CHAPTER 1

INTRODUCTION

1.1. BACKGROUND & SIGNIFICANCE

Homo-sapiens have constructed, over millennia, intricate and complex social and legal systems, cultures, and, also, technologies. These are, undoubtedly, an imposing testimonial to humans’ imagination and intellectual reach. Moreover, inventions and creativity are intertwined with, or cardinal to, humans’ existence but often they raise bewildering and obfuscating legal or social quandaries—illustratively, how much manipulation or tweaking of, or tempering with, natural or physical world is justifiable or legitimate? Or what are technologies’ moral or social implications/costs? In our work, we explore how patent law (part of complex legal system) engages or interacts with one such troublesome technology, namely, biotechnology as used in pharmaceutical sector. Before moving to demarcating or outlining various issues or quandaries involved therein and before determining contours of present research, we must, for contextualization, briefly, describe, inter-alia, Intellectual Property Rights (henceforth, IPRs) and patents.

1.1.1. IPRs: CONCEPTS & KINDS

IPRs embrace special class of property\(^1\), called, “Intellectual Property” (henceforth, IP). IP is nothing but “creations of the human mind”\(^2\). These creations include inventions, novels, logos, sculptures etc. IPRs are described as “legal rights governing

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\(^1\) Property itself can be understood as “a bundle of rights”. See, P. Drahos, \textit{A Philosophy of Intellectual Property} 1 (Ashgate, Surrey, 1996)

\(^2\) Jayashree Watal, \textit{Intellectual Property Rights In the WTO and Developing Countries} 1 (OUP, N. Delhi, 6th Imp., 2014)
the use of such creations”3. This IP embraces or pertains not to the touchable, physical or tangible goods but to abstracts or the intangibles. These are incorporeal or sans any concrete physical form. Consequently, IPRs are “rights in abstract objects”4. Because innovation/creativity is so intrinsic, so fundamental to human society, unsurprisingly, IPRs are omnipresent or ubiquitous, and extremely significant. These propel so-called “knowledge economies”5 of the modern world. They are, unsurprisingly, intrinsic to multitudinous policy discourses; are a progressively important limb of law; important for trade; and are at core of numerous dilemmas or debates, some of which constitute our ambit here.

Interestingly, the expression “intellectual property” is said to be a “twentieth century generic term used to refer to a group of legal regimes”6. Indeed historically there was segregation between “industrial property” and “copyright”, stemming perhaps from the historic frameworks or systems established under Conventions of Paris7, Berne8 and Rome9. Herein the former, i.e., “industrial property” encompasses “patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition”10. In this context “industrial property” must be broadly understood and not as confined “only to

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3 Ibid.
4 Supra 1
5 W.W. Powell and Kaisa Snellman, “The Knowledge Economy” 30 Ann. Rev. Socio. 199-220 (2004), 201. It is defined as “production and services based on knowledge-intensive activities that contribute to an accelerated pace of technological and scientific advance as well as equally rapid obsolescence. The key components of a knowledge economy include a greater reliance on intellectual capabilities than on physical inputs or natural resources, combined with efforts to integrate improvements in every stage of the production process” ... “These changes are reflected in the increasing relative share of the gross domestic product that is attributable to intangible capital”.
6 Supra 1 at 14
7 It is titled, “Paris Convention for the Protection of Industrial Property”, 1883 (henceforth, Paris Convention).
8 It is titled “Berne Convention for the Protection of Literary and Artistic Works”, 1886 (henceforth, Berne Convention).
10 Supra 7 Art. 1(2)
industry and commerce proper”\textsuperscript{11}. The latter, i.e., “copyright” covers “literary and artistic works”\textsuperscript{12} as well as the so-called “neighbouring rights”\textsuperscript{13}. This segregation is now quaint.

Now, WIPO Convention\textsuperscript{14} says that,

“Intellectual Property shall include rights relating to: literary, artistic and scientific works; performances of performing artists, phonograms, and broadcasts; inventions in all fields of human endeavour; scientific discoveries; industrial designs; trademarks, service marks, and commercial names and designations; protection against unfair competition; and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.”\textsuperscript{15}

\textsuperscript{11} \textit{Id.} Art. 1(3), It says that “Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to all agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour”.

\textsuperscript{12} \textit{Supra} 8 Art. 2(1) says that this includes “every production in the literary, scientific and artistic domain, whatever may be the mode or form of its expression, such as books, pamphlets and other writings; lectures, addresses, sermons and other works of the same nature; dramatic or dramatico-musical works; choreographic works and entertainments in dumb show; musical compositions with or without words; cinematographic works to which are assimilated works expressed by a process analogous to cinematography; works of drawing, painting, architecture, sculpture, engraving and lithography; photographic works to which are assimilated works expressed by a process analogous to photography; works of applied art; illustrations, maps, plans, sketches and three-dimensional works relative to geography, topography, architecture or science”.

\textsuperscript{13} These include “rights of performers, producers of phonograms, and broadcasting organisations” which are subject-matter of Rome Convention. Here, “performers” imply “actors, singers, musicians, dancers, and other persons who act, sing, deliver, declaim, play in, or otherwise perform literary or artistic works”, See, \textit{Supra} 9 Art. 3(a) and “Producer of Phonograms” refers to “the person who, or the legal entity which, first fixes the sounds of a performance or other sounds” (Art. 3(c)). “Broadcasting” is “the transmission by wireless means for public reception of sounds or of images and sounds” (Art. 3 (f)).

\textsuperscript{14} It is titled “Convention Establishing the World Intellectual Property Organization”, 1967 (henceforth, WIPO Convention). Art. 1 thereof “established” the “World Intellectual Property Organization” (henceforth, WIPO). Its objectives as per Art. 3 are, “to promote the protection of intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organization” and “to ensure administrative cooperation among the unions”. The Unions here are those established under numerous international IP instruments including afore-quoted Paris and Berne Conventions.

\textsuperscript{15} \textit{Id.} Art. 2(viii)
Herein, inclusion of “scientific discoveries” might appear anomalous. Interestingly, WIPO does administer “a system for the international recording of scientific discoveries” under Geneva Treaty\textsuperscript{16}. Aim thereof is “to promote information on new scientific discoveries, for the benefit of scientific community and the world at large”\textsuperscript{17}.

Currently under the epochal TRIPS\textsuperscript{18} system, seven distinct IPRs’ categorizations exists, i.e.,

1. “Copyright and Related Rights”\textsuperscript{19}
2. “Trademarks”\textsuperscript{20}
3. “Geographical Indications”\textsuperscript{21}
4. “Industrial Designs”\textsuperscript{22}
5. “Patents”\textsuperscript{23}
6. “Layout-Designs (Topographies) of Integrated Circuits”\textsuperscript{24} and
7. “Protection of Undisclosed Information”\textsuperscript{25} (or Trade Secrets)

The subject-matters embraced by each of afore-quoted kinds or categories vastly differ. So do contours and durations of protection afforded. But common strands exist. These all embrace “mental constructs”\textsuperscript{26} and are all property rights. Similarly, they all operate to “exclude” anybody other than the creator/owner “from exploiting protected

\textsuperscript{16} It is titled “Geneva Treaty on the International Recording of Scientific Discoveries”, 1978.
\textsuperscript{17} \textit{Id.} Preambular Recitals
\textsuperscript{18} It is titled “Agreement on Trade-Related Aspects of Intellectual Property Rights”, 1994 (henceforth, TRIPS). It forms “Annexure 1C” of the WTO-Agreement.
\textsuperscript{19} See, \textit{id.} Part II. 1
\textsuperscript{20} See, \textit{id.} Part II. 2
\textsuperscript{21} See, \textit{id.} Part II. 3
\textsuperscript{22} See, \textit{id.} Part II. 4
\textsuperscript{23} See, \textit{id.} Part II. 5
\textsuperscript{24} See, \textit{id.} Part II. 6
\textsuperscript{25} See, \textit{id.} Part II. 7
\textsuperscript{26} This expression is used by Drahos who maintains that “mental constructs are the stuff of intellectual property relations. Intellectual Property Rights are rights in our mental projections”. See, \textit{supra} 1 at 14
subject matter” unless “explicit authorization” of creator/owner is obtained\textsuperscript{27}. These are all “exclusive rights”, or monopolies\textsuperscript{28}. Here we deal with solely one, i.e., patents.

1.1.2. PATENTS: MEANING, NATURE & LIMITATIONS

Patents are, simplistically, “a limited monopoly that is granted in return for the disclosure of technical information”\textsuperscript{29}. TRIPS, \textit{inter-alia}, says that,

“Patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”\textsuperscript{30}

Hence, aforesaid “technical information” necessarily embraces “inventions” and not discoveries. Also, for policy considerations, as we highlight in ensuing chapters, all or any “inventions” are not eligible. Further, it is said that,

“The extent of patent protection is further limited in terms of territory and temporality. Patent protection is limited to the jurisdiction within which the grant was made. Nation states must provide protection of patents for 20 years from the filing date.”\textsuperscript{31}

They are, hence, statutory, non-perpetual rights. Interestingly, temporal limitation of “twenty years counted from the filing date”\textsuperscript{32} comes from TRIPS. Also, commentators say that,

\begin{itemize}
\item \textsuperscript{27} \textit{Supra} 2
\item \textsuperscript{28} Lionel Bently and Brad Sherman, \textit{Intellectual Property Law} 1 (OUP, New York, 4\textsuperscript{th} Edn. 2014)
\item \textsuperscript{29} \textit{Id.} at 375
\item \textsuperscript{30} \textit{Supra} 18 Art. 27.1
\item \textsuperscript{31} Matthew Rimmer, \textit{Intellectual Property and Biotechnology: Biological Inventions} 2 (Edward Elgar, Glos, 2008)
\item \textsuperscript{32} \textit{Supra} 18 Art. 33.
\end{itemize}
“Patents are territorial and a patent holder has rights only in the territory in which the patent was issued. To gain rights in other countries, the inventor must file a patent application in those countries under their laws. International conventions help this application process.”

Therefore, as quoted above, “the inventor must file a patent application”, triggering a multi-stage process wherein certain compulsory prerequisites ought to be satisfied and only then does this right accrue. Interestingly, a patent by itself “is not an affirmative right to practice or use the invention” but like all IP, simply, it is “right to exclude”. Affirmative use thereof might depend on other regulatory clearances. Hence, “patent is a right granted by the state, and of specific duration to stop third parties from undertaking within that state, certain defined activities as are nowadays delineated by the claims of the patent.”

Likewise, Ayyangar committee said that, “A patent disables other than the patentee or those authorised by him, from manufacturing and selling the patented article or using or imitating the patented process or vending the resulting product.”

1.1.3. PATENTS: THE RIGHTS & EXCEPTIONS

TRIPS says that,

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34 See, ibid.
36 In this regard, it is pointed that “a patentee may hold a valid patent but nevertheless be unable to begin marketing a product until regulations set out under other laws” ... “are satisfied”. See, Elizabeth F. Judge and Daniel Gervais, “The limits of patents” in D. Gervais (ed.) International Intellectual Property: A Handbook of Contemporary Research 247 (Edward Elgar, Glos, 2015)
“A patent shall confer on its owner the following exclusive rights”

... “(a) where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling or importing for these purposes that product.”³⁹

Even if the processes/procedures for aforesaid “making” are unlike the patentee’s, the bar holds. It is rightly observed that “unlike trade secrets, a patent” operates against the one who “independently reached the same invention”⁴⁰. Further, TRIPS says that,

“A patent shall confer on its owner the following exclusive rights”

... “(b) where the subject matter of a patent is a process, to prevent third parties not having the owner’s consent from the act of using the process, and from the act of: using, offering for sale, selling, or importing for those purposes at least the product obtained directly by that process.”⁴¹

Aforesaid bars on “product obtained directly by that process” collapse if the process is different. Nevertheless, sheer power and breadth of rights is unmissable. Being part of mandatory WTO system, all members grant aforesaid sweeping privileges. In India also, consequently and unsurprisingly, its Patents Act’s s. 48⁴² is almost identically

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³⁹ Supra 18 Art. 28.1
⁴¹ Supra 18 Art. 28.1
⁴² The Patents Act, 1970 (Act 39 of 1970), s. 48 says that “Subject to the other provisions contained in this Act and the conditions specified in section 47, a patent granted under this Act shall confer upon the patentee” … “(a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India” and “(b) where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India”
worded. Also, patent’s owner has “the right to assign, or transfer by succession, the patent” and can give licenses.\textsuperscript{43} TRIPS also says that,

“Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”\textsuperscript{44}

Such exceptions include “exceptions relating to research and experimentation on the invention”\textsuperscript{45}, dealt briefly in chapter 5, and “the so-called Bolar or early working exception” which “deals with the use of an invention relating to pharmaceutical product to conduct tests and obtain the approval from the health authority, before the expiry of a patent, for commercialization of a generic version, just after such expiry.”\textsuperscript{46}

Another critical modality called “compulsory licenses”\textsuperscript{47} also exists. TRIPS provides them under clause titled “Other Use Without Authorization of the Right Holder”\textsuperscript{48}, which Correa says “contains a detailed set of conditions and limitations for” granting them\textsuperscript{49} (without actually using the term). Detailed engagement, given our ambit, is irrelevant. Clearly, however, monopoly is not constructed solely or merely for patentee’s unbridled profiteering.

\textsuperscript{43} Supra 18 Art. 28.2
\textsuperscript{44} Id. Art. 30
\textsuperscript{45} Supra 40 at 304, See also, supra 42 s. 47(3)
\textsuperscript{46} Id. at 304-305. See also, Id. s. 107A(a)
\textsuperscript{47} Supra 7 Art. 5A(2) says that “Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work”.
\textsuperscript{48} Supra 18 Art. 31
\textsuperscript{49} Supra 40 at 313
We engage, in chapter 2, with, _inter-alia_, other relevant aspects of patents (international conventions, justifications etc.). Having demarcated, for introduction’s purpose, what these are, we present now, briefly, myriad quandaries or dilemmas plaguing and obfuscating pharma-bio-patents.

### 1.1.4. PHARMA-BIOTECHNOLOGY PATENTING: A MILLION RAGING CONUNDRUMS

Our area-Pharmaceutical Biotechnology (henceforth, pharma-biotech/pharma-bio or bio-pharma) embraces, as elaborated in chapter 2, _inter-alia_, stem cells, vaccines, xenotransplants, cloning, so-called “nature derived drugs”, biopharmaceuticals, genetic researches, including genome, so-called “isolated and purified genes”, genetic testing etc. Obviously, terminator-seeds or GM-food etc. and safety/regulation thereof pertain to agri-biotech and, consequentially, are not researcher’s concern. Now, pharma-bio-monopolies are, unfortunately, extremely polarising or dilemmatic and full of myriad raging conundrums, as briefly mentioned below. Importantly, issues or perspectives below are not exhaustive. Indeed, existence thereof and of antagonistic philosophical positions and ideas, which we extensively engage or negotiate with in ensuing chapters, invariably make pharma-bio-patenting a significantly fertile research area.

Interestingly, generally also, patents are polarising and “there has been a long-standing controversy over the grant of monopolies in respect of scientific inventions and technologies”\(^{50}\). Illustratively, “many have lamented the negative impact of patents on the norm of open science and the commercialization of basic research”\(^{51}\).

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\(^{50}\) _Supra_ 31 at 1

Also, patents can be seen as curtailing “access to knowledge and access to essential medicines”\textsuperscript{52}. U.S. judiciary, indeed, admitted that,

“Patent protection is, after all, a two-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention, by, for example, raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiations of complex licensing arrangements.”\textsuperscript{53}

Within pharma-bio, such controversies or dilemmas get, as ensuing chapters show, even more obfuscatingly complex and amplified. Let’s assess why.

Biotechnology (elaborately described in chapter 2) has “Bio” merged into it. Here, “Bio” signifies biology or, more fundamentally, life. Illustratively, in other fields, e.g. chemistry or mechanics, both raw-ingredients and also finished final products/innovations are invariably inanimate. In pharma-bio, both or either of aforesaid could be animate or living. Indeed, root of all fears, tribulations, dilemmas, troubles and misconceptions is this “Bio” or the presence of life, living beings. This is why even pharma-bio-patenting (often labelled “patents over life” or “patenting of life”) is troublesome. Rimmer classifies problems as, \textit{inter-alia}, “ethical and moral

\textsuperscript{52} \textit{Supra} 31 at 8

\textsuperscript{53} \textit{Mayo Collaborative Services v. Prometheus Laboratories Inc.}, 132 S.Ct. 1289 (2012), 1305
objections”, problem with “commodification of life”, reduced “access to essential medicines” (or to genetic tests) and “biopiracy” etc. These are highlighted below.

The Moral Quagmire and Contours of Protection: A commentator has rightly said that,

“Biotechnology is an area in which many morally questionable inventions are generated. Controversial patented biotech inventions include: isolated genes, sequenced DNA, medical procedures, embryonic stem cells, genetically modified transgenic animals, and methods of cloning mammals. The moral controversies surrounding these and other biotech inventions stems from several concerns including those arising from the mixing of human and animal species, the denigration of human dignity, the destruction of potential human life, and the ownership of humans. The availability of a government imprimatur granting exclusive rights over morally controversial inventions is especially problematic in the area of biotechnology.”

It is, therefore, often argued that “biological material should not be patented for ethical reasons”. Cook calls this an “ethical issue” which pertains to “exclusion from patentability for inventions which are contrary to ordre public”. Interestingly, such rejection or challenge to pharma-bio-patenting (or generally, bio-patenting) is very much allowed by TRIPS. It says that,

54 Supra 31 at 8
56 G. V. Overwalle, “Reshaping bio-patents: measures to restore trust in the patent system” in Han Somsen (ed.), The Regulatory Challenge of Biotechnology 241 (Edward Elgar, Glos, 2007)
“Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited under their law.”

Understanding this threshold of “*ordre public* or morality” remains, in our work, a recurrent and ubiquitous theme. Interestingly, commentators point that this “confrontation of ethics and patent law is difficult, to say the least, and usually ethics are seen in this context as a disturbance”\(^{59}\). There are questions, pointed in chapter 3, over whether “*ordre public* or morality” yardstick should exist? Moreover, regarding bio-patenting, TRIPS, *inter-alia*, specifically says that,

> “Members may also exclude from patentability” ... “(b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes”\(^{60}\).

But this is a “may” provision. What about the artificial or the non-essential “biological processes”? What about humans or their bio-material or xenotransplants? Trouble, therefore, is fixing “the limits on what can, and what cannot, be patented”\(^{61}\). What we banish? What we include and what be the contours or boundaries of such inclusion? In our chapters 3 to 5, we explore these.

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\(^{58}\) *Supra* 18 Art. 27.2

\(^{59}\) *Supra* 56

\(^{60}\) *Supra* 18 Art. 27.3(b)

\(^{61}\) *Supra* 57
Diagnostics, Medical Methods and “Access to Medicines”: Gibson also points to “discussions regarding access to medicines, access to seeds”\(^{62}\) etc. However, the latter is within agri-bio-monopolisation and former, i.e. “access to medicines” is a post-grant dilemma. Both are not, as specified later in our scope (see, part 1.4), our present concerns. However, “access to medicines” might be facilitated in another manner. Illustratively, since, “diagnostic, therapeutic and surgical methods for treatment of humans or animals”\(^{63}\) might be excluded, it might enhance access. Hence, “access to medicines” is achieved by rendering certain things non-monopolizable. This limited aspect alone shall, therefore, be explored.

**Detrimental Impact on Innovation:** It is felt that monopolisation of early-stage/basic or foundational techniques/inventions is “impeding follow-on innovation”\(^{64}\). It means that “access and use might be hindered by the existence of a patent thicket: a dense web of overlapping patents a researcher or a company must hack its way through in order to actually develop and commercialize a new product”\(^{65}\). As mentioned above, sometimes such “exclusivity can impede the flow of information that might permit, indeed spur, invention” and can compel “potential users to conduct costly and time-consuming searches of existing patents” and then to negotiate “complex licensing arrangements.”\(^{66}\) Heller *et. al.* call it “The Anticommons in Biomedical Research” problem\(^{67}\). Also, another commentator notes that, “some studies have pointed at possible negative effects of bio-patents on scientific research in general”\(^{68}\). Several

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\(^{63}\) Supra 18 Art. 27.3(a)

\(^{64}\) Supra 56 at 247

\(^{65}\) Id. at 244

\(^{66}\) Supra 53

\(^{67}\) M. A. Heller and Rebecca S. Eisenberg, “Can Patents Deter Innovation? The Anticommons in Biomedical Research” 280 *Science* 698-701 (May 1998)

\(^{68}\) Supra 56 at 243
circumventing mechanisms or modalities and solutions have been tried or suggested. We, in chapter 5, *inter-alia*, engage with this.

**Biopiracy**: Bio-innovation is, as pointed above, unsurprisingly, based on or reliant on raw bio-materials. Hence, a commentator points that,

“The search for new pharmaceutical, biotechnological or agricultural applications has led to a growing interest in genetic resources and indigenous traditional knowledge. The contribution of indigenous communities has tended, however, not to be rewarded when the resulting products have been patented and commercialized. In order to remedy this various countries turned to the Convention on Biological Diversity.”

It is alleged that “biodiversity-rich third world countries acted as gold mines of raw materials for” bio-innovators who adopted a “take and run policy i.e. the researcher coming at the site, collecting their sample and departing with their plunder, without payment of any kind” leading to “biopiracy”. This creates, within patent law, something called the “source issue” which imposes “obligations to identify the source of material, and in particular genetic material, that already exists in nature and on which the patent is in some way based”. Such a disclosure of “country of origin of the material in any patent specification” can invariably help “the source country or countries to ensure that they benefit from the material used”. This and also concerns of protecting “indigenous knowledge” are elaborately dealt in chapter 6.

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69 *Id.* at 248
71 *Supra* 57 at 201
72 Tony Howard, “The Legal Framework Surrounding Patents for Living Materials” in *Supra* 62 at 22
**Other Concerns:** Interestingly, several environmental and safety dilemmas (labelled “Bio-safety issues”) also arise pertaining to release of so-called “Genetically Modified Organisms” (GMOs). Those, however, belong to regulatory domain and don’t, in our present endeavour, concern us.

Now all afore-mentioned conundrums or quandaries plaguing pharma-bio’s monopolisation are, unsurprisingly and clearly, emotive, obfuscating and strong. So, we humbly seek, how Indian patent system can be appropriately tweaked or adjusted or improved, if at all, to better address or flexibly adapt to these? Can we, in doing so, look for or imbibe invaluable perspectives or insights from others, i.e. other jurisdictions? This, the researcher most humbly feels, will be exhilarating and significant to explore.

1.1.5. **U.S., EPC & INDIA: BASIC COMPARATIVE FRAMEWORK**

Since researcher invariably will, throughout his work, engage with, *inter-alia*, European, U.S. and Indian perspectives, brief non-exhaustive background framework thereof becomes necessary. Indeed, there are other laws/treaties and, also, jurisdictions relied on, which, as necessary, we, in ensuing chapters, mention and deal with. Also, framework here does not embrace biodiversity laws. Researcher confines himself, in this brief segment, only to patenting frameworks.

**U.S.A.:** Interestingly, U.S. constitution itself mandates that,

“The Congress shall have the power to” ... “promote the progress of science and useful Arts, by securing for limited times to authors
and inventors the exclusive right to their respective writings and discoveries.”

Consequently, there exists Patents Act, 1952, also called “35 U.S. code” (henceforth, “35 U.S.C.”) wherein, *inter-alia*, “the United States Patent and Trademark Office” (henceforth, U.S.P.T.O) “is established as an agency of the United States, within the Department of Commerce”\(^{74}\). Within USPTO, there is “a Patent Trial and Appeal Board”\(^{75}\) (PTAB) which, *inter-alia*, reviews “adverse decision of examiners upon applications for patents” etc\(^{76}\). Interestingly, there is also “a specialized patent court”\(^{77}\), namely, “Court of Appeals for the Federal Circuit” (henceforth, CAFC) which combined erstwhile “two existing courts, the Court of Customs and Patent Appeals and the Claims Court”\(^{78}\). CAFC has been labelled as “pro-patent”\(^{79}\) and has controversially and “systematically eliminated time-honoured categorical exclusions from patent eligibility”\(^{80}\) and has been wrongly embracing “virtually anything within patentable subject matter”\(^{81}\). Also, their Supreme Court (SC) exists above CAFC. We shall, throughout our ensuing work, engage with extensively or study, *inter-alia*, CAFC’s and SC’s rulings. Another relevant law titled, “The Leahy-Smith America Invents Act, 2011” (henceforth, AIA) was recently enacted “to provide for patent reform”\(^{82}\) and will, naturally, be engaged with.

\(^{73}\) U.S. Constitution, Art. 1 §8(8)
\(^{74}\) 35 U.S.C. §1
\(^{75}\) Id. §6(a)
\(^{76}\) Id. §6(b)(1)
\(^{78}\) Id. at 778
\(^{79}\) See, id. at 779
\(^{80}\) Supra 31 at 113
\(^{81}\) Ibid.
\(^{82}\) The long title of AIA says, “To amend title 35, United States Code, to provide for patent reforms”.

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EUROPE: Europe, interestingly, has a treaty titled, “Convention on the Grant of European Patents” or “European Patent Convention” (henceforth, EPC). It establishes “a system of law, common to the Contracting States, for the grant of patents for invention”\(^{83}\). Although existing since “5 October 1973”, it underwent tectonic amendment/revision in “November 2000” to be in its current form\(^{84}\) (henceforth, EPC, 2000). Its rationale is “to strengthen cooperation between the states of Europe in respect of protection of inventions” and that the “protection may be obtained in those states by a single procedure for grant of patents and by the establishment of certain standard rules governing patents so granted”\(^{85}\). 38 European countries including “Austria, Belgium, Switzerland, Czech Republic, Germany, Denmark, Spain, France, United Kingdom, Greece, Croatia, Italy, Monaco, Norway, Poland, Portugal, Romania, Sweden, Turkey” etc. are members\(^{86}\).

Patents granted therein are called “European patents”\(^{87}\). It also establishes “a European Patent Organisation”\(^{88}\) and also its organ, the “European Patent Office” (henceforth, EPO)\(^{89}\). It says that, “the task of the Organisation shall be to grant European Patents. This shall be carried out by the European Patent Office supervised by the Administrative Council”\(^{90}\). The afore-mentioned “organisation shall have a legal personality”\(^{91}\) and “in each of the Contracting States, the Organisation shall enjoy the most extensive legal capacity accorded to legal persons under the national

\(^{83}\) EPC, 2000, Art. 1
\(^{85}\) Supra 83 Preamble
\(^{86}\) Information available at https://www.epo.org/about-us/organisation/member-states.html (last visited on February 1, 2017)
\(^{87}\) Supra 83 Art. 2
\(^{88}\) Id. Art. 4(1)
\(^{89}\) Id. Art. 4(2)(a)
\(^{90}\) Id. Art. 4(3)
\(^{91}\) Id. Art. 5(1)
law of that state”\textsuperscript{92}. Also, it’s headquartered in Munich, “with a branch at The Hague”\textsuperscript{93}. Within EPO, there are “Examining Divisions” which are “responsible for the examination of European patent applications”\textsuperscript{94}. Therein, there are also “Opposition Divisions” which are “responsible for the examination of oppositions against any European patent”\textsuperscript{95}. Within EPO, there are also “Boards of Appeal”\textsuperscript{96}. These are “responsible for the examination of appeals from decisions of the Receiving Section, the Examining Divisions and Opposition Divisions, and the Legal Division”\textsuperscript{97}. Amongst afore-mentioned “boards of appeal”, decisions of so-called “Technical Board of Appeal” (henceforth, TBA) shall, in this work, be extensively engaged with. Then there is “Enlarged Board of Appeal”\textsuperscript{98} (henceforth, EBoA), “responsible for (a) deciding on points of law referred to it by Boards of Appeal under Article 112; (b) giving opinions on points of law referred to it by the President of the European Patent Office under Article 112; deciding on petition for review of decisions of the Boards of Appeal under Article 112a”\textsuperscript{99}. Apart from aforesaid, EPC contains, \textit{inter-alia}, “Substantive Patent Law”\textsuperscript{100}, contents of “The European Patent Application”\textsuperscript{101}, “Procedure Up To Grant”\textsuperscript{102} etc. which shall, in our work, be extensively studied.

(henceforth, EUBD) also exists. It was adopted by “the European parliament and the Council of the European Union”\textsuperscript{103}. It was adopted because “effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology” and because “the European Parliament and the Council have determined that the legal protection of biotechnological inventions requires clarification”\textsuperscript{104}. Interestingly, European Union comprises “28 member countries”\textsuperscript{105}. This alongwith its EUBD is absolutely distinct from afore-discussed EPC. Also, a separate “Court of Justice for European Union” (henceforth, CJEU) interprets all EU law including EUBD.

However, for harmony’s sake, the so-called “Implementing Regulations to the Convention on the Grant of European Patents” (henceforth, EPC Regulations) state that,

“For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this Chapter. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation”\textsuperscript{106}.

Also, EPO amended “the EPC implementing regulations to accord with the Directive” and “the amendments introduced new rules” therein\textsuperscript{107}. Interestingly, in this context, EPO also promptly and rightly modifies/adapts or tweaks its practices, practice.

\textsuperscript{103} See, EUBD, 1998
\textsuperscript{104} Id. Recitals 3 and 4
\textsuperscript{105} https://europa.eu/european-union/about-eu/countries_en (last visited on February 1, 2017)
\textsuperscript{106} EPC Regulations, 2006, r. 26(1)
\textsuperscript{107} Supra 57 at 146
manuals and, also, guidelines etc. to reflect, when necessitated, all CJEU rulings about EUBD.

To obfuscate further, there is also a “Council of Europe” comprising “47 member states, 28 of which are members of European Union” and this council “is the continent’s leading human rights organisation”\footnote{See, www.coe.int/en/web/about-us/who-we-are (last visited on February 1, 2017)}. This also has, as we shall be discussing in remaining chapters, treaties/recommendations pertaining to our ambit.

**INDIA**: Here, there is the law titled, “The Patents Act, 1970”. Herein, a “patent means a patent for any invention granted under this Act”\footnote{Supra 42 s. 2(1)(m)}. Also, “invention” signifies “a new product or process involving an inventive step and capable of industrial application”\footnote{Id. s. 2(1)(j)}. Certain subject-matter is disqualified as “not inventions within the meaning of this Act”\footnote{Id. s. 3}. These aspects shall, later be, extensively studied. Moreover, “the Controller General of Patents, Designs and Trade Marks” (henceforth, CGPDTM) “appointed under sub-section (1) of section 3 of the Trade Marks Act, 1999 (47 of 1999), shall be the Controller of Patents”\footnote{Id. s. 73(1)} also. Hence, CGPDTM is the main authority. Also “an office which shall be known as the patent office” is also established therein\footnote{Id. s. 74(1)}. We shall call it IPO (“Indian Patent Office”). Much of our endeavour, in Indian context, will naturally rely on, *inter-alia*, its practices and manuals/guidelines apart from, obviously, Supreme Court and High Courts’ judgments.

**1.2. LITERATURE REVIEW**
Given the afore-discussed controversial, quagmire-ish, dilemmatic and extremely morally hazy or obfuscating landscape of so-called “biological inventions” and, as corollary, of patents thereon, unsurprisingly, plethora of very rich materials exists.

Illustratively, Rimmer in his epochal work “Intellectual Property and Biotechnology Biological Inventions” remarks that, “the contemporary debate over patent law and biological inventions is not new”\(^\text{114}\). He then, himself describes his master text as “First, this book is a larger project of seeking to document the historical origins of the biotechnology industry” and “Second, this text explores whether patent law, and allied rights, have an impact on the social norms of scientific communities”\(^\text{115}\). But from our endeavours’ perspective, Rimmer points that “Third, this book considers how the legal problems in respect of biological inventions have been addressed in a number of key jurisdictions, including the United States, the European Union, Canada, Australia and New Zealand”\(^\text{116}\). His chapters include, *inter-alia*, “patent law and micro-organisms”, “patent law and plant breeders’ rights”, “patent law and animals”, “patent law, research tools and experimental use”, “patent law and genetic testing”, “patent law and human embryos” etc\(^\text{117}\). He finally recommends that “patent law should be technology-specific, especially when dealing with the demands of particular fields of biotechnology”\(^\text{118}\) and that “the criteria for patentability should be applied strictly in respect of new technologies”\(^\text{119}\). Also, he suggests that “the patent system is broken and needs to be reformed”\(^\text{120}\). Rimmer’s endeavours, for this researcher, become an illuminating window to galaxy of so-called “biological inventions”. However, Rimmer doesn’t engage with Indian scenario, nor with

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\(^{114}\) *Supra* 31 at 1  
\(^{115}\) *Id.* at 9-10  
\(^{116}\) *Id.* at 10  
\(^{117}\) See, *Id.* “Contents”/Chapters  
\(^{118}\) *Id.* at 299  
\(^{119}\) *Ibid.*  
\(^{120}\) *Ibid.*
biopiracy, and, written in 2008, his treatise, logically, doesn’t deal with tectonic and epochal changes occurring since then.

Likewise, Cook in his 2009 work titled, “Pharmaceuticals Biotechnology and the Law” focuses, as obvious, on pharma-bio, and engages broadly with all laws\textsuperscript{121}, including, “regulatory, tort and competition law in Life Sciences”\textsuperscript{122}. Importantly, for us, Cook engages also with “Patents and Biotechnology”\textsuperscript{123} and critically with “ethical, variety and source issues”\textsuperscript{124} in bio-patents. The “source issue” is of relevance to biopiracy. Cook argues that most issues or “objections” are nothing but “a fundamental misconception as to what patents are about”\textsuperscript{125}. Cook speaks predominantly from European (EPC, U.K.) and U.S. perspectives, with his pro-monopoly stance sometimes evident. Obviously, post-2009 epochal changes and Indian perspectives find no mention.

Coming to “Patenting Lives: Life Patents, Culture and Development” edited by Gibson\textsuperscript{126}, one commentator engages with, \textit{inter-alia}, “the ethic of patents on genetically modified organisms”\textsuperscript{127} and emphasises that “the interaction of patent law and biotechnology illustrates a gradual expansion of the former to include a broader number of aspects of the latter”\textsuperscript{128}. Another contributor engages with, \textit{inter-alia}, impact of “European Directive on the Legal Protection of Biotechnological Inventions” and “European Patent Convention” on U.K. patent law and the

\textsuperscript{121} See, supra 57
\textsuperscript{122} \textit{Id.} at 9-21
\textsuperscript{123} \textit{Id.} at 143-219
\textsuperscript{124} See, \textit{Id.} at 199-201
\textsuperscript{125} \textit{Id.} at 202
\textsuperscript{126} See, supra 62
\textsuperscript{127} Kathryn Garforth, “Life as Chemistry or Life as Biology? An Ethic of Patents on Genetically Modified Organisms” in \textit{id.} at 27
\textsuperscript{128} \textit{Ibid.}
“patentability of Biotechnology Inventions” therein\(^{129}\). He also, importantly for researcher, discusses “traditional knowledge, genetic resources and biopiracy” and the importance of “disclosure of origin” to foil biopiracy\(^{130}\).

Likewise Grubb and Thomsen in “Patents for Chemicals, Pharmaceuticals, and Biotechnology: Fundamentals of Global Law, Practice and Strategy” deal extensively with, \textit{inter-alia}, “what is biotechnology” and monopolisation thereof\(^{131}\). It deals with meaning of “recombinant DNA technology”\(^{132}\), “Sufficiency, Enablement, and the Written Disclosure Requirement”\(^{133}\), and with “patenting of animals, plants and human cells” in U.S. and EPC. Engaging with “\textit{ordre public} and morality”, it asks, “Can patent office examiners be judges of morality”\(^{134}\)? It mentions the grouse that “attempts are also made to mobilize religious opinion to fight patents on life”\(^{135}\) and further attempts to answer “why are patents being targeted” in context of, \textit{inter-alia}, “transgenic animals or human embryonic stem cell lines”\(^{136}\). While being deeply informative, it lacks both Indian position and, obviously, post-2010 scenario.

Interestingly, Jessica Lai in her article on “Myriad Genetics and the BRCA Patents in Europe” deals with how “the U.S. Supreme Court assessed the patentability of gene-related technologies, particularly with respect to the two genes associated with breast and ovarian cancer (BRCA1 and BRCA2)”\(^{137}\) and its 2013 epochal decision in “\textit{Myriad Genetics}, declaring that simply isolated genes and genetic sequences” are

\(^{129}\) See, \textit{supra} 72 at 9-15
\(^{130}\) \textit{Id}. at 21-22
\(^{132}\) \textit{Id}. at 279-280
\(^{133}\) \textit{Id}. at 287
\(^{134}\) \textit{Id}. at 317
\(^{135}\) \textit{Id}. at 318
\(^{136}\) \textit{Id}. at 319
\(^{137}\) Jessica C. Lai, “Myriad Genetics and the BRCA Patents in Europe: The Implications of the U.S. Supreme Court Decision” 5 \textit{UCILR} 1041-1076 (2015), 1042
simply “not capable of being inventions for the purposes of patent law”\textsuperscript{138}. She also informs how “patents relating to BRCA1 and BRCA2 had been strongly opposed throughout the EPO for over ten years, resulting in Myriad Genetics having only a handful of very narrow patents in Europe”\textsuperscript{139}. Her article explores “the potential effects of the Myriad decisions on the European context”\textsuperscript{140}. Discussing Indian context, Elizabeth NG’s article titled, “Patenting Human Genes: Wherein lies the balance between private rights and public access in India and the United States?” examines, \textit{inter-alia}, “the issues relating to the patent-eligibility of human genes”\textsuperscript{141}. She admits that “the subject-matter is capable of dividing the world along ethical and policy lines and even self-interest” and then she states that she “investigates this issue by providing a comparative study on the patent-eligibility of human genes in India and the United States”\textsuperscript{142}. Interestingly, B. Ravi in his article on “Gene Patents in India”\textsuperscript{143} argues that “there is a need to ensure that there is a consistency in granting patents” and that “patenting human genes will only restrict better diagnosis, health care and development”\textsuperscript{144}.

Numerous commentators explore pharma-bio’s moral dimensions. Illustratively, Jaswal \textit{et.al.} engage with “Germ-Line Engineering”\textsuperscript{145} and comment that, \textit{inter-alia}, “such gene therapy would open the door to attempts at altering human traits not associated with disease, which could exacerbate problems of social discrimination”\textsuperscript{146}.

\textsuperscript{138} \textit{Ibid.}
\textsuperscript{139} \textit{Ibid.}
\textsuperscript{140} Id. at 1044
\textsuperscript{141} Elizabeth Siew-kuan Ng, “Patenting Human Genes: Wherein lies the balance between private rights and public access in India and the United States?” 11 \textit{IILT} 1-51 (2015), 4
\textsuperscript{142} \textit{Ibid.}
\textsuperscript{144} Id. at 328
\textsuperscript{146} Id. at 7
Likewise, Ajai Kumar in his article titled, “Human Cloning: A Socio-Legal and Ethical Appraisal”\textsuperscript{147} has explored its “Ethical and Social Implications”\textsuperscript{148} and its “legal aspects”\textsuperscript{149}. In U.S. context, Margo Bagley\textsuperscript{150} comments that “without statutory bars to the issuance of morally controversial patents, the public and Congress are continually in a reactive instead of proactive mode in assessing the potential impact of patenting such subject matter”\textsuperscript{151}. Her article maintains that “if Congress does not settle limits on patenting morally controversial subject matter, no one will, and asking patent questions later will one day be too late”\textsuperscript{152}. Indeed, Pharma-bio-patenting’s moral/social impact or dilemmas and history form, \textit{inter-alia}, theme of several other illustrious articles/commentaries, which helped our understanding\textsuperscript{153}.

Regarding “The Anticommons in Biomedical Research”, we mentioned above work of Heller \textit{et.al}\textsuperscript{154}. Basheer \textit{et.al}\textsuperscript{155} in this context, explore “experimental use exception” which “shields experimental activities from charges of patent infringement”\textsuperscript{156}. They assess, \textit{inter-alia}, allowing “exception to even cover the testing of patented inventions with a view to creating improvements or inventing around such patents”\textsuperscript{157}. Isaac and Park in “Open Development: Is the Open Source analogy relevant to biotechnology” also explore how “proliferation of IPRs may raise

\begin{thebibliography}{99}
\bibitem{Kumar} Ajai Kumar, “Human Cloning: A Socio-Legal and Ethical Appraisal” 52(1) \textit{JILI} 92-109 (2010)
\bibitem{Id} \textit{Id.} at 97-100
\bibitem{Id} \textit{Id.} at 100-106
\bibitem{Supra} \textit{Supra} 55
\bibitem{Id} \textit{Id.} at 479
\bibitem{Id} \textit{Id.} at 482
\bibitem{Basheer} \textit{Supra} 67
\bibitem{Basheer} Shamnad Basheer and P. Reddy, “The Experimental Use Exception through a developmental lens” 50(4) \textit{IDEA} 831-873 (2010)
\bibitem{Id} \textit{Id.} at 833
\bibitem{Ibid} \textit{Ibid.}
\end{thebibliography}
the cost of innovation” and explore whether “Open Source” or “OpenBio” are a remedy.\textsuperscript{158}

Also, for patents, “Indian Patent Law and Practice” by Kankanala et.\textit{al.} proved illuminating. It emphasises, \textit{inter-alia}, on “patentability requirements in India”\textsuperscript{159}. It extensively deals with, \textit{inter-alia}, “inventive step”\textsuperscript{160} and “Specification”\textsuperscript{161} and “sufficiency of disclosure”\textsuperscript{162}. Other such texts were also studied\textsuperscript{163}. Coming to biotechnology, we relied on technical texts\textsuperscript{164}. Illustratively, “Biotechnology Fundamentals” by Firdos Khan describes “what is biotechnology”\textsuperscript{165} and describes science of “embryonic stem cells”\textsuperscript{166}, “cloning”\textsuperscript{167}, “xenograft”\textsuperscript{168} etc. Likewise, book titled, “DNA and Biotechnology”\textsuperscript{169} illuminated us about “human therapeutic cloning”\textsuperscript{170}, intricacies of “xenotransplantation”\textsuperscript{171} and how “human genome research continues to have a large impact on our understanding of human genetic diseases and the large role that genes play in conferring biological traits”\textsuperscript{172}.


\textsuperscript{159} Kalyan C. Kankanala, Arun Narasani et.\textit{al.}, \textit{Indian Patent Law and Practice} 17 (OUP, New Delhi, 2010)

\textsuperscript{160} See, \textit{id.} at 32-42

\textsuperscript{161} See, \textit{id.} at 113-126

\textsuperscript{162} \textit{Id.} at 123

\textsuperscript{163} For e.g., P. Narayanan, \textit{Patent Law} (ELH, Kolkata, 4\textsuperscript{th} Edn., 2010) and \textit{ supra} 28

\textsuperscript{164} See, e.g., John Smith, \textit{Biotechnology} (CUP, New York, 5\textsuperscript{th} Edn., 2009) and H.D. Kumar, \textit{Genomics and Cloning} (EWP, New Delhi, 2004)

\textsuperscript{165} Firdos A. Khan, \textit{Biotechnology Fundamentals} 1-2 (CRC Press, Florida, 2012)

\textsuperscript{166} \textit{Id.} at 286-288

\textsuperscript{167} \textit{Id.} at 307-310

\textsuperscript{168} \textit{Id.} at 304-307

\textsuperscript{169} Molly Fitzgerald-Hayes and F. Reichsman, \textit{DNA and Biotechnology} (Elsevier, London, 3\textsuperscript{rd} Edn., 2010)

\textsuperscript{170} \textit{Id.} at 326-327

\textsuperscript{171} \textit{Id.} at 323-324

\textsuperscript{172} \textit{Id.} at 290
provided poignant insights on, *inter-alia*, “patentable subject matter”\(^{173}\) and critically on “exclusions to patentability”\(^{174}\) including the much obfuscating “*ordre public* and morality”\(^{175}\) yardstick. Interestingly, Correa strongly argued for rejecting “patentability of genes, claimed in various forms, including human genes, as found in nature, even if isolated or purified”\(^{176}\). Another such work, albeit from developing countries’ perspective, namely, Watal’s “Intellectual Property Rights in the WTO and Developing Countries” became, for researcher, indispensable. It focussed, *inter-alia*, on “TRIPS and Biotechnology”\(^{177}\). It also highlighted “a major concern” namely “the blocking of research tools by patents” which obstructs further inventing\(^{178}\). Watal also says that “the relationship between IPRs and biodiversity emanates from the concept of bioprospecting”\(^{179}\) and says that “developing countries are demanding that when profits are gained through bioprospecting the benefits and technologies developed should be shared with the original suppliers of genetic resources or traditional knowledge”\(^{180}\). Interestingly, both books emphasize on how “the issue of patentability and exclusions thereto was one of the main areas of controversy in TRIPS negotiations”\(^{181}\). Indeed, the balance therein is precarious.

About biopiracy, in the work titled, “The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing”, ten-Kate and Laird, highlight how “molecular biologists developing transgenic organisms require access to genetic

\(^{173}\) *Supra* 40 at 271-281

\(^{174}\) See, *id.* at 287-294

\(^{175}\) See, *id.* at 287-291

\(^{176}\) *Id.* at 273

\(^{177}\) *Supra* 2 at 131-170.

\(^{178}\) *Id.* at 168

\(^{179}\) *Id.* at 170

\(^{180}\) *Id.* at 171

\(^{181}\) *Supra* 40 at 271
resources”. Within pharmaceuticals” context, they highlight “the role and value of natural product-derived drugs”. They emphasise that “natural products have long formed an integral part of drug discovery” and give numerous examples thereof. Interestingly, both Jonathan Curci and Jim Chen, explore the obfuscating “Biodiversity and Biotechnology” relationship. Curci’s brilliant article proffers “interpretative suggestions to reconcile TRIPS and CBD in a mutually supportive manner that increases the confidence of genetic resource provider countries through increased transparency in the intellectual property (IP) system”. He analyses both “the impact of TRIPS on the access to genetic resources” and, more importantly for us, “on the protection of traditional knowledge”.

Suriender Verma’s many articles embracing both “genetic resources” and “traditional knowledge” also proved illuminating. In the former, she argues that “the Biodiversity Convention” no doubt “provides mechanisms for the successful exploitation of the genetic resources as well as for an adequate reward for the access to those resources. But the laudable objectives of the Convention are not easily achievable”. She comments that “the United States and the European countries are incensed with the provisions of the Convention and their industry is concerned that it

183 Id. at 40-45
184 Id. at 40
187 Supra 185 at 4
188 See, id. at 18-19
189 See, id. at 19-22
will lead to an erosion of IPRs when they have to share technology on a *quid pro quo* basis”193. Another author stressing that “between prospecting and applying technology, importance of biogenetic resources cannot be disputed” is Ragavan194. He then evaluates “instruments that developing countries can successfully use to create returns on local biodiversity resources”195. Biodiversity and “impact of biotechnological developments” thereon, is explored also, by others196.

Coming to TK, Dutfield197 investigates painstakingly “meaning of the term traditional knowledge and estimates the importance of TK to the global economy”. He also investigates “Why not protect TK through patents, copyrights or trade secrets?”198 He also views “traditional knowledge” as a “biodiplomacy”199 issue, asking whether “developing countries are using this issue to introduce new IPR standards on TK into TRIPS?” or “are they simply using this issue either to obtain non TRIPS-related trade concessions or to justify implementing an agreement they dislike as slowly as they can get away with?”200 This is not a holistic view. TK is not just “biodiplomacy” as we show later. Likewise, Daniel Gervais201 also explores “the notion of traditional knowledge” and examines “to what extent traditional knowledge is commensurate with intellectual property”202. He acknowledges that “there is a significant pressure to

193 Id. at 211
194 Srividhya Ragavan, “New paradigms for protection of biodiversity” 13 *JIPR* 514-522 (Sep. 2008), 515
195 Id. at 514
198 See, *id.* at 248-260
199 *Id.* at 260
200 *Id.* at 274
202 *Id.* at 139
integrate traditional knowledge and the related issue of biodiversity protection in the WTO set of rules” but holds that “I do not believe that integrating a full sui generis right (in TRIPS or otherwise) is possible or even desirable in the current context”.

Verma goes further and examines “why protect TK?”204 She laboriously enlists all “International Initiatives for Protection of Traditional Knowledge” till 2004205. She makes two conclusions. First, “national measures hold the key for the protection of TK”206 and that “looking at the complexity of the subject matter, a single, all-encompassing sui generis instrument would not be able to address all the concerns of the holders of traditional knowledge”207. We partly disagree with former. Similar approaches are taken by Ragavan208 and others209. None of these, however, solely emphasise on so-called “Traditional Medicinal Knowledge” (or “TMK”) with which we engage. Also, the afore-quoted “disclosure of origin” or “source issue” is not extensively addressed by Ragavan or Verma.

The Review here is illustrative, non-exhaustive panorama of materials. Numerous other authors via commentaries/articles etc. have engaged with or dwelled on multitudinous obfuscating quandaries or concerns embraced by us. Clearly, though, Indian perspectives on so-called “anticommons” problem; on TMK; comparative “patent-eligibility” yardsticks etc. need, in this dilemmatic and perpetually-evolving area, more exploration. We, therefore, study that in ensuing chapters.

203 Id. at 166
204 Supra 191 at 767-771
205 See, id. at 771-785
206 Id. at 803
207 Id. at 805
208 Srividhya Ragavan, “Protection of Traditional Knowledge” 2(2) Minn. IPLR 1 (2001)
1.3. STATEMENT OF PROBLEM

Pharma-Bio innovations, in current times, are briskly altering medical landscape. Despite immense promise, these do invariably evoke or raise multitudinous quandaries or dilemmas, particularly in patenting context. These so-called “biological inventions” get acutely dilemmatic as regards eligibility or desirability of allowing monopolies thereon and create or raise patentability conundrums. Equally, monopolizing early-stage or foundational techniques and technologies can, unfortunately, create the so-called “anticommons problem” or obstruct further innovation. This is undesirable. Apprehensions arise also with respect to using raw bio-materials invariably necessitated for some bio-innovations, and how patent system could be tweaked or adapted/modified to forestall biopiracy thereof. In view of such urgent dilemmas or quandaries, it is apposite to assess suitability or preparedness of Indian patent system in facing or resolving aforesaid quandaries or dilemmas and to see what it might learn or imbibe from US/EPC practices.

1.4. SCOPE

Biotechnology, as our chapter 2 explains, is utilised or employed in several distinct industries/sectors. Amongst those, researcher’s focus is solely: pharmaceuticals. Hence, our work is on pharma-biotech (pharma-bio). There exist multitudinous problems or perspectives or vantage points of analysing or studying pharma-bio, e.g. regulatory mechanisms or price control. But we are, herein, solely restricted to monopolisation or patenting thereof. Therefore, our work is on pharma-bio-patents (or pharma-bio-patenting).

Within above, we confine or focus on conundrums or dilemmas at only pre-patent-grant (or pre-grant) stage, i.e. its desirability/eligibility (e.g. what is, or is not, an
“invention”; also termed “subject matter”) and on criterion or yardstick(s) thereof (e.g. “inventive step” etc.). Within latter, i.e., criterion, we include also the so-called “disclosure requirements” or written specification requirement since, commentators opine that “requirements in India are: (1) Patentable Subject Matter; (2) Industrial Applicability; (3) Novelty; (4) Inventive Step; and (5) Specification” and that “non-satisfaction of even one of the requirements will make an invention ineligible for a patent grant”\(^{210}\). Also, afore-mentioned “anticommons problem” is studied. Also, biopiracy and so-called “Access and Benefit Sharing” or “ABS” modalities in only so-far as these engage with or are interlinked/intertwined with patenting, are also studied.

Clarifying further, aspects like plant variety laws, e.g. UPOV or Indian Act titled, “The Protection of Plant Varieties and Farmers’ Rights Act, 2001” are not covered, being pertaining to agri-bio. Lastly, post-grant aspects- illustratively- infringement, modality of “compulsory licenses” etc. lie beyond our ambit, being identical or commonly dilemmatic across all industries/areas. Voluminous literature exists on them, and they can all, undeniably, be scope/ambit of distinct works/analysis.

1.5. ISSUES

The issues or conundrums, we shall be engaging with herein are as follows,

1. Bio-patenting gets incessantly obfuscated by multifarious and myriad religious and moral quandaries or dilemmas. These pertain, as elaborated in our work, to, \textit{inter-alia}, arguments like “commodification of life”; “Humans playing God”; “Environmental and social impact of biotechnology” etc. Patent system, incredibly, turns into a very broad, all encompassing dexterous forum for

\(^{210}\) \textit{Supra} 159 at 17
engaging with or addressing these multi-hued, varied objections or arguments.

But should this system be used or rather stretched to accommodate or balance such varied objections, and to what extent?

2. Within India, regarding stem cell and genetic research’s monopolisation, one dilemma or quandary subsists that do we tweak/adapt or improve upon our eligibility yardsticks to accommodate or suit current happenings or advancements. Another related dilemma or quandary, regarding monopolising human’s genetic materials, remains, namely: are IPO’s practices in consonance or synced with actual law and policy.

3. If too many primary or foundational techniques/technologies—on whom, invariably, making or evolution of plethora of much advanced or much complicated techniques/technologies depends—get monopolised then so-called “follow-on” or advanced inventing will, unfortunately, get blocked or hindered (called “anticommons problem”). Resolving this is indeed crucial and we need to evolve appropriate remedies for this predicament.

4. Coming to biopiracy, patenting being at core of this crisis or issue, measures or mechanisms to foil or rather obliterate it must exist in, or be supported by, patent system. Interestingly, India does possess several such methodologies or mechanisms. But are those proving sufficient? And, how we resolve or address this predicament internationally, since bio-stealing, logically, happens not in same country but cross-jurisdictionally.

1.6. OBJECTIVES

1. To analyse, in pharma-bio-patents’ context, the multi-hued, multitudinous dilemmas and conundrums.
2. To assess, in above context, current Indian patentability yardsticks and eligibility hurdles and to proffer, if required, any changes or alterations thereto. For this, norms and perspectives/practices of prominent jurisdictions are also looked into.

3. To assess further, in pharma-bio-patents’ context, workability of “Open-Source” modality and proffer modification thereto.

4. To analyse how patent system engages with biopiracy, and how former can be tweaked or adapted to foil or avert the latter.

1.7. HYPOTHESIS

In light of above, we formulate, for our research, the following hypothesis: -

Provisions of Indian Patent Law are insufficient to deal with patentability and eligibility conundrums arising due to biotechnology innovations in the pharmaceutical industry.

Meaning of terms: For us, “patentability” encompasses also the “disclosure” or specification requirement.

1.8. RESEARCH METHODOLOGY

Researcher’s work is doctrinal. Here, Pharma-bio-patenting is analysed, from comparative view of, majorly, U.S., EPC, and Indian perspectives or practices. Emphasis, naturally, is on last. Elaborate frameworks thereof were described above.

This endeavour, we humbly hope, enables researcher to comprehend and appreciate how multifarious conundrums or dilemmas are negotiated, circumvented or engaged with elsewhere, and utilise that to carve out or proffer workable solution for India.
Also, other jurisdictional practices/perspectives, e.g. Canadian and U.K., will also, where relevant, be seen.

Interestingly, we shall be studying/analysing, extensively, granted patents/applications, from online official databases, titled, “U.S.P.T.O. Patent Full-Text and Image Database” (“PatFT”) and the “U.S.P.T.O. Patent Application Full-Text and Image Database” (“AppFT”), the EPO’s “European Patent Register” and IPO’s “Indian Patent Advanced Search System” or “inPASS”. Moreover, judgements from EPO, U.S., U.K., Canada etc. are much illuminating and will be, invariably, extensively engaged with. TRIPS is, unsurprisingly, core of our endeavour, being, in our ambit’s context, the “common” and “uniform” yardstick-setting ubiquitous treaty. Likewise, CBD\[211\], CBD’s protocols, other relevant instruments etc. will all be engaged with. The WIPO materials also guide us. Plethora of literature, partly highlighted in Review, also is our guiding force and is accessed from, inter-alia, online databases, e.g. “HeinOnline” etc. and from libraries. Interestingly, being a lawyer-researcher, our understanding and knowledge of biotech.’s and pharma-bio’s nuances required extensive engagement with books thereon.

1.9. CHAPTERIZATION

In light of the afore-discussed, researcher’s work is divided into and comprises of the following chapters,

Chapter One, titled, “Introduction” contextualizes our work and provides groundwork for ensuing chapters. It comprises, inter-alia, objectives, methodology and our hypothesis. Also, we present, herein, elaboration of our problem. We provide, in context of so-called “biological inventions”, elementary details and glimpses of the

\[211\] Convention on Biological Diversity, 1992
obfuscating multi-hued conundrums. Applicable European, U.S., and Indian legal framework is also presented.

Chapter Two titled, “Concepts of Patents & Pharma-Biotechnology” focuses on, *inter-alia*, biotech.’s basics. Uses, definitions, the concept of so-called “old and new biotechnologies”, constituent techniques/technologies therein, etc. are, *inter-alia*, elaborated here. We elaborate also on various techniques/technologies, e.g. Genes and “recombinant DNA”, antibiotics, Embryonic Stem Cells (“ESCs”), Vaccines etc. Also, patent law’s basics are discussed, including TRIPS.

Chapter Three is titled “Patentability & Eligibility Criteria: Comparative Perspective”. Firstly, patentability yardsticks, from TRIPS, EPC, U.S. and Indian perspective, including tests thereof, are studied. Then, from bio-patenting perspective, certain relevant and critical eligibility norms are, likewise, studied. Here, we engage with, *inter-alia*, so-called “Product of Nature” concept, the “*ordre public* or morality” hurdles, evergreening issues etc. Some suggestions are also proffered. The discussion or analysis herein is bedrock for chapters 4 and 5.

Chapter Four titled, “From Microbes to Xenotransplants: Analyzing the Bio-Patenting Conundrums” is devoted to how eligibility and grant criterion are evolved and applied for various bio-innovations. We start with GM-microbes, moving onto other transgenic-beings including humans. We engage with cloning and xenotransplantation. U.S., EPC and Indian perspectives are viewed. The chapter presents the varied fears, polarisations, oppositions, arguments and dilemmas across jurisdictions, in context of afore-mentioned innovations and monopolisation thereof.

Chapter Five is titled, “Patenting Human Biological Material & the Anti-Commons Conundrum: Challenges & Possible Solutions”. Stem-Cell patenting is first discussed.
Core dilemmas and eligibility conundrums thereof are assessed. We also examine how scientific advancements obliterate some dilemmas or fears therein. As usual, U.S., EPC and Indian perspectives are engaged with. Next, researcher engages, in context of genetic research, with so-called “isolated and purified genes”, ESTs, SNPs, gene-testing, etc. Lastly, we turn gaze to the “anticommons problem” or how downstream innovation can, unfortunately and counter-productively, be obstructed or hindered by excessive privatization or locking-up of foundational or basic inventions and evaluate how something called “Open Source” might be an antidote thereof.

Chapter Six, titled, “Specification, Deposit Requirements & Disclosing the Geographical Origin: Combating Biopiracy through Patent Law” engages with, inter-alia, specifications and biopiracy. The former, also called “disclosure requirement” is discussed in detail, including components or parts thereof. This “disclosure requirement” might be modified or adapted to require the so-labelled “disclosure of source” for foiling biopiracy. We discuss also, inter-alia, bio-resources and “traditional medicinal knowledge” (or “TMK”) and value thereof. We view also, in our context, interplay of patenting system and biodiversity laws.

Lastly Chapter Seven, titled “Conclusions and Recommendations”, offers this work’s conclusions. Based thereupon, discrete recommendations also get proffered. The same, researcher humbly hopes, resolve or iron-out the myriad highlighted quandaries or dilemmas in studied area, imparting in this obfuscating field, much necessitated clarity.