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Dr. Daniel Vasella
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Lausanne, 22 February 2011

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NGO Open letter over Novartis' persistent legal actions in India

Dear Dr. Vasella,

Please find attached an Open letter by civil society organizations expressing grave concerns over Novartis' persistent legal actions in India regarding the patent application for imatinib mesylate (Glivec®/Gleevec®).

Yours sincerely,

Patrick Durisch
Health Programme Coordinator
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**OPEN LETTER TO DR. DANIEL VASELLA
CHAIRMAN OF THE NOVARTIS BOARD OF DIRECTORS**

Date: 22 February 2011

Dear Sir,

We, the undersigned civil society organizations striving for access to medicines for all, are writing to express our grave concern about Novartis' persistent legal actions in India regarding the patent application for imatinib mesylate (Glivec®/Gleevec®). We reiterate our previous calls and strongly urge Novartis to drop the case that is currently being heard in the Supreme Court of India. In addition, we call on the company to refrain from trying to influence the government of India to introduce laws or policies that will hinder access to medicines.

In June 2009, the Intellectual Property Appellate Board (IPAB) of Chennai ruled that Novartis' patent application on a medicine used to treat Chronic Myeloid Leukemia (CML), the beta crystalline form of imatinib mesylate, is *not patentable*. The IPAB declared that the application fails to meet section 3(d) requirements under the Indian Patents Act.

This decision followed previous rejections in January 2006 and again in March 2009 of patent applications for the beta crystalline form, and the alfa crystalline form of Glivec, respectively.

In addition, Novartis challenged the constitutional validity of section 3(d) of the Indian Patents Act in May 2006, claiming it to be inconsistent with the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). In August 2007, the High Court of Chennai ruled that section 3(d) was *not in violation* of the Indian Constitution, and accordingly dismissed Novartis' petition. The court duly referred the question of TRIPS compliance to the WTO's Dispute Settlement Body. Novartis did not appeal this decision, but has since then, sought alternative strategies to challenge India's patent laws.

In addition to the pending case at the Supreme Court, Novartis filed at least three patent applications related to other crystalline forms of imatinib mesylate to the Indian Patent Office¹ between October 2007 and November 2009, despite repeated rejections.

Despite legal setbacks and massive international outcry, in August 2009, Novartis filed yet another appeal to the Supreme Court of India² to continue its attempt to weaken section 3(d).

Recent news article³ have reported that the Organisation of Pharmaceutical Producers of India (OPPI, of which Novartis is a member) is seeking a more stringent intellectual property regime in India, going beyond what is mandated under the TRIPS Agreement, including data exclusivity, patent linkage and amendments to section 3(d) of the Indian Patent Law. We are concerned that these lobbying activities will negatively influence the outcomes of the bilateral free trade agreements currently under negotiation between India and the European Union, and the European Free Trade Association. TRIPS *plus* provisions, such as those mentioned above, would have a significant impact on current and future access to medicines across the world, because of India's status as the leading supplier of generic medicines to developing countries.

The battle for exclusive patent rights over Glivec is one of the longest and most controversial

intellectual property debates on medicines since India aligned its patent rules in conformity with the TRIPS Agreement in 2005. Section 3(d) of the Indian Patent Act is a legitimate and invaluable flexibility in the TRIPS Agreement that represents an important public health safeguard in Indian law meant to support access to essential medicines.

At Glivec's launch, you publicly affirmed that no patient in need should be denied life-saving cancer treatments such as Glivec⁴. Despite the establishment of the Glivec International Patient Assistance Program (GIPAP) to counter the problem of high prices, the GIPAP is nowhere near covering all the public health needs. Compared with the estimated 25 to 30,000 people newly affected by Chronic Myeloid Leukemia each year in India, according to Novartis figure⁵ the GIPAP has benefited only between 7 to 11,000 patients. As a life-long treatment, we believe that many more patients could benefit simply by more affordable prices, which is a more sustainable solution than drug donation.

Treatment with Glivec currently costs around 2,500 USD per month, a sum that the vast majority of Indians simply cannot afford, whilst local generic versions are available for around 10% of that price.

In response to the R&D investment argument ("hundreds of millions of dollars") to justify why Novartis set a single global price for Glivec⁶:

- all the basic research and preclinical investigations were done in academic institutions, overwhelmingly funded by taxpayers and other non-profit support.
- Glivec was granted "orphan drug" status in the United States and was therefore eligible for tax rebates equal to half the cost of clinical testing.

Novartis' certainly deserves credit for the development and production of Glivec, but evidence suggests that its R&D investment was below the average costs cited by the originator pharmaceutical industry.

We strongly urge you to drop the case which is currently in the Supreme Court in India, and to stop refrain from attempts to influence the government of India to introduce laws and policies that will hinder access to medicines, putting the lives of millions at stake, in India and across the globe.

Yours sincerely,

SIGNATORIES

1. The Berne Declaration
2. Health Action International (Europe)
3. Health Action International (Africa)
4. Health Action International (Asia Pacific)
5. Third World Network
6. Knowledge Ecology International

REFERENCES

1. Patent applications 1518/DELNP/2008, 4000/DELNP/2008, 7532/DELNP/2009, identified through the Indian Patent Information Retrieval System of the Office of the Controller General of Patents, Design and Trademarks (<http://www.ipindia.nic.in/ipirs1/patentsearch.htm>, last accessed on 16.02.2011). Two other patents applications also concern imatinib (8340/DELNP/2007 and 9474/DELNP/2007)
2. <http://www.business-standard.com/india/news/sc-issues-notice-to-govt-othersnovartis-petition/369855/> (last accessed on 16.02.2011)
3. <http://business.rediff.com/report/2010/aug/19/pmo-renews-patent-debate.htm>, last accessed on 16.02.2011)
4. http://www.novartis.com/downloads/about-novartis/Novartis_position-Glivec_Gleevec_patent_case_india.pdf (last accessed on 16.02.2011) or <http://www.evb.ch/fr/p25012589.html>
5. <http://www.evb.ch/fr/p25012589.html> and <http://www.business-standard.com/india/news/sc-issues-notice-to-govt-othersnovartis-petition/369855/> (last accessed on 16.02.2011)
6. Consumer Project on Technology: Health Care and Intellectual Property: Therapy and Treatment Areas: Specific Medicines: Imatinib Mesylate (Gleevec/Glivec/STI571) last accessed on 16.02.2011 at <http://www.cptech.org/ip/health/gleevec/>. CPTech operates since 2006 under a new name, Knowledge Ecology International, with a redefined mission.