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Dr. APJ Abdul Kalam
President of India
Rashtrapati Bhavan
New Delhi 110004
India

Dear President:

Re: Patent (Amendment) Bill 2005

We write to you to express our deepest concern that recent amendments to India's patent legislation will lead to unnecessary suffering and death for millions of people in your country and in many others, particularly in the developing world. We urge you to send the Patent (Amendment) Bill 2005 back to Parliament for reconsideration, so that the interests of public health, in India and globally, are given priority.

Indian manufacturers have been a significant source of more affordable generic medicines used in many developing countries. The path your country takes in amending its patent law will have dramatic implications for people in developing countries needing medicines. For millions of people this is literally a matter of life and death.

We are a Canadian organization dedicated to protecting and promoting the human rights of people living with HIV/AIDS and of communities and individuals who are at heightened vulnerability to both HIV and the denial of human rights. We base our work on the universal human rights enshrined in international law. For many years, we have worked in collaboration with other like-minded organizations in Canada and around the world, including human rights defenders in India. We therefore wish to join them in drawing to your attention grave concerns with recent patent law amendment bill, concerns which are shared by many around the world.

We note that international law recognizes every person's human rights to life and to enjoy the highest attainable standard of health for everyone. Under such law, the Indian government is legally obliged to take measures to respect, protect and fulfil these rights. It has been recognized in numerous international legal instruments, as well as by all member states of the UN General Assembly (including India), that access to medication is a fundamental element of realizing the right to health. When taking legislative measures, India must act to honour those binding commitments, including when implementing other aspects of international law, such as the intellectual property

rules set out in the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights.

However, the bill recently passed by the Indian Parliament fails to adequately reflect these human rights obligations of the Indian state, adding to domestic patent law provisions that are not required by the WTO regime and that will adversely affect access to afforable medicines. We wish to note a number of specific concerns.

(1) Patentability criteria

The Bill's approach to defining the criteria for securing patents will restrict access to lower-cost generic medicines for Indians and others. For example, we are concerned about such features as the definition of "inventive step" that allows economic significance to be a factor. In addition, the use of the word "mere" throughout section 3 of the bill creates unnecessary opportunities for vexatious litigation that could delay or prevent access to more affordable generic products. Defining the criteria for patentability is one of the areas in which sovereign countries who are WTO Members have the greatest degree of flexibility.

It is vital that Indian law not adopt unjustifiably and unnecessarily lax standards for obtaining patents, thereby allowing the further enclosure of the scientific commons by multionational companies whose interest is not public health but profit. India should show international leadership by ensuring the appropriately high threshold for granting private patent monopolies on knowledge. The Bill passed by Parliament is deficient in this regard and would benefit from careful reconsideration.

(2) Compulsory licensing

If affordable drugs are to be quickly available within India and abroad, as is desperately needed, then the procedures for compulsory licensing set out in the law must be clear, simple, functional and swift. Compulsory licensing of pharmaceuticals, with payment of an appropriate remuneration to the patent holder in exchange, is a critical tool for improving access to affordable medicines. The importance of ensuring that Indian generic manufacturers can secure such licences cannot be overstated, given the vital role that such producers have played, and continue to play, as the sources of many of the medicines widely used in other developing countries today, including for such public health needs as HIV/AIDS.

Yet the Bill recently passed by Parliament provides that compulsory licensing is only permissible after a period of 3 years from the grant of the patent, a restriction that is not required by the WTO's TRIPS Agreement, nor under the Doha Declaration on the TRIPS Agreement and Public Health (which India played a key role in negotiating). Even after this period has expired, the procedures set out in the Bill are complex and cumbersome, meaning unnecessary – and deadly – delay in getting generic versions of medicines onto the market.

Let us note another particular concern: there is no clear specification of the royalty rate that is to be paid to the patent-holder in the event of a compulsory licence being issue. Canada recently passed legislation aimed at enabling compulsory licensing of pharmaceutical products for export to developing countries, the first country in the world to take such a step in implementing an August 2003 decision of the World Trade Organization permitting such a measure. While that legislation suffers from other defects that should be corrected, one of its most positive features is that it clearly defines what the royalty payable in any given instance, and does not leave this up to the discretion of the courts or the Commissioner of Patents who issues a compulsory license.

This is a point that we and dozens of other non-governmental organizations insisted upon during the drafting of the legislation. We did so because we recognized that uncertainty and lack of definition would invite litigation over the royalty rates. This would have constituted a major disincentive for generic producers to seek compulsory licenses at all, thereby rendering the legislation meaningless. In response to these concerns, the government added to the law a formula that (a) ties the royalty payable on any given compulsory licence to the ranking of the country importing the generic medicines on the UN's Human Development Index, and (b) effectively caps the maximum royalty payable at 4% of the value of the generic producer's contract.

While this is not the only way to legislate clearly on the issue of compulsory licences, so as to avoid patent-holders derailing any use of the law through lengthy and costly litigation, it is one attractive model that could usefully be considered by other jurisdictions addressing this question. It is most unfortunate that the Indian legislation fails to address this fundamental concern that could undermine the entire value of theoretical access to compulsory licences. This is one issue, among several, that clearly would benefit from further reconsideration by Parliament in order to ensure that this legislation protects public health interests and is consonant with India's human rights obligations under international law.

To date, India has played a key role, both political and practical, in responding to global health needs. It has not only the ability, but the responsibility, to continue demonstrating such international leadership, by designing its patent laws so as to put the lives and health of millions of poor people before unnecessary benefits for multinational pharmaceutical companies.

We therefore urge you to exercise your powers under Article 111 of the Indian Constitution to send the Patent (Amendment) Bill 2005 back to Parliament for reconsideration of the amendments in light of these concerns that have been expressed by many Indians and others from around the world.

Respectfully yours,

Richard Elliott
Director, Legal Research & Policy