Access and Benefit Sharing for domestic entities

Case comment on Divya Pharmacy v. Union of India & others

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The Uttarakhand High Court recently decided upon a question pertaining to the access and benefit sharing under Biological Diversity Act, 2002 in *Divya Pharmacy v. Union of India and others.* The judgment has opened a Pandora's Box which may have a huge impact on the indigenous Ayurvedic industry. The Court, in the judgment held that the State Biodiversity Board has the power, under Section 7 read with S. 21 and 23, to demand fair and equitable benefit sharing from Indian companies, too.

Facts

Divya Yog Mandir is a trust manufacturing Ayurvedic medicines and nutraceutical products. It has its manufacturing unit in Haridwar and is an Indian entity. The state Biodiversity Board raised a demand for royalties under the head 'Fair and Equitable Benefit Sharing' as provided under Biological Diversity Act and the regulations framed in 2014. The demand was challenged by the petitioner as the regulations apply only to a foreign entity under S. 3 of the Biodiversity Act.

Held

The Court held that the fair and equitable sharing applied to both the Indian and foreign entities. To reach this conclusion, the court relied upon the purposive interpretation in the light of Convention on Biological Diversity and Nagoya Protocol. It held that the provisions on access and benefit sharing would be applicable not only to the entities which have to apply for prior approval of State Biodiversity Boards, but also to entities which have to give prior intimation to the State Biodiversity Board under Section 7 of the Act.

Analysis

Before going into the judgment, it is pertinent to look at the outline of the relevant provisions in Biological Diversity Act, 2002. S. 3 talks about approval from State Biodiversity Board for research, commercial utilization or bio survey and bio utilization. As per the section, this approval is required by a non-citizen of India, a non-resident or a body incorporate, association or organization not incorporated or registered in India or having a non-Indian participation in its share capital or management. S. 7 specifically states that the Indian entities need only a prior intimation, not the prior approval of State Biodiversity Board. This section also states that prior intimation is not required for local people or communities in the area, including the cultivators of the Biodiversity. Fair and Equitable sharing of resources is dealt under S. 21 of the Act, which applies to only the approvals given to the entities under S. 3. S. 23(b) talks about regulation by granting of approvals or otherwise requests for commercial utilization or bio-survey and bio-utilization of any biological resource by Indians.

The Court interpreted the power under S. 23(b) to regulate expansively. It held that State Biodiversity Board will have the power to make a monetary demand for access and benefit sharing to an Indian entity. The court relied on purposive interpretation which calls for looking at the context in which the law was enacted to determine the intention of the legislature. The Court first went into the reasons for which the Act was enacted, that is, to implement the Convention on Biological Diversity. It then looked into Convention on Biological Diversity and Nagoya protocol to the Convention and held that the Convention and the Protocol do not differentiate between national and foreign entities and domestic entities for the purpose of Access and Benefit sharing. Thus, the legislature could not have intended to make such a distinction in Indian law.

However, while interpreting the same, the Court failed to consider the doctrine of *Cassus Omissus pro omisso habendus est,* that is a conscious omission on the part of the legislature. The Act makes a conscious effort to differentiate between a domestic and a foreign entity under the Act. This conscious differentiation is visible from different provisions of the Act. For instance, the Act requires only a prior intimation by a domestic entity (S.7) unlike a foreign entity (S.3). Similarly, Chapter IV and Chapter V of the Act applies only to a foreign entity, and not to a domestic entity. However, Section 6 of the Act puts domestic and foreign entities on an equal footing while making an application for any intellectual property right based on any biological resource in India. Thus, the decision to limit fair and equitable benefit sharing is a conscious decision by the legislature to limit it to foreign entities.

It is incorrect to say that Indian entities are completely outside the ambit of Access and Benefit Sharing. S. 41(3) authorizes Biodiversity Management Committee to levy charges by way of collection for accessing or collecting any biological resource. In the current case, however, the levy has been put for access and benefit sharing by the Biodiversity Board, rather than the committee. Hence, if at all any levy has to be put on the Indian entities, it has to be put by Biodiversity Management Committee rather than the Biodiversity Board, as in the present case.

An issue which needs some examination here is the Court's interpretation of Indian law in the light of Convention on Biological Diversity. The Constitution of India does not stipulate that the treaty which has been signed by India has a direct effect on Indian law. The Constitution puts a non- binding obligation on the state to be in compliance with its treaty obligations. Article 253 of the Constitution allows the Parliament to make a law to implement any treaty, convention or agreement to which India is a party. The Courts have interpreted this in different ways. In *Vishakha v. State of Rajasthan,*the Court read the Indian law in the light of Convention on Elimination of All forms of Discrimination against Women (CEDAW) as the law in that area was non-existent. In *Novartis v. Union of India,*the Madras High Court refused to rule upon the compatibility of S.3(d) of Patent Act, 1970 with TRIPS Agreement, holding that international agreement was a contractual arrangement which provided an international forum to resolve the dispute and the Indian court was not the proper forum for the same. In *Divya Pharmacy,* the court supplied its interpretation on access and benefit sharing in the light of CBD. Such an approach is useful if the Indian law is silent on the issue of Access and Benefit sharing for Indian entities. However, it is not so and hence, the Court's interpretation of CBD goes against the approach taken by High Courts and Supreme Courts in previous cases.

Another provision which seems to have been ignored by the Hon'ble Court is the proviso to S. 7. The proviso specifically excludes cultivators and growers of biodiversity form the ambit of S.7, and therefore control of State Biodiversity Board. Thus, if an Ayurvedic entity is merely growing or cultivating the biodiversity, it cannot be 'regulated' by the State Biodiversity Board. A similar provision is applicable to vaids and hakims, a term not defined anywhere in the Act. The domestic Ayurvedic entities would come under the ambit of this provision either as cultivators or as vaids/hakims.

The domestic and foreign entities need to be differentiated for utilizing the scope of AYUSH in India and abroad. While China offers a positive protection to traditional Chinese medicine, it is ironic that producers of Ayurvedic medicines would be subjected to demands by State Biodiversity Boards. If at all it is felt that the domestic entities be brought under the ambit of Access and Benefit Sharing, the right approach would be an amendment to the legislation, not the judicial law making as the issue would involve the interests of several stakeholders. This judgment by the Hon'ble High Court would create an environment of uncertainty amongst the producers and cultivators of biodiversity, which may have a negative rather than a positive impact on it.

Disclaimer: Views expressed are personal and do not express the views of CIIPC on the matter.

Divya Pharmacy v. Union of India & others, Writ Petition (M/S) No. 3437 of 2016

Biological Diversity Act, S.3:

"(1) No person referred to in sub-section (2) shall, without previous approval of the National Biodiversity Authority, obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilization.

(2) The persons who shall be required to take the approval of the National Biodiversity Authority under sub-section (1) are the following, namely:

(a) a person who is not a citizen of India;

(b) a citizen of India, who is a non-resident as defined in clause (30) of section 2 of the Income-tax Act, 1961;

(c) a body corporate, association or organization- (i) not incorporated or registered in India; or (ii) incorporated or registered in India under any law for the time being in force which has any non-Indian participation in its share capital or management."

Biological Diversity Act, S. 7:

"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 for commercial utilization except after giving prior intimation to the State Biodiversity Board concerned:

Provided that the provisions of this section shall not apply to the local people and communities of the area, including growers and cultivators of biodiversity, and vaids and hakims, who have been practicing indigenous medicine."

Biological Diversity Act, S.21:

"(1) The National Biodiversity Authority shall while granting approvals under section 19 or section 20 ensure that the terms and conditions subject to which approval is granted secures equitable sharing of benefits arising out of the use of accessed biological resources, their by-products, innovations and practices associated with their use and applications and knowledge relating thereto in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers.

(2) The National Biodiversity Authority shall, subject to any regulations made in this behalf, determine the benefit sharing which shall be given effect in all or any of the following manner, namely:

(a) grant of joint ownership of intellectual property rights to the National Biodiversity Authority, or where benefit claimers are identified, to such benefit claimers;

(b) transfer of technology;

(c) location of production, research and development units in such areas which will facilitate better living standards to the benefit claimers;

(d) association of Indian scientists, benefit claimers and the local people with research and development in biological resources and bio-survey and bio-utilization;

(e) setting up of venture capital fund for aiding the cause of benefit claimers;

(f) payment of monetary compensation and non-monetary benefits to the benefit claimers as the National Biodiversity Authority may deem fit.

(3) Where any amount of money is ordered by way of benefit sharing, the National Biodiversity Authority may direct the amount to be deposited in the National Biodiversity Fund: Provided that where biological resource or knowledge was a result of access from specific individual or group of individuals or organizations, the National Biodiversity Authority may direct that the amount shall be paid directly to such individual or group of individuals or organizations in accordance with the terms of any agreement and in such manner as it deems fit.

(4) For the purposes of this section, the National Biodiversity Authority shall, in consultation with the Central Government, by regulations, frame guidelines."

Biological Diversity Act, S. 23:

"The functions of the State Biodiversity Board shall be to–

…(b) regulate by granting of approvals or otherwise requests for commercial utilization or bio-survey and bio-utilization of any biological resource by Indians."

Biological Diversity Act, S. 6(1):

> "No person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application…" — *S. 41(3) of Biological Diversity Act, 2002:*

"The Biodiversity Management Committees may levy charges by way of collection fees from any person for accessing or collecting any biological resource for commercial purposes from areas falling within its territorial jurisdiction."

Shamnad Basheer and Prashant Reddy, "Ducking" Trips In India: A Saga Involving Novartis and the Legality of Section 3(d), National Law School of India Review, Vol. 20, No. 2, pp. 131-155, 2008. Available at SSRN: https://ssrn.com/abstract=1329201

Article 51(c) forms a part of Directive Principles of State Policy, which is non justiciable. It reads:

> "…foster respect for international law and treaty obligations in the dealings of organized peoples with one another — *Article 253 of Indian Constitution…"*
>
> "Notwithstanding anything in the foregoing provisions of this Chapter, Parliament has power to make any law for the whole or any part of the territory of India for implementing any treaty, agreement or convention with any other country or countries or any decision made at any international conference, association or other body." — *Vishakha v. State of Rajasthan , AIR 1997 SC 3011*

Novartis AG v. Union of India, (2007) 4 MLJ 1153

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