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An open letter from Novartis regarding the Glivec legal challenge in India:
Why Novartis thinks improving patent law will benefit patients and society

(for response, please email public.affairs@novartis.com)

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In the last few weeks we have received concerns regarding our ongoing legal challenge against the Indian patent law, following the denial of the patent for our ground-breaking cancer treatment Glivec®/Gleevec®. We have heard these concerns and want to clarify our perspective.

In India, Novartis is faced with a globalization dilemma that characterizes many emerging economic powers today: two markets within one country. India has a booming middle class on one hand, and a vast number of extremely poor people on the other. In order to make responsible business decisions, we have carefully considered the following aspects:

- Access to our cancer treatment Glivec in India and globally
- India as an emerging growth market and global competitor
- India's current role in supplying medicines to the developing world

As a result, in India, we are pursuing a dual, patient-focused strategy. We are aware of the many obstacles poor patients face regarding access to medical care there, and that is why 99% of patients who receive Glivec in India receive it free from Novartis. At the same time, we take affluent India seriously as a formidable power with all the rights and obligations that such status brings with it. As a consequence, we seek to establish effective protection for pharmaceutical innovation in India.

In the following, we outline our approach in more detail:

Novartis has secured access to Glivec both in India and globally
When we launched Glivec, Novartis committed that no patient in need should be denied this life-saving cancer treatment. We fulfilled this commitment by establishing the Glivec International Patient Assistance Program (GIPAP), which is one of the most far-reaching patient assistance programs ever implemented on a global scale. In India, Novartis currently provides Glivec at no cost to more than 6 600 diagnosed patients. Glivec treats two rare cancers: chronic myeloid leukemia (CML) and gastrointestinal stromal tumors (GIST). The GIPAP covers every person in India who is prescribed Glivec and cannot afford this life-saving medicine. For more information, please visit the Max Foundation which administers the program, www.themaxfoundation.org.

Sustainable access to medicines in developing countries is complex and requires much more than the availability of generic drugs. Generics alone do not solve the issue. For example, in India the cost of a one year treatment with generic imatinib is USD 2 100, or 4.5 times the average annual income. Even our critics recognize that generic versions of Glivec are not the solution for the poor in India. Furthermore, generic makers in India have yet to come forward with an access program for generic imatinib.

Glivec is not an exception. As a matter of business principle, Novartis is deeply concerned that patients have access to the medicines they need, as demonstrated by our well-regarded record in social responsibility.

In 2006, our access-to-medicines program reached 33.6 million patients. Novartis spent USD 755 million / EUR 582 million last year alone programs and research. We seek to move beyond philanthropy to develop new business models. That is why we engage in many innovative public-private partnerships with efforts spanning a number of disease areas, including our partnerships with WHO to combat leprosy, malaria and tuberculosis. Novartis also established an Institute for Tropical Diseases in Singapore dedicated entirely to drug discovery for neglected diseases.

We take India seriously as an emerging growth market and global competitor
While we are committed to access to Glivec, it is clear that we seek business opportunities in India's growing economy. We also compete with Indian companies globally in attractive markets, and the export of copies of our products into richer countries is a major concern to us.

Protecting innovation is the foundation for massive R&D investments made by the pharmaceuticals industry that are vital to medical progress. Companies can continue to bring improvements and innovations to patients and societies only with effective patent laws. For a research-based company such as Novartis, patents are not negotiable.

That Glivec is a tremendous innovation is widely recognized throughout the scientific community; it has received numerous awards for innovation. Glivec has been awarded a patent in 36 other countries, including China. The journey of Glivec through the patent process in India illustrates the difficulties faced in a country in transition. The Indian patent law creates new hurdles for pharmaceutical innovation, unjustifiably and illegally narrowing what is patentable.

Many of the points we have raised around India's patent laws have been corroborated by the recent Mashelkar Committee report on patent issues in India. The Government-established Mashelkar Committee voiced its views in favor of incremental innovation and held that certain provisions of the Indian Patent Act are not compliant with international agreements, specifically WTO's TRIPS agreement (Trade-related Aspects of Intellectual Property Rights).

Respect for intellectual property will strengthen, not weaken, the Indian economy, helping India reach its aspiration of becoming a pharmaceutical powerhouse. Incremental innovation is exactly the area where local Indian companies have made first steps into research and development and registered patents worldwide.

We are seeking clarity. Knowing we can rely on patents in India benefits government, industry and patients because research-based organizations will know if investing in the development of better medicines there is a viable long-term option.

Our actions in India do not hinder the supply of medicines to the poor
We are contesting the provision of Indian Patent Law that has led to the rejection of the Glivec patent in India. Our case does not challenge provisions that provide for access under international trade agreements, specifically the TRIPS and the Doha Declaration. These flexibilities allow production for export under compulsory licenses that have been issued for public health reasons. They have been put in place to allow poor countries to safeguard access to medicines that do not have sufficient local production capacity. In fact, political agreement on the Doha flexibilities has been reached in order to mitigate impact of TRIPS implementation in India.

Novartis supports the TRIPS conditions that promote access for developing countries. Our patent strategy preempts some of these flexibilities by not filing patents in the poorest countries. Furthermore, we believe that in the case of essential and life-saving medicines, special pricing arrangements in developing countries must, and can, occur within the context of sufficient intellectual property and trade-related safeguards.

Denial of patents for better medicines will not improve patient access to medicines. These restrictions will instead negatively impact patient access by denying new drugs either through research-based pharmaceuticals or, at the appropriate time, through the generic companies.

Access to medicines in the developing world is a complex problem in which medicine prices and intellectual property rights are but two pieces of the puzzle. A range of underlying or related issues such as appropriate infrastructure and distribution networks must be addressed in parallel. This can only be achieved through the collaboration of all involved stakeholders working together to ensure that patients in need receive proper care. We seek an open dialogue with all groups, one based on mutual trust and tolerance with the aim of long-term success – not only in access-to-medicines initiatives but also in day-to-day business activities.

Thank you for reading this perspective. For more information about this legal challenge and about our extensive corporate responsibility and patient access programs, please visit www.novartis.com/corporate_citizenship/en/index.shtml.

Yours sincerely

Head of Public Affairs
Novartis International AG