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RIS Policy Brief

Access, Technology Development and National IPR Policy

1. The Government of India is engaged in drafting a new National IPR (Intellectual Property Right) Policy. This is for the first time that the Government has undertaken such a task. So far there has been no formal policy statement encompassing all the Intellectual Property Rights, mentioned in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). The various legislations, however, contained the policy approach of the Government as, for example, Section 83 of the Patents Act. The changes in the policies were made not through formal statements but through periodic amendments or promulgation of new laws such as the amendments in the Patents Act in 1999, 2002 and 2005) or the new Trademarks Act enacted in 1999. Towards drafting a new policy, the Government set up in October, 2014 an Intellectual Property (IP) Think Tank . The first Draft of the National IPR Policy (hereafter 'the Draft') was submitted to the Government by the Think Tank on 19 December 2014. The Draft evoked wide-spread comments, both positive and negative. The positive comments were about the comprehensiveness, the need for such a policy and about including promotion of innovation within the rationale for IPR Policy. The negative comments reflected the concerns about public health and public interest and also about the timing of the Policy. There have been voices which argued for an IP Policy more on the lines of the developed countries. This Policy Brief assesses the Draft from the angles of access to knowledge and technology development. It also argues for an IP Policy that will not adversely affect access to medicine by large populations. The focus is on key policy issues from India's role in South-South cooperation.

Emerging Context

2. India's IP regime is generally viewed as a model by other developing countries. In that context, its IP Policy must reflect the general realities of the South and the developmental needs of the developing world. The South, except for the Least Developed Countries (LDCs), has been having an IP regime in line with the global standards with minor variations, but with differing results. IP policies now have an overarching influence on economic and trade relations among countries. Therefore, the need for South-South cooperation and IP diplomacy should be specifically stressed and policy directions and appropriate strategies should be incorporated in the Policy, so that the experience of India and its innovative IP implementation models could benefit other developing countries. This is particularly needed for India to take leadership among developing countries on IP matters.

3. Considering the international trade and investment scenario, there is need for providing IPR laws as per the TRIPS standards which are the current global international norms on IPRs. At the same time, the National IPR Policy needs to avoid the temptation of basing its premise on

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…promotion of technological innovation and transfer and dissemination of technology …

an unproven assumption that without IP, creativity and innovation will not take place and that with IP protection these two will happen automatically. Empirical studies have not been so conclusive. The policy document needs to take an unbiased approach in this respect. It will have to look at the actual role played by IPRs in the whole development process in the light of India's own experience and that of other countries of the South.

4. Financial returns to creators, innovators and scientists are not necessarily major factors to be weighed in for the need to have a National IPR Policy. Whether it is artists or litterateurs or scientists, they are not always innovating and practising for the sake of financial gains alone, though it matters. They engage themselves in artistic creations and scientific research many a time to satisfy their creative urge, and curiosity and thirst for exploring new areas in search of answers to the riddles of nature and science and technology (S&T) . The issue of monetary return is, of course, major concern of investors, who need IPR protection when they take over the marketing of results of creativity and scientific research. They also need it for investing in commercialising and exploiting IPRs as well as R&D, so that they could get certain monopolies in the market over their products. The whole policy approach in IP is to be nuanced to this reality.

5. The Policy has to focus on creating IP in India by Indians. Creation of IP is important from both cultural and economic angles since it pushes up national pride and, at the same time, being a tradable commodity raises the GDP. It is advisable to make a study as to whether the present policy and laws which have been in existence without change since 2005 have helped to achieve this objective and , if not, what are the reasons for that, before making policy correction. At least in the area of patent filing in India, the share of Indians remains very low around 20-22 per cent. Promotion of local industry, including employment generation and avoiding being a mere market for others in the name of globalisation, should be an objective of the Policy.

6. India's present levels of technology and how the trade in 'technology' will be affecting our economy have also to be taken into consideration. As of now, India is a net importer of patented technology as well as copyright products such as books, films, music, and so on. We are also importing foreign branded products and services and also designed products which all have intellectual property content. The objectives of the Policy should be to reverse that trend and not merely restate the importance of IP from the publications of certain organisations. Technology transfer, though stated in various international agreements including the TRIPS, has been not really taking place from developed to developing countries. The Policy will have to address the critical issue of technology transfer and the factors inhibiting that more extensively than in the present Draft.

Retaining the Balance

7. While the Draft Policy appears to have been well conceived, the text has moved over to more of details such as specific implementation points than warranted in a national policy statement. The Policy should state clearly the philosophy and rationale that guide it, its mission, objectives and aims and present the policy pathways that would lead to achieving the objectives. It may also contain cogent narration as to how absence of a policy document in the past has adversely affected the implementation of IPR laws in the country. It could be stated in the 'rationale' section why a felt need is there now to make a policy statement, when India has been having a TRIPS compliant regime since 2005. In this context, recommendations such as the one to "review existing IP laws, where necessary, to update and improve them or to remove anomalies and inconsistencies, if any;" (para.3.1 of the Draft) are rather dangerous and not consistent with India's

long term stand in international fora that the Indian laws are fully TRIPS compliant and there is no need to review them as of now. This recommendation will be caught on and pursued by countries and elements who wanted our patent law to be diluted. Given the state of its technology and the needs of the domestic industry India is not yet ready to go for TRIPS plus obligations that are included in various bilateral and multilateral trade and investment agreements. The Policy should avoid such pitfalls and be fully in the national interest.

8. There appears to be other such disconnects between the statements in the 'Introduction' and the text of the rest of the Draft document. This needs to be corrected. While the 'Introduction' contains a balanced and nuanced perspective on IPR regime for developing countries in the post-TRIPS era, the contours of the rest of the Draft fails to adequately highlight the merits and perils of over-arching IP protection in the developing country context. Generation of knowledge in developing countries happens, as in developed countries, largely through technology and knowledge dissemination. Often these countries are neither in a position to purchase proprietary knowledge nor tap adequately appropriate domestic knowledge resources. Hence, knowledge is looked upon vehemently as a public good by them and universal access to knowledge resources is of critical importance for those countries. This has been stated upfront in the TRIPS Agreement in Article 7 which reads, "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations". The Indian National IP Policy should reflect this and thereby be a model for the South.

9. It has been stated in the Draft that India has been following the principle of 'balance between the private rights and public interests'. This is the fundamental principle of any well conceived IP policy. Therefore, before drawing up a fresh policy document, it is necessary to appraise whether there has been any lack of clarity or shortcoming in following this principle in the past, whether there has been any tilting of the balance, and if so, to which side has it been and what could be the reasons for the same. It should be this assessment that should guide the Policy statement. For example, health sector in India is one that will be largely impacted by IPRs such as patents. In fact, public health in other developing countries will also be greatly affected by any changes in India's patent law since as of now because of its strong generic pharmaceutical industry India is considered as the pharmacy of the world which supplies, cheap, reliable and safe generic medicines, consequent on a conscious policy adopted in 1970. It is, therefore, necessary to add in the Policy the specific focus on public health and the need of IP system to respond to public health concerns, considering the necessity to provide universal health care for the largely poor and mostly illiterate population of the country, through the use of the 'flexibilities' in patents, as available under the TRIPS Agreement. This is particularly so since India was the driving force behind the Doha Declaration on Public Health (2002) which reinforced the rights of WTO member-states to interpret the TRIPS provisions and also to use the flexibilities provided therein to address public health concerns. Similarly, it should give special attention to the educational needs of and for making text books available to the students, and also to the liberal use of 'exceptions and limitations' under the copyright regime.

Building on India's Strength

10. Two important areas missing in the Draft are Protection of Biological Diversity and Traditional Knowledge (TK) and Traditional Cultural Expressions (TCEs), which have been

…Make IP a tool in 'Make in India' Campaign …

…Highlight innovative approaches such as OSDD and TKDL .. .

given peripheral attention only. India has in place the Biological Diversity Act (BDA) since 2002 in accordance with the Convention of Biological Diversity (CBD). However, the implementation of the same has not been very effective. It should be remembered that enforcement of BDA is the responsibility of the government, being community rights and public property unlike the case with other IPRs which are private property rights. Since this is a matter concerning our heritage and has close relationship with patents, the Policy should make very explicit statements on this. IPR system has been inadequate in managing knowledge held by communities in developing countries. This is what forms TK and is mainly known and used in traditional medical and agricultural practices. It contains information which can make significant contribution to current scientific research. Many individuals, institutions and corporations explore TK and come out with refinements that enable them to claim IPR protection. But the communities and countries who were custodians of such knowledge are denied any share in the benefits derived from the commercialisation of the value addition. The proposed Policy should adequately capture these issues in the larger national interest and provide for policy directions towards protecting TK and TCEs.

In the WIPO (World Intellectual Property Organisation) Inter Governmental Committee (IGC), India has been arguing for the last fifteen years for extending protection to the areas of TK and TCEs. India had on its own developed the Traditional Knowledge Digital Library (TKDL) as a defensive measure to ensure that patents are not granted on Indian TK. This is an original concept introduced by India in the world of IPRs and it has been well received by the developed countries also and should be prominently stated in the Policy. Though drafting a *sui generis* legislation for protection of Traditional Knowledge has been proposed in the Draft, its objective and what it would achieve in the light of the experience of the past two decades need to be brought out clearly in the Policy.

11. The Policy document should also take note of recent developments such as the WIPO Development Agenda (2007), WHO (World Health Organisation) Guidelines on Health, the UN Millennium Development Goals as well as Sustainable Development Goals, and also Climate Control Measures under discussion in the UN bodies. On all of those issues IPR protection impacts. It should be remembered that in finalising the WIPO Development Agenda, India had played a crucial role. These documents spell out the 'public welfare' aspect of IPR protection and how such protection should be regulated to achieve that. These issues will situate the proposed Policy in the current global agenda.

12. The Draft has not addressed the issue of exploitation of creators and inventors by industrialists and publishers. This is a major problem in India. Most scientists do not get any part of the royalty which the R&D institutions and industries are receiving. So also, authors, particularly academic researchers, are denied any pie in the profits that publishers make and, in addition, many a time have to contribute to getting their works published. The conditions are not much different in other developing countries. Ways to remedy this situation will have to be explored in the proposed Policy.

13. The Open Source Drug Discovery (OSDD) project of India has been totally ignored in the Draft. The OSDD is an innovative way to encourage innovations in areas where big corporations are not interested such as tropical diseases like malaria, TB and so on. It is India's contribution to the world of IP and alternative innovation strategies and applauded by academics and civil society globally. The world community is eagerly looking forward to its positive outcomes. It should find a prominent place in the Policy and strategy.

14. One of the specific recommendations made in the Draft Policy is to have an IP legislation for public funded research in India. The necessity of such a law in the Indian context is still not clear. Bill for this was

introduced in the Parliament in 2008. Such a law is largely along the lines of the US Bayh Dole Act of 1980. Contexts of India and the US are very different. In the case of US, IP ownership of public funded research was not clear at that point of time. The government funding agencies staked claims and came in the way of IP licensing by the universities. This slowed down the process of technology commercialisation. Moreover, prior to *Bayh Dole*, public funded research results could not be licensed exclusively and hence industry was reluctant to pursue university inventions. The Bayh Dole Act addressed both these problems. The ownership of public funded IP was transferred to the university (not the scientist or the funding agency) and exclusive licensing of public funded IP was allowed. One should remember that US universities by then were world leaders in innovation. Even then, the Bayh Dole Act could only generate mixed results. Evidence suggests that patenting increased, but commercialisation did not pick up at the same pace. Moreover, the quality of university patents degraded. In India, apparently government funding agencies have rarely come in the way of technology licensing, and in many cases, the first right of refusal for university generated IP remains with the university. Moreover, many universities and laboratories have policies allowing exclusive licensing. Therefore, any new law for IP from R&D funded by public resources should have clear guidelines on ownership of public funded innovations, management of IP portfolio and norms pertaining to commercialisation of IP. It should take into consideration existing best practices in Indian public funded institutions with respect to technology commercialisation and academia-industry collaboration. Such laws should not be used to create a solely IP-driven model of public funded research. Including IP creation as a key performance metric for public funded R&D entities may dilute basic research and the institutions will give more focus to such technologies which will lead to patent filings rather than advancing our scientific needs. Public funded R&D is the foundation on which private enterprises build on for commercialisation and if this becomes a competitor with them, instead of their source, it may not be good for scientific and technological advancement in the long term. Focus should be on quality of research. Finally, given that the National IPR Policy is meant to signal prudent IP provisions and practices, such grey areas can be avoided. At best, sector specific importance of IP may be highlighted within the larger framework of utilisation of public funded innovations and channels of technology transfer.

Specific Concerns

15. Though India's patent system does not expressly recognise the option for seeking 'utility patents', it is time that the national policy and patent regime take serious view for ensuring that people in India use this option. This will encourage small innovators. But the new law should not dilute the provisions in the Patents Act relating to non-acceptance of 'ever-greening' through minor improvements. It is advisable to avoid 'Utility Models' in pharmaceuticals. They may be agreed to in engineering and mechanical products only.

16. It would not be in the national interest to re-open the core areas in the Indian IP legislation which have been finalised after long deliberations by Parliamentary Committees and have stood the test of time. These would include, (i) Use of Flexibility allowed in TRIPS regarding definition of the terms 'invention', 'novelty', etc; (ii) Maintaining rigorous standard of patentability by not allowing minor improvements to be patented; (iii) Pre-grant opposition; (iv) Consumer friendly Compulsory Licence (CL) regime - which has 'affordability' of medicines as a major condition; (v) Governmental powers relating to CL or government use; and (vi) TRIPS compliant limited scope of data protection without any data exclusivity. They are essential for public health and promoting India's own industries. Dilution of these provisions will not be in the interest of access to health.

17. The trend towards overindulgence in monopoly creation in patents should be addressed in the IP Policy. While IPRs are exclusive rights given to owners, such rights should not be used to shut out all competition and innovation. The Policy should further enhance its focus to deal with issues of patent trolls and other similar entities to minimise issues of hoarding. A close linkage of the patent regime with the Competition Act is necessary.

18. India has been arguing for quite long in the international fora for having the same level of IP protection for geographical indications across products, that is, having the same level of protection for agricultural and handicraft products as what is currently extended to wines and spirits. This is necessary for Indian products such as Darjeeling Tea, Basmati Rice, etc. This should find a specific mention in the Policy.

19. The Draft stresses the need for creating IP awareness and gearing up the governmental machinery for its enforcement. But there is no mention of encouraging use of open source software, the commons licence, etc., to keep the people from becoming infringers. This is necessary. It is also needed to reduce avoidable expenditure by public institutions. There are several studies which have established the idea of open innovation in formulation of STI

20. The Policy should also suggest means for harmonising and streamlining sectoral and departmental IP policies that are currently in place. The level of coherence and conflicts between IP strategies and policies need to be assessed with a view to having a common but differentiated approach for dealing with IP regime development and implementation in India.

21. There has been much discussion and suggestions in the Draft on IP enforcement such as setting up special mechanisms, development of databases of offenders and so on. Policy document may focus more on key policy issues and less on administering and enforcing mechanisms by private parties on others concerned. The detailed strategies and operational details or specifics could be separately stated instead of keeping them as part of the policies. It would be a good idea to have a two part IP Policy: the first one, an exposition of the policy, and the second one, an elaboration of the programme of action. The detailed strategies, of course, should be left to the line Ministries and states to device according to the broad policy directions and law.

22. Overall the IP Policy should highlight India's commitment to provide an intellectual property right regime in compliance with its TRIPS obligations and, at the same time, safeguard the public interest concerns in health, education, etc. It should also address alternative models such as OSDD and innovative ways of ensuring that IP protection is granted to only genuine innovation and not to traditional knowledge or minor tinkering of existing inventions. The policy should also focus on how to make IP a tool in India's campaign for 'Make in India' and also in generating more innovations that benefit the South. It should address the technological and development needs of the nation.

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