



March 7, 2007

Dear Member of the European Parliament,

You have received a ~~letter from Novartis~~ requesting you to not sign the Written Declaration concerning the Novartis court case against the Indian Government. Declaration was introduced by 5 MEPs from 4 different parties (Pierre Schapira, Kader Arif, Johan Van Hecke, Luisa Morgantini and Caroline Lucas)

Through this Declaration MEPs recognise the crucial role of India as main supplier of generic drugs to developing countries, and express their support to the Indian Government who implemented the TRIPs agreement in a pro-public health way in order to ensure the availability of affordable medicines in developing countries according to the Doha Declaration on TRIPs and Public Health. They request Novartis to withdraw the case and call the EU Commission and EU Council to take a similar position.

As Humanitarian and development organisations, Oxfam, ActionAid, MSF, we are highly concerned about the stakes of the Novartis's action against the Indian Government in view of the increase need of affordable essential medicines in our programmes.

We therefore would like to respond to some of the misleading points made by Novartis in their letter. To this end please find below some clarifying comments in the text of the Novartis letter (text box).

We urge you to sign this Declaration to provide support to the Indian Government in the defence of the Indian Patent Act before the judgment that will come up by the end of March.

For additional information about this issue see also the following link:
http://www.maketrade-fair.com/en/index.php?file=a2m_novartis_12022007.htm

With best regards,

MSF Alexandra Heumber, OXFAM Jennifer Brant, ACTIONAID Marta Monteso

Letter from Novartis to the MEPs faithfully re-transcribed.

Date : 2 march 2007

Dear XXXX (member of the European Parliament)

A group of MEPs has tabled a Written Declaration seeking actions 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 arguments is that our actions would deny access to medicines to the poor. This is 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.

This only supports the case that it is indeed about access and not about Glivec as they seem to be saying that they are not selling Glivec for profit reasons in the developing world. If this was true why the challenge ? The case does concern access to medicines. Novartis says that they are giving the medicine for free with respect to philanthropy and to the rationale that most individuals cannot afford the medicine at any price, and therefore the need for public health safeguards to reduce medicine prices is all the more necessary.

- Our legal action in India does not undermine the provision 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.

Novartis challenges section 3(d) of the Indian Patents Act. Legal experts agree that this section does not violate India's obligations under TRIPs. A report by the Mashalkar Commission Novartis used in its legal arguments to support its claim that 3(d) was not TRIPs compliant has been withdrawn by the authors after a legal group presented evidence that parts of the report were verbatim copies of an Industry funded report. Novartis was one of the funders of the report.

- Our legal case has no impact on pending patent applications for new HIV treatments. Most new HIV treatments are now compounds, thus falling completely outside the scope of the current dispute.

This is not true. There are several patent applications pending relevant to AIDS drugs that likely will not get a patent if examined under section 3(d). For example combination products or heat-stable versions of AIDS drugs much needed in developing countries.

- 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.

Yes even the most affordable medicines are often too expensive for poor people. But this can hardly be a reason for increasing exclusivity and arguing that therefore price does not matter. The generic price of Glivec is 200 US dollars, Novartis price is 2600. No one can argue that this does not make a difference to many people.

- 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.

Having as many patents as possible is not in the public interest. It is in the public interest to award real innovations- this is what the Indian law strives to do by excluding non essential follow- up changes to an original compound from patentability.

- 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.

Aside from the fact that industry does not treat- they sell drugs. On Indian generic sales, Novartis claims that 8% of sales go to developing countries, based on data they commissioned from IMS and that are not publicly available. If true, it does not contradict that about 60% of exported Indian medicines (volume not sales) go to developing countries.

- 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.

Novartis had 7.5 billion dollars in Glivec sales alone which put the 755 million on access programmes in perspective. No matter how laudable this is. It is good that Novartis wants to explore access to medicines- but we do not think challenging a pro-health patent law is the way to do this. There indeed needs to be serious discussions on new ways of providing medicines- in other words having both innovation and access. In today's model R&D is primarily financed through high drug prices which inevitably leads to rationing and exclusion Of the poor. We find this unacceptable.

- 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.

India does recognise patents and grants patents when patentability criteria are fulfilled. Recognition of Intellectual Property does not mean that a drug company get a patent whenever it ask for one. Each country examines patent applications and applies patentability criteria that may vary per country.