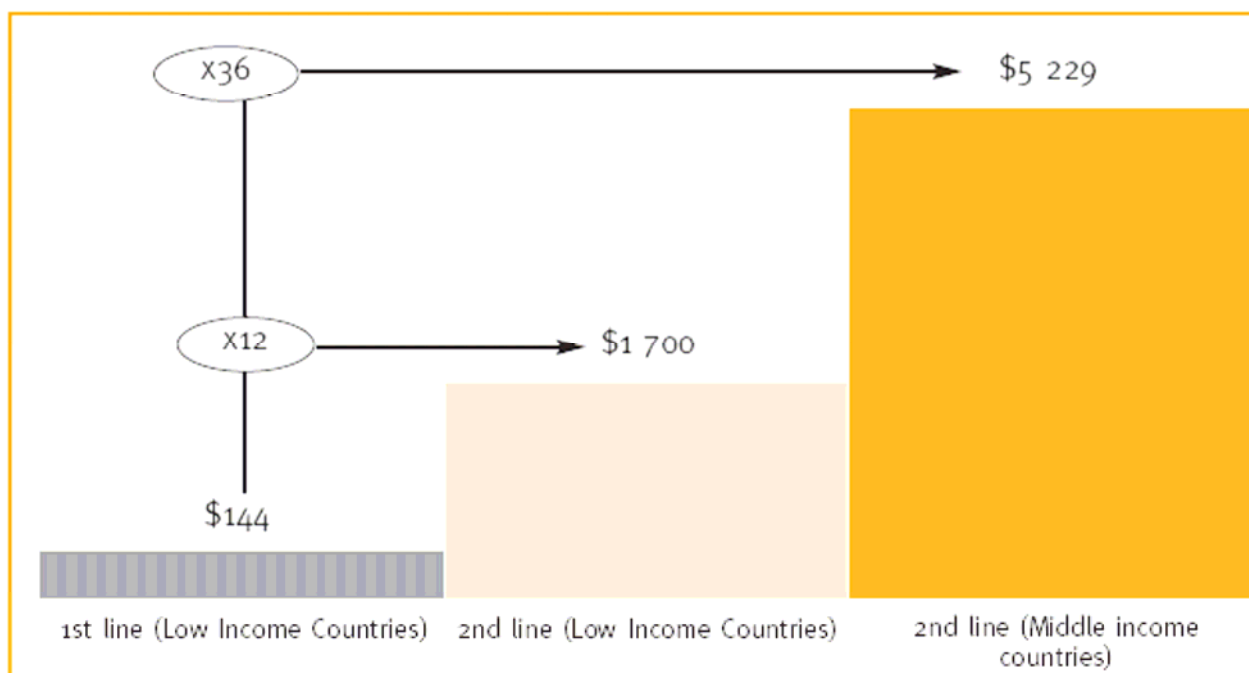
However, a new problem is looming. Assuring the availability of newer and improved drugs is crucial, as after a certain amount of time people become resistant to the drug combinations they take and inevitably need to be switched to newer “second-line” drug regimens. Data from one of MSF’s longest-running treatment programmes, in Khayelitsha, South Africa, shows that 17.4% of people who have been on treatment for five years have had to switch to such second-line therapy. Additionally, improved first-line medicines also require newer drugs.

Today, however, newer AIDS medicines are largely still only available from originator companies. Contrary to medicines used in first-line regimens, these newer drugs are under patent in other key countries with generic production capacity, Brazil and Thailand, which keeps prices high and availability low. These medicines are also awaiting patent review in India, which explains why competition on these newer medicines is still limited among Indian manufacturers. If patents are granted on these medicines in India, production of generic versions will not be possible. Even the production of medicines for which patent applications are pending is a high-risk investment for generic manufacturers, as companies do not know if they will be able to continue production and

⁴ Untangling the Web of Price Reductions: A pricing guide for ARVs in the developing world, 9th edition, 2006

sell the drugs in the future. This lack of competition on newer AIDS drugs today has had the result of prices for these medicines remaining much higher than those for older drugs, despite price reductions offered by originator companies (see graph 2)⁵.

Graph 2: Average weighted prices paid in 2005, reported to WHO GPRM for second-line ARVs in low- and middle-income countries, compared with first-line regimens



PUBLIC HEALTH SAFEGUARDS INCLUDED IN INDIA’S PATENTS ACT

WTO rules made it mandatory in 2005 for India to have a patent regime for medicines, and as a result, the Indian parliament approved the country's new Patents Act, thereby allowing pharmaceutical products to be patented in India. This new law puts severe constraints on generic competition. However, the new law at least contains several crucially important features to prevent patents from being granted too easily, such as provisions that specifically prohibit patenting of known compounds, and the possibility for anyone to object to a patent before it is granted.

An effort to prevent “evergreening:” Section 3(d)

At the time of amending the Patents Act, the Indian parliament was aware of the concerns about patenting of medicines that are not new. As a result, Indian lawmakers introduced a provision in the Patents Act that stipulates 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 in India for medicines

⁵ Untangling the Web of Price Reductions: A pricing guide for ARVs in the developing world, 9th edition, 2006

that are not actual inventions, such as drug combinations or slightly improved formulations of existing medicines.

This part of the law [section 3(d)] was specifically targeted at preventing a common practice used by drug companies of trying to get additional patents on insignificant improvements of drugs already patented. The provision was an effort to reward innovation, which is the rationale of the patent system to begin with. It also aimed to ensure that patents do not unnecessarily restrict access to medicines. It is this part of the law that Novartis is challenging, claiming it is in violation of WTO rules.

Further, manufacturers of patented medicines make minor variations to existing medicines in order to extend companies' monopolies for as long as possible. Also called "evergreening," this practice impacts the ability of patients to access affordable medicines by delaying or restricting the introduction of competition among other pharmaceutical manufacturers that could lead to lower prices.

An example of evergreening is the case of the ulcer medicine omeprazole, which Astra Zeneca sells under the brand name Losec. Sale of generic omeprazole in Canada was successfully blocked by the evergreening of patents by Astra Zeneca. As the basic patent on omeprazole was about to expire, Astra Zeneca switched the product from a capsule to a tablet and acquired new 20-year patents on the tablet form.

Pre-grant oppositions: the right to oppose a patent before it may be granted

India's Patents Act also allows room for any interested party to oppose a patent application that is awaiting a patenting decision. This "pre-grant opposition" process was used for the first time on an AIDS medicine in March 2006, when the Indian Network for People Living with HIV/AIDS (INP+) filed the an opposition to the patent claim for a fixed-dose combination of zidovudine and lamivudine filed by GlaxoSmithKline (GSK). INP+ based its opposition on Section 3(d) of the patent law, as the patent claim in question was not for a new invention but simply for the combination of two existing drugs. Similar oppositions on AIDS medicine patent applications have followed as most of the patent claims are for known pharmaceutical substances such as polymorphs, salts, and combinations. Soon after its patent was opposed in India, GSK announced the withdrawal of all its patents and patent applications for the fixed-dose combination of zidovudine and lamivudine.

In January 2006, the Indian patent office for the first time rejected a patent, on Novartis' patent application for the cancer drug imatinib mesylate, which the company sells under the brand name *Gleevec*. The patent was rejected on grounds that the application claims a "new form of a known substance." The rejection was a major success for the Cancer Patient Aid Association of India, which had submitted a pre-grant opposition to the patent office.

NOVARTIS'S CHALLENGE AGAINST THE INDIAN GOVERNMENT COULD HAVE GLOBAL CONSEQUENCES

If Novartis succeeds in its challenge against Section 3(d) of India's Patents Act, patents could end up being granted in India just as broadly as they are in wealthier countries. This would mean that virtually no generic versions of newer drugs could be produced by Indian manufacturers during patent terms lasting at least 20 years. And that would mean that much of the developing world would no longer be able to rely on Indian manufacturers for their supply of cheap essential medicines, in particular newer medicines.

Patent applications have been filed in India by originator companies for all newer AIDS medicines needed for second-line treatment regimens. These applications now await patent examination in Indian patent offices. Under the terms of Section 3(d) of India's Patents Act, many of these medicines may not be granted a patent in India because the molecule is already known and therefore does not represent a real innovation. If patents on these newer drugs are not granted, Indian generic manufacturers will be allowed to produce generic versions, compete amongst each other and with originator companies and sell these urgently-needed medicines at prices much more affordable for people in developing countries.

But if Novartis succeeds in getting the Indian Patents Act changed, India may apply the same standards of intellectual property protection as wealthier countries, granting far more patents than required by the WTO or envisioned by India's lawmakers. This could lead to generic competition on newer drugs ending entirely and prices for these in both India and developing countries increasing. This in turn would further deteriorate access to essential medicines in the developing world.

Likely patent for newer AIDS medicine lopinavir/ritonavir if Novartis succeeds

Lopinavir and ritonavir are two key AIDS medicines that need to be taken in combination by people who have developed resistance to their first set of medication. Although both medicines were first discovered in the early 1990s, pharmaceutical company Abbott Laboratories has applied for patents in India on new forms of these known medicines, in order to be granted a monopoly in India. Both patent applications are still under review at the Indian patent office, and have been opposed by civil society organisations.

DIFFERENT COUNTRIES NEED DIFFERENT PATENT REGIMES

Although the TRIPS Agreement obliges all WTO countries to grant patents on medicines, nothing obliges developing countries to replicate patent systems of wealthy countries. The agreement allows each country to set its criteria of patentability and does not prevent countries from including safeguards against the grant of patents for known substances, i.e. trivial patents. The Doha Declaration on TRIPS and Public Health, which was signed by all WTO countries, 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."⁶ Developing countries

⁶ Doha Declaration on TRIPS and Public Health, signed at WTO Ministerial meeting in Doha, Qatar on 14 November 2001

therefore have the right to design their patent laws in a way that takes their public health needs into account. This is precisely what India did when it amended its Patents Act in 2005. India fulfilled its obligation to grant patent protection according to WTO rules. The consequences for access to newer medicines for developing countries are severe; they should not be worsened further by making patenting too easy. Novartis should not be standing in the way and challenging India's rights.

NOVARTIS APPEALS PATENT REJECTION ON CANCER DRUG IMATINIB MESYLATE (GLEEVEC)

Novartis filed patent applications for the cancer drug imatinib in most countries in 1993. The company was not able to do so in India, as the country was not granting product patents at that time. In 1998, Novartis applied for a more specific patent on the beta-crystalline polymorph of a mesylate salt of imatinib i.e. imatinib mesylate, in order to try to obtain a patent monopoly in India

In January 2006, the patent on imatinib mesylate, which Novartis produces under the brand name *Gleevec*, was rejected in India on the grounds that it only represented a new form of a known substance and therefore was not an innovation and not patentable under Indian law. In May 2006, the company filed an appeal to the patent rejection, as well as a challenge against Section 3(d) of India's Patents Act.

Imatinib mesylate (Gleevec) is a crucial cancer drug essential in prolonging the life of patients suffering from chronic myeloid leukemia. In countries where Novartis has obtained a patent on Gleevec, the drug is sold at US \$2,600 per patient per month. In India, generic versions are available for less than US \$200 per patient per month. Novartis is now trying to have the patent decision overturned, so it can sell Gleevec at the same price in India as in other countries. The company is also challenging the Indian patent law, in an effort to make patents as easily granted in India as they are in most other countries.

**MSF LETTER SENT TO NOVARTIS CEO DR. DANIEL VASELLA ON
OCTOBER 19, 2006**



Novartis International AG

Dr. Daniel Vasella

Schwarzwaldallee 215
4002 Basel

Geneva, October 19, 2006

Dear Dr. Vasella,

We would like to express our concerns regarding the legal proceedings that Novartis initiated in India in May 2006, challenging the rejection of its patent application for imatinib mesylate (Glivec/Gleevec) as well as questioning the compliance of the Indian Patents Act with the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

This action contradicts the WTO Doha Declaration on the TRIPS Agreement and Public Health that states 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."

Médecins Sans Frontières (MSF) is concerned about the consequences of these actions for hundreds of thousands of people in need of medicines produced in India, which includes people treated through MSF programs. For this reason, MSF supported the NGO letter dated October 10th that urged Novartis to drop the case.

We have taken note of your comments in the *Financial Times* of September 30th, in which you state your reservations about the capability of the existing system to provide sustainable access to innovative medicines for people in poorer countries. We would be interested in your thoughts as to which extent the implementation of the recommendations of the World Health Organization "Commission on Intellectual Property, Innovation and Public Health" can be a starting point to fundamentally address issues concerning innovation and access to medicines in poorer countries.

We would welcome the opportunity to discuss these issues with you further as soon as possible. Please let us know what dates would be convenient for you.

Best regards,



Christian Captier
Director General
MSF Switzerland



Tido von Schoen-Angerer
Director
CAMPAIGN FOR ACCESS TO
ESSENTIAL MEDICINES
MSF International

INTERVIEW WITH DR. TIDO VON SCHOEN-ANGERER, DIRECTOR OF MÉDECINS SANS FRONTIÈRES (MSF) CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES (IN SWISS NEWSPAPER *BASLER ZEITUNG*, DECEMBER 7, 2006)

“There is no alternative to India”

The director of MSF’s Access Campaign on generic drug supply and the Novartis case

Interview: DIETER BACHMANN

Dr. Tido von Schoen-Angerer of Médecins Sans Frontières (MSF) fears a shortage of affordable medicines in developing countries if the patent on the cancer drug Gleevec is granted to Novartis by an Indian court.

MR. VON SCHOEN-ANGERER, MSF IS AN AID ORGANISATION; ISN’T THERE MORE IMPORTANT WORK FOR YOU TO DO THAN LEAD CAMPAIGNS AGAINST PHARMACEUTICAL COMPANIES?

TIDO VON SCHOEN-ANGERER: For a long time now, we have been confronted with difficulties in accessing affordable drugs. In addition, there is not enough tropical disease research. We started this campaign because of the crisis we face in our projects.

Gleevec is a cancer drug. Is cancer treatment really the most urgent task in your projects?

We are very concerned about the case filed by Novartis, because a grant of that patent and the tightening of the patent law would have disastrous results on drug supply in developing countries.

Why is that?

India is the most important provider of affordable generic drugs for developing countries. For example, 84% of the HIV drugs we use come from India.

You wrote Novartis a letter – how did the company respond?

We have still not received any satisfying response, namely an announcement that the company will drop the case. That said, Novartis is one of the few companies that does show an interest in neglected diseases. In Singapore, Novartis set up a malaria, tuberculosis and dengue fever research institute. But all the work that is being done there will be ruined if the company does not drop the case against the Indian Patents Act.

NOVARTIS PROBABLY HAS THE OPPOSITE POINT OF VIEW: THE REJECTION OF THE CASE WOULD DECREASE INTELLECTUAL PROPERTY PROTECTION IN INDIA...

We agree with Mr. Vasella [Novartis CEO] that the traditional patent system is not able to supply people in developing countries with drugs. A system based on patents and profits does not enable adequate research in tropical diseases. The system has failed.

YOU CLAIM THAT THE PATENT SYSTEM DOES NOT STIMULATE ENOUGH RESEARCH. WOULD THERE BE MORE RESEARCH WITHOUT PATENTS?

Patent protection alone is not sufficient. The tightening of patent laws in developing countries has occurred because of pressure from pharmaceutical companies arguing that it is the only way to have more research in neglected diseases. But that is not the case.

How do you convince companies to get involved in this field?

This problem cannot be solved by companies alone, which rely on profits. Governments have to get involved in formulating other research priorities.

Should governments pay for the research?

Governments should contribute to it. Drug prices should not be determined according to high research and development costs. This week, the Ministers of Health of all countries will meet in Geneva in a WHO-working group, in order to discuss an alternative framework to stimulate and fund this kind of research.

Switzerland is one of the countries that supports strong patent protection in international committees – does MSF use pressure on the political level?

Switzerland contributed to the setting up of the working group. Now, the question is whether Switzerland will encourage Novartis to drop the case.

NOVARTIS CLAIMS TO SUPPLY GLEEVEC FOR FREE IN INDIA IN MOST CASES. SO WHAT IS THE PROBLEM THEN?

We have typically had bad experiences with company donation programs, because they are often subject to complicated conditions and are geographically limited.

Does MSF as an aid organisation receive Gleevec for free?

We have not used the drug yet.

SUPPOSING NOVARTIS DROPS THE CASE: WOULDN'T ANOTHER PHARMACEUTICAL COMPANY TRY TO JUMP IN?

There is a possibility that other companies whose patent applications are not granted would try to do so. Actually, the same thing happened five years ago in South Africa. Various pharmaceutical companies failed with a patent complaint against the government of Nelson Mandela. That is why I do not understand why Novartis is trying the same thing again now in India.

It seems that everything is working to the advantage of the Indian generic industry at the moment. What is their position?

Fierce competition among companies in India is causing prices of generics to decrease. If more patents are granted in the future, Indian pharmaceutical manufacturers might lose their interest in supplying developing countries with drugs. The companies would concentrate on western markets, on drugs where patents have expired. There are already signs of this.



THE INDIAN MANUFACTURERS WILL PRODUCE THEIR OWN PRODUCTS SOONER OR LATER AND WILL SUPPORT MORE STRICT LEGISLATION...

While Indian companies invest more and more in to research and development, only a small fraction of the patent applications in India are from Indian companies. Most of them are submitted by western companies.

So you think that the Indian generics companies want Novartis to drop the case?

I am sure of it. Nevertheless, we are witnessing that the mere application for a patent discourages companies from investing in the production of newer generic drugs.

If Novartis' wins and your statements prove to be true, who could supply developing countries with generic drugs?

There is no alternative. China is an important producer, but the same patent law issues are about to come up there. And it is not realistic to think that production of needed drugs could occur in Africa only because there is a deferment of patent protection until 2016. Pharmaceutical companies are increasingly granting voluntary licences. But due to strict controls over the production process by originator companies, the prices of these drugs are not really low.