

Is Biological Diversity Act hampering biodiversity research?

The Biological Diversity Act 2002 was enacted to meet the obligations of the Convention on Biological Diversity (CBD) and ensure fair and equitable sharing of benefits arising from India's rich biodiversity. This was followed by the establishment of the National Biodiversity Authority (NBA) which regulates the access of biological resources in the country. The act and the rules that followed were found to be too restrictive by many and even the Department of Biotechnology and the Ministry of AYUSH, Government of India (GoI) have raised several objections to them. The matter was further complicated by the way some provisions are being interpreted by the administering Ministry, i.e. the Ministry of Environment, Forest and Climate Change (MoEFCC), GoI, and the lack of coordination that resulted in different states making their own rules which in some cases are contradictory to the central act.

The major concern for the scientific community is that the law does not make distinction between research and commercial exploitation. Although it defines research and commercial utilization as different activities, when it comes to regulation it puts both together. Section 3(1) states that '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'. According to sub-section (2), the entities – commonly referred as 3(2) entities – that need prior approval from NBA for the above-mentioned activities are non-resident Indians, persons who are not Indian citizens, and bodies, associations and organizations that are not registered in India, or 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. Scientific research now is more global than it was ever. International collaborations between large groups are the norm rather than the exception, and the way these provisions of the act are being interpreted presently has put severe restrictions on collaborative research and affected research in general.

The classical case is that of microbial taxonomists desirous of describing new taxa. Microbial taxonomy is a well-organized activity that is governed by the International Committee for Nomenclature of Prokaryotes (ICNP). The rules demand that while describing a novel

taxon, a deposit of the corresponding culture needs to be done in at least two culture collections in two different countries. Also, this culture should have unrestricted access for further research. These deposits are made for reference purpose and ensure that the culture used for defining a new taxon is available to researchers all over the globe for comparison. Further, all the reputed culture collections distribute these cultures purely for research purpose and not for any commercial use. They mandate that the accession number provided by them for the said culture, be utilized in any publication resulting from the use of this culture. They also provide a detailed history of their accessions that make it easy to trace the origin of any deposit. However, the provisions of the Biological Diversity Act make it impossible for Indian researchers, to deposit a culture anywhere. This is because Article 3(1) of the Act makes it necessary for any researcher outside India wanting to access this culture from any collection to first approach the NBA for permission. Further accentuating the issues is not only the delay to get this permission, but also the ironical situation where the fees paid to the NBA are much more than the actual cost of the culture. Most importantly, the ICNP and culture collections abroad interpret this as 'restricted access' and hence decline to accept the cultures with this condition. At the same time, the deposits made with culture collections within India are not recognized for publication purpose for the same reason. This has strangled microbial taxonomy research in the country, which was picking up a few years ago. However, due to these limitations, it is now lagging far behind the leaders in microbial taxonomy research: USA, China and Korea. While we talk about the rich diversity in our country, we are unable to document it. Thus we are losing opportunities to claim several novel taxa that could have been documented as 'discovered in India'. Similar organisms are being identified from other countries and reported from there. The cure has thus become reason for a kill.

Unfortunately, a similar fate looms large over researchers from other branches of life sciences, of which they are not aware. For modern-day biological research, DNA sequencing has become an integral part. It comes in a variety of forms: whole genome sequencing of organisms, partial sequencing, re-sequencing and transcriptomics. Today, microbiome is considered an equally important component of living organisms. In this, the study

involves sequencing of either a part of the rRNA gene (amplicon sequencing), or of genomes of the entire microbial population within an ecosystem, i.e. metagenomics. Rapid developments of sequencing technologies have not only resulted in increase in the output, but also significant cost reduction. The development of portable instruments has actually enabled sequencing to be performed on site and within the reach of an average researcher. However, unlike most others, these experiments do not end at generating the sequence data, and this is merely the first step in the experiment. Subsequent steps involve extensive analysis of the generated data and, most importantly, comparative analysis with the existing data. The data for such comparisons are available in huge databases that are present and accessible worldwide, the best example being NCBI. Publication of the research warrants deposition of sequence data, at times, raw data generated from the instruments in such databases. This is similar to deposition of microbial strain in culture collections. The sequence information from genetic resources is termed 'Digital Sequence Information' (DSI) in these discussions.

In December 2016, CBD initiated discussion on whether or not DSI falls in the purview of the Nagoya Protocol (NP). There are contradicting views on this issue. One view states that it is only the physical entity of DNA that should fall under CBD and NP, and not DSI. The other view, taken by countries like Brazil and India, is that both CBD and NP recognize physical entity as well as information content in the genetic material, and hence the sequence information too falls within their purview. The Biological Diversity Act defines biological resource as 'plants, animals and micro-organisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but does not include human genetic material;..'. India's official communication to CBD clearly states that 'Genetic as well as biochemical composition is nothing but the gene sequence whether digital or tangible. Synthesising the DNA with access from digital sequence would therefore fall within the scope of utilization under the Nagoya Protocol. In other words, accessing digital sequence information amounts to accessing the genetic resource itself, and its utilization would fall within the scope of CBD/Nagoya Protocol, qualifying for application of ABS regulatory framework even though there is no physical access of the genetic material'. (ABS stands for access and benefit sharing.)

Thus, there is inherent danger of all sequence analysis-based research going the same way as microbial taxonomy research. Today, all the sequence information is available in public domain with open access databases. Before rushing into bringing them in the purview of NP, the complexities of the issue need to be completely understood. Some of these are: actual value of sequence information, role and functioning of public access databases, monetary and non-monetary aspects of information-sharing, role of sequence information in the documentation and conservation of biodiversity, and cur-

rent mechanisms of implementing intellectual property rights to sequence information. If sequence information is going to be treated the same way as actual biological resource, it imposes the user to approach the NBA and pay the fees every time it is accessed. Under these conditions, no database in the world would be ready to accept depositions from Indian researchers. Presently, there is no database equivalent of NCBI in the country, but even if it is created, the depositions in it will not be acceptable to scientific journals. There is also an urgent need to understand that even ABS with sequence information is a complicated issue. There are only a few cases where a commercial product is developed directly from sequence information. In most cases it is derived from a complex comparative analysis of several sequences available in the database from several sources, and ABS becomes difficult in such situations.

Unfortunately there seems to be a total lack of awareness among researchers about this imminent danger. There was no representation from major scientific institutions for the meetings called to discuss the issue. It is necessary that the researchers awake to this danger and come up with an acceptable solution. Access of any biological resource whether it is the actual resource or the sequence information for research purpose should be made possible with minimum hindrance. The suggestion by Prathapan *et al.* (2018) to the Conference of the Parties (CoP) and CBD to follow the model of the 'Seed Treaty' and add an explicit treaty or annex to promote and facilitate biodiversity research, conservation, and international collaboration for the exchange of biological materials, which includes sequence information for the conservation related research, including taxonomy, is worth considering. There are global bodies like the World Federation of Culture Collections or International Nucleotide Sequence Database Collaboration that formulate the guidelines for functioning of culture collection and databases respectively. Their involvement will ensure adherence to ABS. In case of microbial cultures, the global culture collections have no problems negotiating with partner culture collections in the country instead of going to a third entity. It is thus appropriate that the culture collections within the country, especially those recognized as designated repositories by NBA itself, should have the powers delegated for providing access to cultures under suitable Material Transfer Agreement. A similar mechanism could be evolved for the sequence information in the databases.

Finally, it must be understood that a full potential of any resource can be availed only if it is utilized. If it is only preserved for its perceived value, it is worthless. The key to success is to develop proper mechanisms for its utilization, so that the benefits are availed by all the stakeholders.

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