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THE MISSING LINK: PRIOR INFORMED CONSENT



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India is one of the 12 mega-biodiverse countries of the world. Realising the importance of genetic resources (GR), in 1994 it joined the Convention on Biological Diversity (CBD) to regulate access to the country's GR and ensure equitable sharing of benefits arising from it. The CBD provides discretionary powers to member countries to implement an effective legal framework and, *inter alia*, requires interested parties to obtain "prior informed consent" (PIC) from government authorities or traditional knowledge-holders of the country to which the GR belongs. Article 8(j) and Article 15.5 of CBD particularly mandate that PIC of the community be taken before GR or knowledge related to it is used in any manner.

To enforce and implement the objectives of CBD, India enacted the Biological Diversity Act, 2002 (BDA). Section 6 of this statute reads: "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 biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority (NBA) before making such application". Accordingly, when an invention utilises GR from India, PIC must be obtained from the NBA before applying for a patent in or outside India. Another provision states that such approval can be obtained any time before the grant of a patent by the Indian Patent Office (IPO). Furthermore, given the seriousness of the objective, sanctions for non-compliance are prescribed under Section 55 of the BDA.

However, under the Patents Act, 1970, no corresponding provision has been incorporated to complement Section 6 of the CBD. The patent statute mandates only "disclosure" of source and geographical origin of GR in patent applications under Section 10(4)(d)(ii)(D). Interestingly, the recently released *Manual of Patent Office Practice and Procedure* does indicate the requirement to furnish evidence of PIC. But given that non-compliance does not offend any statutory requirement or invite any penalty under the Patents Act, one may rarely witness an objection regarding a lack of PIC in an examination report issued by the IPO. The absence of a mandatory requirement in the Patents Act for submitting evidence of PIC by a patent applicant cripples the IPO's potential ability to act as a useful check against GR misuse. In such a scenario, where the existing system fails to provide requisite checks to ensure effective implementation of the objectives of the CBD and, thereby, prevent misappropriation of GR and grant of erroneous patents, the BDA is rendered a toothless legislation. Therefore, the need of the hour is to bridge this gap by establishing a suitable link between the Patents Act and the BDA.

If examined in the context of international treaties and obligations, the alleged missing link may be attributed to the apparent inconsistency between the CBD and the TRIPS agreement. Realising the significance of this issue, India

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has proactively raised its concerns at various international forums. Along with other developing countries, it has proposed the introduction of a new article—29bis—in the TRIPS agreement which would make it mandatory to file evidence of PIC issued by a competent authority in the country of origin of a GR. However, such measures have encountered strong resistance from developed countries, particularly the US.

Shifting focus back to India, to ensure compliance with the BDA's provisions, it is essential that the 'requirement' of PIC be included in the Patents Act, either as a 'condition for grant' or as a 'ground of opposition or revocation' (in case of non-compliance). Alternatively, the IPO may be put to task to obtain such information directly from the NBA, as in the case of applications related to atomic energy or defence.

In summary, the flagrant inconsistency between the two statutes lays down serious hurdles in achieving the objectives of the CBD and ensuring effective implementation of the provisions of BDA. Whatever path India opts for, it is the gap between the two statutes which is ultimately required to be bridged. ■

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