ISSN: 0972-7566 Vol. 24 | No. 3 | November 2022

ASIAN BIOTECHNOLOGY AND DEVELOPMENT REVIEW

Asian Biotechnology and Development Review

This journal is abstracted/indexed in CAB International, Scopus, Elsevier Database and EBSCO host™ database. ABDR is also listed in the UGC-CARE List of Approved Journals.

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RNI Registration No. DELENG/2002/8824.

Asian Biotechnology and Development Review

Asian Biotechnology and Development Review

Vol. 24 No. 3 November 2022 ISSN: 0972-7566

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Research and Information System
for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

Asian Biotechnology and Development Review
Vol. 24, No. 3, pp 1-3

Editorial Introduction

Krishna Ravi Srinivas*

Welcome to Volume 24 No 3 issue of Asian Biotechnology and Development Review (ABDR).

We have three articles and three book reviews in this issue. Digital Sequence Information (DSI) has become very important for harnessing the plant genetic resources and although there are issues related to defining DSI, it's importance is beyond doubt. Should rules for accessing DSI be modelled after rules for accessing genetic resources that are material resources based on Nagoya Protocol? Or do we need norms that facilitate open access and sharing with limited benefit sharing as DSI is not a material resource per se. Between, these two questions based on diametrically opposite positions there are many such questions, answers and options. Interestingly even as this debate continues the conclusion of negotiations on Treaty on Biodiversity Beyond National Jurisdiction (BBNJ) has added another aspect to these questions as BBNJ covers Marine Genetic Resources (MGR). In 'Negotiating ABS and DSI in the CBD: Challenges and Opportunities for Fair and Equitable Sharing of Benefits' , Deepa Kharb and Saumya Sharma, unpack and contextualize the issues, putting them as part of the long-drawn discussions on Access and Benefit Sharing. They drawn attention various aspects including synthetic biology, rights and claims of indigenous people. They suggest that Nagoya Protocol has to adopt a more flexible approach. While the 15th Conference of Parties to Convention on Biological Diversity (CBD) has taken the issue forward with the proposal of a multiltateral benefit sharing fund, as the authors point out there is time but a limited time to find an amicable solution to the DSI conundrum.

The importance of diagnostics is too obvious to be over-emphasized. The Covid Pandemic underscored the need for rapid development and deployment of diagnostics. In Vitro Diagnostics (IVD) became popular during the Pandemic. In Role of In Vitro Diagnostics in Economic Development and Healthcare Applications- A Systematic Review of Global and Indian Scenario, Sadhana Srivastava gives a global over view of IVD, their development, regulation and application and links them to the developments in India in IVD. In particularly she describes, the Intellectual

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Property(IP) aspects in IVD and their importance for innovation. While patentability per se of diagnostic methods is controversial, her article points out how the limitations can be overcome by making claims that are admissible. On the other hand she takes the view that IP protection in IVD sector is important and R&D efforts should take this into account. Her long article covers a whole range of issues and needs a thorough reading to grasp the issues discussed.

In 'CBD COP 15: Kunming-Montreal Global Biodiversity Framework' Amit Kumar provides an overview of the Global Biodiversity Framework and the outcomes of COP 15 and their importance for the future of biodiversity. He highlights the challenges as well as the ambitious targets set out to be achieved. We hardly have three decades between now and 2050 and whether humankind will fulfill the 2050 vision of 'Living in Harmony with Nature' is a big question before us.

Three book reviews add value to the issue. Your views and suggestions are welcomed.

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Asian Biotechnology and Development Review
Vol. 24, No.3, pp 3-22

Negotiating ABS and DSI in the CBD: Challenges and Opportunities for Fair and Equitable Sharing of Benefits

Deepa Kharb* and Saumya Sharma**

Abstract: Digital sequence information (DSI) is crucial to technological advancements in diverse product areas from agriculture to environment and therapeutics. Advances in DNA sequencing technology have made it possible to generate and share vast amounts of genetic information data of various organisms at the global level at a relatively low cost. Advocates of open science support open access to DSI of genetic resources stored in public and private databases in silos. Due to the existing conundrum over the application of ABS mechanism under the Convention on Biodiversity (CBD) and its Nagoya Protocol(NP) to intangible genetic data, much of the DSI usage is happening without obtaining Prior Informed Consent(PIC) of provider countries and communities, a mandatory requirement for access and utilisation of genetic material. This is hampering the negotiations under the CBD and NP framework for sharing of benefits of commercial utilisation of the resources with the resource providers. Allowing free access to genetic resource sequence information without PIC and Mutually Agreed Terms (MAT) will be detrimental to the interests of indigenous peoples and local communities who foster and preserve biodiversity in their jurisdictions. The paper examines the issues and arguments surrounding DSI and investigates the possibility and prospects of applying the ABS under the CBDNP framework to DSI. It will analyse the negotiations taking place under the United Nations Convention on Biodiversity as well as the decisions on DSI that arrived in the COP15(Committee of Parties) held in Montreal in December 2022.
Keywords: Access and Benefit Sharing; Genetic Resources; Convention on Biodiversity; Nagoya Protocol; Biodiversity; Indigenous People.

Introduction

The conservation of biodiversity is inextricably linked to the sharing of benefits derived from the utilisation of its genetic resources. The 1992 Convention on Biological Diversity (CBD) established a mechanism for resource access and benefit sharing, which was refined by the Nagoya Protocol (NP) in 2010. Through a fair distribution of benefits between

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provider and user nations, this mechanism aimed to promote research and innovation while also incentivizing biodiversity preservation. CBD has implemented the Access and Benefit Sharing (ABS) policy, which connects access to genetic resources and traditional knowledge with the sharing of monetary and non-monetary benefits with providers. This approach is considered a vital component of the conservation effort. The CBD model views biodiversity as a common responsibility of all humankind and recognizes the obligation of each state to conserve it through domestic protective measures. Additionally, the requirement for Prior Informed Consent (PIC) for genetic resources and traditional knowledge ensures fairness in decision-making processes, while fair and equitable benefit sharing aligns with the principles of international justice.

DNA sequencing and synthesis have disrupted this arrangement. Advancements in biotechnology have made it possible to decode the genetic information of various organisms, resulting in the generation of large quantities of data in digital form, commonly referred to as "digital sequence information(DSI)." This data is made accessible to the scientific community through public repositories and is utilized for a multitude of purposes including disease diagnosis and the development of new treatments, therapies, and genetically modified organisms. Routine DNA, RNA, and protein sequencing have become a widespread practice for scientists across various branches of biotechnology.

The utilisation of Digital Synthetic Biology (DSI) is of paramount significance in the realm of synthetic biology research. DSI has the capability to not just act as a subsidiary but completely replace the original GR during the R&D process, which can help in reducing the cost of research to a great extent. Thus, its economic value must not be undermined. All the issues with the storage and transportation of biological/genetic resources can be addressed owing to this characteristic of DSI. Furthermore, they have the capability to modify the existing biological forms or their attributes through the utilisation of modular DNA components, which are rearranged and combined in innovative ways, leading to the creation of complex biological systems with predictable and well-defined characteristics. These achievements in the junction of biotechnology and digital technology result in practical solutions for a diverse range of fields.

Though open access to such information is beneficial for the biotechnology industry and user countries but poses a challenge to the interests of indigenous and local communities that play a crucial role in maintaining biodiversity.

International regulation of Digital Sequence Information (DSI) is still developing, with various legal instruments and initiatives addressing different aspects of DSI. Some important international agreements and legal frameworks relevant to DSI include:

- The Convention on Biological Diversity (CBD) is an international agreement aimed at preserving biodiversity, promoting its sustainable use, and ensuring that the benefits of using genetic resources are distributed equitably. The Nagoya Protocol, an extension of the CBD, establishes a framework for genetic resource access and benefit-sharing (ABS), including digital sequence information (DSI) linked to a genetic resource.
- World Intellectual Property Organisation (WIPO): WIPO, a specialized agency of the United Nations, is accountable for promoting the protection of intellectual property rights across the globe. Among WIPO's activities in the area of IP and genetic resources are the development of guidelines on the patentability of genetic resources and DSI, as well as the management of IP-related aspects of access and benefit-sharing (ABS).
- World Health Organisation (WHO): The World Health Organisation (WHO) is a specialized UN organisation responsible for advancing health worldwide. WHO's work on digital sequence information (DSI) involves the creation of a global strategy for health-related DSI, which aims to encourage the exchange of DSI and tackle the ethical, legal, and social issues associated with DSI usage.
- UNCLOS: The United Nations Convention on the Law of the Sea (UNCLOS) is an international agreement that governs the use and management of the world's oceans and their resources. UNCLOS has provisions that cover digital sequence information (DSI) associated with marine genetic resources and their distribution.

Apart from the international legal frameworks discussed earlier, various regional and national laws and policies exist that oversee access to and benefit-sharing of digital sequence information (DSI).

The CBD framework's inclusion of DSI is still being debated. Benefit-sharing regulations for digital DNA, it is argued, would be difficult to enforce and would contradict the open-access research culture. It has also been stated that "*if DSI is added in the purview of the Nagoya Protocol, the official process to request access to the digital sequence data (which would no longer be open access) and negotiations focused on adequate benefit sharing may discourage or unnecessarily prolong the research process*(Golan *et al.,* 2022)." In fact, putting ABS standards on DSI would be impossible for both users and government agencies to implement because compliance, monitoring, and verification would be extremely onerous, if not impossible (Report of the ICC Task Force).[1]

Nevertheless, the work on incorporating DSI as a subject matter within the ABS regime is in progress. The Access and Benefit-Sharing Regulation enacted by the European Union contains regulations that address the utilisation of DSI connected with genetic resources.

Although the Nagoya Protocol was mainly developed to address traditional genetic resources, it also includes provisions relating to digital sequence information (DSI).

It is essential for parties to ensure that the access and use of DSI should align with the objectives of the CBD and the Protocol. The Protocol also specifies that the access and benefit-sharing responsibilities related to genetic resources would also apply to DSI, provided that they are connected to a genetic resource and required for the use of that genetic resource. The parties may choose to make it mandatory for users to obtain prior informed consent (PIC) and agree upon mutually acceptable terms (MAT) with the suppliers of resources before using DSI associated with genetic resources, but the Protocol does not mandate it.

The Protocol acknowledges the need to facilitate the sharing of scientific and technical knowledge related to genetic resources and their associated DSI, while also ensuring that such sharing is consistent with the objectives of the CBD and the Nagoya Protocol.

It is important to note that there is ongoing discussion and debate about how the Nagoya Protocol's rules should be applied to DSI, specifically whether or not DSI should be considered a different type of genetic resource. Yet, these provisions offer a place to start regulating DSI-related access and benefit-sharing.

Due to the legal conundrum existing under the current framework relating to the rules for accessing digital sequence information produced from genetic resources there was a need felt for exploring and mapping out a framework that supports biodiversity monitoring and conservation, maintains open access to the information, and enables equitable sharing of benefits, both monetary and non-monetary. Such a framework should also foster green growth and support the objectives of the Convention on Biological Diversity.

After prolonged discussions and negotiations, the parties to the CBD were able to come to a compromise on several related agenda items amid the ongoing global pandemic. In December 2022, the Kunming-Montreal Global Biodiversity Framework (GBF) was established, which includes a decision on benefit-sharing for the use of digital sequence information (DSI) associated with genetic resources. This decision aim is to align the CBD framework with technological advancements and to uphold the Convention's third objective of fair and equitable benefit-sharing.

The decision on benefit-sharing from the use of digital sequence information (DSI) on genetic resources is especially significant as it aims to tackle the impact of technological progress in DNA sequencing and synthesis on access and benefit-sharing in genetic resources that have traditionally been regulated by the Convention on Biodiversity (1992) and the Nagoya Protocol (2011).

Access and benefit-sharing of digital sequence information (DSI) has become a cause for concern as it could lead to the exploitation of genetic resources by biotechnology industries and user countries, especially in the absence of clear guidelines for accessing this information under the current ABS framework. To address this, the Global Biodiversity Framework (GBF) aims to establish a multilateral framework for DSI that would support the conservation and monitoring of biodiversity, while promoting open access and fair benefit-sharing, including monetary and non-monetary benefits and enabling sustainable economic growth(Press release on Landmark UN Biodiversity Agreement dated 19 Dec 2022).[2] The article also discusses the impact of DSI on the rights of indigenous communities.

Conundrum Under CBD-NP Framework Over DSI

Confusion regarding the Concept

The concept of digital sequence information (DSI) as it pertains to genetic resources is still in the process of being defined by the governing body of the Convention on Biological Diversity. While the term is commonly used as a placeholder, there is no widely agreed-upon definition, leading to discussions on its meaning, scope, and whether a different term should be used instead. In a technical sense, DSI refers to the knowledge of the location, role, and structure of a gene, but it is recognized that not all information related to genetic resources is stored in digital form. Instead, it encompasses elements such as structural annotation of genomic components, functional annotation of genomic regions, amino-acid sequences of proteins produced from gene expression, molecular structures of gene products and derivatives, contextual information such as the location of origin and ecological relationships, behavioural data, morphological data and phenotype, taxonomy, and any other related information stored in databases or elsewhere (Kharb, 2021).

In legal terms, the definition of digital sequence information (DSI) can encompass information about a single gene or the complete genomic sequence of an organism. From a policy and regulatory perspective, it could include all research related to plant genome sequencing, its value and potential applications. Given that the term can have different components and meanings in different fields of research and disciplines, it is important to adopt a broad understanding of its scope in the context of the obligations under the Convention on Biological Diversity and its Nagoya Protocol's Access and Benefit-Sharing (ABS) provisions.

Confusion over the Terminology

A clear, precise and legally binding definition of DSI is crucial to ensure compliance with the obligations established by the Nagoya Protocol of the Convention on Biological Diversity. Although the concept of DSI is

intuitive, it is challenging to define. In 2016, the Conference of the Parties (Decision adopted by COP14 on November 30, 2018)[3] to the Convention on Biological Diversity in Cancun adopted a decision that included the term DSI, as a placeholder term until an alternative term is agreed and established the Ad Hoc Technical Expert Group(AHTEG) to prepare a broad list of subject matter that could be included in the term DSI.

In a narrow definition, DSI could only encompass sequence data. However, a broader definition may include related information such as annotations and data interpretation. At its broadest interpretation, DSI could encompass all immaterial, electronically saved data related to genetic resources (GR), which are defined as materials of plant, animal, microbial, or other origins that contain functional units of heredity and are comprised of the physical carriers of hereditary information, such as DNA and RNA. Recommendations from different members advocate for the inclusion of core nucleotide DNA and RNA proteins and metabolic information, as well as traditional knowledge, in the definition. The focus in defining DSI is also on its role in shaping the global flow of genes, including enabling breeders to understand the location, role, and structure of DNA in a given genetic resource.

The AHTEG(First meeting in Montreal, January 7-11, 2020)[4], in clarifying the scope of digital sequence information, agreed that the first three groups- Group 1-DNA and RNA; Group 2- Group 1 + proteins + epigenetic modifications; Group 3- Group 2 + metabolites and other macromolecules proposed in Study 1(Report of AHTEG January 2020)[5] could be considered as digital sequence information, while Group 4 of associated information, including traditional knowledge associated with genetic resources, Group 1,2 and 3 and digital sequence information and other types of information associated with a genetic resource or its utilisation, is not digital sequence information(Report of AHTEG March 2020).[6] The proposed groups describing Digital Sequence Information and associated knowledge can provide conceptual clarity and is important to ensure legal clarity in all circumstances.

Confusion over the application of ABS Mechanism

The implementation of the Access and Benefit-Sharing (ABS) policy, a vital component of the Convention on Biological Diversity (CBD) and Nagoya Protocol, is encountering significant challenges due to the potential expansion of its scope to Digital Sequence Information (DSI). The term DSI is open to a broad interpretation, which could encompass all sequence data and other digital information relating to genetic resources available on public databases. The CBD Committee of Parties (COP) is grappling with the complexities of regulating non-physical genetic resources.

The CBD framework was established based on tangible genetic resources, with the scope of the regime covering "genetic material of any origin - plants, animals, microbial or other - containing functional units of hereditary". As per Article 2 of CBD[7]:

> "Genetic resources" means genetic material of actual or potential value. Genetic material here means any material of plant, animal, microbial or other origin containing functional units of heredity.

It seems that the current definition emphasizes the physical aspect of genetic resources alone. However, the term "functional" could encompass both the genetic structure itself and the information encoded in the DNA sequence, which could be analyzed and converted into a digital format while still retaining its original characteristics.

The question of whether only physical material is included, or if the information dimension of genetic resources should also be covered when it is transferred to another form, requires clarification. The use of the term "other origin" in the definition of genetic material under Article 2 of the CBD though, seems to suggest a focus on physical material rather than information.

The concepts of biological functionality as genetic material and the value of functional units of hereditary in an organism also need further clarification. The definition of the "functional unit of heredity" is not specified but is considered to correspond to the current scientific understanding of genes (Kharb, 2021). The concept of "functional units of heredity" in the definitions of genetic resources and genetic material, as outlined in the Convention on Biodiversity (CBD) and its Nagoya Protocol (NP), has been limited to physical genetic material. This narrow definition has impeded the development and implementation of ABS policies and regulatory frameworks in areas such as synthetic biology and genomics, which have significant economic implications.

The informational dimension of genetic resources, critical for these fields, has been ignored, resulting in a reduced flow of benefits to indigenous and local communities. The absence of clear provisions for *ex-situ* collections gathered prior to the NP has further complicated the ABS concerns. The recent focus on DSI in the CBD and NP highlights the need for a consistent solution across various international instruments and institutions, such as the Food and Agriculture Organisation, World Health Organisation, World Intellectual Property Organisation, and the United Nations Convention on the Law of the Sea.

Some of the member States argued that non-physical information and data do not align with the definition of "genetic resources" as outlined in the Convention on Biological Diversity (CBD) and thus cannot be considered within the purview of the Nagoya Protocol. One more argument is that open access to DSI itself is a sufficient form of benefit sharing. However,

this suggestion is of no use to Global South provider countries lacking the required technical competence to make use of such open access (Jain, 2021).

Difficulties encountered by non-commercial scientists and researchers:

Biology researchers require quick access to genetic resources such as DNA, proteins, or biochemical compounds to conduct their studies, particularly in the field of public health, where timely access is crucial (Sharma, 2020). As these studies are time-sensitive, new samples must be obtained regularly to ensure ongoing disease surveillance.

Before the CBD and Nagoya convention were established, scientists had relatively unrestricted access to genetic resources, which were considered the "shared heritage of mankind." However, now they are required to enter into an Access and Benefit Sharing (ABS) agreement with the relevant state government, which is responsible for managing genetic resources. If DSI, which is still somewhat under an open access system, is included in the ABS regime, scientists may have to comply with the same regulations (Rourke, 2018).

The main goal of setting up an ABS system was to give the benefits of R&D to the developing countries from which the resources are taken, as well as to protect and use genetic resources in a sustainable way. Nevertheless, the ABS process has not provided the scientific community with any meaningful benefits. In reality, it has made R&D more difficult. Ending the open access to DSI could further cause impediments to researchers and the scientific community.

Non-commercial scientists who want to investigate or conduct research with tiny amounts of genetic material or use DSI of the GR must meet the same regulatory standards as commercial bio-prospectors (often big companies). These non-commercial researchers and scientists pose no existential threat to the resources. In response to this bureaucratic and legislative roadblock, at times, academic scientists are adjusting their research techniques in order to conform to or circumvent the ABS's requirements.

Several technical legal words are difficult to interpret due to a lack of completely developed jurisprudence, causing problems with compliance by these researchers. They expose themselves to the possibility of breaking the requirements of the Act. Researchers and scientists working on a modest scale who are not employed by a commercial enterprise frequently lack even the most fundamental forms of legal support or a public relations team. All of the obstacles and difficulties make it impossible for them to undertake biological research, frequently compelling them to quit initiatives.

Rights of Indigenous Peoples in Relation To Biodiversity

Indigenous peoples have special rights due to their close affinity to the land and biodiversity, as well as their traditional knowledge and ritual practices. These rights encompass the protection of indigenous knowledge, conservation of biodiversity through sustainable traditional methods, involvement in decision-making processes and self-determination. Ensuring recognition and safeguarding of Indigenous and Local Community Peoples'(IPLCs)' rights is essential for preserving Traditional Knowledge (TK), and cultural heritage, and advancing equity and social justice.

International human rights law, particularly ILO Convention 169[8] and UNDRIP[9], offers a structure for safeguarding the rights of Indigenous and Local Community People (IPLCs) concerning the environment and biodiversity. Some of the significant rights covered include the right to participate in decision-making processes, the right to traditional knowledge and culture, the right to lands, territories and resources, the right to self-governance, and the right to free, prior and informed consent.

International law recognises and protects the right to self-determination, which is enshrined in several key international instruments, including the United Nations Charter[10], the International Covenant on Civil and Political Rights (ICCPR)[11], and the International Covenant on Economic, Social and Cultural Rights (ICESCR)[12]. The right to self-determination is a fundamental human right and a core principle of international relations, affirming that all peoples are entitled to determine their own political status and pursue their social, economic, and cultural development freely.

The Convention on Biological Diversity (CBD) and UNDRIP further recognize the right of IPLCs to access and benefit sharing from their traditional knowledge and resources and to participate in the development and implementation of policies related to biodiversity. Many countries have also adopted laws and policies that recognize the rights of IPLCs in relation to biodiversity (Bonn Guidelines and Wan Izatul Asma *et al.,* 2012).[13] By asserting and protecting these rights, IPLCs can contribute to the preservation of their biodiversity, traditional knowledge, and cultural heritage.

One of the most significant issues in exploiting Traditional Knowledge-based technologies and products is the lack of appropriate protection through intellectual property laws and policy measures at both the national and international levels. The rising trend of misusing or misappropriating TK to gain intellectual property rights for example the turmeric (Balasubramanian, 2017)[14], ayahuasca and neem patent cases, without adequate recognition of TK holders' contributions is becoming a matter of concern given the current surge in bioprospecting activities that involve the utilisation of genetic resources and associated TK.

Article 8(j) of CBD, requires member countries to ensure that the use of indigenous resources for commercial purposes is done with the agreement and involvement of those who possess such knowledge. However, the article does not specify who exactly holds this knowledge, innovations, and practices. Some other challenges which indigenous peoples face due to imbalanced power structures at the local, national, and global levels include:

- The lack of recognized and enforceable rights over their territories and resources.
- Inadequate capacity to participate and secure favourable outcomes in decision-making regarding the management of natural resources, even when they have rights.
- Limited or no representation in decision-making processes.
- Development pressures that conflict with their cultural and environmental priorities.

The Convention on Biological Diversity (CBD) acknowledges that countries have sovereign rights over the biological and genetic resources within their borders, granting them the power to manage and regulate access to these resources. Nonetheless, this recognition of national sovereignty over such resources may sometimes clash with the rights of indigenous peoples to safeguard their traditional knowledge. In certain situations, if a country permits access to a specific resource or genetic material, it may put at risk the traditional knowledge and practices of indigenous peoples who have a cultural or spiritual connection to that resource.

The Convention on Biological Diversity emphasizes the importance of protecting and promoting the use of biological resources based on traditional cultural practices that align with sustainability and conservation.[15] However, this provision does not confer any rights to indigenous peoples. The Convention's bioprospecting approach through ABS agreements highlights the need for obtaining the informed consent of genetic resources and traditional knowledge holders and ensuring equitable sharing of benefits. Nonetheless, the Convention has faced criticism for disregarding the status of indigenous peoples as rights holders and treating them as stakeholders on par with corporations, academic institutions, and non-governmental organisations (Debra Harry, 2005).

The challenge in protecting traditional knowledge under the Convention on Biological Diversity (CBD) is the lack of clarity regarding who holds such knowledge, innovations, and practices. Article 8(j) requires that commercial use of indigenous resources be carried out with the consent and active participation of the holders of traditional knowledge, but it does not specify who these holders are. It has been suggested that local communities, who have protected and used these resources for livelihoods for generations, should be recognized as the rightful holders of traditional knowledge and

resources. This highlights the importance of considering the perspectives and rights of indigenous peoples in decision-making processes related to biodiversity conservation and sustainable use.

Despite the lack of clear definition and specification of certain terms such as "traditional knowledge associated with genetic resources" and the coverage of digital sequence information (DSI), the Nagoya Protocol still recognizes two important rights for Indigenous peoples. These rights include the right to receive free prior and informed consent (PIC) for the use of their traditional knowledge[16] and the right to fairly share the benefits derived from such use. These rights serve as important protections for Indigenous communities, as they provide avenues for them to participate in decision-making processes and ensure that they receive equitable benefits for their contributions to the use of traditional knowledge,[17] though again, subject to the State's recognition of the indigenous peoples' rights to their traditional knowledge.

Despite this limitation, the process of obtaining prior informed consent remains crucial in safeguarding such knowledge. This mechanism enables indigenous communities and knowledge holders to have a say in decision-making processes, thereby ensuring the protection of their traditional knowledge (Jain, 2021).

Intersection of DSI and the Rights of Indigenous Peoples Under CBD-NP Framework

The use of digital sequence information (DSI) in projects related to biodiversity can have important economic consequences, but it also raises ethical and moral concerns about how to ensure the equitable sharing of benefits and respect for the rights of indigenous and local communities (IPLCs). IPLCs play a crucial role in conserving biodiversity and hold valuable cultural knowledge and solutions to global challenges such as climate change. However, their involvement and representation in discussions and processes related to DSI under the Biodiversity Convention have been limited to date. Empowering IPLCs is crucial in creating a fairer global system for benefit sharing and upholding their importance as biodiversity stewards.

With the shift from genetics to genomics in biotechnology research, the dependence on physical genetic material has diminished. Genomic research can now be conducted directly from component nucleic acids in a laboratory setting, without the need for access to physical genetic resources. DSI could be used to evade benefit-sharing requirements (Hammond, 2020). As a result, the requirement for obtaining Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) for access and utilisation of genetic resources may no longer be enforceable, as it becomes increasingly difficult to track the use of

sequence information from open databases or the country of origin. In one such instance, Regeneron, an American pharmaceutical company developed Ebola treatment using DSI of C15 strain of Ebola virus uploaded in the GenBank by the Pasteur Institute, France and Nocht Institute of Germany using blood samples of victims from West Africa. Regeneron patented its drug REGN-EB3 in several countries, including the US, Nigeria, and South Africa, and secured deals worth over $400 million. As the digital sequence information (DSI) used was in open access (Kharb, 2021), the company avoided the obligation of benefit sharing. However, if they had obtained a physical sample of the Ebola virus, they would have been required to share benefits through a material transfer agreement with Africa. The utilisation of DSI from open access databases raises issues regarding the protection of traditional knowledge and equitable benefit sharing, leading policymakers to seek a balance between different stakeholder interests through appropriate access and benefit-sharing (ABS) frameworks and policies.

Issues Before Policymakers

The indigenous and local communities (ILCs) are custodians of traditional knowledge and have been trying to protect their interests against commercial exploitation, but their efforts have been unsuccessful thus far. Preserving biodiversity and the traditional knowledge systems associated with it has also become a central challenge in the strategies of developing nations to attain economic growth and improve the well-being of their populations.

There are two major concerns related to DSI and Prior Informed Consent (PIC) rights of Indigenous and Local Communities (IPLCs). The *first* concern is the oversimplified understanding of the impacts of DSI on traditional knowledge and IPLCs' rights. The *second* concern is the potential consequences of solutions that imply PIC is needed for the use of DSI of biodiversity linked to IPLCs. There is an apprehension raised before policymakers that the bureaucratic procedures required for obtaining PIC from IPLCs for DSI could impede the progress of biological research. However, this argument cannot be justified as an excuse for DSI policies that deny IPLCs their rights.

There are two distinct cases to consider when thinking about DSI and PIC: new access to a physical genetic resource and access to DSI in databases, including DSI generated from samples already collected. In the first case, for newly accessed physical genetic resources, IPLCs have the right to control the use of DSI generated from such resources through prior informed consent (PIC) and mutually agreed terms (MAT). IPLCs can dictate the permitted uses of DSI, limit who the DSI can be shared with, and/or require a new PIC for its use. They need national legally binding access and benefit sharing (ABS) rules that make these instruments enforceable through national law. In the second case, the issue is about the DSI of genetic

resources linked to IPLCs that is already present in databases like Genbank, which was collected without proper PIC and MAT. This includes DSI that is generated from already collected resources and DSI generated from the plants and other biodiversity of IPLCs. Generally, medicinal and agricultural plants of IPLCs are being sequenced and uploaded into the database, linked to publications, and being exploited without proper PIC and MAT.

Some proponents of "open access" databases argue that they have no moral or legal obligation to consider IPLCs' rights, but they use disclaimers to absolve themselves of legal liabilities in rights disputes(Amber Hartman Scholz *et al.,* 2022).

The debate surrounding the access and benefit-sharing of digital sequence information (DSI) presents a complex challenge for policymakers in the fields of biodiversity, agriculture, and health.

One option could be that the definition of DSI will be limited to DNA and RNA sequences and exclude traditional knowledge (TK), however, this narrow interpretation overlooks the potential for DSI to facilitate the piracy of TK and genetic resources linked to Indigenous and Local Community (IPLCs). It is crucial for policymakers to address the rights of IPLCs in the DSI discussion and avoid repeating the historical injustices in conservation policies. However, finding solutions that align with the goals of the Convention on Biological Diversity (CBD) may require creative approaches to benefit sharing.

In relation to the Nagoya Protocol and its biodiversity-related aspects, traditional biodiversity-related knowledge, which is produced collectively through a process of trial and error is comprehensive in nature and has a close association with the surrounding environment & cultural values. Therefore, traditional knowledge acts as a key identifier of cultural identity and can be defined as knowledge held by members of a specific culture, acquired through culturally-specific methods, and related to both the culture and its local environment.

For the purposes of the Nagoya Protocol and its biodiversity-related aspects, traditional biodiversity-related knowledge holds a significant importance. This type of knowledge is collectively produced through a process of trial and error and is characterized by its holistic nature and close association with the surrounding environment and cultural values. As a result, traditional knowledge serves as a means of cultural identification and is defined as knowledge held by members of a distinct culture and acquired through methods specific to that culture, relating to both the culture and its local environment.

There is the opportunity to build a benefit-sharing mechanism from the utilisation of DSI. Such a system may include a need-based assessment mechanism, the construction of a personalised funding strategy, and conversations with a diverse group of stakeholders to fine-tune the system.

The paying public domain model, the subscription model, micro-levies, public-private partnerships, bonds, and certification schemes are all examples of possible models. Different models would have different levels of regulatory intervention, different groups of people involved, and different amounts of resources that could be used. To ensure the effectiveness of the funding mechanism and to protect the incentives for users to participate in such a system, transparency, accountability, and clear verifiable indicators are required. According to the distinct needs of the participating nations, a sizeable portion of the funding should be set aside to assist biodiversity conservation and sustainable usage (WiLDSI project).[18]

Negotiation on DSI Under UN Convention on Biodiversity

The discussions regarding digital sequence information in relation to genetic resources were initiated at the Conference of the Parties (COP) to the Convention on Biological Diversity and the Nagoya Protocol held in December 2016. In 2018, the COP, at its 14th meeting, passed Decision 14/20(Open-ended Working Group,2021)[19], recognizing the differing opinions on the subject and established the Ad Hoc Technical Expert Group (AHTEG) consisting of experts from various regions to address the issue. The COP considered the impact of using digital sequence information on genetic resources to achieve their respective objectives and adopted decisions 14/20 and NP-3/12. The AHTEG deliberated on the terminology and scope of digital sequence information, examined the relevance of associated traditional knowledge, and emphasized the obligation to share benefits from its utilisation.

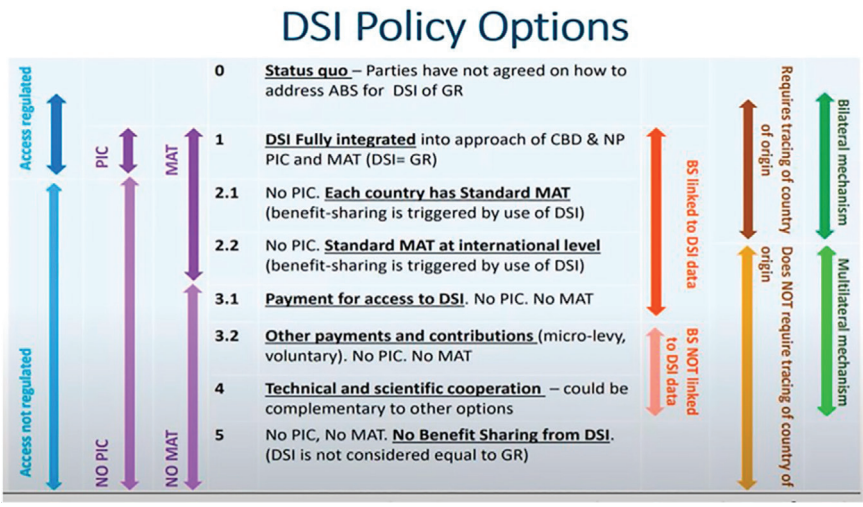
The policy options deliberated by the Group for regulating access to Digital Sequence Information (DSI) vary based on regulation degree, consent requirement, benefit-sharing obligation, product/service link, origin tracing, and benefit- sharing mechanism.

- Option 0 is the current state with no agreement,
- Option 1 is full integration into CBD and Nagoya Protocol, requiring compliance with national ABS laws and MAT for access,
- Option 2 is a standard MAT approach, with benefits shared bilaterally or via an international system under standard licenses,
- Option 3 involves payments or contributions to a multilateral fund, and
- Option 4 focuses on improved collaboration to democratize DSI access,
- Option 5 recognizes that DSI is not considered equivalent to genetic resources and has no suggestions (Golan, 2022).

The Outcome on DSI

The 15th Conference of the Parties to the Convention on Biological Diversity decided to establish a mechanism for benefit sharing of digital sequence information through the Global Benefit-sharing Fund (Press

Figure 1



Source: United Nations Convention on Biological Diversity Open Ended Working Group, 2021.

Release, December 19, 2022), which aims to provide both monetary and non-monetary benefits and improve the situation of indigenous peoples and local communities. However, policy considerations such as governance, benefit triggering points, contributions, and benefit sharing remain to be determined.

To execute the decision made at the 15th Conference of the Parties to establish a mechanism for the benefit sharing of digital sequence information, a working group was formed to develop recommendations for its operation, which will be finalized at the 16th Conference of the Parties to be held in Turkey in 2024. The Ad Hoc Technical Expert Group[20], in clarifying the scope of digital sequence information, agreed that the first three groups proposed in Study 1[21], will include:

- Group 1-DNA and RNA;
- Group 2- Group 1 + proteins + epigenetic modifications
- Group 3- Group 2 + metabolites and other macromolecules

On the other hand, Group 4 of associated information, which includes traditional knowledge associated with genetic resources, Group 1, 2, and 3, and other types of information associated with a genetic resource or its utilisation, is not considered digital sequence information(Report of AHTEG, Mar.2020).[22]

Figure 2

	Information related to a genetic resource			
	Genetic and biochemical information			Associated information
Group reference	*Group 1*	*Group 2*	*Group 3*	
High-level description of each group	DNA and RNA	Group 1 + proteins + epigenetic modifications	Group 2 + metabolites and other macromolecules	
Examples of granular subject matter	• Nucleic acid sequence reads; • Associated data to nucleic acid reads; • Non-coding nucleic acid sequences; • Genetic mapping (for example, genotyping, microsatellite analysis, SNPs, etc.); • Structural annotation.	• Amino acid sequences; • Information on gene expression; • Functional annotation; • Epigenetic modifications (for example, methylation patterns and acetylation); • Molecular structures of proteins; • Molecular interaction networks.	• Information on the biochemical composition of a genetic resource; • Macromolecules (other than DNA, RNA and proteins); • Cellular metabolites (molecular structures).	• Traditional knowledge associated with genetic resources • Information associated with digital sequence information Groups 1, 2 and 3 (for example, biotic and abiotic factors in the environment or associated with the organism) • Other types of information associated with a genetic resource or its utilization.

Source: CBD/DSI/AHTEG/2020/1/7, Clarifying the Scope of Digital Sequence Information on Genetic Resources.

Concluding Remarks

The current access and benefit-sharing framework seems inadequate to address the issue of DSI, and it obstructs international collaborations in biodiversity research which are vital for the conservation of biological diversity. The Nagoya Protocol needs to adopt a more flexible approach to adapt to this new and inevitable reality of DSI resulting from rapid scientific advancements.

The mismatch in ownership and technological capacity has given rise to a dichotomy in the CBD community. The research and scientific groups from different countries share convergent point of view in the DSI debate and favour the open access and no obligation model. According to them, open access system enables efficient and broad- scale knowledge generation and capacity building and in that sense, DSI itself is a sufficient non- monetary benefit sharing- everyone has something to lose and gain (Amber Hartman Scholz, 2022). However, the developing countries do not support the open access model for obvious reasons- economic interests as holders and providers of the biological resources and the rights of their indigenous communities and local communities with respect to the utilisation of biological resources and associated knowledge. They also lack the technological capacity to harness the DSI therefore, this option is of no use without technology transfer and capacity building.

Open data and science practices are now common, but this makes it difficult to track the use of biological data and establish conditions for benefit sharing with IPLC. This is particularly problematic as data infrastructures have limitations in recording Indigenous provenance, which hinders support for IPLC self-determination. Furthermore, the ease of sharing DSI across borders makes it even more challenging to establish how it should be considered under the ABS principles of the Nagoya Protocol(Golan, 2022).

For DSI utilisations in which no physical access is needed to utilise genetic information, a bilateral approach would be effectively impossible because the uses cannot be traced or genetic information from multiple organisms is being used, a global multilateral benefit-sharing mechanism(GMBSM) may provide a possible way forward(Margo A Bagley, 2022).

The ongoing negotiations regarding the formation of a multilateral mechanism have yet to reach a conclusion regarding several technical issues. One of the main points of discussion is the inclusion of digital sequence information (DSI) under the category of "genetic resources" as defined in the Nagoya Protocol, which governs the access and sharing of benefits related to biodiversity. The questions of how to appropriately share the benefits derived from DSI without hindering its rapid dissemination are yet to be resolved and will be the subject of future negotiations.

The outcome of the COP15 decision regarding digital sequence information on genetic resources resulted in the establishment of a

Multilateral Mechanism for sharing benefits arising from the use of such information including a global fund. The objectives of the mechanism include the provision of both monetary and non-monetary benefits, the promotion of sustainable use of biological diversity, the recognition of traditional knowledge, and the improvement of the situation of Indigenous peoples and local communities. Despite these goals, the precise manner in which the mechanism will be implemented and issues related to the concept, terminology and scope of DSI as well as the application of ABS mechanism and Nagoya Protocol on DSI along with the governance of the fund have been reserved for further consideration. Similarly, other policy considerations, including indigenous rights, data governance, & the role and interests of industry and academia. has yet to be determined, with a working group being established to make recommendations for its development and operation. These recommendations are expected to be finalized at the 16th Conference of the Parties. Till the time, scientists, researchers and companies have been given a ticket to generate, share and utilise DSI stored in databases.

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Asian Biotechnology and Development Review
Vol. 24, No.3, pp 23-46

Role of In Vitro Diagnostics in Economic Development and Healthcare Applications- A Systematic Review of Global and Indian Scenario

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Abstract: Medical diagnosis determines the condition of the disease through a person's symptoms and signs. Diagnosis can be done through differential pattern and pattern recognition, where the former depends on the candidate's diseases or conditions that can possibly cause the signs or symptoms, followed by their treatment and the latter recognizes a pattern of clinical characteristics based on the signs and symptoms or signs of the diseases. In the present review, we focus on the current prominent diagnostic technique i.e. In Vitro Diagnostics (IVD). During and post Covid-19 phase, the market of IVDs has shown a rapid flux with a number of new emerging technologies that are both of healthcare and economic importance. Regulatory requirements of IVDs prior to the market phase areimplemented as per the Plan of Quality Management System (PMS). Further, the IP can also now be generated from the in-vitro diagnostic methods provided they are not practiced on the living body. Currently, among the total number of IP generated through ICMR- funded projects, 48.7 per cent of Patents accounts for In-Vitro Diagnostics, thus this is the major leading platform in the current scenario.
Keywords: In Vitro Diagnostics, Economic Development, Healthcare

Introduction:

In vitro diagnostics (IVDs) are tests that can detect diseases, conditions and infections. In vitro simply means 'in glass', meaning these tests are typically conducted in test tubes and similar equipment, as opposed to in vivo tests, which are conducted in the body itself. In vitro diagnostics may also be used in precision medicine to identify patients who are likely to benefit from specific treatments or therapies. These in vitro diagnostics can include next- generation sequencing tests, which scan a person's DNA to detect genomic variations. Some tests are used in laboratories or other health professional settings and other tests are for consumers to use at home.

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In healthcare systems, clinicians regularly use IVDs to diagnose conditions, guide treatment decisions and even mitigate or prevent future disease (for example, through screening tests that indicate a patient's risk of developing a given condition in the future). Further, biological samples are used to determine the status of a person's health. In vitro diagnostic (IVD) testing has become an indispensable tool in clinical practice for diagnosing and monitoring diseases, as well as providing prognosis and predicting treatment response [Raman *et al*., 2013 and Billings, 2006]. In addition, IVD is used to assess the potential risk of developing a disease or disorder and to guide patient management [Raman *et al*., 2013]. As a cornerstone of modern medicine, IVD tests use blood, saliva, and other human samples to detect the presence or risk of certain diseases. Doctors and patients rely on them to guide life-or-death medical decisions, from choosing a cancer treatment[1] to managing a pregnancy [A. Schuessler, 2019]. They also have been critical tools in the fight against COVID-19. The WHO EDL (Essential In Vitro Diagnostics) includes IVDs for outbreaks and emergencies that countries may adopt. For example, tests for the Zika virus were added in the second edition (2019). In response to the ongoing COVID-19 pandemic, two SARS-CoV-2 tests were added in the third edition (2021), which includes SARS-CoV-2 nucleic acid tests and antigen rapid diagnostic tests, with corresponding links to the WHO Emergency Use Listing for IVDs to detect SARS-CoV-2 and WHO guidance on SARS-CoV-2 laboratory and diagnosis. Further, it is important that IVDs for outbreaks also be considered for inclusion in NEDLs (national essential in vitro diagnostics lists) [World Health Organization, 2021].

Unlike therapeutics, if we focus on economic development through IVDs, diagnostics seems to provide information that indirectly influences patient management as well as the economic efficiency of healthcare systems [Rohr et al., 2016]. The global IVD market is projected to reach USD 113.1 billion by 2026 from USD 98.2 billion in 2021, at a CAGR of 2.9per cent during the forecast period. The growth of the IVD market is mainly driven by the rising geriatric population and the subsequent growth in the prevalence of chronic and infectious diseases, increasing adoption of fully automated and POC instruments in developed regions, growing awareness regarding diseases diagnosis in developing regions, and growing R&D investments by industry players to launch new IVD products [https://www.marketsandmarkets.com/Market-Reports/ivd-in-vitro-diagnostics-market-703.html]. Indian In-Vitro Diagnostics Market is Segmented into By Test Type (Clinical Chemistry, Molecular Diagnostics, Immunodiagnostics, Hematology, and Other Test Types), Product (Instruments, Reagents, and Other Products) and is estimated to be valued at USD 1255.18 million in 2020, expected to reach approximately USD 1990.99 million in 2026, registering a CAGR of nearly 7.10 per cent during the forecast period. in

July 2020, the Indian Institute of Technology (IIT), Delhi, launched a COVID-19 test kit and was approved by the Indian Council of Medical Research (ICMR). In September 2020, the Central Drugs Standard Control Organization (CDSCO), which regulates pharmaceuticals and medical devices in India, approved the manufacture and sale of 'CoViDx One,' an RT-PCR test kit developed by Pune-based GenePath Diagnostics. The major factors that are driving the growth of the Indian in-vitro diagnostics market are the high prevalence of chronic diseases, increasing use of point-of-care (POC) diagnostics, and rising awareness and acceptance of personalized medicine and companion diagnostics (https://www.mordorintelligence.com/industry-reports/india-in-vitro-diagnostics-market). Asian Pacific market growth is dependent on the regulatory scenario and the rising geriatric population with subsequent increase in the prevalence of chronic diseases [Stuckler, D., 2008]. Prevalence of chronic and infectious diseases has increased the adoption of fully automated instruments; adoption of POC testing and growing awareness of personalized medicine [https://www.reportlinker.com/p04436645/In-Vitro-Diagnostics-IVD-Market-by-Product-Technology-Application-Forecast-to.html?utm_source=GNW] The global IVD market that is estimated to be of 98.2 USD Billion in 2021 is further projected to reach USD 113.1 billion by 2026 at a CAGR of 2.9 per cent during the period of forecast. While the North American IVD market is projected to grow at a steady rate. Further, emerging IVDs in the Asia Pacific and Latin America are expected to offer lucrative growth opportunities for the major market players with the Asian Pacific market leading at 20 per cent during the forecast period [https://dataintelo.com/report/global-in-vitro-diagnostics-ivd-market/].

In vitro diagnostic medical devices shall be classified on the basis of risk parameters as specified in Part II of the First Schedule, as under: Low risk - Class A; Low moderate risk- Class B; Moderate high risk- Class C; High risk- Class D. This classified list of In Vitro Diagnostic Medical Devices has been published on the website of the Central Drugs Standard Control Organisation approved by CLA. WHO published the first edition of the Model List of Essential In Vitro Diagnostics (EDL) in May 2018. This was followed by two further editions, in 2019 and 2021. The aim of the WHO EDL is to ensure the availability of tests for universal health coverage (UHC) and health emergencies and to promote healthier populations, which are the three strategic priorities of the WHO Thirteenth General Programme of Work (2019–2023). WHO published its 21st edition of EDL in 2019.

World Health Organization's In Vitro Diagnostic's list

WHO's EDL (Essential Diagnostic List) for medical devices has been created to provide guidance for every country regarding the use of different tests, which to use and which not to use [Ortiz *et al*., 2021]. This list was

first published in the year 2018 [Ortiz *et al*., 2021 and Yann Le, 2020] and was further reviewed/revised in the succeeding years 2019 and [Ortiz *et al*., 2021 and Yann Le, 2020]. The third edition of this list was published in the year 2020 [Ortiz *et al*., 2021 and WHO Technical Report Series, No. 1031, 2020-21].

EDL is based on two types of communities: First, communities where there is no laboratory, are divided into two types of testing: General Tests and Disease-specific Tests [Brochure: The WHO model list of essential in vitro diagnostics (EDL)]. There is a list of diseases for which testing can be facilitated in communities where laboratories are unavailable, these include COVID-19, Hepatitis B and C, Cholera, Chagas Disease, HIV, influenza, Streptococcal pharyngitis, sickling disorders, tuberculosis, syphilis and visceral leishmaniasis [Brochure: The WHO model list of essential in vitro diagnostics (EDL)].

Second, in communities where there is a health care facility with laboratories, tests are divided into either general tests or disease-specific tests for clinical laboratories, and disease-specific tests for blood screening laboratories [The selection and use of essential in vitro diagnostics - 2020]. Further, for each group of tests, the EDL specifies the test's name, purpose, assay format and type of specimen [Brochure: The WHO model list of essential in vitro diagnostics (EDL)].

Essential diagnostic tests can be defined as those that satisfy the priority health care needs of the population and are selected with due regard to disease prevalence and public health relevance, evidence of efficacy and accuracy, and comparative cost-effectiveness" [Moussy *et al*., 2018]. EDL first edition contained 62 test categories and the second was updated to include 122 test categories [The selection and use of essential in vitro diagnostics-2020]. The categories of tests include general laboratory tests and disease-specific tests such as for hepatitis B and C, HIV, HPV, malaria, syphilis and tuberculosis [Ortiz *et al*., 2021 and Moussy *et al*., 2018]. The third edition added a "Do Not Do" recommendation, for tests deemed no longer useful [The selection and use of essential in vitro diagnostics-2020]. Some tests such as a quick test for malaria, do not require a laboratory, a health care setting or professional, or electricity ["First Essential Diagnostics List"].

Objectives of Essential Diagnostics List [EDL]

A group of In Vitro diagnostics recommended by the WHO has been set under the Essential Diagnostics List (EDL) to be used under several tiered laboratory networks. These EDL were designed with the expectation of:

Providing evidence-based guidance to countries that are essential for the development of local essential IVD of their own.

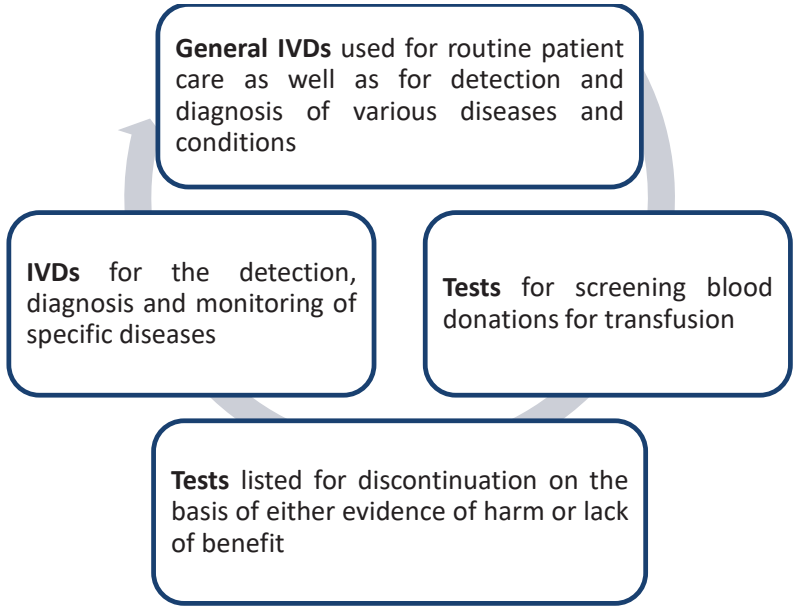
Informing nations (UN), countries, agencies and stakeholders regarding support, regulation, selection, procurement, supply and provision of IVDs.

Providing guidance to the medical technology of private sectors regarding IVD priorities that is mandatory to address the health issues of the nation.

Scope of Essential Diagnostics List

The scope of Essential Diagnostics List described and approved by World Health Organization is as follows, Figure 1:

Figure 1: EDLs divided into four categories: General IVDs; IVDs for detection and diagnosis; IVDs for screening; and IVDs for discontinuation of use of IVDs.



Source: Author compilation.

Classification of IVDs based on FDA rules and regulations

The FDA classifies medical devices, including IVD products, into Class I, II, or III according to the level of regulatory control that is necessary to reasonably assure safety and effectiveness. The classification of an IVD

(or other medical device) determines the appropriate pre-market process. Listed here are the three class:

- Class I (low to moderate risk): **general controls**
- Class II (moderate to high risk): general controls and **Special Controls**
- Class III (high risk): general controls and Premarket Approval (PMA)

General Controls (under FD&C Act)	Special Controls
1) 501: Adulterated devices	1) Performance standards
2) 502: Misbranded devices	2) Postmarket surveillance
3) 510: Registration of producers of devices	3) Patient registries
4) 516: Banned devices	4) Premarket data requirements
5) 518: Notifications and other remedies	5) Guidelines
6) 519: Records and reports on devices	
7) 520: General provisions respecting control of devices intended for human use	

Essential diagnostic list [EDL] formulated by Indian Council of Medical Research.

India has got its first National Essential Diagnostics List (NEDL) [Sonam et al. 2021] finalized by the Indian Council of Medical Research (ICMR), which aims to bridge the current regulatory system's gap that do not cover all the medical devices and in-vitro diagnostic device (IVD). The Key role behind this was to improve health and quality of life and ICMR noted that the key challenges anticipated during implementation of the National EDL include — "Adoption by States and harmonisation with local standard diagnostic protocols and treatment guidelines, provision of requisite infrastructure, processes and human resources, ensuring quality of tests including EQAS and quality control and adequate utilization of EDL tests for making informed decisions for treatment protocols." In India, diagnostics (medical devices and in vitro diagnostics) usually follow a regulatory framework based on the drug regulations under the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules 1945. Diagnostics

are regulated under the regulatory provisions of the Medical Device Rules, 2017 [Vijay *et al.*, 2021].

Currently, IVD is used to assess the potential risk of developing a disease or disorder and to guide patient management [Raman *et al*. 2013]. IVD of analytes originating from body specimens, including blood and tissue biopsies, is used alone or in combination with clinical investigations [Billings *et al*., 2006] and is perceived as an important tool for high-quality medical outcomes [Blendon *et al*., 2004]. There are over 40,000 different IVD products available that provide information to doctors and patients on a huge range of conditions. These comprise markers for inorganic chemistry (electrolytes, toxins, and heavy metals), markers for organic chemistry/biochemistry (proteins, lipids, and carbohydrates), as well as molecular biologic procedures (sequencing and polymerase chain reaction). One German study revealed that up to 187 of 584 diagnoses can be confirmed exclusively by an IVD testing [Wilke *et al*., 2002]. Routine diagnostics and population screening programs, such as the Pap smear for cervical carcinoma, have the potential to identify high-risk individuals and to prevent disease onset or progression [Peto *et al*., 2004 and Liu *et al*., 2001]. The introduction of cervical cancer screening programs in Europe has led to a substantial decrease in mortality [Levi *et al*., 2000 and Peto *et al*., 2004]. Furthermore, timely IVD testing allows more early-stage and cost-effective interventions, instead of advanced-stage therapy, which is generally associated with a worse prognosis and higher use of healthcare resources [Mignogna *et al*., 2002 and Cressman *et al*., 2014].

Analysis of the value of in Vitro Diagnostic Testing in Medical Practice and Global Economics

In vitro diagnostic (IVD) testing has emerged as a crucial tool in clinical practise for disease diagnosis, monitoring, prognosis, and therapy response prediction (Raman *et al*., 2015; Billings, 2006). Moreover, IVD is employed to determine the likelihood of contracting a disease or illness and to direct patient care [Raman *et al*., 2015]. Cancer genetic testing can be done using IVD or point-of-care devices.

Genetic tests are progressively being used for cancer detection and treatment, as well as noncancer conditions. Cancer genetic tests differ from noncancer genetic tests in that they have a greater number of tests for somatic mutations. Further after conception, somatic cells can experience somatic mutations, which are genetic changes. If growth regulators within the cell are harmed by toxins, radiation, a random mistake in cell division, and other reasons, somatic mutations are frequently observed as cancer develops. Somatic mutations only impact the lineage of cells formed from mutant cells and cannot be passed down through the gene pool. In contrast,

germ cell mutations, which frequently originate from inherited mutations from a parent, will affect all of the body's cells [Raman *et al*., 2015]. IVD of analytes from biological specimens, such as blood and tissue biopsies, is utilised either alone or in conjunction with clinical investigations [Billings *et al*., 2006] and is regarded as a crucial tool for excellent medical outcomes. There are more than 40,000 different IVD products available that give clinicians and patients knowledge about a wide variety of illnesses. They include molecular biologic processes, indicators for organic chemistry/ biochemistry (proteins, lipids, and carbohydrates), and markers for inorganic chemistry (electrolytes, toxins, and heavy metals) (sequencing and polymerase chain reaction). According to a German study, only IVD testing can confirm up to 187 out of 584 diagnoses [Rohr *et al*., 2016].

Measures to overcome Barriers in IVDs growth

The adoption of new technology and compensation are key roadblocks to the creation and application of novel diagnostics, and health imperialism is a further obstacle to making IVDs a growing platform [Billings, 2006]. Emphasizing on the global scenario, it was extrapolated that around 3per cent of the $2 trillion spent on healthcare annually in the United States goes towards paying for laboratory-based testing expenses. While there is no disputing the relevance and significance of laboratory results in determining health risks, making diagnoses, choosing treatments, and keeping track of illnesses and therapies, this information is essential to providing high-quality clinical care. Over the past 20 years, actual spending on this aspect of managing health and illness has fallen in inflation-adjusted amounts [Billings, 2006].

One significant goal and hurdle at the same time is the establishment of gold standards. For instance, the Human Genome Project, biotech investments, and other basic biological research have led to the development of a wide range of novel assays and testing platforms that can be used in the study of human health and illness. Yet, it is not always obvious or simple to verify whether these tests and approaches yield data of significant clinical utility and offer genuine insights that are superior to those presently accessible. In fact, demonstrating true clinical value can be challenging, time-consuming, and expensive due to the increasingly strict evidence-based medicine standards being applied to diagnostics and the expanding coupling of testing to therapy choice and monitoring [Billings, 2006]. The International Human Genome Sequencing Consortium's successful completion of the Human Genome Project on April 14, 2003, which provided the whole human genome, has since sped up research into human biology and enhanced medical practice [Burrone, 2018]. Since then, despite initiatives to keep genomic sequences in the public domain, a rise in the patenting of genomic sequences has sparked some worries that ongoing

pharmaceutical research and development may be impeded without the widespread licencing of such research tools. It was asserted that a patent pool may "enable better creativity, parallel research and development, the elimination of patent bottlenecks, and quicker product creation" [Burrone, 2018]. Thus, in order to understand the patenting bottlenecks, what tests these important constituencies demand, innovators must better communicate with physicians, public health specialists, and payers. A translation process that is more focused on relevant questions and markets could arise from this information exchange. Adoption of highly reproducible, objective, and quantitative laboratory assays to replace expert judgments is another way to get around these obstacles, but this is frequently challenging. Research that refutes established gold standards are challenging to design and infrequently published. Even when laboratory testing seems to be more useful, professionals are frequently reluctant to abandon established practices. Thus, the main objectives of researchers should be the promotion of establishment of these standards with major focus on the Innovation Research [Billings, 2006].

IVDs role in improvement of the critical concerns like affordability, import dependency and accessibility globally

The ongoing education and training of the healthcare workforce is one of the significant gaps that have conspicuously resurfaced the growth of IVDs as a result of the pandemic. The majority of healthcare workers in the nation have limited and far-flung access to high-quality educational resources and learning opportunities. Using online education tools specifically created for the healthcare sector can close this gap. Even though the government has started the National Digital Health Mission, it would benefit the entire healthcare ecosystem if the mission included the healthcare ed-tech industry. The government must suggest tax breaks and incentives for IVD manufacturers' investments. Moreover, the government ought to promote technological adoption in order to make the IVD industry self-sufficient, advanced, and productive. To support the rapidly expanding domestic IVD business, the budget can suggest subsidies for technology imports from wealthy nations. Additionally, it can put forth a foundation for a successful public-private partnership (PPP) model for economically advantageous technology transfer. In order to guarantee the provision of affordable healthcare, the budget also needs to reexamine the tax obligations on the IVD sector. Due to the expanding use of point-of-care testing and a shift in the global healthcare paradigm from sickness to wellness, the IVD business has enormous export development potential thus accessibility to these IVDs globally should be promoted by designing a more affordable, durable and sustainable product.

Indian Market Dynamics: In 2017, the Indian IVD instruments and reagents market were valued at over 6000 crore rupees, and a 20 per cent compound annual growth rate (CAGR) is predicted for 2018. Reagents account for roughly 80 per cent of this market. The transition from manual to semi-automatic (SA) and automated devices, increased health care knowledge, preventative health screenings, and are significant drivers. 95per cent of fully automated (FA) instruments are in place in various categories, and this tendency is quickly catching up with their SA counterparts as well, but this trend is more common in the private sector. Instruments that are globally automated are gradually displacing their SA counterparts. But, the situation is a little different in India. 2017 projections place the Indian immuno chemistry market at Rs. 2170 crore. Market size estimates for equipment and reagents range from Rs. 1550 crore to Rs. 290 crores for fast tests and Rs. 330 crores for ELISA kits. 2017 saw income for reagents of Rs. 1385 crore and for instruments of Rs. 165 crores.

Global Market Dynamics: Global market is projected to reach USD 87.93 biilion in 2023 from USD 68.12 in 2018. The global market is dominated with IVDs specific to immunohisto chemistry/immunoassay, among the others like molecular diagnostics, hematology, microbiology etc. due to its ability to deliver faster results with higher sensitivity and more accuracy.

Indian Imports of IVDs

India's imports of in vitro diagnostics (IVD) reagents and consumable & disposable medical devices lead to the growth of medical devices imports during the year 2020-21, when the Covid-19 pandemic has hit the markets across the world. The electronics equipment, surgical instruments and Implants imports were lower during the year compared to the 12 months of previous fiscal year. The overall imports of medical devices during the year 2020-21 was $6.24 billion, registering a growth of 6.76 per cent compared to the $5.85 billion imports during the previous year. According to the data released by the ministry of chemicals and fertilisers, the imports of consumables and disposables, which may include the syringes, needles, medical gloves, catheters, gowns, masks among others, grew 36.7 per cent to $1.47 billion in 2020-21, compared to $1.07 billion during the previous year. It may be noted that the requirement for these devices went up when the Covid-19 pandemic hit the country during the years 2020 and 2021.

The imports of IVD reagents have also shown a growth of 65.4 per cent during the year, to $871.89 million as against $527.20 million during the previous fiscal year. The growth, while a continuation to the growing imports from the FY 2018-19, was also driven by the Covid-19 pandemic and resulting higher need for IVD reagents for diagnostics. Experts said that the Covid-19 pandemic has resulted in an increased usage of IVD reagents for kits

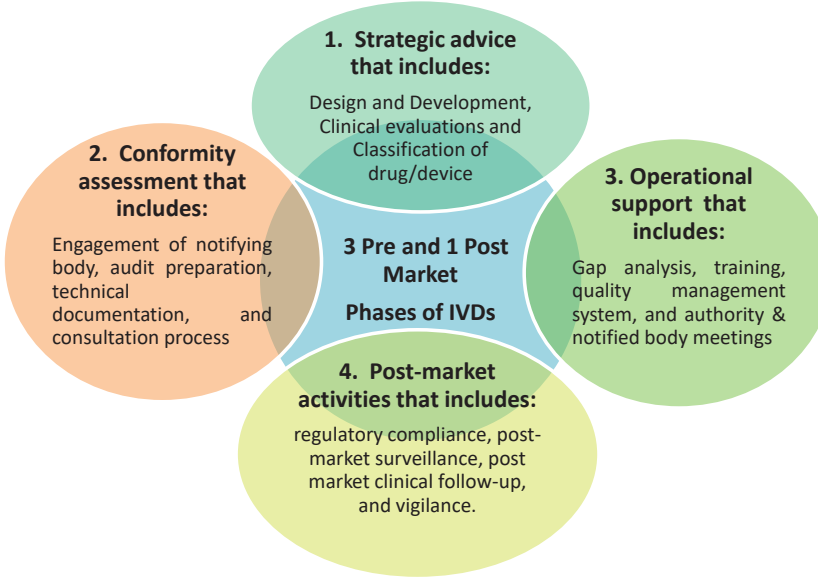
and assays used for the detection of Covid-19 virus. The imports of implants, which was on a growth in the FY 2019-20, when it registered $415.35 million imports, declined almost 46 per cent to $225.63 million in the year 2020-21. The imports of implants were at $384.79 million in the year 2018-19. The Covid-19 pandemic has hit various elective surgeries, which could have an impact on imports as well. Surgical instruments have also declined 42.5 per cent during the year 2020-21, as it registered a $103.62 million imports during the period as against $180.10 million in the previous year. The decline in imports of surgical instruments has been a continuation from FY 2018-19, when it registered an import of $190.18 million, shows the data.

Electronic equipment in medical devices has registered a marginal decline of two per cent during FY 2020-21, at $3.57 billion as compared to $3.65 billion during the previous fiscal year. The segment also saw a decline in imports during FY 2019-20 compared to the previous year of 2018-19, when the imports were at $3.77 billion.

Market Phases before commercialization

In- Vitro Diagnostics undergoes several phases that include both pre- and post- market phases before getting approved for the use by humans. The different phases are being described in Figure 2 below.

Figure 2: The pre- and post- market phases of IVDS assessment.



Source: Author compilation.

Regulatory requirements that need to be taken care regarding IVDs

Since In vitro diagnostic products are those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae and intended for use in the collection, preparation, and examination of specimens taken from the human body. Therefore, regulatory issues arise during its import or marketing. In vitro diagnostic medical devices are covered by the EU (European) regulations that were established in the 1990s. In order to modernise the industry and solidify the EU's position as a global leader in this field, EU lawmakers changed the regulations to improve the safety of medical devices to reflect the significant technological and scientific advancement in this field over the last 20 years.

IVDs are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, and may also be biological products subject to section 351 of the Public Health Service Act. Like other medical devices, IVDs are subject to premarket and post-market controls. Therefore, the following regulations need to be followed before releasing the product in the market:

- New pre-market scrutiny mechanism to establish stricter previous control for high-risk devices by the involvement of a pool of experts at the EU level.
- New criteria for designation and processes for oversight of notified bodies reinforced by the higher authorities.
- Aesthetic devices that present the same characteristics and risk profile under analogous medical devices.
- A new risk classification system for in vitro diagnostic medical devices.
- 'Implant card' must be introduced for patients containing information about implanted medical devices.
- Reinforcement of the rules on clinical evidence, including a European Union coordinated procedure for authorising multi-centre clinical investigations.
- For the requirement of manufacturers-strengthening the post-market surveillance.
- Coordination mechanism should be improved between European countries and India in the fields of vigilance and market surveillance.

Further FAQs referring to general guidelines for regulatory procedure of In Vitro Diagnostics of CDSCO, DCGI can be accessed at https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/IVD/FAQs/FAQ_IVD_MDR-2017_2.pdf

Evaluation of performance and testing for lot release

Manufacturer accountability: When utilised by intended users, IVDs should have performance characteristics (such as sensitivity, specificity, linearity, etc.) suitable for the intended situation. To guarantee that these performance qualities can be attained, special considerations for the varying conditions encountered in various settings should be taken into account during the design and development of the IVD. These factors can include using the IVD with operators of varied skill levels and in environments with temperature and humidity extremes. The manufacturer ought to have taken these factors into account while performing a complete risk analysis, and they ought to have proof—from performance testing and other sources—that using the IVD as intended by the intended users will be advantageous, outweighing any potential risks.

Also, the manufacturer must have efficient lot release procedures in place to guarantee that performance attributes are preserved for each manufactured lot of the product. By assessing an adequate number of pertinent specimens, lot release testing should guarantee that, as needed, the sensitivity and specificity or other crucial performance parameters for each lot remain unchanged. To maintain consistency over time, the maintenance of lot release panels is a crucial step in the QMS process [WHO].

Regulation-making body/conformity assessment body (CAB): Regulatory/evaluating agencies frequently base their conclusions about the effectiveness of IVDs primarily on data from studies carried out by or on behalf of the manufacturer. In order to enhance or validate those made by the manufacturer, others carry out their own independent evaluation through performance studies. The need for independent evaluation should adhere to the risk-based principles outlined in the GHTF guidance Principles of conformity assessment for in vitro diagnostic (IVD) medical devices. These principles take into account factors like the IVD's risk class, novelty of the technology, the manufacturer's level of experience with the type of IVD, and whether the IVD type raises any particular public health concerns. The assessment may take the form of a performance study attesting to the manufacturer's claims of performance or it may involve lot testing to make sure each lot satisfies predetermined standards. The goals of performance studies for regulatory purposes and those for health technology assessment (HTA) purposes are distinct from one another. While the clinical utility is being examined for HTA, clinical validity is typically the goal for regulation. HTA studies look into cost-benefit analyses of implementation strategies while taking facility, training, and educational requirements into account [WHO].

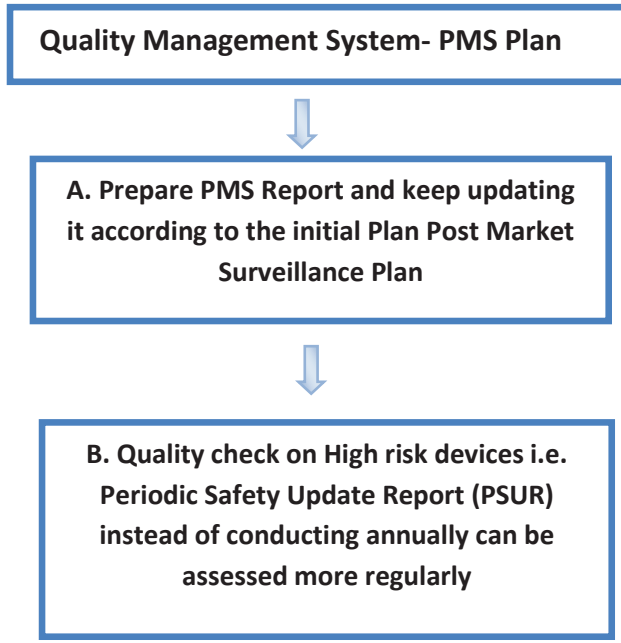
The RA or the CAB can conduct lot testing to guarantee the assays' quality prior to distribution in light of the probable impact of transportation on product performance when it is shipped into the nation. A review of

the manufacturer's lot release data for each of the lots accepted into that jurisdiction may be an alternative to lot testing by the regulatory authority, depending on the risk class of the product and its use in a specific jurisdiction [WHO].

Challenges faced by the IVDs post-covid phase

During the pandemic, most of the organizations adopted work from home and this continued for over 1 and half year until the lockdown was completely taken off and staffing returned to pre-pandemic levels and on-site work resumed. During this time, all the IVD manufacturers and others in the industry had to resume typical daily operations, catch up on work delayed due to the pandemic, and continue working toward IVDR compliance while remaining competitive and innovative in the market. The most difficult situation faced by the industries was the complexities of both performance evaluation and postmarket requirements felt across them.

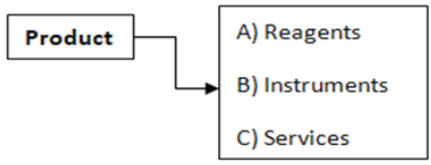
To tackle this situation, PMS plan need to be established under each manufacturer for example, If industries and working manufacturer has



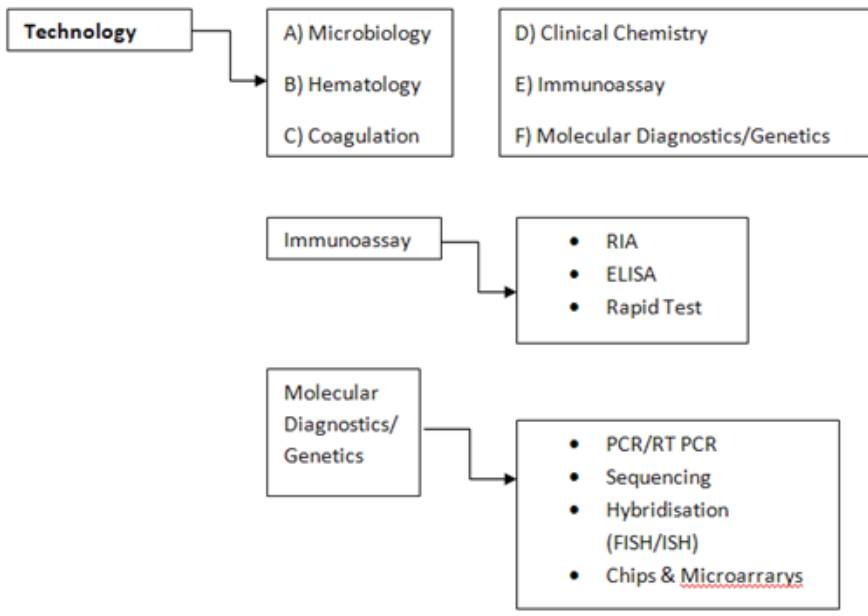
Source: Author compilation.

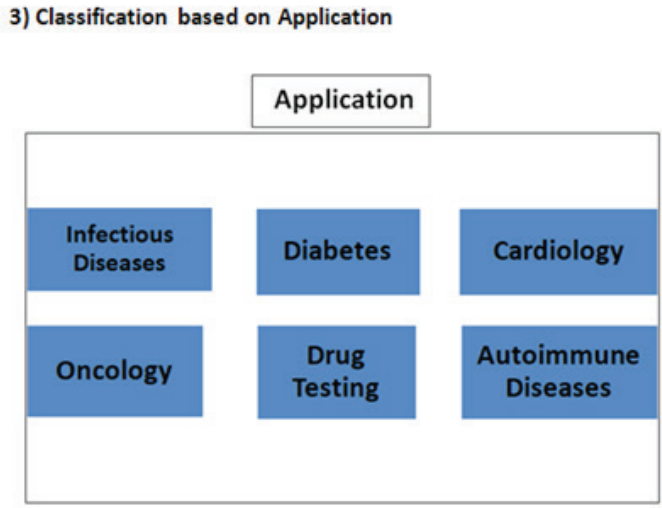
a quality management system (QMS) that already includes a built-in post market surveillance process as per (see Article 10(8i)), postmarket surveillance planning can begin easily along with pairing of postmarket surveillance and understanding of the IVD/device itself, including risk assessment outputs, novelty, and complexity.

1) Classification based on Product



2) Classification based on Technology/Test Type





Source: Author compilation.

Segmentation of IVDs based on market requirement and their application

In Vitro Diagnostics has been classified into three categories based on their requirement and application in the market.

How IVDs can advance the medical industry

Only 1per cent of NHS spending is allocated to diagnostic testing, despite the fact that 70 per cent of all clinical decisions made within the UK National Health Service are driven by IVDs. Only slightly better is the US version of the narrative. More than 66 per cent of clinical decisions are influenced by IVDs with just 2 per cent of the entire healthcare budget. This shows the stark disparity between the importance we place on diagnostics and the money we spend on them. A diagnostic error occurs in at least 5 per cent of American outpatients, according to the National Academy of Medicine. Diagnostic mistakes cause six to 17 per cent of unfavourable outcomes in hospitals and 10 per cent of patient fatalities. This is undoubtedly a major difficulty that we are now facing. Underfunding, however, won't change the current situation since, as COVID-19 showed us, IVD testing is essential for managing and controlling pandemics. Also, IVDs are crucial to the development of our healthcare system and must be enhanced in a number of ways.

To overcome these lacunas following should be improved:

- Testing for everyone, including more at the point of care and testing at home, is part of the process of democratising accessibility.

- Shorter time to result - increased efficacy by earlier diagnosis to the doctor and even initiating the proper treatment while the patient is already in a clinical setting.
- Accuracy improvement and a decrease in false positives and negatives.
- Cost savings and the elimination of usage restrictions.

Generation of IP from the evolving IVDs

Patents/Copyright or other Intellectual Property protection for genetic discoveries have been issued to encourage innovation and provide protection for financial investors in genetic research. These patents can claim a composition-of-matter (e.g., genes), methods, platform technology developed for the performed analysis, or a combination of all.

In the POC diagnostic device market, the primary areas of concern are those dealing with the rapid advances in molecular microbiology and nucleic acid-based methods, particularly the use of PCR – a technique for amplifying, detecting and cloning DNA sequences.

Today's limitations and challenges in the clinical implementation and development of new diagnostics, in particular POC diagnostics, come from the need to use and apply knowledge from previously issued patents for genes or gene-based methods of analysis.

In addition to concerns about legality and moral issues surrounding the patenting of genes, particularly human genes, new concerns have been raised about potential harm of gene patenting and licensing practices to biomedical research and public health. While many arguments for the limitation on patentability of genes and genetic methods have been worded in terms of human genes, the same arguments apply to the use of these patents for microorganisms analysis, which use the same methodology and the thus the same patents.

Challenges/ Complexities in getting patent on IVD (In vitro Diagnostics)

In addition to concerns about the legality and moral issues surrounding the patenting of genes, particularly human genes, new concerns have been raised about the potential harm of gene patenting and licensing practices to biomedical research and public health.

Bottlenecks:

- **Expense of patented diagnostics tests:** Because many diagnostics are based on already patented technology or processes, the cost of licences or royalties add to the basic cost of development of new diagnostics. For example, the discovery of the gene for haematochromatosis at first stimulated research in 119 United States laboratories but, as soon as a patent was issued to one of these laboratories a few months later, a third

of the laboratories stopped their related research. The patent holder was asking for an up-front fee of US$ 25 000 from academic laboratories and US$ 250 000 from commercial laboratories, plus a fee of US$ 20 per test [32].

- **Ownership of the patents:** A gene patent holder has absolute power for 20 years from the day the patent is filed to control any use of the respective gene. This means that they have the power to prevent others from developing and marketing cheaper public health genetic testing. With regard to infectious diseases [33], this could have grave consequences for diagnostic development and drug research surrounding antibiotic-resistant strains. Patentability of the methods to do these analyses adds yet another layer of potential obstacles inhibiting discovery and development of new diagnostics.
- Licensing approaches may have a negative impact on biomedical research as well as health care accessibility. In the United States, neither patent law nor the USPTO regulates licensing strategies and practices. The owner of a patent gives rights to licensees to use their invention through two major types of licences: exclusive and non-exclusive.
- The exclusive licence is used in two ways. An exclusive-all-fields-of-use licence gives the user exclusive rights but only in a given "field" (which can be a country, a market area, a technology, or another pre-determined meaning) [34].

Patenting Diagnostic Methods around the globe

A patent is a set of exclusive rights granted by the government of a country to an inventor or their assignee for a limited period of time in exchange for a public disclosure of an invention. The procedure for obtaining a patent protection for invention in India involves; 1) a patentability opinion- through proper prior art search, three patentability criteria- novelty, inventiveness & industrial application are being established, 2) preparation and filing of the patent application, 3) prosecution of the patent application viz. filing RFE, response filing towards FER, attending hearing, processing NBA approval for invention using biological material 4) issuance, abandonment, or appeal of the patent application and 5) maintenance fees to be paid annually for granted patent.

Patenting of medical methods is prohibited in India according to Section 3 (i) of the Indian Patent Act, which states that "any process for the medicinal, surgical, curative, prophylactic [diagnostic therapeutic] or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products." This flexibility has been conferred by TRIPS

in its Article 27(3) which states that "members may also exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals".

The Patent Scenario in Indian is similar to European Patent Law where according to Article 52(4) of the EPC, in-vitro diagnostic methods are found to be patentable. However the exact scope of such exclusion is not clearly defined at the moment due to the lack of the interpretation of the Courts unlike in Europe where the extent of the auspices of patentable subject matter is litigated a large number of times in Courts. Under US Patent Law, all medical methods including Diagnostic Methods are patentable. Additionally, under the Indian Patent Law, there have been instances when the examiners have rejected the in-vitro diagnostic methods too under the pretext of Section 3 (d) of the Act citing lack of inventive step involving "mere use of a known process".

For example, if the detection method as well as the biomarker in the sample is already known and the proposed invention only identifies the use of the marker in the detection of a disease, there are high chances that the method would not be patentable. Thus, where the method involves a novel biomarker or one or more novel detection method steps, the chances of patentability become high. Indian Granted Patent IN 228031, for example, claims a rapid method for heat- mediated ELISA characterized in using an activated solid support for the detection of minute quantities of biomolecules such as antigens, antibodies etc. The method has a profound technical advancement of reduction in the total time required for ELISA to around 3 hours. Another Indian- granted Patent IN 223553 claims an in vitro method of determining an expression level of a plurality of genes in the sample consisting of genes No. 1 to 562 in predicting the prognosis of a biological condition in animal tissue. The Indian Patent IN 220274 claims a method for detecting a risk of gastroesophageal reflux disease by assaying the analytes pepsinogen I, fasting gastrin-I7 and a marker for Helicobacter pylori infection. Another Indian Patent claims a method of for detecting antibodies to INGAP 104-118 peptide contacting a test sample with the peptide bound to the solid support. The Indian Patent IN 233723 claims a new Scintillation Proximity Assay for the detection of peptidoglycan synthesis. Thus, we have seen that all these granted patents describe one or more novel procedural steps in the diagnostic methods described therein. However, subject to the lack of the exact scope, the patenting of diagnostic methods in India is still decided more often on a case-by-case basis.

ICMR technologies for generation of IP in diagnostics or Point-of-Care devices

Activities under the IP management of ICMR include i) examine new invention disclosures for patenting, provide techno-legal support and

facilitate in drafting and filing of patents ; ii) finalize completion of eligible applications working with the inventors; iii) liaise with the ICMR empanelled IP law firms for conducting due diligence for filing of patent applications in time; iv) prosecution of patent applications by working with inventors and IP law firm and v) hand-hold inventors whose patents not found acceptable to file patents. vi) maintain the patent portfolio; v) weed out unproductive patents; and vi) create a policy framework for the above. All the activities under i to v are strictly time-bound as per the Indian patent laws.

Existing capabilities of Patent filing in diagnostics- Global vs. Indian scenario

Modern medical care is not comprehensive without the use of medical gadgets, which have become a vital aspect of daily life and include anything from bandages to surgical robots and heart valve replacements. In particular, when competitors enter the market, medical gadgets are also a part of a highly competitive and litigious environment. A patent that has been awarded gives the owner exclusive legal rights over the technology it claims (the medical device and/or the method of using the medical device). A medical device manufacturer must submit a separate patent application for each nation (or region, in the case of the European patent application), in which it desires to protect its investment and invention, in order to be granted such patent protection. Because the process to secure a patent takes a sizable expenditure after filing the application, the time, money, and effort required to obtain U.S. and worldwide patents is a crucial consideration.

However, if the medical device can be patented (and after it has been patented), the manufacturer of the medical device will be entitled to improve the value of the medical device company by increasing ownership in the business and generating assets that may draw more investments. Provide legal obstacles to entry for competing products by restricting anyone from duplicating, marketing, or producing the patented device.

With respect to Indian Scenario, major organizations like CSIR, DBT, DST etc. have their IP governing cell, which liaison with the patent office for all the IP procedures. ICMR is handling more than 500 projects that deal with innovation and Translational research to generate IP in terms of Patent, Copyright and Design. A total of 84 patent applications have been filed with ICMR as co-applicant between 2016 and 2022. These application or technologies include process/method, article, device, diagnostic kits, and therapeutic formulations. Among these 48.7per cent of patents accounts for In-Vitro Diagnostics that involve the use of gene panel, biomarker panel, siRNA technology, nanocarriers, biocompatible materials, surface protein receptors, aptamers, LAMP, Lateral Flow Immunoassay, Monoclonal antibodies, etc. Some of the technologies related to the field of diagnostics

that are recently being patented include the early detection of cancer using gene expression analysis of the identified gene panel through Meta analysis. Another technology that deals with the Development and Evaluation of Novel Multifunctional Nanocarriers loaded with Rivastigmine and siRNA for the management of Alzheimers Disease has recently being patented. This is promising, emerging and new technique for drug delivery in case of AD. Other than these many other technologies are still under patentability by ICMR paneled attorney. This information claims the importance and robust emergence research in the field of in-vitro diagnostics that may further ease the applications in the field of diagnostics as well therapeutics.

Conclusion

Intellectual property management and technology transfer of in vitro diagnostics is a new emerging platform of growth and development in the R & D sector worldwide. Although, patenting of medical treatment methods is not allowed in many countries like United Kingdom, as they pose risk to human health and also leads to the infringement on patent rights. However, the shortcomings in these rights can be resolved by securing an IP claiming the potential use for an existing drug is discovered or patent can also be secured for the discovery of new and effective doses of a new drug. In India, in-vitro diagnostic methods can be protected if they do not claim to be performed on the body/human body, for example- In- vitro testing of a blood sample for the presence of a biomarker is patentable as long as the step of taking the blood sample is not included under the claims section, thus not under the scope of protection. Although the market of IVDs is emerging at a robust rate and revisions in patents rules are being made periodically but still, the scope of the Patentability of Diagnostic methods in India is still not clearly defined due to the lack of the interpretation of the Courts unlike in Europe where the extent of the auspices of patentable subject matter is litigated a large number of times in Courts. Therefore, the IP protection of this emerging technology is a topic to be given extra focus in terms of development in the Research and Development sector of the country.

Acknowledgement: Authors wants to thanks Indian Council of Medical Research (ICMR), New Delhi for all the funding and support

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Asian Biotechnology and Development Review
Vol. 24, No.3, pp 47-54

Perspective

CBD COP 15: Kunming-Montreal Global Biodiversity Framework

Amit Kumar*

Introduction

The Conference of the Parties to the Convention on Biological Diversity in its Phase 2 i.e. Part II of the Fifteenth Meeting (COP 15) held in Montreal (Canada) during 7-19 December 2022, adopted the Kunming-Montreal Global Biodiversity Framework vide Decision 15/4 on 19 December 2022. It is to be noted that COP 15 was held in two phases. Phase 1 i.e. Part I took place virtually, from 11-15 October 2021in Kunming (China) followed by the second Phase i.e. Part II Meeting in Montreal (Canada). With the adoption of the Framework, it has been decided that this Framework should be used as a strategic plan for the implementation of the Convention and its Protocols, its bodies and it's Secretariat over the period 2022-2030. The Kunming-Montreal Global Biodiversity Framework builds upon the *'Strategic Plan for Biodiversity 2011–2020'*, its achievements, gaps, and lessons learned, and the experience and achievements of other relevant multilateral environmental agreements, and it sets out an ambitious plan to implement broad-based action to bring about a transformation in our societies' relationship with biodiversity by 2030, in line with the 2030 Agenda for Sustainable Development and its Sustainable Development Goals (SDGs), and ensure that, by 2050, the shared vision of '*Living in Harmony with Nature'* is fulfilled. With the adoption of the Kunming-Montreal Global Biodiversity Framework, the long and extensive rounds of consultations, which began with the release of the first draft of the post-2020 Global Biodiversity Framework in 5 July 2021, came to a fine end. The author had captured the salient features of the first draft in a perspective piece published in the previous issue of this journal (Kumar, 2021).

Salient Features of the Kunming-Montreal Global Biodiversity Framework and Preliminary Analysis

The Framework aims to *'catalyse, enable and galvanise urgent and transformative action'* by governments, and sub-national and local

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authorities, with the involvement of 'all of society' including indigenous peoples, local communities, civil society and businesses, to halt and reverse biodiversity loss, to achieve the outcomes it sets out in its vision, mission, goals and targets, and thereby contribute to the three objectives of the CBD and to those of its Protocols viz. the conservation of biological diversity; the sustainable use of the components of biological diversity; and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.

Following eighteen considerations have been listed for the implementation of the Framework:

1. *Contribution and rights of indigenous peoples and local communities*: The Framework acknowledges the important roles and contributions of indigenous peoples and local communities as custodians of biodiversity and as partners in its conservation, restoration and sustainable use and thereby states that Framework's implementation must ensure that the rights, knowledge, including traditional knowledge associated with biodiversity, innovations, worldviews, values and practices of indigenous peoples and local communities are respected, and documented and preserved with their free, prior and informed consent, including through their full and effective participation in decision-making.

2. *Different value systems*: The Framework recognizes and considers the diverse value systems and concepts, including, for those countries that recognise them, rights of nature and rights of Mother Earth, as being an integral part of its successful implementation.

3. *Whole-of-government and whole-of-society approach*: Framework exhorts for the 'whole of government' and the 'whole of society' approach, wherein the success requires political will and recognition at the highest level of government and relies on action and cooperation by all levels of government and by all actors of society.

4. *National circumstances, priorities and capabilities*: Framework envisions that each Party would contribute to attaining the goals and targets of the Framework in accordance with national circumstances, priorities and capabilities.

5. *Collective effort towards the targets*: Framework also envisions that the Parties will catalyse implementation of the Framework through mobilization of broad public support at all levels.

6. *Right to development*: Recognizing the 1986 United Nations Declaration on the Right to Development, the Framework enables responsible and sustainable socioeconomic development that, at the same time, contributes to the conservation and sustainable use of biodiversity.

7. *Human rights-based approach*: The Framework acknowledges the human right to a clean, healthy and sustainable environment and states that the implementation of the Framework should follow a human rights-based approach, respecting, protecting, promoting and fulfilling human rights.

8. *Gender equality and empowerment*: Framework mentions that the successful implementation will depend on ensuring gender equality and empowerment of women and girls, and on reducing inequalities.

9. *Fulfilment of the three objectives of the Convention and its Protocols and their balanced implementation*: The Framework is to be implemented in accordance with the three objectives of the CBD, with the provisions of the Convention, and with the Cartagena Protocol on Biosafety (CPB) and the Nagoya Protocol on Access and Benefit-sharing, as applicable.

10. *Consistency with international agreements or instruments*: The Framework needs to be implemented in accordance with relevant international obligations. Nothing in this Framework should be interpreted as agreement to modify the rights and obligations of a Party under the Convention or any other international agreement.

11. *Principles of the Rio Declaration*: The Framework recognizes that its implementation should be guided by the principles of the Rio Declaration on Environment and Development.

12. *Science and innovation*: The Framework recognises the role of science, technology and innovation and states that its implementation should be based on scientific evidence and traditional knowledge and practices.

13. *Ecosystem approach*: This Framework is to be implemented based on the ecosystem approach of the Convention. The ecosystem approach is a strategy for the integrated management of land, water and living resources that promotes conservation and sustainable use in an equitable way. Thus, the application of the ecosystem approach will help to reach a balance of the three objectives of the Convention: conservation; sustainable use; and the fair and equitable sharing of the benefits arising

out of the utilization of genetic resources. This approach is based on the application of appropriate scientific methodologies focused on levels of biological organization, which encompass the essential structure, processes, functions and interactions among organisms and their environment. It recognizes that humans, with their cultural diversity, are an integral component of many ecosystems.[1]

14. *Intergenerational equity*: Framework states that its implementation should be guided by the principle of intergenerational equity which aims to meet the needs of the present without compromising the ability of future generations to meet their own needs and to ensure meaningful participation of younger generations in decision-making processes at all levels.

15. *Formal and informal education; science-policy interface studies and Traditional Knowledge systems*: The Framework also mentions that its implementation requires transformative, innovative and transdisciplinary education, formal and informal, at all levels, including science-policy interface studies and values and knowledge systems of indigenous peoples and local communities.

16. *Access to financial resources*: The Framework acknowledges that the full implementation of the Framework requires adequate, predictable and easily accessible financial resources.

17. *Cooperation and synergies*: The Framework states that enhanced collaboration, cooperation and synergies between the CBD and its Protocols, other biodiversity-related conventions, other relevant multilateral agreements and international organizations and processes, in line with their respective mandates, including at the global, regional, sub-regional and national levels, would contribute to and promote the implementation of the Framework in a more efficient and effective manner.

18. *Biodiversity and health*: The Framework acknowledges the inter-linkages between biodiversity and health and the three objectives of the Convention. The Framework envisions to be implemented with consideration of the One Health Approach, among other holistic approaches that are based on science, mobilise multiple sectors, disciplines and communities to work together, and aim to sustainably balance and optimize the health of people, animals, plants and

ecosystems, recognizing the need for equitable access to tools and technologies including medicines, vaccines and other health products related to biodiversity, while highlighting the urgent need to reduce pressures on biodiversity and decrease environmental degradation to reduce risks to health, and, as appropriate, develop practical access and benefit-sharing arrangements.

These 18 considerations listed in the Kunming-Montreal Global Biodiversity Framework were not there in the First Draft, which was released in July 2021. These considerations cover a wide range of important issues including that of rights of indigenous people and local communities, human rights, traditional knowledge and value systems, collective efforts, gender equality, STI, ecosystem approach, education, access to financial resources, cooperation, synergy, benefit sharing, One Health and equitable access to tools and technologies. One can hope that all of these significant and key considerations are sincerely taken into account during the implementation of the Framework.

The vision of the Kunming-Montreal Global Biodiversity Framework is a world of living in harmony with nature where *"By 2050, biodiversity is valued, conserved, restored and wisely used, maintaining ecosystem services, sustaining a healthy planet and delivering benefits essential for all people".* The mission of the Framework for the period up to 2030, towards the 2050 vision is *"To take urgent action to halt and reverse biodiversity loss to put nature on a path to recovery for the benefit of people and planet by conserving and sustainably using biodiversity and by ensuring the fair and equitable sharing of benefits from the use of genetic resources, while providing the necessary means of implementation"*. The phrase '*while providing the necessary means of implementation*' is an important addition as it was not mentioned in the First Draft.

To achieve the stated vision and mission, the Kunming-Montreal Global Biodiversity Framework has listed four long-term goals for 2050. These are as follows:

1. ***Goal A:*** The integrity, connectivity and resilience of all ecosystems are maintained, enhanced, or restored, substantially increasing the area of natural ecosystems by 2050; Human induced extinction of known threatened species is halted, and, by 2050, the extinction rate and risk of all species are reduced tenfold and the abundance of native wild species is increased to healthy and resilient levels; The genetic diversity within populations of wild and domesticated species, is maintained, safeguarding their adaptive potential.

2. ***Goal B:*** Biodiversity is sustainably used and managed and nature's contributions to people, including ecosystem functions and services, are valued, maintained and enhanced, with those currently in decline being restored, supporting the achievement of sustainable development for the benefit of present and future generations by 2050.

3. ***Goal C:*** The monetary and non-monetary benefits from the utilization of genetic resources and digital sequence information on genetic resources, and of traditional knowledge associated with genetic resources, as applicable, are shared fairly and equitably, including, as appropriate with indigenous peoples and local communities, and substantially increased by 2050, while ensuring traditional knowledge associated with genetic resources is appropriately protected, thereby contributing to the conservation and sustainable use of biodiversity, in accordance with internationally agreed access and benefit-sharing instruments.

4. ***Goal D:*** Adequate means of implementation, including financial resources, capacity-building, technical and scientific cooperation, and access to and transfer of technology to fully implement the Kunming-Montreal Global Biodiversity Framework are secured and equitably accessible to all Parties, especially developing country Parties, in particular the least developed countries and small island developing States, as well as countries with economies in transition, progressively closing the biodiversity finance gap of USD 700 billion per year, and aligning financial flows with the Kunming-Montreal Global Biodiversity Framework and the 2050 Vision for biodiversity.

These four long-term goals are quite overarching and more or less capture the whole spectrum of related issues that are critical for biodiversity conservation. The inclusion of fair and equitable sharing of sharing of monetary and non-monetary benefits from the utilization of genetic resources and digital sequence information (DSI) on genetic resources in Goal C is a welcome step. DSI was not covered in the First Draft. The goal-corresponding Milestones, as was listed in the First Draft, have also been dropped in the adopted Framework.

The Kunming-Montreal Global Biodiversity Framework has 23 action-oriented global targets for urgent action over the decade to 2030 (*First Draft had 21 such targets*). The actions set out in each target need to be initiated immediately and completed by 2030. Together, the results will enable achievement towards the outcome-oriented goals for 2050. These 23 action-oriented global targets are clubbed into following three broad outcomes:

- Reducing threats to biodiversity (Targets 1-8)
- Meeting people's needs through sustainable use and benefit-sharing (Targets 9-13)
- Tools and solutions for implementation and mainstreaming (Targets 14-23)

For details of each of these 23 action-oriented global targets, please refer to the full text of the adopted Framework[2]. Most of them are the same ones as stated in the First Draft. An analysis of the key targets among them has been captured by the author already in the previous issue of this journal (Kumar, 2021). However, in the final adopted Framework, couple of the following new inclusions are noteworthy:

- *Target 13:* Take effective legal, policy, administrative and capacity-building measures at all levels, as appropriate, to ensure the fair and equitable sharing of benefits that arise from the utilization of genetic resources and from digital sequence information on genetic resources, as well as traditional knowledge associated with genetic resources, and facilitating appropriate access to genetic resources, and by 2030, facilitating a significant increase of the benefits shared, in accordance with applicable international access and benefit-sharing instruments.
- *Target 20:* Strengthen capacity-building and development, access to and transfer of technology, and promote development of and access to innovation and technical and scientific cooperation, including through South-South, North-South and triangular cooperation, to meet the needs for effective implementation, particularly in developing countries, fostering joint technology development and joint scientific research programmes for the conservation and sustainable use of biodiversity and strengthening scientific research and monitoring capacities, commensurate with the ambition of the goals and targets of the Framework.

Target 13 is an important one because it clearly calls for taking effective legal, policy, administrative and capacity-building measures at all levels, as appropriate, to ensure the fair and equitable sharing of benefits that arise from the utilization of genetic resources and from *digital sequence information* on genetic resources. The inclusion of DSI is quite relevant and necessary in the whole discourse of Access and Benefit Sharing (ABS).

Target 20 is another significant target as it calls for strengthening capacity-building and development, access to and transfer of technology, and promote development of and access to innovation and technical and scientific cooperation, including through South-South, North-South and triangular cooperation. Including all these three modalities of development cooperation is a pragmatic step.

Conclusion

The adoption of the Kunming-Montreal Global Biodiversity Framework during the COP 15 Part II Meeting held in Montreal (Canada) in December 2022 is a remarkable event as it marks the release of an ambitious, comprehensive and outcome-oriented Framework to address the critical challenge of biodiversity loss, by espousing 'whole of the government' and 'whole of the society' approach. The eighteen considerations stated in the Framework document are quite significant and wide ranging. The four long-term goals along with the twenty-three action-oriented global targets are very apt and relevant. However, to achieve them by 2030 requires an urgent action by the Parties and all stakeholders. The full implementation of the Framework will require the provision of adequate, predictable and easily accessible financial resources from all sources on a needs basis. It further requires cooperation and collaboration in building the necessary capacity and transfer of technologies to allow Parties, especially developing country and Least Developed country Parties, to fully implement the Framework. The implementation of the Kunming-Montreal Global Biodiversity Framework will be supported by the additional decisions adopted by the COP 15 which include decisions on the monitoring framework; on planning, monitoring, reporting and review; on resource mobilization; on capacity-building and development and technical and scientific cooperation; on digital sequence information on genetic resources; and decision on cooperation with other Conventions and international organizations. Given the holistic approach undertaken in this Framework, it can be hoped that the goals and targets are timely achieved and the three objectives on the CBD and the 2050 vision of '*Living in Harmony with the Nature*' is realised.

Endnotes

1 For further details on Ecosystem Approach, please see: CBD COP 5 Decision V/6. https://www.cbd.int/doc/meetings/esa/ecosys-01/other/ecosys-01-dec-cop-05-06-en.pdf

2 Kunming-Montreal Global Biodiversity Framework, CBD COP 15 Decision 15/4. https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-04-en.pdf

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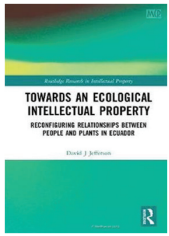
Asian Biotechnology and Development Review
Vol. 24, No.3, pp 55-65

Book Review

Title: Towards an Ecological Intellectual Property: Reconfiguring Relationships Between People and Plants in Ecuador



Author: David J Jefferson

Publisher: Routledge

Year: 2020

ISBN: 9780367517700

Page: 238

Price: £36.99

The book primarily looks at the question of how the law and intellectual property rights (IPR) intersect with the utilisation of the biosphere for human needs and the ideological bases for this anthropological and utilitarian view. It looks at the story of Ecuador, and how Indigenous and subaltern movements can intersect with conservation efforts, which can be used to create a type of eco-centric thinking that places plant life at the centre of legal systems. The book argues how through legal mechanisms such as IPR recognition of Indigenous traditional knowledge, it is possible to create regimes that take seriously the ontologies of non-human entities. This can produce solutions to environmental issues that are both ethical and equitable.

Through the use of IPR laws, the book shows how developed Northern nations and multinational corporations conduct a practice of 'biopiracy' in the Global South by utilising patents over their genetic resources and traditional knowledge. Thus, the resource providers and owners, which are usually Indigenous and peasant communities and have developed their resources sustainably over a long period of time, are left in an inequitable distribution where they cannot benefit from their resources and knowledge. This means that resource providers like Indigenous communities become consumers through the commodification of the genetic resources that they have improved through the centuries, resources that are then patented and used for profit by corporations from industrialized nations.

The book argues that this system is perpetuated by an establishment of conflicting international treaties and obligations that limit the extent of national jurisdiction. Thus, the book puts forward that by recognizing Indigenous community rights over their own resources, environments and traditional systems of knowledge, natural resources can be distributed

equitably and sustainably. Further, it asks us to reevaluate the way we approach nature and vegetal life as a whole and argues that we should move away from a 'human-centric' model to an eco-centric approach that respects the rights of plants and puts nature at the centre.

The book contains two parts. The first part talks about how an anthropocentric view has been used to turn plants into intellectual property and the various related international treaties, while the second part deals with alternatives to this approach with reference to Ecuador. Part A of this review will contain a summary of the major thematic areas of the book. Part B will be a critical analysis of the arguments presented by Jefferson and will analyse each chapter based on the surrounding legal literature and further empirical evidence. It will primarily look at whether the arguments have been conceptualized accurately and properly substantiated with reference to the wider literature and empirical evidence available. The final part will be a conclusion and will look at how the book helps readers understand this topic.

Anthropocentric View of Nature

In Chapter 1, Jefferson argues that the way we understand nature is itself deeply flawed and misunderstood. We, as human beings, have a tendency to relegate nature and plant life to the background of human activity, as a domain that gets its meaning from our utilization of it, something that is used to subjugate the biosphere to human needs and interests. According to him, this type of thinking doesn't base itself on scientific evidence and fails to account for the unique way nature and plant life has deontological meaning. One notable feature is how prevalent this type of thinking is. Even arguments ostensibly made for protecting plant life routinely fall into the category of preserving nature solely for its sustainable and continual exploitation or the possibility of utilization by future generations. Debates around deforestation usually revolve around the importance of forest products or their role as 'carbon-sinks' to clean up manmade pollution. Similarly, conflicts between 'foreign' and 'native' crop species invariably involve discussions on national identity and historical cultural character, just as various animal and plant species can emerge as 'national symbols'. These examples illustrate how an anthropocentric bias does not give the Plant Kingdom the warranted level of recognition, and thus Jefferson brings up the important question of whether plants should also have 'rights' like people or corporations do. This would involve a revolution in the way we think about the biosphere, moving away from a human-centric to an eco-centric model which places non-human life at the forefront.

IPR for Plants

In Chapter 2, Jefferson mentions how plants and genetic resources can be protected under the IPR regime. The patents of living organisms took off

with *Diamond v. Chakrabarty*, a case revolving around the ownership of bacteria capable of breaking down petroleum, in which IPR was practically extended to "anything under the sun that is made by man"[1]. Today, not only plant varieties but also micro-organisms and genetically modified animals are patentable. Even patents for human genetic material have been granted.[2] Plants are complex chemical storehouses, and their components can yield a variety of goods, much of this information is known by Indigenous groups and thus this knowledge is useful to a range of industries from pharmaceuticals to cosmetics.[3] He talks about how such IPR laws take ownership of a variety of non-human life, through which plant life is reduced to an instrumentalist vision of human development. Thus, the book argues for an intellectual property model that is eco-centric by placing plant life at the centre and recognizing the inherent value that vegetal life has.

Indigenous Communities and Biopiracy

In Chapter 4, Jefferson talks about how industrialized nations use these protections in a process of 'biocolonialism' or 'biopiracy' (the term being introduced as a play on 'bioprospecting'), – a neo-colonial process through which 'gene-poor' developed nations acquire both the genetic resources as well as the traditional knowledge of 'gene-rich' developing nations, and hinder both national development and Indigenous rights in the process. This is evidenced by the fact that around 90% of genetic information and related traditional knowledge is found in developing nations.[4] Through patenting genetically modified products without prior informed consent, corporations can misappropriate tremendous amounts of genetic material and related knowledge. It may include information on trees and plants that grow well together and indicator plants, including those that show soil salinity or that are known to flower at the beginning of the rains. It includes practices and technologies, such as seed treatment, storage methods and tools used for planting and harvesting.[5] Traditional knowledge also plays an important role in maintaining agro-biodiversity by producing new strains of crops that protect farmers against risk. This biodiversity forms a crucial part of the ecosystem without which food security and agricultural sustainability are at grave risk.

International Treaties

In Chapter 3, Jefferson mentions the various international treaties that create intellectual property obligations on individual countries. He explains the various international treaties such as The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the International Union for the Protection of New Varieties of Plants (UPOV) govern and require members to create intellectual property rights for member-states either as part of a national IPR regime or as a *sui generis* model. Through organizations like the World Trade Organization (WTO), these

international treaties bind the majority of nations under their provisions to create an IPR scheme for plant varieties which by extension form the basis of Free-Trade Agreements with developed nations such as the USA or the European Union. Civil society actors in nations in Latin America have protested such measures, but the trend of conforming with international IPR standards seems to be guaranteed and non-negotiable. This is contrasted with other treaties such as the Food and Agricultural Organization's (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture (otherwise known as the Plant Treaty) and the Nagoya Protocol which are based on an agroecological view of plant life and include provisions to protect farmers' rights, agricultural biodiversity and reaffirm national sovereignty over genetic resources. Each of these treaties advocates for a particular approach that sometimes overlaps and is sometimes contradictory, the nuanced differences between these various regimes create challenges for lawmakers, who often find themselves subjected to conflicting obligations. Jefferson, however, argues that this dichotomy is intrinsically flawed, as both sides are built upon an anthropocentric viewpoint that views plants only as resources to be exploited.

Alternatives and the Ecuadorian Approach

In the second part of the book, Jefferson discusses various alternatives to the existing IPR model and how the Ecuadorian experiments can provide us crucial insights into how to transform the existing system. Over the past several decades, efforts have been undertaken around the world to create legal systems that would formalise protections for the knowledge of Indigenous and other subaltern peoples. Diverse developments, which have occurred over the previous twenty years in the United States, India, New Zealand, Canada, Ecuador, Bolivia, Columbia, Uganda, Bangladesh, and other states fall under the umbrella term 'Rights of Nature'.[6]

Jefferson deals with the novel Ecuadorian perspective introduced in the wake of their new Constitution in 2008, and whether such legal experiments can provide a basis for a new and plant-centric basis for IPR and legal regimes in general. These include 3 broad areas – i) constitutional rights, ii) criminal protections, and iii) new IPR laws. The novel introduction of the Rights of Nature can take a much larger and comprehensive form than mere protections for natural features. It is the combination of rights with "Indigeneity" that forms the backbone of the Ecuadorian model and provides a potent structure for recognizing the needs of people alongside nature. Through the politicization of Indigenous interests, demands of these communities such as water for irrigation and food security can be met through the lens of natural preservation, revolving around the concept of sumak kawsay or 'living well'.

Thus, as Jefferson points out, through the protection of these communities, such as through safeguarding their agriculture or through recognizing their traditional knowledge, an institutional structure can be created that is equitable and just. Furthermore, these ideas are comprehensive enough that they can serve as a framework for Indigenous rights all over the globe. It can serve the diverse ends of extending participative democracy, women's rights[7], achieving national development goals, food security, cultural recognition and so on, without reducing the rights of traditional communities to a rationalist, neoliberal structure.

Critical Analysis of the Book

Lack of a Pragmatic Approach

Jefferson points out that the dichotomy that is drawn between Indigenous life-worlds with Eurocentric models of nature, along with the assumption that Indigenous knowledge is 'primitive' has been proven incorrect time and time again. The value of Indigenous experience in conserving nature such as in Brazil[8], West Africa[9], Venezuela[10], Bolivia[11], the US[12,] India[13], and several other nations has been well demonstrated. Indigenous life is directly wrapped up with their environment, and it is important to recognize their role in preserving wildlife, plant-life, agricultural biodiversity and mineral resources. Native American cultures, including large and urban Native American civilizations, recognized and continue to recognize themselves as being part of a broader whole in which conservation is a fundamental part of life.[14]

However, in this process, Jefferson might not be adequately addressed the conflict between traditional knowledge and intellectual property. The dichotomy between the two has been drawn by several authors; however, it still remains to be seen what model could evolve that would actually solve the problems raised. Systems such as 'access and benefit' agreements or questions about State ownership of genetic resources remain underdeveloped and unresearched. While agreeing with Jefferson's argument, it still remains restricted to the binary distinction between intellectual property and traditional knowledge, while not discussing the possibility of how to actually create new alternatives.

The book also does not mention how eco-centric thinking can resolve contradictions that occur by applying traditional knowledge. Traditional knowledge forms an integral part of Indigenous identity, however, any sort of 'mystical' or 'spiritual' emphasis detracts from its actual utility.[15] Traditional knowledge is highly localized and deals with their immediate surroundings, and should not be applied to yield general principles about

how nature should be governed.[16] Accordingly, there might be situations when colonial processes have developed economic models that form part of the livelihood of Indigenous communities removed from their 'authentic' cultural processes. This might lead to situations where the utilization of resources might often conflict with conservation approaches.[17]

Are the Rights of Nature Truly Eco-Centric?

It could be said that climate change and discontent with economic strategies that favour economic growth over the well-being of the people, as well as a new emphasis on Indigenous movements have started to recognize an independent legal presence of nature (Epstein, 2022). However, the emphasis, even if through Indigenous lenses, remains anthropocentric in the sense that plants are still primarily looked at as being utilised for human needs. Then, what is being advocated for is not an eco-'centric' approach, but an eco-'oriented' approach that still takes place within the realm of anthropocentric ideology and aims at the creation of more eco-friendly laws. The primary question remains about how natural resources are to be used and distributed. Jefferson posits some Ecuadorian laws that might provide useful insights into how natural law can be constructed, but it remains to be seen whether such laws actually provide real alternatives to the human-centric model since the legal experiments that he cites remain primarily anthropocentric at their base. Jefferson himself, claims that eco-centric laws will provide the best for both "human and non-human life", suggesting that its utility is directly tied to and flows from the existence of some advantages that accrue to mankind. It can be seen that the primary areas of concentrated effort are where human and natural interests intersect. It is unclear how exactly legal provisions can move towards the development of an IPR system that uses an eco-centric model, and furthermore, why exactly this is a necessary evolution.

Evidentiary Lapses

Jefferson argues for the fact that IPR practices adversely impact the traditional knowledge of communities, but the evidentiary aspects of this are lacking in the sense that very few real-life examples have been provided to give context to the arguments. Traditional knowledge, to be exact, does not refer to the actual knowledge itself but in the way that it is handed down and disseminated, by communities usually orally from generation to generation, and thus has been accumulated over time and has no one single inventor and has no one single set of defined values, but must be ascertained from context to context. Researchers are constantly developing new technologies to assess the chemical makeup of plants, and they realize that using medicinal plants identified by native peoples makes research more

efficient and less expensive.[18] For example, the natives of Madagascar knew rosy periwinkle had medical properties, leading pharmaceutical giant Eli Lilly to research it heavily, thereby finding treatments for Hodgkin's disease, childhood leukemia, and malaria.[19] Other examples would include patents for coloured cotton, long cultivated by Native American communities, or the neem plant for medicinal purposes, traditionally recognized in Indian medicine for that purpose.[20]

Jefferson argues that by introducing IPR laws for Indigenous communities' traditional knowledge, legal systems can be created that protect both human communities and the environment. However, a lacuna in the reasoning might include the actual impact of such laws on Indigenous communities in reality. Some scholarship[21] suggests that the number of patents filed by large corporations in developing nations that utilize traditional knowledge is not as large as it seems, especially for pharmaceuticals. As he mentions, the vast array of patents filed is for ornamental plants like flowers or certain export-oriented crops, and not those which indigenous communities primarily utilise and depend on. It remains unproven whether IPR protection for traditional crops based on an eco-centric model which will protect them from large multinationals has the sort of moral necessity that Jefferson argues. The argument could have been based around the fact that the commercialisation of nature as a whole, greatly damages ecological diversity, but the argument has remained confined to the impacts of intellectual property patents only.

Forum Shopping – Conflicting Views of International Organizations

IPR laws are obligated on nation-states through a complex superstructure of international treaties and agreements that are either - i) aimed at advancing the interests of free trade, usually valorised by the industrial north, and ii) those aimed at conserving biodiversity, farmer or indigenous rights, equitable distribution of resources, usually spearheaded by several civil society actors. Most of the former, including the UPOV, advocate for the IPR recognition of plant and genetic resources and require the members to frame laws accordingly. However, many are ambiguous related to how far IPR laws can be modified. Article 27.3(b) of TRIPS lays down that plants, animals and "essentially" biological processes can be excluded from patenting, (but micro-organisms and non-biological and microbiological processes have to be eligible for patents). Plant varieties have to be eligible for protection either through patent protection or a system created specifically for the purpose ("sui generis"), or a combination of the two.[22] The opinions of member-states still diverge and are debated.[23]

To be compliant with TRIPS, it is necessary that even in a sui generis regime, plant varieties have to be subject to protection. Prime facie, it seems that modification can only be extended to plant breeders' rights (PBRs) as

opposed to patents, such as farmers' rights[24] (also similar to UPOV 1978). This seems to be the case. In India, a country where a large portion of the population is engaged in small-scale agriculture and seeds are distributed informally – a sui generis regime has developed that protects the rights of farmers to save, use and sell seeds including those of protected variety if they are unbranded. They are entitled to recognition for their efforts at developing new varieties and can claim compensation if purchased seeds fail to perform.[25] This is also the same in Thailand.[26] These conditions conform with TRIPS but not with UPOV 1991, which places severe restrictions on the rights of farmers.[27] Moreover, these sui generis systems are usually the exception and not the norm, considering FTAs usually operate under UPOV principles.

It is important to note that both the Convention on Biological Diversity (CBD) and the Plant Treaty might not be non-conforming with TRIPS principles or even UPOV principles, since both emphasize the rights of farmers as plant breeders, and thus work under a sui generis TRIPS system. However, it is important to note the direct conflicting ideological influences that have inspired such treaties. While UPOV and TRIPS are primarily for the interests of free trade and IPR, the latter treaties are specifically for the purpose of the protection and maintenance of farmers' rights and biological diversity. The FAO, for example, introduced the "International Undertaking on Plant Genetic Resources" in response to growing alarm over the loss of biodiversity and the Nagoya Protocol was introduced to protect the interests of farmers and resource providers. Thus, proponents of these bills, including Jefferson, rightly point out that at several core points, TRIPS and UPOV can hinder the true realization of pro-farmer treaties. Furthermore, by advocating for principles of national sovereignty over genetic material, they are conceived as State property, while intellectual property regimes will invariably reduce them to exclusively owned economic goods.

Thus, it remains to be seen how far actual change can be affected and how eco-centric models will develop with respect to international treaties. The book does not propose a solution on how to create systems of law that Jefferson claims would be compatible with the global liberal structures. Jefferson does not mention how the various international treaties could come to an agreement or compromise or how this could be used to build eco-centric and equitable legal structures.

In conclusion, the book provides a deep and necessary insight into the conflict between the IPR laws and Indigenous rights relating to natural genetic resources. It asks us to rethink the way we approach questions of conservation and ownership of nature as a whole. The book opens the reader's eyes to this often ignored topic in a comprehensive and logical way. It provides us with a novel approach to many of the problems plaguing the

field of natural conservation and Indigenous rights. By providing an in-depth example from Ecuador, it provides us a context of how these issues can and have been tackled before, and thus how they can be applied to other countries and the global structure in general. The book further goes into detail about the conflict between international obligations and national legislations, along with how they can be reconciled and what changes are still needed to be made. Through protection of traditional knowledge under intellectual property, the book shows how both Indigenous rights and vegetal life can be sustained and preserved. Lastly, it provides a convincing argument for a revolution that is both ideological and legal that would accord nature and vegetal life a prominent place as a legal subject, and how such systems can ultimately better both human and plant life.

The reviewer has gone over the major arguments and analysed the issues posed with reference to the wider literature available. It has provided a comprehensive understanding and further substantiation of many of the major thematic areas. The review has also raised certain gaps in the argumentation and mentions how a lack of evidence for several claims put forward means that some of the arguments are not properly substantiated. It discusses whether the book remains confined to the dichotomy between traditional knowledge and intellectual property and whether this binary is not correctly problematized. Further, it talks about how far new models for IPR are impacted by the obligations that the various international treaties impose such as the ones made by the WTO.

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Acknowledgments: I thank for the assistance of Mr. Tejas Misra, B.A. LL.B student, NLUD for putting together this Book Review in this form and shape.

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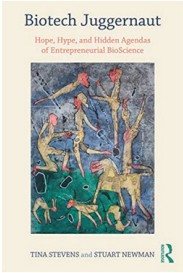
Asian Biotechnology and Development Review
Vol. 24, No.3, pp 67-72

Book Review

Title: Biotech Juggernaut Hope, Hype, and Hidden Agendas of Entrepreneurial BioScience
Author: Tina Stevens and Stuart Newman.
Publisher: Routledge, 2019.
ISBN: 978-1-138-04319-0 (hbk)
978-1-138-04323-7 (pbk)
978-1-315-17326-9 (ebk)
Pages: 206



The focus on technology development and promotion of emergent technologies like genetic engineering technologies, has, unfortunately, not been accompanied by equal stress on regulating the risks, which could arise out of the application of such technologies, and the current mechanisms of regulatory governance offer little scope for reflection on the purposes of science and innovation or on their wider social and ethical downstream impacts. Further, the solidification of university-industry partnerships has led to what some scholars have termed "academic capitalism", which is the reprioritisation of universities towards pursuing knowledge with the potential of revenue generation (Rhoades & Slaughter, 2004). There has been some realisation that rapid technological and scientific developments typical with emerging technologies like biotechnology, which have been fraught with controversy, put governing systems under much strain and require new conceptions of governance. Also, a need to change their approach to governance, to avoid the mistakes with emerging methods such as gene editing and gene drives have been made (Kaebnick et al. 2016; Kuzma et al. 2016; Kuzma et al. 2018). In this regard, it is important that new governance policies and programs that could help incorporate public desires and concerns into research and innovation in these emerging technologies be designed and implemented.

Tina Stevens and Stuart Newman's book Biotech Juggernaut: Hope, Hype, and Hidden Agendas of Entrepreneurial BioScience, provides a critical perspective on the rise of bio-entrepreneurialism and its troubling aspects as they relate to human genetic engineering. The book makes an interesting case for understanding and analysing genetic engineering

technologies and their commercialisation and provides an opportunity to reflect on the governance of the biotechnology industry, particularly its application of gene-based biotechnologies to humans.

The book has 5 chapters, excluding the introductory and the concluding chapter. Chapter 1 provides the schema of the book Biotech Juggernaut, which the authors explain as the converging vectors of economic, political, social, cultural, and ethical elements driving biotechnology's swift advance, especially in regard to applications to human biology. The authors make a case for the "critical reflection on the roots, ramifications, prospects, and promises of this highly consequential field".

Chapter 2 provides an illustrative account of the emergent technologies anticipated by postwar scientists, delving into their promise, their limitations, and their challenges, both technical and social. The chapter discusses three merging biotechnologies, viz., cloning, embryonic stem cells, and embryo gene modification, having serious implications for the genetic modification of humans and blurring the boundary between industrial products and humans. The chapter provokes a few crucial questions pertaining to the governance of technology – should such biotechnologies be left to the whims and fancy of bioentrepreneurs, or should they be subjected to comprehensive democratic consideration and oversight?

The next two Chapters explore some of the technologies and practices described in Chapter 2 through a case study of events in California – a hotbed of research and development and financing in biotechnology. Highlighting the troubling practices adopted by bioentrepreneurs, including "redefining terms to avoid public recognition contentious aspects (e.g., Prop 71's prioritisation of cloning technology, that technology's need of women's eggs, and the health risks to women of acquiring those eggs), camouflaging controversies behind scientific jargon, hyping the promise and possibilities for patented applications, bringing legal action to silence critics, and concealing marketplace conflicts of interest by cloaking corporate titles under the feigned neutrality of academic credentials", again raises pertinent questions on governance related to surpassing the legislative mandate and elite decision- making in sanctioning and funding projects that widen the door to human germline genetic engineering.

Chapter 5 delves into the emerging science and technology platform, "synthetic biology" also referred to as "extreme genetic engineering" and "genetic engineering on steroids" - its distinguishing characteristics from recombinant DNA technology and the commercial efforts to apply them. Elucidating the politics of development of this emergent technology, the authors observe: "Such hijacking of microbial processes is resulting in vast fortunes for many biocorporations in the industrial north. But for traditional guardians of plant-based economies, chiefly farming and peasant societies

in the global south, synthetic biology as practised destroys livelihoods and communities." A letter of protest drafted by the Friends of the Earth U.S. (FOE), the Erosion, Technology and Concentration Group (ETC), and the International Center for Technology Assessment (ICTA) consequent to the release of the Presidential Commission's 2010 report cited "ignoring of the precautionary principle, lack of adequate concern for the environmental risks of synthetic biology, dependence on unsubstantiated technologies for environmental safety, and reliance on the mirage of self-regulation". The author raises questions such as, whether suitably extreme regulatory caution has accompanied this "extreme genetic engineering? What are the safety and ecological implications of the release of the novel, self-replicating organisms? What do some of the field's practitioners intend for the future of the human species, and how are they selling this vision? thus, bringing forth the need for adopting responsible regulation and governance of such technologies.

Highlighting the strategies being adopted by proponents of such controversial technologies into broader public acceptance, viz., usage of neutral terms and masking controversial aspects of the methodologies in question, and framing all discussion in terms of guarantees of cures, the authors in Chapter 6, "The Road to Gattaca," delves into several troubling aspects of bio-entrepreneurialism including cloning, "three parent" embryos, gene editing, synthetic genome creation and human-animal embryonic combination and also revisits the crucial distinction between somatic cell modification and germline genetic modification with respect to the quest for cures.

Finally, the concluding chapter reflects on the authors' motivation for undertaking this project in providing a historical and scientific explanation of pertinent issues with regard to genetic engineering technologies enabling public understanding and deliberation much needed in such contexts.

Rejecting the misconceived notions of perfecting humans based on genetic theories, which are marred by vagueness and uncertainty, the authors in the book emphasise that introducing irreversible experimental errors in pursuit of human biological improvement would be an entirely novel and troubling development in human civilisation. With a warning that: "the anticipated genetic revolution could, if left unguided by moral reflection and unlimited by ethical boundaries, encourage a science-spurred version of the same eugenic outcome", the book is interspersed with serval pertinent observations on the governance of technologies, such as, "failure to account for new science, failure to acknowledge the potential for misuse, false analogies, and, occasionally, outright deception worked to hide radical transformation", "how science is practised and how scientific research is funded makes even research that is clearly circumscribed".

Whereas the technology is developing at a rapid pace, there are knowledge gaps and uncertainties over risk assessment methodologies, standards development and adequacy of existing legislation to regulate biotechnology. There are a number of such contested technologies like biotechnology, genetically modified organisms, nuclear technology and the like in which societal needs and ethical concerns regarding these innovations were not adequately identified at the outset and were insufficiently incorporated in their design and development. While considerable investments have been made, to develop these technological innovations, it is important that early consideration of ethical aspects and societal needs can lead to more efficient spending of resources for research, development and innovation. The risks, concerns and uncertainties of new technologies oftentimes are considered only at a late stage, often just before market introduction and their implications are not made to bear upon the design and development of new research, products and services. Innovation in the present market-based economy is driven by the successful diffusion and commercialisation of knowledge generated into products, systems and services. However, markets are typically not suitable to take into account ethical concerns or societal needs, which do not translate immediately into prices, because these externalities cannot be internalised due to complex causalities. To reconcile multiple objectives of technology development, risk regulation and taking care of socio-economic implications, the scientific uncertainty and the limits in capabilities of the various players, a transparent governance framework characterised by increased participation and cooperation between the different players and stakeholders is the need of the hour. The book provides several avenues for exploring such interstices in responsible stewardship of emerging technologies.

The governance of genetic engineering technology has tended to be overshadowed by technological pragmatism, and there exists little space and appetite to deliberate on the socio-ethical dimensions. Science and innovation do not exist in an autonomous sphere, and the technical and social contexts are intertwined and mutually reinforcing (Jasannof, 2005). An 'informed choice' on the part of the consumers and engaging the public in regulatory processes can go a long way in the responsible development of emerging technologies (Sahu & Anand, 2011). To gear research, development and innovation more effectively to societal needs and ethical concerns, the notion of responsible research and innovation has emerged in the recent past. Responsible research and innovation is described as "a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper

embedding of scientific and technological advances in our society)" (von Schomberg, 2011). Responsible research and innovation is an inclusive approach to research and innovation, to ensure that societal actors work together during the whole research and innovation process. The case of human genetic engineering provides an interesting case to explore the potential of responsible research and innovation to shape a technology that might already be locked into certain paths in society (Collingridge, 1980; Macnaghten, 2016).

The book authors, with a background in the history of science and cell biology and anatomy, provide a vivid and methodical description of the present state of biosciences and a broader critique of the role of new genetics in society, prompting the readers to imagine what could lie ahead if science is led and steered by scientists leaving aside the societal, philosophical and ethical debates. This compelling book tries to balance the fulcrum of science and emerging technology governance, reflecting on the cultural politics of science in the age of bioentrepreneurialism and highlighting the importance of societal engagement.

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Asian Biotechnology and Development Review
Vol. 24, No.3, pp 73-77

Book Review

Title: Biotechnology: Scientific Advancement versus Public Safety

Author: Conrad B Quintyn

Publisher: World Scientific Publishing Co. Pte. Ltd., Singapore.

Year: 2022

Price: USD 128.00

Pages: 328

Ethical implications of biotechnological advances such as gene editing, cloning etc. has been a topic of discussion since the turn of last century. Yet several questions remain unanswered. For example, clustered regularly interspaced short palindromic repeats/Cas9 (CRISPR/Cas9) technique allows scientists to make precise and targeted modifications to the DNA of living organisms and can be used for several applications ranging from snipping out mutated copy of gene causing cancer and other genetic diseases to pest resistant crops. Though the technique has the potential to revolutionize medicine to agriculture, yet there remains danger of off-target editing (genome editing that occurs in the wrong place leading to a new disease or unintended genetic changes) to bioterrorism, creation of 'designer babies' with predetermined traits etc. The question which automatically comes to mind is whether these advances are the next step in human evolution. Are we transitioning from natural to unnatural? Do we need to redraw boundaries? Should genome editing be regulated as a technology or a drug? The book "Biotechnology: Scientific Advancement versus Public Safety" by Conrad B Quintyn discusses some of these questions and mainly focuses on how and where should the line be drawn for pursuing genetic engineering while keeping in mind both public safety and scientific advancement. The book is organised into 15 chapters with overlapping themes. Overall, the book tries to find an answer to five key questions regarding the balance between public safety and scientific advancement in genetic engineering, differentiation between therapy and elective enhancement, effects on the genome of organisms, potential risks and benefits, and access to enhancements leading to social competition.

Old versus New Eugenics and Social competition

The book highlights the sudden shift in meaning from eugenics (promoting the genetics of one social or racial group) to new eugenics (using biotechnology to promote health for all) in the 1960s to early 1970s when paediatricians/ scientists realized that human genetics was a useful tool to test diseases or deficiencies to pursue subsequent treatment. New eugenics, fuelled by biotechnology aims to improve all life forms, including humans and non-human species, through gene therapy, cloning, xenobiology, and genetic editing applied to diseases, Assisted Reproductive Technologies, animals, and plants. The universality of DNA has allowed genetic manipulation of non-human species to generate relevant results for biological systems in humans, making it a key component of bioengineering. The author points out that with advancements in new eugenics, the danger of going back to the old eugenics persists even though we may not realise it. One potential risk that he points is the creation of a genetic class, where people with less desirable genetic traits are stigmatized and discriminated against. This could exacerbate existing social inequalities and create a new form of social competition based on genetic advantages. He further explained using the case of designer babies and nanobiotechnology development. Designer babies with enhanced cognition can occupy higher economic and political positions creating a new form of social stratification based on genetic advantages. Also, such an opportunity to engineer babies would be limited only to the wealthier section of the society. Similarly, the use of nanotechnology to enhance say hearing or eyesight of individuals or to create super soldiers could be available only to the wealthy, leading to the creation of a modified and unmodified population. This could lead to the perception of superiority among the modified, resulting in a situation similar to old eugenics.

Risk and Benefits

The author highlighted the dichotomy of public safety and scientific advancement in various chapters of the book. The central theme being, how the benefits and risks could be distributed between what seem like two opposing views. He pointed out how researchers often ignore warning signs to promote short-term benefits over long-term risks. He further elaborated using the case of gene therapy treatment, which was approved to be given to a four-year-old girl who suffered from ADA-SCID [1]. Scientists located and replaced the mutant genes in order to restore the immune system. Although the treatment was not a complete cure, it was considered safe, and it boosted support for the field of gene therapy. However, within a few years, unexpected side effects occurred when five out of 20 children treated for X-linked severe combined immunodeficiency, developed leukaemia-like conditions due to recombinant viruses triggering nonstop cell division. He

notes that in some cases of clinical trials even death of participants does not deter the researchers to rethink or stop their trial. The author acknowledges that the benefits of scientific breakthroughs are significant, and it is impossible to control the momentum of scientific advancement as many researchers across the globe work independently to solve nature's puzzles. However, he stresses that scientists should proceed cautiously, considering both short-term successes and long-term changes for the species.

He also highlighted that scientists have recognized that natural evolutionary processes are not keeping pace with the rapidly changing environment. Introducing genetically superior or artificially enhanced organisms into the wild could pose risks, such as out-competing native species, infecting them with lethal pathogens, changing their genetic composition through hybridization, or reducing genetic diversity.

Unintended consequences

In the last few chapters, the author explores the potential unforeseen consequences that may arise from modifying the populations of both human and non-human organisms. The author asserts that while scientists may have good intentions to enhance life, they may become fixated on pursuing fame, wealth, patents, or hubris, leading them to 'blindly tinkering with nature'. As a result, they may overlook the potential danger that such actions could pose to humans, other species, and the ecosystem.

The author also differentiated between two concepts, transhumanism and new eugenics, emphasizing that they are not interchangeable terms but has risks associated with them if not used responsibly. While both concepts deal with enhancing human conditions, transhumanism (or reprogenetics) employs an interdisciplinary approach to understand and evaluate the opportunities to enhance the human condition by utilizing advancement in technologies like genetic engineering, information technology, as well as futuristic technologies like molecular nanotechnology, artificial intelligence etc. (Bostrom, 2005). Unlike new eugenics, transhumanism includes safety and ethics in its definition but its advancement with the use of AI, antiaging materials, cybernetics, or brain computing in addition to biotechnology could eventually lead to the evolution of a new species known as Homo evolutis. Also, the quest for enhanced intelligence may lead to the creation of a super-intelligent group with economic and political power, ultimately leading to the exploitation of non-enhanced individuals. In essence, certain individuals can bypass natural selection and accelerate change without the influence of the natural environment. In the process create engineered traits or novel traits that are not naturally occurring in any human population. Also, these novel traits may not be adaptive either in the short or long term and may lead to altogether new problems.

The ultimate point that the book tries to establish is 'scientific advancement if not guided responsibly and with public input, can be detrimental to public safety.' At a 2018 international summit, the idea of establishing a global standard for genetic engineering through a United Nations treaty was raised again. It was suggested that universal values should be adopted in the application of genetic engineering due to the strong influence of market forces. The organizing committee reiterated that clinical use of human germ line editing without continued international discussions and oversight would be irresponsible. They added that germline editing could become acceptable in the future if risks are addressed and certain criteria are met, including strict independent oversight, a compelling need, and attention to societal effects. Continued transparency and discussions involving various stakeholders are important to prevent the biological sciences from going down the dark paths of old eugenics.

Overall the book provides a comprehensive overview of the risks and benefits of biotechnology, including its potential impact on human health, the environment, and society and is a useful resource for anyone interested in this topic. The author explores a range of ethical issues, including concerns about the use of biotechnology to enhance human performance and the potential for biotechnology to exacerbate existing social and economic inequalities. The author has described several examples and quotes from scientists to prove the same. However, the book talks very little about how policies and regulations can enable responsible use of such technologies.

The book add further to the debate of what research should be pursued and prioritised, however, he does not provide any simple answer to this. This question has been troubling few scientists for long. If we recall the conversation on 'The Future of Humans: Gene Editing and the Unthinkable Power to Control Evolution' between Jennifer Doudna, a Nobel Laureate and Siddhartha Mukherjee, scientist and author, the later proposed a triangle of ideas to keep in focus when intervening on human genetics: the degree of extraordinary suffering, the degree of certainty of the effects of genetic changes, and the justifiability of the choice to intervene (Berkley News, 2018). However, each of these ideas is blurry and raises questions about who defines extraordinary suffering, who mandates choice, and whether cultural or political pressure disproves of one's true choice. Though, it is argued that the goal of biotechnology is to improve human life through repairing damaged cells, curing diseases, or improving crops, yet, one has to identify or recognise the problem in the broad concept of dual-use dangers, gene drives, market forces and countries with limited regulations.

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Endnotes

[1] ADA-SCID – Adenosine deaminase deficiency linked severe combined immunodeficiency. It is a rare, inherited disorder (in which the immune system is damaged, causing a person to have a complete lack of B lymphocytes and T lymphocytes (types of white blood cells that help the body fight infection). ADA-SCID is caused by mutation in ADA gene which results in extremely low level or complete absence of ADA enzyme. Lack of the ADA enzyme prevents the immune system to develop normally.

See https://medlineplus.gov/genetics/condition/adenosine-deaminase-deficiency/ (accessed on 2nd April, 2023)

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(e) Unpublished Work:

Sandee, H. 1995. "Innovations in Production". Unpublished Ph.D thesis. Amsterdam: Free University.

(f) Online Reference:

World Health Organisation. 2000. "Development of National Policy on Traditional Medicine". Retrieved on March 31, 2011 from http://www.wpro.who.int/sites/trm/documents/Development+of+National+Policy+on+Traditional+Medicine.htm

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