

Committee on Trade and Environment
Council for Trade-Related Aspects
of Intellectual Property Rights

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PROTECTION OF BIODIVERSITY AND TRADITIONAL KNOWLEDGE – THE INDIAN EXPERIENCE

Submission by India¹

I. INTRODUCTION

1. Biological diversity encompasses all species of plants, animals and micro-organisms and the variation between them, and the eco-systems of which they form a part. It occurs at three levels, namely: (i) species level - refers to number and kinds of living organisms; (ii) genetic level - refers to genetic variation within a population of species; and (iii) eco-system level - refers to the variety of habitats, biological communities and ecological processes that occur in such habitats.

2. Traditional knowledge (TK) associated with biological resources is an intangible component of the resource itself. TK has the potential of being translated into commercial benefits by providing leads for development of useful products and processes. The valuable leads provided by TK save time, money and investment of modern biotech industry into any research and product development. Hence, a share of benefits must accrue to creators and holders of TK.

3. India is one of the twelve-megabiodiversity countries of the world. With only 2.4 per cent of the land area, India already accounts for 7 per cent to 8 per cent of the recorded species of the world. This number is based on the survey of 65 to 70 per cent of the total geographical area of the country. Over 47,000 species of plants and 81,000 species of animals have been recorded by the Botanical Survey of India and the Zoological Survey of India respectively. It is anticipated that some of the remaining areas (e.g., Himalayan region, A & N Islands) may be far richer in biological diversity than most of the areas already surveyed. India is also one of the twelve primary centres of origin of cultivated plants and is rich in agricultural biodiversity. India is equally rich in traditional and indigenous knowledge, both coded and informal.

4. India is a party to the Convention on Biological Diversity (CBD), which came into force on 29 December 1993. It has three main objectives, namely, the conservation of biological diversity, the sustainable use of its components and fair and equitable sharing of benefits arising out of the utilization of genetic resources.

5. CBD envisages that the benefits accruing from commercial use of TK have to be shared with the people responsible for creating, refining and using this knowledge. Article 8(j) of the CBD provides for respecting, protecting and rewarding the Knowledge, Innovations and Practices (KIP) of local communities.

¹ India has requested the Secretariat to circulate this submission in both the Committee on Trade and Environment and the Council for Trade-Related Aspects of Intellectual Property Rights.

II. THE BIOLOGICAL DIVERSITY BILL 2000

6. The CBD offers opportunities to India to realize benefits from these resources. It is, therefore, proposed to enact a legislation to realize the benefits arising out of this Convention. The Bill has been introduced in the Parliament in the Budget Session of the year 2000.

7. The proposed legislation addresses the basic concerns of access to, and collection and utilization of biological resources and knowledge by foreigners, and sharing of benefits arising out of such access. The legislation provides for a National Authority, which will grant approvals for access, subject to conditions, which ensure equitable sharing of benefits.

III. TRIPS, BIODIVERSITY AND PATENT ISSUES

8. In the recent past, there have been several cases of bio-piracy of TK from India. First it was the patent on wound-healing properties of haldi (turmeric); now patents have been obtained in other countries on hypoglycaemic properties of karela (bitter gourd), brinjal, etc. An important criticism in this context relates to foreigners obtaining patents based on Indian biological materials. There is also the view that the TRIPS Agreement is aiding the exploitation of biodiversity by privatizing biodiversity expressed in life forms and knowledge.

9. Patents are granted under national patent laws and have territorial application only. The TRIPS Agreement provides minimum standards of protection for intellectual property rights including patents, while WTO Members are free to grant a higher level of protection under their national laws. Thus, India is free to deny patents on life forms, except on micro-organisms and microbiological and non-biological processes, as per the provisions of the TRIPS Agreement. At the same time if, for example, the United States chooses to grant patents on plants or other life forms, we cannot object. Nevertheless, such patents will have force only in the United States and cannot be enforced in India.

10. To assess the WTO compatibility of a patent granted by a foreign patent office to an invention based on biological material obtained from India, we need to check whether the criteria of patentability (novelty, non-obviousness and usefulness) are satisfied, and to challenge it where the criteria are not met. We examine cases that need to be examined. A patent granted in the United States on the wound-healing properties of turmeric, for example, was revoked after such an examination. Similarly, a patent granted on the need as a fungicide was revoked in the European Patent Office in May 2000. The exercise could be extended to other such patents also. But the time, effort, and money involved in getting individual patents examined and revoked in foreign patent offices is prohibitive. Hence, an internationally accepted solution to such bio-piracy is necessary.

11. The problem of bio-piracy may not be resolved with such revocation actions and domestic biodiversity legislation alone. There is a need to provide appropriate legal and institutional means for recognizing the rights of tribal communities on their TK based on biological resources at the international level. There is also a need to institute mechanisms for sharing of benefits arising out of the commercial exploitation of biological resources using such TK. This can be done by harmonizing the different approaches of the Convention on Biological Diversity on the one hand, and the TRIPS Agreement on the other, as the former recognizes sovereign rights of States over their biological resources and the latter treats intellectual property as a private right. India has proposed, in this context, that patent applicants should be required to disclose the source of origin of the biological material utilized in their invention under the TRIPS Agreement and should also be required to obtain prior informed consent (PIC) of the country of origin. If this is done, it would enable domestic institutional mechanisms to ensure sharing of benefits of such commercial utilization by the patent holders with the indigenous communities whose TK has been used. Simultaneously, provisions have been introduced for disclosure of the source of biological material in the amendments proposed to the Patents Act 1970 through the Patents (Second Amendment) Bill 1999. The Bill is currently before the

Parliament. What is required in addition, to prevent bio-piracy, is the acceptance of this practice of disclosure and PIC by all patent offices in the world.

IV. PROTECTION OF TRADITIONAL KNOWLEDGE ASSOCIATED WITH BIOLOGICAL RESOURCES

12. Issues relating to protecting, recognizing and rewarding of TK associated with biological resources are very complex. The modalities for protecting TK are still emerging and evolving. The nature of entitlements and share in benefits is also a grey area. Even at the international level, clarity has as yet not emerged and countries are grappling to understand the issue.

13. As regards protection of knowledge, innovations and practices associated with biological resources, these do not seem to fall in the conventional legal systems of IPR protection (e.g., patents, copyrights, trademark, etc.). These conventional forms of IPRs are inadequate to protect indigenous knowledge essentially because they are based on protection of individual property rights, whereas TK is, by and large, collective. Further, the informal knowledge presents other difficulties in being recognized for the purpose of IP protection, such as:

- Knowledge is developed over a period of time and may either be codified in texts or retained in oral traditions over generations. The conditions of novelty and innovative step necessary for grant of patent are therefore not satisfied.
- Communities quite often hold knowledge in parallel.

14. Nevertheless, the development of an appropriate form of protection for the knowledge of local communities is of great interest to countries which are rich in biodiversity, and also rich in TK, such as India.

A. SUGGESTIONS/OPTIONS FOR PROTECTING TRADITIONAL KNOWLEDGE

15. Various suggestions have been advanced to extend protection to knowledge, innovations and practices. These include: (i) documentation of TK; (ii) registration and innovation patent system; and (iii) development of a *sui generis* system.

Documentation of traditional knowledge

16. It is sometimes believed that proper documentation of associated TK could help in checking bio-piracy. It is assumed that if the material/knowledge is documented, it can be made available to patent examiners the world over so that prior art in the case of inventions based on such materials/knowledge are/is readily available to them. It is also hoped that such documentation would facilitate tracing of indigenous communities with whom benefits of commercialization of such materials/knowledge has to be shared.

17. On the other hand, others believe that documentation may facilitate bio-piracy. They argue that a trade secret of an indigenous community would be maintained only until it is closely held by the community - as soon as it is put on paper, it will become accessible to pirates and would be purloined. This dilemma is the subject of discussions in national and international debates on benefit sharing. Some suggest the empowerment of the indigenous communities themselves so that they are able to get legal protection for closely-held knowledge without the involvement of outside agencies. Nevertheless, documentation has one clear benefit. It would check patents based on TK in the public domain that are today difficult to prevent due to lack of availability of information with patent examiners.

18. In India, preparation of village-wise Community Biodiversity Registers (CBRs) for documenting all knowledge, innovations and practices has been undertaken in a few States.

19. The State Plan for Kerala has also actively promoted documentation of local knowledge regarding biodiversity in people's biodiversity registers. One pilot project on this has been completed in Ernakulam District. Two other projects at a single Panchayat level have been initiated by the Tropical Botanic Garden and Research Institute and the Kerala Forest Research Institute. Another interesting development in Kerala is the development of a benefit-sharing arrangement between the Tropical Botanical Garden Research Institute and the Kani tribe, based on whose knowledge a drug was developed and then marketed.

20. The state of Karnataka presents a unique example of NGO initiatives in the formulation of Peoples' Biodiversity Registers (PBRs). Some experts who were part of the State Planning Board recommended the Karnataka Biodiversity Conservation Order in 1996. This order envisaged biodiversity boards at the state and sub-state levels, with a wide range of stakeholders being members of the board, and envisaged PBRs as part of the responsibilities of the boards. One of the organized and widespread attempts of NGOs has been towards initiating and completing biodiversity registers.

21. Some of the other experiences include:

- (a) The efforts of the Centre for Ecological Sciences, Indian Institute of Science, Bangalore, spearheaded by Dr. Madhav Gadgil were the pioneering effort in this field. By mid 1998, 75 Plant Biodiversity Registers had been established in ten States with the help of Indian Institute of Sciences and others.
- (b) Gene Campaign has undertaken work on documentation of biodiversity and knowledge relating thereto among three tribal populations: the Munnars in South Bihar (in the Chotanagpur region); the Bhils of Madhya Pradesh; and the Tharus of the Terai region. Medicinal plants and knowledge related thereto was sought to be documented with the help of educated tribal youth. Elders in the village, medical practitioners and traditional healers were consulted in the collection and understanding of the information.
- (c) The Research Foundation of Science, Technology and Ecology (RFSTE) initiated a movement called the Jaiv Panchayat: Living Democracy, started in early 1999. According to the RFSTE, the Jaiv Panchayat movement aims to establish definitive sovereignty of local communities on their biodiversity resources. Activists from RFSTE and Navdanya have been interacting with local villagers in different parts of India (their strongest presence being in the state of Uttar Pradesh) to constitute informal community-level institutions called Jaiv Panchayats, comprising volunteers from a village. The members of the Jaiv Panchayat are entrusted with the task of inquiring and recording information on biological resources, and various uses of the same in the form of Community Biodiversity Registers (CBRs). The first Jaiv Panchayat to complete the register was in Agasthyamuni village Garhwal district, Uttar Pradesh, where on 5 June 1999, the CBR prepared by the local people was presented. It is estimated by the RFSTE that efforts towards Jaiv Panchayats were under way in 292 sites in the country.
- (d) SRISTI, the Society for Research and Initiatives for Sustainable Technologies and Institutions based in Ahmedabad, has been involved in documenting innovation developed by individuals at the village level. The HoneyBee Network, as the initiative is called, documents not elements of biodiversity *per se*, but their uses and in particular innovation surrounding these elements. This network has been growing

since the late 1980s. It aims, through this documentation and subsequent accrual of benefits, to provide a platform through which biodiversity and local knowledge bases can be conserved.

- (e) The efforts of Kalpavriksh and the Beej Bachao Aandolan (Save the Seeds Campaign), Tehri-Garhwal, Uttar Pradesh. Kalpavriksh, in collaboration with the villagers in Jardhar of the Teri Garhwal district of Uttar Pradesh, initiated an exercise in 1995 to document the various bio-resources used by the community and conservation practices. The members of the Beej Bachao Aandolan (Save the Seeds Campaign) - a network of local farmers who have been involved for a number of years now in reviving and spreading indigenous crop diversity, actively collaborated with the Kalpavriksh members. By mutual agreement between Kalpavriksh and the villagers, it was decided that a copy of the register would be kept in the village and another copy would be kept by Kalpavriksh, and that all the information in the register can be used and distributed only with the consent and knowledge of the villagers.
- (f) Drawing on the experience in Karnataka, the Biodiversity Register Programme evolved further at subsequent workshops organized by the Centre for Ecological Sciences, to encompass all elements of biodiversity, and also knowledge and perceptions of individuals, households, ethnic and multi-ethnic groups. PBR activities along these lines were initiated at ten sites in four states along the Western Ghats region, as part of the Western Ghats Biodiversity Network. These efforts were followed in conjunction with a larger project - the Biodiversity Conservation Prioritization Programme (BCPP). The geographical extent of the BCPP-PBR exercise was 56 sites across seven states. Many other organizations have since taken up the initiative, and at present about five villages each in Karnataka, Andhra Pradesh and the rest of India are involved in developing PBRs.

Traditional Knowledge Digital Library

22. In the recent past, there have been several cases of bio-piracy of TK from India. For preventing such instances in future there is a need for developing digital databases of prior art related to herbs already in the public domain. Following patents on brinjal, etc., in India, an exercise has been initiated to prepare easily navigable computerized database of documented TK relating to use of medicinal and other plants (which is already under public domain) known as TK Digital Library (TKDL). Such digital database would enable Patent Offices all over the world to search and examine any prevalent use/prior art, and thereby prevent grant of such patents and bio-piracy.

23. Documentation of TK is one means of giving recognition to knowledge holders. But mere documentation may not enable sharing of benefits arising out of the use of such knowledge, unless it is backed by some kind of mechanism for protecting the knowledge. This necessitates the need for extending some kind of protection to TK. Documentation of TK may only serve a defensive purpose, namely that of preventing the patenting of this knowledge in the form in which it exists. Documentation *per se*, however, will not facilitate benefit sharing with the holders of TK.

Registration and innovation patent system

24. This involves creating a system for registration of innovations by inventors. Such registration will be tantamount to giving right to the inventor to challenge any use of the innovation without prior permission. For novel and useful innovations, some kind of petty patent giving protection for a limited duration may be worked out.

25. Regarding registration, some limited efforts have been made in India. For example, the HoneyBee database, established ten years ago in India, is a facility for registration of innovations by innovators. The database can be accessed for adding value to these innovations and sharing benefits with the knowledge providers and innovators. Thus, the HoneyBee Network involves documentation, experimentation and dissemination of indigenous knowledge. The network has probably the world's largest database on grassroot innovations, having now about 10,000 innovations, with names and addresses of the innovators (individuals or communities). Through the HoneyBee Newsletter, grassroots innovations have been disseminated to more than 75 countries. For example, this database has entries on traditional use of fish and fish products, improving crop productivity, etc.

Development of a *sui generis* system

26. Some experts have suggested that a *sui generis* system separate from the existing IPR system should be designed to protect knowledge, innovations and practices associated with biological resources. However, the parameters, elements and modalities of a *sui generis* system are still being worked out. This is in addition to the *sui generis* system of protection for plant varieties. The *sui generis* system of protection for plant varieties is separately developed in India and a Bill in this regard is before the Parliament.

Some other aspects

27. Another relevant aspect relating to TK is the need for value addition to this knowledge for converting it into economically profitable investments or enterprises. Many of the innovators, however, do not have the capacity for value addition. Thus, there is a need for providing institutional support in scouting, spanning, sustaining and scaling up of grassroot innovations and to enhance technical competence and self reliance of these innovators, through establishment of green venture promotion funds and incubators. It was also proposed as part of the 1999-2000 national budget of India that a National Innovation Foundation would be set up. This foundation, with an initial corpus of Rs.20, is intended to build a national register of innovations, mobilize intellectual property protection, set up incubators for converting innovations into viable business opportunities and help in dissemination across the country. The foundation is in the process of being set up.

B. PROVISIONS IN THE BIODIVERSITY BILL 2000 AND PATENTS (SECOND AMENDMENT) BILL 1999

28. Realizing the need to ensure that the holders of TK which is not still in the public domain should be able to get the benefits arising from the use of such knowledge, an enabling provision has been made for protecting the TK in the Biodiversity Bill, 2000. Relevant provisions of this Bill are discussed below.

29. Section 36(iv) provides for protection of knowledge of local people relating to biodiversity through measures such as registration of such knowledge, and development of a *sui generis* system. For ensuring equitable sharing of benefits arising from the use of biological resources and associated knowledge, Sections 19 and 21 stipulate prior approval of the National Biodiversity Authority (NBA) before their access. While granting approval, NBA will impose terms and conditions, which secure equitable sharing of benefits. Section 6 provides that anybody seeking any kind of intellectual property rights on a research based upon biological resource or knowledge obtained from India, need to obtain prior approval of the NBA. The NBA will impose benefit-sharing conditions. Section 18(iv) stipulates that one of the functions of NBA is to take measures to oppose the grant of IPRs in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource.

30. In the Patent (Second Amendment) Bill 1999, the grounds for rejection of the patent application, as well as revocation of the patent, include non-disclosure or wrongful disclosure of the source of origin of biological resource or knowledge in the patent application, and anticipation of knowledge, oral or otherwise. It has also been made incumbent upon patent applications to disclose the source of origin of the biological material used in the invention in their patent applications.

31. The above mentioned provisions in the Biodiversity Bill 2000 and the corresponding provisions in the Patent (Second Amendment) Bill 1999 would ensure equitable sharing of benefits arising from the use of TK with the holders of such knowledge.

V. INTERNATIONAL ACTION

32. Even though provisions of Article 8(j) of CBD are subject to national legislation, India is of the view that securing benefits arising out of the use of TK related to biodiversity cannot be limited to national action alone, and a basic understanding and respect for an internationally recognized regime to ensure rights to these communities is an absolute must. These two requirements, therefore, have to go hand in hand. To secure this, suggestions have been made by India in international fora under the aegis of CBD as well as WTO, that applications for patents should disclose the following:

- The source of knowledge and biological material; and
- an undertaking that the prevalent laws and practices of the country of origin have been fully respected.

33. While securing benefits to the creators and holders of knowledge for the use of this knowledge is subject to national legislation, national action alone is not sufficient to ensure realization of benefits. The onus must also be shared by the users of this knowledge all over the world so as to ensure compliance of the consent requirement for using the knowledge and equitable sharing of benefits as visualized in the CBD.
