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U.S.-India IP Policies

How to bring convergence in narratives?

Intellectual Property (IP) protection approach – particularly in pharmaceuticals and agriculture – has been one of the key contentious issues between India and the U.S. since the Uruguay Round of multilateral trade negotiations (1986-94). The IP narratives of the two countries have largely remained the same, leading to stalemate. While India claims adherence to the minimum standards prescribed under the WTO Agreement on Trade-Related Aspects of Intellectual Property Right (TRIPs), the U.S. demands India to go much beyond TRIPs. No wonder, India has perpetually been featuring on the Priority Watch List of the Special 301 Reports released every year by the United States Trade Representative, and 2018 was no exception. Will 2019 be any different?

This Policy Note identifies key concerns of both the countries and suggests possible measures on the part of both to bring convergence between the two narratives, in a way that facilitates closer ties on trade and investment, while addressing domestic political economy concerns. A way forward would be to take cognisance of respective concerns and accommodate them through continuous dialogue.

The U.S. Concerns

- Difficulties for innovators to receive and maintain patents in India, particularly for pharmaceuticals
- Insufficient enforcement action and policies to curb the problem
- Copyright policies not properly incentivising the creation and commercialisation of content
- Outdated and insufficient legal framework for protecting trade secrets
- Positions that India takes at multilateral fora on IP issues

Indian concerns

- Technology transfer remains below expectation, which is necessary to meet India's development needs
- False creation of perception amongst consumers and prescribers that Indian generic drugs are of low quality, which acts as non-tariff barrier for exports
- U.S. firms' adhering to various restrictive practices, including refusal to give samples of biologics[1] that impedes manufacturing of biosimilars in India
- U.S. 'border measures', which unnecessarily impede goods in transition

What India can (or cannot) consider

Patentability criteria

The U.S. has been vocal about its concerns with respect to the Indian IP legislations and their enforcement. The key irritant for the U.S. are provisions in Indian patent law which makes patentability criteria stricter (e.g. S.3 (d) of Patents Act, 1970) and hence obtaining patents difficult, particularly pharmaceutical patents with minor improvements.

However, the Indian patent law is cited globally as a template on TRIPs flexibilities, when it comes to access to medicines,[2] which include stricter patentability criteria to check 'evergreening'. There is enormous pressure from public health fora in most countries, including developed countries, to ensure high quality of patents and discipline patenting strategies of firms

[1] D G Shah, *New Frontiers of Divide: Competition vs Exclusivity*; CPhI Annual Industry Report 2017

[2] UNDP "Good Practice Guide: Improving Access to Treatment with Flexibilities in TRIPS"; WHO-ICTSD-UNCTAD "Guidelines for examination of pharmaceutical patents – Developing a public health perspective"

that defeat competition. The anti-trust fora also tend to corroborate this approach.[3]

Therefore, due to domestic pressures and wider international acceptability, India is unlikely to bring any legislative changes to provisions related to patentability criteria.

Data protection (Art 39.3 TRIPs)

For similar reasons as stated above, India is unlikely to yield on 'data exclusivity' approach as desired by the USTR. The recent removal of the requirement to submit information about a product's patent status by drug approval applicants is in line with India's lock-n-key approach towards data protection.

India could, however, start recognising that its approach for data protection gives free ride to its generic industry over the investments made on clinical trials by 'originator' firms. Consequently, India may like to consider mandating its generic applicants to pay certain amount to the originator firm to recoup such investments. However, this may face severe opposition from Indian firms and civil society, who have been arguing that the 'trade-off' has already happened by enhancing patent protection period from 14 to 20 years.

Gene patent and Patent-PVP conundrum

A judgement by the Delhi High Court on the patentability of Monsanto's Bt Cotton has unsettled the gene patenting issue, posing uncertainty in investors in the biotechnology sector. Though the Supreme Court of India has overruled the said High Court order on procedural grounds, the patentability of Bt technology remains unresolved.

India may like to develop guidelines to resolve the seemingly conflicting mandates of the Patents Act and the Protection of Plant Varieties and Farmers Rights Act vis-à-vis genetically modified seeds.

Protection of trade secrets

India does not have a specific law to protect trade secrets, which at present is dealt under the principles of common law. Therefore, it may like to consider a specific *sui generis* legislation as mandated under Article 39.2 of the WTO TRIPs Agreement, which will help attract foreign investment and promote fair competition. India had made an attempt earlier in the form of draft National Innovation Bill, 2008.

Stronger copyright enforcement

India's copyright regime is good but its enforcement is an issue, particularly in digital markets. Since India is globally competitive in the creative sector, it would gain by tightening the enforcement of its copyright regime.

What the U.S. can consider

Technology transfer

The U.S. can commit towards enhanced technology transfer and enhanced investment, which could promote 'Make in India' and create more jobs.

Trade facilitation for Indian generic drugs

The U.S. government can help discouraging false propaganda that creates negative perceptions about the quality of the Indian generic drugs among U.S. consumers and healthcare professionals. It may also remove hurdles to obtain samples of biologics, which is necessary for the Indian manufacturers to generate bioequivalence data for obtaining marketing approval.

The U.S. may further like to reconsider softening border measures related with goods in transition to export destinations other than the U.S. Trade facilitation of Indian quality generics in the U.S. will benefit U.S. consumers who are facing high drug prices.

Stronger protection to Indian GIs

India, being an ancient civilisation and a biodiversity rich region, has a good repository of products that can have a Geographical Indication (GI) tag. By promising a stronger protection of Indian GIs, the U.S. can help India in reaping more benefits in the U.S. market.

Conclusions

The above-stated measures could mark a beginning towards greater and more constructive cooperation between India and the U.S. on some of the contentious IP issues.

Furthermore, creation of a favourable environment in both countries, rather than adopting pressure tactics, could facilitate the convergence of narratives, which in turn, could present a win-win situation for both countries. A way forward would be the creation of an informal platform where informed debate and discussions can take place among industry, academia as well as civil society groups from both the countries.

[3] See: European Commission pharmaceutical sector enquiry (2009)

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