



2 March 2007

Dear Mr. Romeva I Rueda,

A group of MEPs had tabled a Written Declaration seeking action from the EU institutions to persuade Novartis to drop its legal action against the Indian Government regarding the patentability of its breakthrough cancer treatment, Glivec. Their central argument is that our actions would deny access to medicines to the poor. This is a fundamental misunderstanding of the issue.

We would like to request you **not** to sign this Written Declaration for the following reasons:

- The legal case does not concern access to medicines. On the contrary, 99% of the Indian patients who take Glivec (circa 6,600 patients in total) receive it from Novartis for free. Worldwide, Novartis is donating Glivec at no cost to approximately 19,000 patients in 80 countries.
- Our legal action in India does not undermine the provisions that allow access to medicines. Novartis only challenges those provisions of Indian Patent Law which are not currently in compliance with international law. Novartis fully supports the TRIPS conditions that promote access to medicines for developing countries and the Doha declaration.
- Our legal case has no impact on pending patent applications for new HIV treatments. Most new HIV treatments are new compounds, thus falling completely outside the scope of the current dispute.
- Our case concerns incremental improvements of earlier compounds. Novartis's position is that such innovations should also be patented. Our opponents argue that such stepwise innovations do not deserve to be protected as they often bring no additional value. This is however, a strange argument. Patents for incremental innovation do not prolong the life of the original patent. Thus, generic companies can always produce medicines based on the initial compound when the patent expires if they believe that the incremental innovation does not add value to the original product.
- The case also concerns the conflicting interests of Indian generic manufacturers and the innovative pharmaceutical industry. Indian generic manufacturers target the middle income populations but not the 'real poor'. In India, the generic version of Glivec costs 4.5 times the average annual income.
- A strong patent law is in the interest of India. One third of pending patent applications for pharmaceuticals comes from Indian pharmaceutical firms. Indian companies have a strong interest in having patents for incremental innovations and they have publicly supported our case.
- Novartis contests strongly that our case undermines the supply of affordable medicines to the developing world. Indian generic companies focus on the developed world and India; only 8% of their sales goes to the developing world outside India. By contrast, the innovative pharmaceutical industry treats 716,000 HIV patients in the developing world.



- Novartis is deeply concerned that patients have access to medicines. In 2006, our access to medicines program reached 33.6 million patients. Novartis spent USD 755 million last year alone. Public private partnerships can play an important part. Novartis is committed to explore the issue of access to medicines. But, any solution must be sustainable. Generics and the demise of the patent system is not a viable solution in the long-term.
- As the world's second largest manufacturer of generic medicines, Novartis understands and recognizes the contribution of generics once drug patents expire; our concern is with the non-recognition of intellectual property rights that ultimately advance pharmaceutical research and development for better medicines so that patients needs will be met in the future.

We attach a position paper which explains these issues in more detail.

Sincerely

A handwritten signature in cursive script, appearing to read 'Meni Styliadou'.

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## Novartis Position Paper on India/Glivec-case

### **The Facts:**

- Glivec is a breakthrough drug for a rare form of leukemia. When it was invented, India did not have patent protection for pharmaceuticals and as a result, Glivec has never been granted a basic compound patent in India.
- In July 1998 Novartis filed a mailbox application<sup>1</sup> for the beta crystal form of Imatinib mesylate, the active ingredient of Glivec.
- However a number of Indian companies had already started the commercialization of both the beta crystal of Imatinib mesylate and the alpha crystal. Most interestingly, both the alpha and the beta crystal forms are being exported from India to a number of markets. To date, in addition to India, registration of the alpha form has been granted in Argentina, Chile, Peru, Guatemala, Dominican Republic, Morocco and Egypt with the use of Novartis registration data in all cases. To date, registration applications are pending in several countries including Turkey, Colombia, Venezuela, Uruguay and Lebanon.
- In 2003, Glivec was granted exclusive marketing rights.
- In December 2005 the India Patent Office rejected the Novartis beta crystal patent application on the basis of section 3(d). Novartis decided to challenge this rejection as well as the constitutionality of the section 3(d) of the Indian Patent Law and its compatibility with TRIPs.

### **The Legal Arguments:**

Under article 3(d) of the Indian Patent Law salts, esters, ethers, polymorphs and other derivatives of known substances are not patentable unless it can be shown that they differ significantly in properties with regard to efficacy. In our view this section 3(d) is contrary to TRIPs in two respects:

- Article 27 of the TRIPs agreement provides a non-extendable list of types of subject-matter that can be excluded from patent coverage. This list does not include 'new forms of known substances lacking enhanced efficacy'. Therefore, section 3(d) goes beyond the framework provided by the TRIPs agreement.
- Section 3(d) represents an additional hurdle for patents on inventions specifically relating to pharmaceutical compounds and therefore the Indian law is in conflict with the non-discrimination principle also provided by TRIPs Article 27.

### **The Novartis Perspective:**

- a) **This case is NOT about access to medicines. 99% of the Indian patients who take Glivec, receive it from Novartis for free.**

Novartis has introduced a 'market segmentation' model for the distribution of Glivec in order to address access to medicines issues. Right from the beginning, Novartis has put in place the 'Glivec International Patient Assistance Program' (GIPAP) whereby Glivec is being donated at no cost to eligible patients on a global basis. Currently approximately 19,000 patients in 80 countries are receiving the drug free of charge. In India as of August 2006, more than 6,700 people (an estimated 99% of patients who receive Glivec in India) –are obtaining the drug at no cost through GIPAP.

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<sup>1</sup> The mailbox application regime was a transition measure introduced by TRIPs in the countries who were granted the right to postpone the adoption of a patent law to 2005 as was the case of India. Under this regime, inventors could file a 'mailbox application' that would give them the right to seek a patent when the patent law enters into force according to the state of the art on the day of the mailbox application and NOT on the day of the examination of their patent application.

Interestingly the price of the generic imatinib in India is 4.5 times a person's annual average income. This proves yet again that generics do not constitute a panacea for access to medicines.

**b) Our legal action in India does NOT challenge any provisions that provide for access to medicines.**

Novartis supports the TRIPS conditions that promote access to medicines for developing countries and the Doha Declaration. Indeed we believe that the Doha Declaration introduced a system that allows developing countries to address adequately public health risks while at the same time respecting fully their obligations under TRIPS.

However, India has failed to comply with its obligations under TRIPS as explained above. It is also important to underline that the Doha Declaration did not create an overriding right for developing countries to waive their obligations under TRIPS. It allowed for the export of medicines produced under compulsory licenses issued for public health reasons. These provisions safeguard access to medicines in poor countries that do not have sufficient local production capacity. Also, on a national level in India, there is the possibility for national compulsory licenses. Novartis fully supports these provisions and our legal action in India does not challenge them.

In other words, we challenge India because we believe it has failed to comply with its international obligations under TRIPS. And this is something that should concern all EU citizens. India is a major trading partner of the EU. It should thus be a priority for EU policy makers to ensure that India complies with its international trade obligations.

**c) Our legal case has no impact on the patentability of new compounds including new HIV treatments; our legal case concerns only stepwise innovation.**

It has been alleged that our case will impact some 10,000 patent applications currently pending before the Indian Patent Office or the availability of AIDS drugs and other essential medicines. In reality, our legal action in India concerns a specific article of the Indian patent law that endangers patents for stepwise improvements of medicines and has no impact on the patentability of most new HIV treatments which are new compounds.

We are also attacked, however, for the very reason that we ask for incremental innovations to be patented. The argument of our opponents is that incremental innovation does not add value to the original product and therefore should not be patented. However, if this is indeed the case and the incremental innovation provides no added value we do not understand why this may be an issue for the generic manufacturers. A new patent for an incremental improvement does not prolong the life of the initial patent for the basic compound and generics companies can always manufacture medicines based on the initial compound.

**d) This case is about trade and the conflicting interests of the Indian generic manufacturers on one hand and the innovative pharmaceutical industry on the other hand.**

Although the case has been portrayed as concerning access to medicines, the underlying issue is the level of patent protection in India and the extent to which it can favor local generic producers. However, the Indian generic manufacturers are not concerned about the 'real poor'. Their target is the middle income populations of India as well as several Latin American and North African countries. Lower patent standards in India do not translate into better access to medicines, as can be seen from the availability of HIV treatments in India. Anti-retroviral treatments were not granted patent protection until 2005 and can thus be manufactured and sold by Indian generic manufacturers. However, only 6% of HIV/AIDS patients in India receive antiretroviral treatment. .

- e) **A strong patent law protecting among others stepwise innovation is first and foremost in the interest of India itself.**

There is sound evidence that a strengthening of patent protection leads to an increase of foreign direct investment inflows<sup>2</sup>, especially for IP sensitive industries<sup>3</sup> such as pharmaceuticals. The case of Jordan<sup>4</sup> sets an excellent example: IP protection helped the national pharmaceutical industry to climb up the value chain and transform itself from an imitator to an innovator. India is an emerging economy with an important pharmaceutical industry. Already now, one third of patent applications pending for pharmaceuticals in India come from Indian firms. Ranbaxy the biggest Indian pharmaceutical company has publicly supported that incremental innovations should be protected by a patent<sup>5</sup>. Other smaller companies have also started voicing similar views. It's also noteworthy that 83 patents on stepwise innovations such as salts, esters, and other modifications of existing patents are pending in Brazil, filed by Indian companies. That means that Indian companies are interested in having such patents, if they are made available.

- f) **We contest strongly the statement that, depending on the outcome of our case, India may cease to be able to export affordable medicines to the developing world.**

According to data provided to us by IMS<sup>6</sup>, the 10 biggest Indian generic manufacturers representing 77% of the global Indian generics sales by value, receive **only 8%** of their revenue from exports to developing countries outside of India. Their focus is clearly the developed world and India.

On the other hand, the research based pharmaceuticals industry treats over 716,000 HIV patients in the developing world out of a total of 1.3 million HIV/AIDS patients treated in poor environments according to WHO and UNAIDS estimates<sup>7</sup>. By comparison, MSF treats 60,000 patients in 30 countries according to its estimates on their website.

- g) **Novartis is deeply concerned that patients have access to medicines as demonstrated by our far-reaching access to medicines program.**

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<sup>2</sup> Thursby J and Thursby M (2006: Here or Here? A survey of factors in multinational R&D location – Report to the Government-University-Research Roundtable (2006), National Academy of Sciences, National Academy of Engineering, Institute of Medicine

<sup>3</sup> OECD (2003) The impact of trade-related intellectual property rights on trade and foreign direct investment in developing countries

<sup>4</sup> Jordan has benefited massively from adopting its IP regulations after joining the WTO. Jordan's generic pharmaceutical companies have benefited from a stronger IP-protection both by gaining access to new export markets and by starting to engage in innovative research. Between 1999 and 2002 the exports of the local industry grew by 30%. The Jordanian company Triumpharma is now developing improved formulations of off-patent drugs that are patentable. These new products bring benefits to patient and can be exported to the developing and the developed world.

<sup>5</sup> The Economic Times, Mumbai, 26<sup>th</sup> of February 2007.

<sup>6</sup> IMS report "Analysis of Indian generic companies strategies and other questions related to Glivec" (February 2007). IMS Health is an independent company which provides objective and unbiased data and business intelligence to, *inter alia*, pharmaceutical companies, governments and public health institutions, drug safety and patient advocacy organizations, medical and academic researchers, healthcare regulatory agencies and industry observes. See [www.imshealth.com](http://www.imshealth.com)

<sup>7</sup> This is the number of patients treated by the Accelerating Access Initiative (AAI) is a cooperative endeavor of UNAIDS, the World Health Organization, UNICEF, the UN Population Fund, the World Bank, and seven research-based pharmaceutical companies (Abbott Laboratories, Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Gilead Sciences, Merck & Co., Inc. and F. Hoffmann-La Roche). For further information on the scope of this initiative please visit

[http://www.merck.com/cr/enabling\\_access/developing\\_world/hiv/hiv\\_access.html](http://www.merck.com/cr/enabling_access/developing_world/hiv/hiv_access.html)

In 2006 our access to medicines program reached 33.6 million patients. Novartis spent USD 755 million last year alone. We engage in a number of innovative public-private partnerships (PPPs) with efforts spanning a number of disease areas, including our three PPPs with WHO to combat leprosy, malaria and tuberculosis. Novartis has also established an Institute for Tropical Diseases in Singapore dedicated entirely to drug discovery for neglected diseases. These actions among others, lead to Novartis being named industry leader in the 2006 Dow Jones Sustainability Index.

However, we are the first to acknowledge that access to medicines is a very complex issue that requires cooperation among several partners from both the public and the private sector. We believe that effective Public Private Partnerships can be an important piece in this puzzle and we are committed to working with partners in order to explore sustainable business models. However, we contest strongly that generics and the demise of the patent system is 'the solution' to the access to medicines problem.