



Interfaith Center on
Corporate Responsibility

Inspired by faith, committed to action

475 Riverside Drive, Suite 1842
New York, NY 10115-0050
www.iccr.org

Tel: 212-870-2295
Fax: 212-870-2023
info@iccr.org

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Dr. Daniel Vasella
Chief Executive Officer
c/o
Investor Relations
Novartis U.S.A
608 Fifth Avenue
New York, NY 10020

Dear Dr. Vasella,

We are Members and Associates of the Interfaith Center on Corporate Responsibility (ICCR), an international, interfaith coalition of institutional investors. Together, we are urging you to withdraw your legal challenge to Section 3(d) of the Indian Patent Act, in a case concerning the patent status of the cancer drug Gleevac / Glivec (imatinib mesylate).

Balancing Innovation and Access to Medicines

The patent status of essential medicines in least developed and developing countries is a heated issue around the world. As faith-based and socially responsible investors exposed to the pharmaceutical sector, we are faced with the challenge of balancing intellectual property rights with the need to respect and affirm the human right to health of billions of the world's poor.

Novartis faces the same challenge, and has often responded admirably. In ICCR's August 2006 report *Benchmarking AIDS*, Novartis received our highest possible rating in neglected disease research. Novartis also scored above the industry mean in four additional categories.¹ Novartis provides 6500 Glivec patients in India with free medicine.² We respect the balance you are attempting to strike – but on this topic, we suggest Novartis is not succeeding.

¹ Kieran Hartsough, Daniel Rosan, and Lisa Sachs. [Benchmarking AIDS: Evaluating Pharmaceutical Company Responses to the Public Health Crisis in Emerging Markets](#). *Corporate Examiner* vol. 34 no. 6-7, August 1 2006.

² Novartis position – Glivec patent case in India. December 2006.

In 2005, the democratically elected Indian Parliament wrestled with this same need to balance intellectual property rights and public health needs in a country where 25% of the population lives in poverty and per capita GDP is \$3,500. As result, the Indian Patent Act contains a number of provisions which take advantage of the flexibilities allowed by the World Trade Organization's Doha Declaration – flexibilities Novartis is on record as supporting:³

The tension between intellectual property rights and access to medicine is address by the Doha declaration offering the instrument of compulsory licenses to tackle public health problems, and Novartis supports the flexibilities offered in this declaration.

Patents are one mechanism to create incentives for innovation. We do not dispute the importance of medical advancements – indeed, we advocate for greater research into diseases of poverty. However, as The Commission on Intellectual Property, Innovation, and Public Health points out in its report, “the monopoly costs associated with patents can limit the affordability of patented health-care products required by poor people in the absence of other measures to reduce prices or increase funding.”⁴

The Legal Situation Today

Shortly after the Indian Patent Law went into effect in January 2005, Novartis sought a patent on the cancer drug Gleevac / Glivec (imatinib mesylate). That patent was denied after opposition by a local NGO, the Cancer Patients Aid Association. Novartis is asking the Chennai High Court to reverse the January 2006 decision not to patent Gleevac / Glivec (imatinib mesylate). Novartis alleges Section 3 (d) of the Indian Patent Act is not in compliance with World Trade Organization rules. Section 3 (d) states that slight improvements of known molecules are not subject to patent protection. This selectivity in the patent law is intended to protect patients from patents on trivial changes to existing medicines.

It is our understanding the next hearing on this matter may be as soon as January 29th. Major international development organizations such as Medecins Sans Frontieres have asked Novartis to withdraw the suite.⁵ The medical journal *Lancet* has endorsed the same position.⁶

Implications for Access to Medicines

Prior to 2005, Indian patent law protected only the manufacturing process of pharmaceuticals, not the compounds themselves. In this legal environment, combined with high-quality manufacturing expertise, India became the world's source for high-quality, affordable generic versions of innovative medicines still under patent protection in other countries. No patients have benefited more than people living with HIV. Due to market competition from Indian companies, first-line AIDS treatment regimes now cost approximately \$130/patient/year. Just a few years

³ Ibid.

⁴ Available at <http://www.who.int/intellectualproperty/en/>

⁵ MSF Urges Novartis to Drop Case Against Indian Government. Press Release, December 18 2006.

⁶ Undermining TRIPS: protectionism at its worst. Editorial, The Lancet 2007; 369:2.

ago, even philanthropic tenders from brand-name companies were ten times that price. Today, generic companies consistently offer AIDS drugs below the ‘no-profit’ price of originator companies.

A legal reversal of the Section 3 (d) protections in the Glivec case opens the door for more widespread patenting of affordable life-saving drugs, especially those that treat people living with HIV. It comes in an environment of increased patenting of HIV medicines in India. In the Novartis position paper on the case, you point out generic versions of Glivec in India are more expensive than your assistance programs. While this may be the case with generic versions of Glivec, this is clearly not the case with AIDS medicines.

Implications for Novartis

In 2001, Novartis was one of 39 companies who took the government of South Africa to court in a case with similar broad-based implications for access to medicines. The result was widespread embarrassment for the pharmaceutical industry.

Since then, Novartis under your leadership has substantially invested in neglected disease research, policy development, and stakeholder engagement. You have positively differentiated Novartis from the rest of the pharmaceutical industry. Public and NGO perceptions of your actions in this case may undermine that record.

Novartis has made humanitarian commitments to ensure “patients around the world have access to the treatments they need.” Novartis’ legal tactics in this case have raised the stakes higher than the several thousand Indian patients relying on Glivec, to involve the millions of people kept alive today by generic AIDS drugs from India.

Therefore, we reiterate our call for you to withdraw your legal challenge to Section 3(d) of the Indian Patent Act, in a case concerning the patent status of the cancer drug Gleevac / Glivec (imatinib mesylate). We are available to meet with you at your convenience to discuss these issues in more detail. Please contact us via Daniel Rosan at the Interfaith Center on Corporate Responsibility.

Very Truly Yours,

Signatories

Rev Séamus P. Finn OMI
Director
Justice, Peace & Integrity of Creation
Missionary Oblates of Mary Immaculate

Daniel E. Rosan
Program Director
Access to Healthcare
Interfaith Center on Corporate Responsibility

Margaret Weber
Coordinator of Corporate Responsibility
Adrian Dominican Sisters

Lauren Compere
Director of Shareholder Advocacy
Boston Common Asset Management

Donna Meyer
System Director
CHRISTUS Health

Valerie Heinonen, o.s.u.
Consultant, Corporate Social Responsibility
Dominican Sisters of Hope

Cathy Rowan
Corporate Responsibility Coordinator
Maryknoll Sisters

Mark A. Regier
Stewardship Investing Services Manager
MMA Praxis Mutual Funds

Josh Zinner
Senior Advisor, Private Sector Team
Oxfam America

Ruth Kuhn, SC
Chair, Sisters of Charity Corporate
Responsibility Committee
Sisters of Charity of Cincinnati

Vicki Bergkamp ASC
Chairperson
ASC Investment Group

Kathleen Coll, SSJ
Administrator, Shareholder Advocacy
Catholic Health East

Helena M. Sause, O.P.
Leadership Team Member
Dominican Sisters, (Columbus, OH)

Robert Walker
Vice President Sustainability
The Ethical Funds Company

Laurence Loubieres
SRI Analyst
Meeschaert AM, Paris

Judy Byron, OP
Northwest Coalition for Responsible
Investment

Gwen Farry
Sisters of Charity, BVM

Tom McCaney
Associate Director, Corporate Social
Responsibility
Sisters of St. Francis of Philadelphia