South Centre Views on US Review of Indian IPR Policy

Below is the official submission of the South Centre sent to the US Trade Representative regarding the Super 301 out of cycle review that the USTR is undertaking with regard to the IPR policy and practice of India. In this submission the South Centre has expressed concern about the pressures that the US is exerting on India to change its IPR policy and laws.

It also expressed appreciation of the Indian IPR policy which has been of benefit not only to India but also the developing countries which depend on the supply of generic medicines from India for meeting their health needs.

This submission has been filed to the office of the USTR, which has acknowledged receipt.

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Submission by the South Centre on the Special 301 Out-of-Cycle Review of India initiated by the US Trade Representative

Geneva: 31 October 2014

The South Centre is submitting these comments in response to the request by the USTR to provide all necessary and relevant information for identifying and assessing the engagement with the Government of India on IP related issues of concern, in the context of the Special 301 Out-of- Cycle Review (OCR) of India commenced by the USTR.

The South Centre is an inter-governmental research centre, serving the needs of developing countries, in the areas of economic and social development. This submission is made from the perspective of the public interest in the developing countries.

The United States Trade Representative (USTR) has initiated the current OCR of India to evaluate progress of intensive engagement with the Government of India on intellectual property issues to "improve IP protection and enforcement in India…" in the context of specific concerns raised in the Special 301 report for 2014 by the USTR relating to civil IPR enforcement as well as India's IP regimes pertaining to copyright, patents, regulatory data protection, trademarks, trade secrets and localization trends.

The South Centre submits the following comments in relation to implementation of India's IP regime.

Implementation of India's IP Regime

IP Enforcement

The Special 301 report encourages India to strengthen civil IPR enforcement by increasing judicial efficiency, reducing court backlogs, establishing fast-track procedures and specialized judges.

It is our view, however, that India offers adequate judicial and administrative remedies to right holders to enforce their IP rights. India has established a special administrative tribunal known as the Intellectual Property Appellate Board (IPAB) which exercises jurisdiction over trademarks, patents and geographical indications. Right holders can also file an appeal to the High Court against the decision of the IPAB and can also file special leave petitions before the Supreme Court of India.

Indeed, IP right holders have made use of the judicial remedies available in India in a number of cases. For example, the multinational pharmaceutical company Novartis has initiated separate law suits against 8 Indian companies alleging infringement of its patent on vildagliptin, and has been granted injunctions by the courts in four of these cases. BMS has initiated 2 law suits for infringement of its patent on dasatinib. Merck has filed 7 separate law suits against infringement of its patent on sitagliptin and has obtained injunctions in 6 of these suits. Between 1995 to 2014, 366 cases of copyright infringement have been filed in India out of which 80 have been filed by foreign copyright owners and 52 of these have received a favourable ruling under the Indian law. In the area of trademarks, 1593 cases of trademark infringement have been filed between 1995 to 2014 out of which 449 cases have been filed by foreign trademark owners and 302 cases have received a favourable ruling under the Indian law.

This demonstrates that India has a robust system of IP enforcement in place which is fully in accordance with the requirements of Part III of the TRIPS Agreement. It should be stressed here that the TRIPS Agreement does not require a country to establish IP enforcement procedures that are distinct from the country's general law enforcement system. TRIPS only requires a country to make available appropriate judicial or administrative mechanisms to enforce IP rights, which is provided adequately by India.

Copyright

With regard to copyright, it appears that the US would like India to enact anti-camcording legislation, model its statutory licensing relating to copyrighted works upon Berne Convention standards, ensure that collecting societies are licensed promptly and are able to operate effectively, provide additional protection against signal theft, adopt measures to prevent circumvention of technological protection measures, and adopt notice and takedown measures to prevent online piracy.

However it is noteworthy that contrary to the concerns raised in the Special 301 report, the Consumers International IP watchlist report has consistently placed India among the top 3 consumer friendly copyright regimes from 2009 to 2012, meaning that India's copyright regime is regarded as more amenable to access to knowledge rather than restricting access to knowledge through excessive copyright protection. Following the amendment of the copyright law in 2012, India has introduced technological protection measures as well as special fair use provisions. This is in spite of the fact that India is not a party to the WIPO Internet Treaties (WCT and WPPT) and is therefore under no obligation to adopt such measures in its law. Furthermore, enacting a specific anti-camcording legislation in India may not be needed in view of the fact that camcording of a film is already a violation under the current Copyright Act of 1957. Moreover, the provisions on statutory licensing in India's copyright law is fully consistent with Article 9 (2) of the Berne

Convention.

The Use of TRIPS Flexibilities in Patent Law

The USTR report also raises specific concerns in relation to section 3 (d) of the Patents Act and states that it may limit the patentability of potentially beneficial inventions. It also expresses concern about issuance of compulsory license in India, as well as the availability of pre-grant and post-grant opposition.

The establishment by the government of a country of its criteria to grant patents (as provided for in section 3 (d) of the Indian Patent Act and interpreted by the Indian Supreme Court in the Novartis case), the right to issue compulsory licenses, and the use of patent pre-grant and post- grant opposition proceedings are, among others, important flexibilities that serve to protect public health, consistent with the TRIPS Agreement. Additionally, a country may consider and weigh other important policy objectives (such as promotion of access to health) in relation to its grant of IPRs. None of the recent decisions in India to reject patents on known medicines or to issue compulsory licenses on anti-cancer medicines have been challenged before the WTO dispute settlement mechanism. These actions by India are fully consistent with the Doha Declaration on TRIPS and Public Health which clarifies that the TRIPS Agreement can and should be interpreted to advance public health goals and that nothing in the TRIPS Agreement impedes the right of countries to adopt policies to promote public health and access to medicines. Indeed, the concern of ensuring access to medicines while enabling the grant of quality patents on medicines that constitute real innovations is the objective of Indian patent law.

The granting of a compulsory license in India on a medicine is not unique. Many other countries have issued compulsory licenses for ensuring access to affordable medicines to meet their public health needs, including Brazil, Ecuador, Eritrea, Ghana, Indonesia, Malaysia, Mozambique, Thailand and Zambia. The granting of compulsory licenses is TRIPS-consistent and is an important measure that governments are allowed to take in furtherance of the public interest. This has been confirmed by the WTO Ministerial Declaration on TRIPS and Public Health.

It should be recognised and appreciated that the production of generic medicines by the Indian drug industry is of critical importance for the health care not only of Indian citizens but also of millions of people outside of India, especially in developing countries. This is because a large portion of a broad range of medicines used by patients in developing countries is produced by Indian drug companies and imported by these countries from India. The provision of these generic medicines by Indian companies is a very important factor in India's contribution to more affordable access to medicines for many millions of people in developing countries. For example, it is well known that the supply of affordable generic medicines for HIV-AIDS patients by Indian companies, a large proportion of this being supplied under the Global Fund and other charitable funds, has contributed to the saving of millions of lives in Africa and other regions. The presence and use of TRIPS flexibilities (including through the provision on compulsory licensing and other relevant provisions in the Indian patent law) is a significant factor enabling the Indian drug industry to play its important role in the treatment of diseases in India and in the developing countries. These provisions are consistent with WTO rules, and thus India is complying with its international obligations in intellectual property, while also enabling the country to meet its responsibilities in both national and international public health. Therefore it is our view that India should be encouraged to continue to play this role, and that there should be no hindrance placed on the country and its drug industry to maintain its laws and to play its important global role.

The Special 301 report also expresses concern about the role of compulsory licensing in India's National Manufacturing Policy. However, India's option to make use of compulsory licensing in its National Manufacturing Policy as a mechanism available to government entities to effectuate

technology transfer in the clean energy sector can be considered as a component of India's policy objective of shifting its energy sector to clean energy in order to address climate change and air pollution concerns. It should be noted in this context that climate change is both a national and a global problem. Under the UNFCCC, technology transfer is seen to play a key role in enabling developing countries like India to undertake enhanced action for adaptation and mitigation of climate change through the use of environmentally sound technologies. Article 4.1 (c) of the UNFCCC requires all Parties, taking into account their common but differentiated responsibilities and their specific national and regional development priorities, objectives and circumstances to:

"Promote and cooperate in the development, application and diffusion, including transfer, of technologies, practices and processes that control, reduce or prevent anthropogenic emissions of greenhouse gases not controlled by the Montreal Protocol in all relevant sectors, including the energy, transport, industry, agriculture, forestry and waste management sectors".

Further, Article 4.5 of the UNFCCC states that:

"The developed country Parties and other developed Parties included in Annex II shall take all practicable steps to promote, facilitate and finance, as appropriate, the transfer of, or access to, environmentally sound technologies and know-how to other Parties, particularly developing country Parties, to enable them to implement the provisions of the Convention. In this process, the developed country Parties shall support the development and enhancement of endogenous capacities and technologies of developing country Parties. Other Parties and organizations in a position to do so may also assist in facilitating the transfer of such technologies".

Therefore, cooperation on technology transfer for clean technologies is a treaty commitment for all parties under the UNFCCC, with developed countries such as the US also being treaty-obliged to take all practicable steps to promote, facilitate and finance, as appropriate, the transfer of, or access to, environmentally sound technologies and know-how to developing countries. Therefore it is appropriate for India adopt policies supportive of access to clean technologies in its National Manufacturing Policy to enhance a shift to clean energy for which transfer of technology is necessary. This is in fact similar to what the US has itself done in promoting the use of compulsory licenses or mandatory licenses to facilitate access to clean technologies under Section 308 of the US Clean Air Act.

Regulatory Data Protection

The Special 301 report also expresses a desire for India to provide effective protection against unfair commercial use and unauthorized disclosure of test or other data generated to obtain marketing approval for pharmaceutical and agricultural products.

However, there is no obligation upon India or any other country under the TRIPS Agreement to introduce market exclusivity while protecting data on clinical trials before marketing approval is given to a pharmaceutical product.

Article 39.3 of the TRIPS Agreement requires WTO members to establish protections for submitted test data only under certain conditions. Test data must be protected in national authorities that require its submission. But Article 39.3 does not require protection to be given to already public data. Moreover, the obligation under TRIPS is to protect such marketing approval data against unfair commercial use. What constitutes unfair commercial use is determined by national law of each country. Indeed, TRIPS negotiators considered and specifically rejected language requiring exclusive rights to test data. Therefore, there India's law on regulatory data protection is fully consistent with the TRIPS Agreement.

We consider that maintaining the Indian law on this issue is very important because this facilitates the production and marketing of generic medicines by Indian drug companies. In our view, the model of data protection requested by the US administration would be detrimental to the ability of generic companies to supply generic medicines for the period of market exclusivity, and this would have serious significant negative impact on access to medicines, affecting patients not only in India but also many other countries.

Conclusion

The South Centre is concerned that developing countries such as India have been facing pressures from administrative and review processes in the United States with regard to their intellectual property laws and practices. It would appear that a major part of the pressure originate from various business organisations which naturally have their own commercial interests in mind. However we believe it is important that in this out-of-cycle review process, a broader view of the public interest in India, and the global public interest, especially the interests of people in the developing countries, should be taken.

It is our view that the Indian IP laws include balanced provisions to ensure that IP rights do not hinder the ability of the government to adopt measures for promoting development priorities, particularly in the area of public health. These are fully in line with the TRIPS Agreement and reaffirmed by the Doha Declaration on TRIPS and Public Health.

We thus view with concern the pressures placed on India by the out-of-cycle review (OCR) of India by the US Trade Representative to evaluate intellectual property issues as well as the investigations by the International Trade Commission (USITC) against India on trade, investment and industrial policies in India particularly on intellectual property protection and enforcement.

The South Centre views these recent developments as most inappropriate, as it is against the spirit of the landmark Ministerial Declaration on TRIPS Agreement and Public Health. India and other developing countries have the right to use the flexibilities in the TRIPS Agreement to the fullest extent for advancing public health needs and other development priorities. The legal and regulatory measures that India has used for protecting public health are fully consistent with the WTO TRIPS Agreement. The continued threat of unilateral trade sanctions by the US to developing countries through USITC investigations and the Special 301 review undermines the legitimacy of the WTO, particularly the TRIPS Agreement and the WTO's dispute settlement system.

The USTR investigations, including the current OCR, may lead to unilateral trade sanctions that would be illegitimate under the WTO rules. Moreover, the mere threat of sanctions by placing a country in any specific category in the US watch list would appear to violate the WTO Dispute Settlement Understanding. A WTO panel noted, in a dispute brought in 1999 by the EU against Section 301 of the US law, that "the threat alone of conduct prohibited by the WTO would enable the Member concerned to exert undue leverage on other Members. It would disrupt the very stability and equilibrium which multilateral dispute resolution was meant to foster and consequently establish, namely equal protection of both large and small, powerful and less powerful Members through the consistent application of a set of rules and procedures."

Continued pressures on developing countries to adopt an IPR regime that would go beyond the minimum standards in the TRIPS Agreement and that do not make use of the flexibilities that are part of the TRIPS Agreement would have adverse social and developmental effects, including on the public's access to medicines.

We therefore request that there be a stop to these pressures that are placed on developing countries, including India.

Submission made on behalf of the South Centre by:

Martin Khor
Executive Director
South Centre
17-19 chemin du Champ d'Anier
1209 Geneva
Switzerland.
Email : director@southcentre.int
Fax: +41 22 798 8531