International Journal for Multidisciplinary Research (IJFMR)
E-ISSN: 2582-2160 ● Website: www.ijfmr.com ● Email: editor@ijfmr.com

Understanding Global and Indian Patent Disclosure Requirements (PDRs) for Genetic Resources (GR) and Traditional Knowledge (TK)

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Abstract:
A thoughtful exploration of Patent Disclosure Requirements (PDRs) within the context of the global patent system and legal policy frameworks of different nations, with special reference to India, and PDRs emergence as a linchpin in the preservation and safeguarding of Genetic Resources (GRs) and Traditional Knowledge (TK), particularly when intertwined with the heritage of indigenous and local communities, their significance as guard against biopiracy, while upholding the doctrine of Access and Benefit-Sharing (ABS) as envisioned by the Convention on Biological Diversity (CBD) and the Nagoya Protocol. PDRs scope to mandate transparently revealing the origins and sources of GRs and TK, deployed in their innovations for patents. PDRs are a litmus test for patent offices and governing authorities to assess the reliability of patent claims and are an indispensable weapon in the fight against biopiracy. Further, different kinds and the evolving nature of PDRs are also acknowledged, as they adapt to cope with new challenges, technological advancements, and the dynamic evolution of the legal framework, finally, positioning PDRs as key protagonists in shaping responsible innovation while preserving biodiversity.

Keywords: Patent Disclosure Requirements (PDRs), Genetic Resources (GRs) and Traditional Knowledge (TK), CBD and the Nagoya Protocol, Access and Benefit-Sharing (ABS).

"A man can only attain knowledge with the help of those who possess it… One must learn from him who knows." George Gurdjieff (1866–1949)[1]

I. Introduction

Patent Disclosure Requirements (PDRs) regarding Genetic Resources (GRs)[2] and Traditional Knowledge (TK)[3] within the realm of intellectual property (IP) and innovation systems[4], have been seen

[1] Bernard O'Connor, Protecting Traditional Knowledge: An Overview of a Developing Area of Intellectual Property Law, 6 J. World Intellectual Property 677 (2005).
[2] Convention on Biological Diversity art. 2, 1992, //https://www.wipo.int/tk/en/resources/glossary.html#23
[3] WIPO, Glossary of Key Terms Related to Intellectual Property and Genetic Resources " knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity". (https://www.wipo.int/tk/en/resources/glossary.html#23)

growing. In the present world, the trend of international diplomacy to set free trade agreements at different levels, both at bilateral and regional levels, has made the developing countries protect their intellectual property rights (IPR) from the Pharmaceutical and biotechnology industries of developed countries. The key interest of developed countries is to access the IP of the developing countries, especially GRs and TK as they are rich in Biodiversity. Under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[5], the contrary to obtaining a patent condition for its disclosure emphasized minimum standards for patent systems. The TRIPS agreement states that all members shall follow that an applicant of a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art."[6]

The developing countries have been pushing and negotiating under the World Intellectual Property Organization (WIPO)[7], since 2010, to develop international legal instruments specifically for protecting traditional cultural expressions, TK, and GRs. WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore[8] (IGC) has been an important forum for these negotiations. At Nagoya, which is a supplementary agreement to the Convention on Biological Diversity (CBD) dealt with Access to GRs and the Fair and Equitable Sharing of Benefits Arising from their Utilization, and provisions including disclosure requirements, parties tried to bring common consensus for mandatory disclosure obligation in the final draft[9], as they failed to do so the parties were left to incorporate such a requirement in their national laws as per their wish. The discussions and developments are a significant first step towards establishing a coherent legal framework for addressing the complex issues like Biopiracy or bioprospecting[10], surrounding TK and GRs within the national legal regime of patents and IP laws. Further, in the years changes in the legal field, technology, and patent landscapes related to GRs and TK have been witnessed and legally binding and non-binding instruments have been adopted by nations.[11]

II. Meaning And Nature Of Patent Disclosure Requirements (PDRs):

The expression "disclosure requirement" refers to the basic idea that the inventor has to disclose information regarding their inventions, the technological advances that they have made in order to acquire a patent[12]. Patent Disclosure Requirements (PDRs) are legal provisions or obligations imposed

[4] Chiarolla & Burcu Kilic, Developing Patent Disclosure Requirements Related to Genetic Resources and Traditional Knowledge – Key Questions (2017), Geneva: WIPO, available at https://ssrn.com.

[5] Agreement on Trade-Related Aspects of Intellectual Property Rights [TRIPS Agreement], Apr. 15, 1994, http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

[6] TRIPS Agreement, supra note 5, Article 29.1

[7] The World Intellectual Property Organization (WIPO), About WIPO, https://www.wipo.int/about-wipo/en/.

[8] *WIPO,* Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore, "folklore is the totality of tradition-based creations, of a cultural community, expressed by a group or individuals and recognized as reflecting the expectations of a community in so far as they reflect its cultural and social identity; its standards and values are transmitted orally, by imitation or by other means. Its forms are, among others, language, literature, music, dance, games, mythology, rituals, customs, handicrafts, architecture and other arts." https://www.wipo.int/tk/en/resources/glossary.html#23.

[9] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the CBD, Oct. 29, 2010, in force on Oct. 12, 2014.

[10] Vandana Shiva, Bioprospecting as Sophisticated Biopiracy, 32 Signs: J. Women in Culture & Society 307 (2007).

[11] International Treaty on Plant Genetic Resources for Food and Agriculture of the FAO, 2001. United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP), 2007. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the CBD, 2010.PIP Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits of the World Health Organization, 2011.

[12] Jason Rantanen, Patent Law's Disclosure Requirement, 45 Loy. U. Chi. L.J. 373 (2013).

on patent applicants regarding the disclosure of specific information like,(i) GRs utilized in the development of the claimed invention; (ii) The country of origin of GRs utilized in the claimed inventions; (iii) Associated TK, practices and innovations utilized in the development of the claimed inventions; (iv) The source of connected TK, practices and innovations; and, (v) Evidence of Prior Informed Consent(PIC)"[13], to address issues related to GRs and TK. This protective mechanism was adopted by many states as per their need and requirement and incorporated in their domestic patent laws to prevent the issues of Biopiracy or Bioprospecting[14].

III. Importance And Need Of PDRs

Many countries realised the need and importance of the protection of GR and TK, when countries like India fought legal battles in Biopiracy cases of Neem[15], Turmeric[16], to strike a balance between the patent laws and legislation related to biodiversity. The patent system and biodiversity-related laws appear to be at odds with each other and to balancing these interests of inventive patent holders with broader societal and community interests in preserving biodiversity and TK has become a challenging task and still an ongoing subject of policy debate and development. In this process, PDRs emerged as a system to promote fair and equitable benefit-sharing between biodiversity-rich countries, indigenous peoples, local communities (IPLCs), and those possessing the modern technologies required for scientific and commercial exploitation. [17] They are important;

1. To Preserve the Biodiversity and Traditional Knowledge the PDRs became essential for ensuring that the utilization[18] of GRs in a manner that promotes the conservation of biodiversity, respects the rights and knowledge of Indigenous Peoples and Local Communities and help to prevent biopiracy, which involves the unauthorized use and commercialization of GRs and TK.
2. PDRs are now a legal requirement to many countries, they are in line with international agreements and conventions, such as the Convention on Biological Diversity (CBD) [19] and the Nagoya Protocol[20], which aid in regulating access to GRs and ensure that the users of that knowledge respect the rights and interests of countries and communities who are custodians[21] of those resources. Compliance with these requirements became crucial to avoid legal challenges and potential patent

[13] WIPO, Technical Study on Disclosure Requirements in Patent Systems Related to Genetic Resources and Traditional Knowledge, https://www.wipo.int/edocs/pubdocs/en/tk/786/wipo_pub_786.pdf (last visited21.11.2023)
[14] Vandana Shiva, Biopiracy: The Plunder of Nature and Knowledge (South End Press 1997).
[15] Regina Jera-Malanda, Biopiracy: Neem, the Wonder Tree, Is a Classic Example of Biopiracy from Which Africa Has a Lot to Learn - the Blatant Pirating of the Neem Tree, Translated by the United Nations as the 'Tree of the 21st Century', New African, December 2003.
[16] S. Kumar, "India Wins Battle with USA Over Turmeric Patent," 350 Lancet 724 (1997).
[17] Stephanie Heyl, Bioanalysis – Techniques for the Characterization of Biological Material, https://www.analytic-news.com/papers/pdf/bioproe2.pdf
[18] In Article 2(c) of the Convention on Biological Diversity defined the term "utilization" as "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention."
[19] Convention on Biological Diversity opened for signature on June 5, 1992, to June 4, 1993, at the UN Conference on Environment and Development (Rio Earth Summit), 168 signatures received. The Convention came into force on December 29, 1993, 90 days after the 30th ratification. Its 1st session of the COP was held from November 28 to December 9, 1994, in the Bahamas.
[20] Nagoya Protocol adopted on October 29, 2010, and came into force on October 12, 2014, as a supplementary agreement to the CBD.
[21]WIPO, Custodian, refers to those communities, peoples, individuals, and other entities which, according to customary laws and other practices, maintain, use, and develop the traditional knowledge and cultural expressions. https://www.wipo.int/tk/en/resources/glossary.html#23.

invalidation under domestic laws, they also provide legal and regulatory clarity for both patent applicants and patent offices in the process of granting a patent.

3. The obligation of the patent applicants to disclose the origin, source of biological materials, and TK of the patent is to enhance transparency and promote accountability, which in the future can potentially avoid the issues of biopiracy[22].
4. The disclosure of the origin and source leads to the fair and equitable sharing of benefits arising out of the commercialization of such knowledge, which also guides to establishing mechanisms for obtaining prior informed consent (PIC) and negotiating mutually agreed terms (MAT) between users and providers of these resources, leading to more balanced benefit-sharing arrangements.
5. PDRs encourage and support responsible innovation by promoting ethical practices in research and development. Patent applicants are encouraged to engage with communities and countries that are the source of GRs and TK, such fostering collaborative and ethical approaches to innovation leads to the exchange of information and promotes international cooperation between countries and stakeholders.

IV. Scope Of The PDRs:

The complete success of the establishment and implementation of PDRs is still far from reality as it is an evolving legal framework, they primarily focus on the disclosure of GRs and TK in patent applications but do not necessarily regulate other forms of IP. They mainly determine the content of obligations, consequences of non-compliance, and mechanisms for enforcement. Which includes,

1. Evidence of Prior Informed Consent (PIC)[23] for their use, often connected to the research that led to the claimed invention, from the provider country. In some cases, consent from Indigenous Peoples and Local Communities (IPLCs) or other resource holders in the provider country is also required.
2. Evidence of establishing contractual arrangements (Mutually Agreed Terms - MAT) for the fair and equitable sharing of benefits resulting from the use of GRs and TK, as mandated by the National Legislation of the provider country.

V. Kinds Of Patent Disclosure Requirements (PDRs)

Countries have opted for different types of Patent Disclosure Requirements in their national patent laws as per their need and requirements, which mainly determined by their economic interest and intention to protect their biodiversity wealth including GRs and TK, mainly these types of PDRs are Voluntary and Compulsory, Formal and Substantive.

(1) Voluntary PDRs:

Under the Voluntary PDRs, the Patent applicants are encouraged but not obligated to disclose information related to the geographical origin of biological materials, genetic resources, or TK in their patent applications. Non-compliance with these requirements normally has no adverse effects on the patent prosecution or the validity of a granted patent. Patent applicants are not penalized or subject to adverse consequences if they choose not to disclose the requested information voluntarily. The countries

[22]. Biopolitics: A Feminist and Ecological Reader on Biotechnology, Vandana Shiva & Ingunn Moser eds., Zed Books 1995.
[23]A right or principle of prior informed consent or free, prior and informed consent is referred in several international instruments, particularly in the environmental field, such as Article 6(4) of the Basel Convention on the Transboundary Movement of Hazardous Wastes, 1989, and the CBD.

that have adopted these requirements are, the European Union (EU)[24], the United States[25], China[26], Japan, which are developed countries.

(2) Compulsory PDRs:

Compulsory PDRs are mandatory legal requirements for patent applicants to disclose specific information related to GRs or TK as part of their patent application and failure to comply with these requirements can have legal consequences and will lead to fines, penalties including potential impacts on the patent application process or even the rejection of a patent application or the validity of granted patents. The main aim is to ensure transparency, promote compliance with access and benefit-sharing regulations, and to prevent the misappropriation[27] of GRs and TK in the context of patent applications. Depending on the goals of the respective legal systems, various countries have adopted this method like Vietnam, Switzerland[28], India[29], and South Africa[30], Andean Community[31] (Bolivia, Colombia, Ecuador, and Peru), Norway[32], Brazil[33], Costa Rica[34], Mexico, Philippines[35]. It's also important to note that the consequences for non-compliance with compulsory PDRs can vary from country to country and the legal landscape is still evolving to protect biodiversity, traditional knowledge, and to promote equitable benefit-sharing.

(3) Formal PDRs:

Formal PDRs focus on procedural aspects. They require applicants to submit specific types of documents or provide specific information related to GRs and TK in a particular format or manner. This can also be called a 'soft requirement', non-compliance with this will result in administrative actions or fines but does not render the patent itself invalid. Section 34(a)[36] of Germany's Patent Act[37], is an

[24] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions (http://www.wipo.int/wipolex/en/details.jsp?id=1440)

[25] The Leahy-Smith America Invents Act (AIA), enacted in 2011 it doesn't specifically mandate voluntary patent disclosures, In practice, companies and inventors voluntarily disclose patent applications to the United States Patent and Trademark Office (USPTO) as part of the patent application process. Patent applications themselves serve as a form of disclosure,

[26]: Article 26 of the Patent Law of the People's Republic of China (PRC) as amended by the Decision of December 27, 2008, which entered into force in October 2009.

[27] "Misappropriation" as defined by Black's Law Dictionary- "the common-law tort of using the noncopyrightable information or ideas that an organization collects and disseminates for a profit to compete unfairly against that organization, or copying a work whose creator has not yet claimed or been granted exclusive rights in the work. The elements of misappropriation are, (a) the plaintiff must have invested time, money, or effort to extract the information, (b) the defendant must have taken the information with no similar investment, and (c) the plaintiff must have suffered a competitive injury because of the taking." Available at https://www.wipo.int/tk/en/resources/glossary.html#23

[28] Article 49(a) of the Federal Act, 1954 on Patents for Inventions.

[29] The Patents Act, 1970 , as amended by Patents (Amendment) Act, 2005.

[30] .Section 30 of the Patents Amendment Act.

[31] Article 26 of Decision No. 486 Establishing the Common Industrial Property Regime (2000) (http://www.wipo.int/wipolex/en/details.jsp?id=9451)

[32] Section 8(b) of the Patents Act, 1967 (Act No. 9 of 1967) and Section 4 of Act, 1993, (Act No. 32 of 1993), relating to Plant Breeder's Rights

[33] Article 47 of Law No. 13.123 of 2015 (Access and Benefits Sharing of Genetic Resources and Associated Traditional Knowledge)

[34] Article 4 of the Costa Rica's Biodiversity Law (BL) of, 1998.

[35]: Rule 12 Section 3(c) of the Implementing Rules and Regulations of Republic Act No. 10055 (Joint Administrative Order No. 02-2010)

[36] Section 34(a) reads as "where an invention is based on biological material of plant or animal origin or if it uses such material, the application is, as a rule, to include information on the geographical origin of such material, if known. This is without prejudice to the examination of applications or the validity of rights arising from granted patents."

example of a formal PDR. It requires applicants to include information about the geographical origin of biological material in their patent applications. Non-compliance does not automatically impact the validity of the patent but only lead to administrative actions. This requirement mainly aims to enhance transparency regarding the origin of biological materials used in inventions, particularly in cases involving genetic resources. It is designed to contribute to fair access and benefit-sharing.

(4) Substantive PDRs:

Substantive PDRs are more closely related to the patentability criteria of invention requirements, it is considered as a condition for granting a patent or upholding its validity. These requirements assess whether the patent application is directly based on GRs or TK. In countries like South Africa, India, and the Andean Community, substantive PDRs GRs and TK are considered during the patent examination process and non-compliance with them will impact the patentability of the invention itself. This means that a patent will not be granted or will be invalidated if the applicant fails to meet these requirements. Examiners or courts assess whether the patent application meets the substantive PDRs before deciding on the patent's grant or validity. In other words, fulfilling these requirements are prerequisite for the patent's, legal status. The patent will lose its legal protection if it is found that the invention does not meet the substantive PDRs.

VI. India's PDRs:

India adopted the Substantive PDR mechanism due to its rich Biodiversity and TK. India's Patent Act, 1970, includes substantive PDR related provisions for the disclosure of involved GRs and TK in the claimed patent. Section 10(4) (ii)(D)[38] of the said Act, as amended, states that if an applicant mentions a biological material in the specification that cannot be described in a way satisfying certain conditions, they must disclose the source and geographical origin of the biological material when used in an invention. Non-compliance with this requirement is substantive. Failure to disclose the source and geographical origin of biological material, when required, will directly impact the patentability of the invention itself. It is an obligation to grant a patent under the Act. The main reason behind India's substantive PDR is aligned with the country's commitment to access and benefit-sharing requirements, ensuring that patents involving GRs and TK are based on legitimate access and those benefits are shared fairly with the source country and communities. PDR can be viewed as an extended mechanism of Access and Benefit Sharing (ABS) which is well implemented after the Nagoya Protocol, mainly to protect GR and TK getting from misused and patented.

VII. Access And Benefit-Sharing (ABS) And PDRs

Access and Benefit-Sharing (ABS) is a broader framework established under an international agreement, the Nagoya Protocol on Access to GRs and the Fair and Equitable Sharing of Benefits Arising from their Utilization. It aims to regulate and ensure fair and equitable sharing of benefits, to indigenous communities or countries who holds such knowledge, arising from the utilization of such resources and associated TK, both commercial and in research purpose. It covers aspects like access

[37] The first German Patent Act was passed on May 25, 1877, also known as "Patentgesetz" in German, Promulgated on May 5, 1936, recent amendment was amended up to August 30, 2021.

[38] Section 10(4) (ii)(D) of the Patent Act, 1970 reads "Disclose the source and geographical origin of the biological material in the specification, when used in an invention". Available at https://indiankanoon.org/doc/1937976/

permits, benefit-sharing agreements between the parties i.e., who hold the knowledge and who are commercially exploiting it, and its provisions will comply with national regulations or laws. Whereas, the PDRs are primarily patent application requirements of certain disclosed information related to the source and origin of biological resources, GRs and TK are used in their inventions or products to provide transparency about the origin of resources which will help to ensure that countries and communities receive equitable benefits from the commercial use of their resources by way of ABS Agreements.

ABS includes a wider range of activities, including research, development, and commercialization of GRs and TK. It will apply to various forms of IP, not just patents, and includes broader regulations for access to and utilization of these resources. PDRs have a very narrower scope as they primarily focus on the disclosure of GRs and TK in the context of patent applications. They are often limited to the patent system and do not necessarily regulate other forms of IP.

The legal framework of ABS is more comprehensive, it involves international agreements[39] and national laws and regulations. ABS goes beyond patents and covers a broader range of activities related to GRs and traditional knowledge, including research, development, and commercialization. On the other hand, PDRs are introduced within national patent laws or regulations, to disclose of GRs and TK in patent applications.

VIII. Conclusion

In the Indian context, the incorporation of PDRs into patent law[40] assumes a critical role in protecting its rich GRs and traditional knowledge. The legal framework that champions the concepts of Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) helps safeguard the rights and interests of local communities and indigenous populations. It is a blend of legal innovation that promotes the dissemination of indigenous wisdom while ensuring that the collective heritage of these communities is protected from exploitation.

On the global landscape, we witness a varied adoption of PDRs as countries experiment with different legal avenues, incorporating these requirements into their patent laws, biodiversity legislation, or Access and Benefit-Sharing (ABS) laws. Countries have approached various methods, ranging from electronic registration systems to mandatory consultations with biodiversity authorities before filing a patent application. Underscoring the dynamic nature of PDRs and the diverse strategies employed to navigate the complex nexus of genetic resources, IP, and traditional knowledge, is still complex.

The effective outcome of this mechanism can be seen in the coming decades, both for the development of innovations based on genetic resources (GRs) and traditional knowledge (TK).

[39] The Nagoya Protocol was adopted on Oct. 29, 2010 and came into force on Oct. 12, 2014.
[40] Section 10(4) (ii)(D) of the Patent Act, 1970.