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COMMENTARY

Infirmities and inconsistencies of Indian legislations on access and benefit sharing

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India, occupying 2.45% of the world's land area, has 16.8% of the world's population and shares a meagre 1.6% of the world's GDP¹. With equally skewed internal distribution of this domestic product, the country has the highest incidence of poverty and malnutrition. Nearly 30% of the world's poor, who are living on less than 1 US \$ a day, are Indians. In contrast, India has a rich biodiversity with more than 15,000 endemic plant species² and a major share of two of the 12 megabiodiversity centres of the world. India is the primary and secondary centre of diversity for about 168 crop and fruit tree species, with equally rich genetic diversity in few other crops. More than 60% of Indians, a good proportion of them poor, are dependent on agriculture and related activities, which contribute one-fourth of the GDP. There is perhaps no other region in the world, where such a huge population is so much dependent on biodiversity for livelihood, food and health security. This way of life of people over centuries had contributed a rich genetic diversity and traditional knowledge on its use and conservation. Therefore, national legislations seeking to safeguard the national wealth against piracy and to conserve and promote the way of living, livelihood, food and health security of vast majority of Indians have immense public interest.

Access and benefit sharing (ABS) is an important principle of equity recognized and legitimized by the Convention on Biological Diversity (CBD). 'Fair and equitable sharing of the benefits arising out of the utilization of genetic resources,

including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over these resources and to technologies, and by appropriate funding' is set out as one of the three overriding objectives of the CBD⁴. Benefit sharing is a legitimate reward to the community *albeit* the country for generating genetic diversity and associated traditional knowledge, conserving them with sustainable use and making them available. The CBD paradigm recognizes the sovereign rights of countries over their biological resources and associated knowledge⁵, and the need for facilitated access to these resources and knowledge by others. The Member countries, which are Parties to the CBD, are required to enact and enforce their own national laws in consistence with the CBD to assert the said sovereign rights and to establish an ABS system⁶.

Two recent Indian legislations, which deal with ABS system are the Protection of Plant Varieties and Farmers' Rights Act (PPVFR Act), 2001 and the Biological Diversity Act (BD Act), 2002. The PPVFR Act was enacted to make India TRIPS compliant with respect to grant of intellectual property protection on plant varieties⁷. The BD Act seeks to establish national sovereignty over the bio-resources and associated traditional knowledge existing within legal territorial bounds, including the economic zone in sea, in pursuance of the CBD and to provide regulation for its conservation, sustainable use and access of its components and ensuring fair and equitable sharing of bene-

fits arising out of its use⁸. This note examines the ABS mechanism provided in these two Acts and discusses the inconsistencies and infirmities therein.

The Biological Diversity Act

The route of access to Indian biological resources and associated knowledge provided in the BD Act differs depending on whether the party accessing is (1) a non-Indian or non-resident Indian citizen, or a body corporate/association/organization not incorporated or registered in India or such bodies having non-Indian participation in capital or management; (2) Indian citizen or a body corporate/association/organization registered in India, and (3) local people and communities inhabiting an area, including traditional medicine practitioners. Access by parties belonging to the first group has to be necessarily with prior approval of the National Biodiversity Authority (NBA)⁹. This access is facilitated through a structured application and payment of Rs.10,000 (US\$ 230) as fee. This application largely conforms to the Bonn Guidelines¹⁰. An access request is expected to be decided within six months time. BD Act has no explicit provision to involve the concerned local community in the decision making with prior informed consent on traditional knowledge associated with the use of genetic resources. The Act, however, provides for the involvement of Biodiversity Management Committee, which is instituted at each Panchayat, in the process of decision making on ABS issues related to local

biodiversity and associated knowledge¹¹. Access by parties belonging to the second group for the purpose of commercial utilization has to be with prior intimation to the State Biodiversity Board¹². There is no restriction whatsoever on the access by local people and practitioners of traditional medicine, except that such use has to be sustainable.

The parties accessing components of biodiversity or associated knowledge are required to enter into an agreement in a framework prescribed by the NBA¹³. This agreement may affirm intended use of the accessed material or knowledge, conditions to be complied for establishing intellectual property rights on innovations generated therefrom, quantum of monetary or non-monetary benefits, scope for establishing fresh agreement on benefit sharing and other conditions. The Act and its Rules also stipulate that patent or any other intellectual property based on research on the accessed material or knowledge could be established only with the prior approval of the NBA, and with public notification of such approvals¹⁴. During such grant of approval, the NBA assisted by an expert committee shall, on mutually agreed terms, determine the types of the benefit-sharing. This may involve monetary benefits with quantum and schedule of payment, and non-monetary benefits such as technology transfer, etc. The benefit-sharing system provided in the BD Act is largely in conformity with the Bonn Guidelines on ABS¹⁰, with case-to-case variation. Royalty and milestone payment, license fee, etc. are the common forms of monetary benefit sharing. The non-monetary benefit sharing may include joint IPR ownership; technology transfer, involving Indian scientists, benefit claimers and the local people; research and development in biological resources and bio-survey and bio-utilization; setting up of venture capital fund for aiding the cause of benefit claimers; and location of production and research and development units in such areas, which will facilitate better living standards to the benefit claimers.

The Protection of Plant Variety and Farmers' Rights Act

The primary goal of this Act is to institute plant breeder's right (PBR) with concurrent safeguard to the traditional rights of farmers on seeds. Plant variety develop-

ment essentially involves access and use of locally adapted plant genetic resources. Hence, the PPVFR Act has provisions on access and benefit sharing. The genetic resources accessed could be farmers' varieties, wild species, elite breeding lines and varieties developed by institutions. This Act under the provision on researcher's rights¹⁵, allows free access without prior informed consent to any genetic resource, including those protected for its PBR by any person for conducting experiment or research or breeding, with the exception that prior informed consent is essential for using a variety protected under this Act for repeated use as a parental line for the commercial production of a new variety. While such liberal access to national plant genetic resources is provided to promote research leading to the development of superior varieties, the person accessing this genetic resource is required to declare the details of parental genetic stocks used while seeking PBR on the new variety. Such details should include identity of the genetic material, its passport data and geographical source, including person, community or institution from whom it was accessed. For the purpose of access, this Act does not differentiate parties as Indian citizens or institutions or otherwise. Such discrimination is outside the scope of this Act. Therefore, eligibility of researcher's right on Indian genetic resources with respect to non-resident Indian or non-Indian citizen and institution with foreign equity or management is subject to the relevant provision on access under the BD Act.

While granting the PBR on the new variety, the Protection of Plant Varieties and Farmers' Rights Authority¹⁶ is to determine the benefit sharing due on the variety. This is done either on the basis of the access declaration made by the breeder or the claim received and admitted from concerned parties¹⁷. The Act and its Rules require notification of grant of PBR on a new variety and to invite applications from parties eligible to receive benefit sharing. Individuals, communities and institutions, who have contributed genetic resource for the breeding of the notified variety are eligible for benefit sharing. The provision on benefit claiming or sharing restricts the beneficiaries to Indian citizens and Indian organizations. The process of decision-making on benefit sharing, according to this Act does not totally follow the concept of mutually agreed terms involving the concerned

stakeholders. The Protection of Plant Varieties and Farmers' Rights Authority almost unilaterally determines the benefit share largely on the basis of genetic contribution of the accessed germplasm to the new variety¹⁸. Benefit sharing under this Act offers scope essentially only in monetary terms. The concerned breeder is required to deposit the awarded benefit share in the National Gene Fund created under this Act within a timeframe, from where it then flows to the eligible parties.

The conflict between BD Act and PPVFR Act in ABS

Both these laws present certain apparent and real discrepancies or conflicts in their ABS provisions. According to the BD Act, prior approval from NBA is mandatory for accessing Indian plant genetic resources for research or for commercial utilization or for bio-survey and bio-utilization by persons who are non-resident Indians or non-Indian citizens or who work in India for a body corporate, association or organization, which is not incorporated or registered in India or has non-Indian participation in its share capital or management¹⁹. Contrary to this, the PPVFR Act allows free access without prior informed consent to any genetic resource, including those varieties protected by plant breeder's right by any person for conducting experiment or research or breeding, with one exception, which was mentioned earlier¹⁵. Unlike the BD Act, the PPVFR Act does not differentiate parties accessing genetic resources as Indian citizens or institutions or otherwise or as may see later, whether the breeding undertaken is conventional or non-conventional. However, for the purpose of benefit sharing the PPVFR Act discriminates the nationality of beneficiaries as Indian citizens or institutions or otherwise²⁰. From the legal perspective, the access regulation on national genetic resources instituted by the BD Act in consistence with the national sovereignty on biodiversity shall define and limit the researcher's right available under the PPVFR Act to the non-Indian entities¹⁹.

The NBA takes decisions on benefit sharing under the BD Act while granting permission to establish IPR on an innovation based on the biological material or associated knowledge accessed from India. The plant breeder's right established on a variety under the PPVFR Act is an intel-

lectual property right of *sui generis* class²¹. The BD Act, which requires prior approval from the NBA for establishing any intellectual property, by whatever name called, on any product or process derived from Indian biological diversity or associated knowledge, provides exemption from this provision to the grant of plant breeder's right under PPVFR Act²². This exemption *inter alia* places the decision on benefit sharing arising out of the plant breeder's right outside the purview of NBA. In this context, it is important to underscore that the jurisdiction of PPVFR Act is national, while the liability for benefit sharing arising from the access and use of Indian plant genetic resources for breeding new varieties could be transnational. Therefore, establishment of an intellectual property right on a plant variety bred outside India using Indian genetic resource, requires prior approval from the NBA. In such cases, the decision on benefit sharing falls under the purview of the NBA. It also means when a patent or *sui generis* protection has to be established in countries outside India on a variety which is registered in India under PPVFR Act, fresh approval of the NBA with possible liability for fresh determination of benefit sharing becomes necessary. Also notwithstanding the legal position that it is the PPVFR Authority which determines the benefit sharing of varieties registered in India, a non-Indian entity, which is accessing Indian genetic resources is required to make prior commitment on benefit sharing under the BD Act during the access process prescribed under the rules of BD Act or the material transfer agreement envisaged thereunder. These prior commitments on benefit sharing also have the scope to specify the type of benefits, monetary or non-monetary, and other details.

The above discussed provisions of these two Acts bring forth two important issues. First is the inconsistency between the BD Act and PPVFR Act on the eligibility for benefit sharing. BD Act provides *quid pro quo* relationship between 'commercial utilization' and benefit sharing²³. Here, the definition of 'commercial utilization' provided in the BD Act assumes importance. 'Commercial utilization' is defined to exclude 'the conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dry farming, animal husbandry or bee keeping'²⁴. According to this definition, the economic gain accrued from IPR protec-

ted crop varieties, which were evolved by selection or conventional breeding is excluded from benefit sharing, despite the fact that the process of breeding could have accessed and used genetic resources and traditional knowledge created and conserved by local communities. In contrast, the PPVFR Act does not discriminate a variety on the basis of its derivation, whether bred by conventional or non-conventional methods, except in the case of essentially derived variety. PPVFR Act does not prescribe a decision on benefit sharing on an essentially derived variety, while its commercialization is allowed only with prior approval of the party who had provided the initial variety²⁵. The said definition of commercial utilization in BD Act has another implication. Indian citizens' organizations, public or private, while accessing genetic resources and associated knowledge for use in conventional breeding gain exclusion from the provision, which mandates that such access should be with prior intimation to the concerned State Biodiversity Board²⁶.

Interestingly, the BD Act itself is contradicting the above discussed exclusion provided under the definition of 'commercial utilization'. Rule 14 of BD Act, which sets out procedures for accessing bio-resource and traditional knowledge and Form I prescribed under this Rule require flow of benefits to the communities out of the 'use of accessed bio-resource and traditional knowledge'. Further, under Section 18 of the BD Act, it is asserted that the (NBA) 'has authority to advise the Central Government on the equitable sharing of benefits arising out of the utilization of biological resources'. These variations in the expressions like 'commercial utilization' and 'use' and 'utilization' for determination of eligibility for benefit sharing are inconsistent and confusing, particularly in the absence of definition for 'use' and 'utilization' either in the Act or in the Rules. According to the *Oxford Dictionary*, the common meaning of 'use' is 'do some thing with an object' and that of 'utilization' is 'to make practical and effective use of'. Therefore, according to Rule 14 and Section 18, anything done with the genetic resource or traditional knowledge accessed entitles flow of benefit share. Thus, the BD Act links the eligibility for benefit sharing with 'commercial utilization', 'utilization' and 'use' of genetic resources and despite a clear exclusion provided under commercial utilization, considerable incon-

sistency and lack of clarity persist in the Act and its Rules on the eligibility for benefit sharing.

The definition of 'commercial utilization' is also causing a major legal infirmity to one of the pivotal provisions of the BD Act, which mandates prior approval of NBA for accessing Indian bio-resource or associated knowledge by non-Indian entities. According to this provision, such an entity can undertake commercial utilization, bio-survey and bio-utilization only after such prior approval¹⁹. Bio-survey and bio-utilization are essentially defined as research activities for exploring the commercial utilization potential of a bio-resource or associated knowledge. Conventional breeding or other practices used in agriculture are not included under bio-utilization. Commercial utilization is defined essentially as an activity, which can generate economic gain, but excluding the conventional breeding and traditional practices in agriculture. Therefore, access to genetic resources and associated knowledge for conventional breeding by non-Indian entity *de jure* does not warrant prior approval from NBA. Once these resources are accessed under this exclusion provision, there is no way to regulate their use in bio-survey or bio-utilization or non-conventional method of breeding. This virtually pre-empts the cause for entering into an access or material transfer agreement in exercise of national sovereignty rights over these resources, particularly the agro-biodiversity, and for ensuring benefit sharing to the local communities who have been creating and conserving these resources. This virtually underwrites the national sovereignty that the BD Act seeks to protect.

The above major infirmity on the national sovereignty over plant genetic resources in conjunction with Section 40 of this Act and the current liberalized seed export policy, opens a wide corridor for legitimized free outflow of Indian plant genetic resources. According to Section 40 of the BD Act, 'the Central Government, may in consultation with the NBA, by notification in the Official Gazette, declare that the provisions of this Act shall not apply to any items, including biological resources normally traded as commodities'. Seeds or other propagating material of plant varieties are tradable commodities. The current national trade policy allows unrestricted trade of seeds and other propagating plant material. This allows export of virtually any seed in any

quantity, including small quantities. In the absence of a credible system at the customs port of exit to verify what is exported and what is purported to be exported, there exists a wide-opened corridor for unrestricted free outflow of seeds of any national plant genetic resource, including improved varieties, farmers' varieties, land races and pre-bred material. This is a corridor now being increasingly used by multinational seed companies to legitimately transfer all valuable Indian plant genetic resources. The law established to protect Indian plant genetic resources is in fact legitimizing their piracy!

Another infirmity on ABS pertains to the Rules of the PPVFR Act related to benefit sharing. According to Rule 41 of this Act, a person or group of persons or a firm or a non-governmental organization is entitled to make a claim for benefit sharing from a variety registered under this Act within a period of six months from the date of publication of its registration²⁷. It further states that such applicants shall provide information on the commercial viability or the actual market performance of the variety in question, apart from other specified information. In the case of a plant variety, irrespective of its possible commercial superiority, its propagation system and the multiplication rate of its planting material may demand a duration much longer than six months for making a realistic assessment of its potential commercial market size. In India, most of the varieties require at least three to five planting seasons to attain their potential commercial market. Therefore, a determination of benefit share made on commercial market size achieved within six months will be highly disadvantageous to the benefit claimants. Another implied aspect of benefit sharing under this Act and its Rules is that the benefit sharing awarded on a breeder for using a given genetic resource contributed by a community for breeding a specific variety is apparently a one-time event. In other words, when the same breeder, institution or seed company repeatedly uses the same genetic resource in the form of certain variety, for which benefit sharing was once awarded, or its derivatives for developing increasingly superior varieties, the liability to share benefit with the community for every such variety remains nebulous. This apparent limitation denies perpetual entitlement of communities or other parties for benefit sharing, whenever a genetic resource or its derivative is

used for evolving newer commercial varieties.

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2. Conservation International, Biodiversity hotspots. 2005, Available at http://www.biodiversityhotspots.org/xp/Hotspots/hotspots_by_region/
3. CBD, Convention on Biological Diversity was adopted on 5 June 1992 at the UN Conference on Environment and Development at Rio de Janeiro, Brazil, participated by 157 countries. This legally binding Convention came into force on 29 December 1993. Currently 188 countries are Parties to this Convention 1993. Convention text available at <http://www.biodiv.org/default.aspx>
4. Article 1 of the CBD sets out the three objectives: the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.
5. Articles 3 and 15 of CBD. Leaving behind the long held 'common heritage of humankind' concept on biodiversity, these articles of CBD conferred sovereign rights to Contracting Parties over their biodiversity.
6. Articles 8 and 15 of the CBD. These Articles mandate the States to enact their own legislations for achieving the objectives of CBD and in particular ABS with respect to its genetic resources and associated traditional knowledge.
7. Article 27.3(b) of TRIPS. This sub-article of Trade Related aspects of Intellectual Property Rights requires Members of World Trade Organization to provide protection to plant varieties either by patent, or an effective *sui generis* system or a combination thereof. PPVFR Act was introduced in the Indian Parliament as Bill No. 123C of 1999 and passed in August 2001. Ministry of Agriculture, Government of India is nodal Ministry.
8. BD Act, This Act introduced in the Indian Parliament as Bill No. 93 of 2000 was passed in 2002 and being enforced from 2003. Ministry of Environment and Forests, Government of India is the nodal Ministry, 2002.
9. National Biodiversity Authority is the apex national institution headed by Chairperson, vested with authority to regulate access to biodiversity, associated knowledge and database, to issue and implement guidelines for ABS in accordance with the Act and directions of Government of India.
10. Sixth Conference of Parties, 2002. Decision VI/24 of Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. Available at <http://www.biodiv.org/decisions/default.aspx?m=cop-06&d=24>
11. Biodiversity Management Committee constituted under BD Act functions at every Panchayat and is vested with the responsibility of documentation, conservation and sustainable use of local biodiversity, and assisting the State Biodiversity Board in ABS decisions.
12. State Biodiversity Board constituted under BD Act may function under the overall guidance of NBA with jurisdiction over the concerned state on conservation and sustainable use of biodiversity and equitable sharing of benefits. Under the Indian federal polity, biodiversity is a concurrent subject with Central and State Governments having legislative/administrative authority.
13. Rule 14 of the BD Act. This rule sets out administrative procedure under the Act for accessing biological resources and associated traditional knowledge.
14. Section 6 of the BD Act and Rule 18. Section 6 of the Act provides statutory regulation to be followed prior to the application for any intellectual property rights on products or processes developed from Indian biodiversity and associated traditional knowledge. Rule 18 deals with the administrative procedure for the said provision.
15. Section 30 of PPVFR Act, 2001 deals with researcher's right.
16. PPVFR Authority is the national apex body established under this Act for its administration. It comprises a Chairperson and a committee of 15 members assisted by Registrar General of Plant Varieties (see Chapter II of the Act).
17. Section 26 of PPVFR Act and Rules 40 to 43 of this Act allow persons, communities or institutions to claim benefit share on a candidate variety based on their contribution of genetic resource to the pedigree of the variety.
18. Vide section 26(5) and Rule 43 of the PPVFR Act.
19. Section 3 of BD Act. It states 'No person, who is not a citizen of India, who is a non-resident Indian as defined under Income Tax Act, 1961, a body corporate, association or organization, which is not incorporated or registered in India or incorporated or registered in India under relevant law in force and having non-Indian participation in its share capital or management, shall without prior approval of the NBA obtain any biological resource occurring in India or knowledge associated thereto for commercial utilization, or for bio-survey or for bio-utilization'.
20. Section 26(2) of the PPVFR Act. Limits the eligibility for benefit claim to a person

or group of persons, who are citizens of India or to a firm or governmental or non-governmental organization established in India.

21. Bala Ravi, S., *J. Intellectual Property Rights*, 2004, **9**, 533–548.
22. Section 6(3) of BD Act states that provisions of Section 6(1) (vide ref. 14 above) shall not apply to any person making an application for any right under any law relating to protection of plant varieties.
23. Section 6(2) of the BD Act. This subsection states ‘The NBA may, while granting the approval [for establishing any intellectual property rights] impose benefit sharing fee or royalty or both or impose conditions, including the sharing

of financial benefits arising out of the commercial utilization of such rights’.

24. Section 2(f) of BD Act. Commercial utilization is defined as... ‘but does not include conventional breeding or traditional practices in the use of any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee-keeping’.
25. Section 23(6) of PPVFR Act. A breeder will become eligible to enjoy plant breeder’s right granted on an essentially derived variety only on authorization of the breeder/conservator (vide Section 43) of the initial variety, which was used for the derivation.
26. Section 7 of BD Act. This section states ‘No person, who is a citizen of India or a

body corporate, association or organization which is registered in India, shall obtain any biological resource for commercial utilization, or bio-survey and bio-utilization except after giving prior information to the State Biodiversity Board concerned’. Each SSB is required to define the administrative procedure for providing prior information.

27. Rule 41 of PPVFR Act.

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