CHAPTER 2

CONCEPTS OF PATENTS & PHARMA-BIOTECHNOLOGY

After demarcating, in chapter 1, contours of our study, and having described, *inter-alia*, patent’s meaning and also breadth of rights therein, we now emphasize, as said in previous chapter, on certain other aspects pertaining to patents. Moreover, importantly, we also describe, thereafter, relevant tools, pharma-bio-innovations, and conceptual scientific matrix of pharma-bio and, more generally, biotech. Based on this, in ensuing chapters, patenting feasibilities and other dilemmas, highlighted in our chapter 1, shall be engaged with in context of these pharma-bio-innovations. Therefore, our description herein clarifies pharma-bio terminologies, science thereof, and contextualizes ensuing patenting deliberations. But before that, researcher engages with, *inter-alia*, yardsticks and justifications for patents.

2.1. PATENTS: THE YARDSTICKS OF MONOPOLISATION

We mentioned in chapter 1 that TRIPS imposes “patents” to “be available for any invention, whether products or processes, in all fields of technology”\(^1\). This means “any invention” in any field- pharmaceutical or biotech or even hybrid fields like pharma-bio, deserves protection. But this protection or rather monopoly is not doled out indiscriminately. There are concrete prerequisites or yardsticks thereof. The afore-quoted clause further says “provided that they are new, involve an inventive step and are capable of industrial application”\(^2\). These three constitute historical or conventional patentability troika. Moreover, laying another yardstick, TRIPS requires “an applicant for a patent” to “disclose the invention in a manner sufficiently clear

\(^1\) TRIPS, 1994, Art. 27.1
and complete for the invention to be carried out by a person skilled in the art\textsuperscript{3}. This is generally labelled “enabling disclosure” or “disclosure”. It is called “one of the pillars of the patent system” and the “very reason why patents are issued”\textsuperscript{4}. We engage with it in our chapter 6. We consider “disclosure”, as mentioned in chapter 1, as very much the fourth parameter or yardstick for grant. Also, there is something called “subject-matter”, i.e. something which is “eligible to get a patent”\textsuperscript{5}. These five mentioned parameters or yardsticks universally and cumulatively control or demarcate the contours or boundaries of monopolisation. Illustratively, within India, “grant of a patent is the cumulative effect of all the requirements and non-satisfaction of even one of the requirements will make an invention ineligible for a patent grant”\textsuperscript{6}. These Indian requirements include, existence of “invention”\textsuperscript{7} which is “a new product or process involving an inventive step and capable of industrial application”\textsuperscript{8}, and lastly, that “a complete specification shall be filed”\textsuperscript{9}. The last one, i.e. “complete specification” inter-alia, must exhibit “enabling disclosure”\textsuperscript{10}. We deal, elaborately and from a comparative perspective, with relevant “subject-matter” conditions and the conventional troika as applicable to pharma-bio, in the next chapter.

It must be added that during “Examination of application”\textsuperscript{11}, in IPO, aforesaid parameters are stringently assessed. During such examination, the IPO examiner assesses “whether the application and the specification and other documents relating

\textsuperscript{3} Id. Art. 29
\textsuperscript{4} Carlos Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement 300 (OUP, New York, 2007)
\textsuperscript{5} Kalyan Kankanala, Arun Narasani et.al., Indian Patent Law and Practice 17 (OUP, New Delhi, 2010)
\textsuperscript{6} Ibid.
\textsuperscript{7} The Patents Act, 1970 (Act 39 of 1970), s. 3. It demarcates “what are not inventions”. Everything else, therefore, is an “invention”.
\textsuperscript{8} Id. s. 2(j)
\textsuperscript{9} Id. s. 9
\textsuperscript{10} See, id. s. 10(4)(a) wherein “every complete specification shall fully and particularly describe the invention and its operation and use and the method by which it is to be performed”.
\textsuperscript{11} Id. s. 12, this is the clause’s heading.
thereeto are in accordance with the requirements of this Act and of any rules made thereunder” and also “whether there is any lawful ground of objection to the grant of the patent”\textsuperscript{12}. Also, in this context, patent “shall be granted” only when, \textit{inter-alia}, it “has been found to be in order for grant of the patent”\textsuperscript{13} and also when “the application has not been found to be in contravention of any of the provisions of this Act”\textsuperscript{14}. The existence, within patent landscape, of such afore-mentioned and stringently observed parameters or yardsticks is due to two factors. These are, determining “on what basis does society rationalise the award of a temporary monopoly to the inventor for their invention” and also “how large a bundle of rights should the inventor receive, i.e. how broad should the monopoly granted actually be”\textsuperscript{15}. The first aspect, i.e. the “basis” to “rationalise the award of a temporary monopoly” is about justifications. It is said that,

“The patent system is perpetuated on the basis that there has ever been and will ever be patents; like them or not, they are part of the scenery. However, when considering modern questions about the breadth of the system, or the scope of grants themselves, it is informative to return to first principles and consider why it is that we provide protection in the first place”\textsuperscript{16}.

We, therefore, now look at justifications, or why this aforesaid “temporary monopoly to the inventor” exists when monopolies are abhorred.

2.2. PATENTS: THE JUSTIFICATIONS

\textsuperscript{12} Id. ss. 12(1)(a) and 12(1)(b)  
\textsuperscript{13} Id. s. 43(1) first para  
\textsuperscript{14} Id. s. 43(1)(b)  
\textsuperscript{15} Matthew Fisher, \textit{Fundamentals of Patent Law: Interpretation and Scope of Protection} 58 (Mohan Law, N. Delhi, 1\textsuperscript{st} Ind. Reprint, 2010)  
\textsuperscript{16} Id. at 59
Justifications described herein, we shall see, are invariably and perpetually revisited or tested in several decisions related to so-called “biological inventions”. It must be noted also that most rationales are inter-related or intertwined. Our summarization here will help understand whether jurisprudence affords or allows for excessive privatization or protection, as is pushed for by “pro-patent” lobby or if the system promotes precarious and delicate adjustments of interests.

1. The Natural Rights Justification: One justification is that inventors/innovators possess “natural rights” in “products of their mental labour” or to put differently, everyone has a “natural property right in their ideas”. This being so, it is easy and understandable to then accord exclusivity to commercialize such aforesaid “products of mental labour”. This rationale comes from what is called, “Lockean Labour theory of property rights” which Drahos neatly summarized as below,

“(1) God has given the world to people in common. (2) Every person has a property in his own person. (3) A person’s labour belongs to him. (4) Whenever a person mixes his labour with something in the commons he thereby makes it his property. (5) The right of property is conditional upon a person leaving in the commons enough and as good for the other commoners. (6) A

\[17\] The notion or concept of “natural rights” stems from philosophy of, *inter-alia*, “Hobbes, Rousseau, and John Locke”. In summary, they argued that “state of nature” preceded human governments. Illustratively, for Locke, this “state of nature”, had a “law of nature” and all humans were free and equal therein. Consequent to some problems, humans abandoned “state of nature” and entered “social contract” thus creating government/state. The “social contract” had a cost, i.e., forfeiture of some freedoms. But humans nevertheless retained few “inalienable natural rights” which no state could deprive them of. The most prominent “inalienable natural rights” are the famed troika of “life, liberty and property”, See, Bertrand Russell, *History of Western Philosophy* 531-542, 584-674 (Routledge, London, 2003). See, also, W. Friedman, *Legal Theory* (Universal, New Delhi, 5th Ed., 2003)


\[19\] *Supra* 15 at 66
person cannot take more out of the commons than they can use to advantage.”\textsuperscript{20}

It is also maintained that “property rights are a just reward for the industrious”\textsuperscript{21}. This implied that in context of “intellectual labour”, humans consequently possess “natural right to their creation”\textsuperscript{22}. However, a criticism is that, if patent or for that matter IP is such a “natural right” why isn’t it ever-lasting? Further, one author opines that,

“If property in ideas is a natural right, there is little logical basis for that right to be limited to a term of years, rather it should be perpetual. In addition, it does not sit comfortably with the concept of knowledge as a non-exhaustible commodity, nor with any criteria of patentability that the inventor must satisfy before this property is acknowledged. Further, it suggests that the scope of the right awarded should be tied to the actual effort, or degree of labour” … “Lockean approach would not justify the provision of an exclusive monopoly where both copying and independent creation are similarly prohibited.”\textsuperscript{23}

Also, irrespective of quantum of afore-mentioned “intellectual labour”, the monopoly’s duration is identical for all. Thus, this theory has not been too prominent nor satisfactory and has been “largely shunned by British and American historians, lawyers and economists” who subscribe to it no or minimal role “in the evolution of a modern Anglo-American system of patents”\textsuperscript{24}.

\textsuperscript{20} P. Drahos, \textit{A Philosophy of Intellectual Property} 43 (Ashgate, Surrey, 1996)
\textsuperscript{21} \textit{Id.} at 44
\textsuperscript{22} \textit{Supra} 15 at 67
\textsuperscript{23} \textit{Id.} at 68
\textsuperscript{24} \textit{Id.} at 67
2. The “Reward” Justification: Perhaps the most simplistic, it requires that “inventor’s contribution should be recognized by the grant of reward”\textsuperscript{25}. Also, it is argued that “the inventor deserved reward and the patent system was the most economical method of providing it”\textsuperscript{26}. This is because prizes or “monetary bonuses” whereby discretion of awarding same lies with other humans, might lead to “partiality or even corruption”\textsuperscript{27}. It is said that,

“The grant of the monopoly will automatically secure to an inventor a reward which is commensurate with the value of his invention. In theory, if the invention is good, the inventor should be able to exploit or sell his patent and thereby make a profit. If the invention is useless, he would receive nothing.”\textsuperscript{28}

However, it’s not true every time because “in some cases the reward which an inventor obtains for his invention might be out of all proportion to the benefit conferred on the general public”\textsuperscript{29}. Also, if motive was to “reward”, disclosure wouldn’t be mandatory, but it is. This “reward” is also linked to “Incentive to Innovate” justification.

3. The “Incentive to Innovate” Justification: It’s an oft-proffered economic rationale. It means “that in order for inventive activity to be maximised it is necessary to offer specific enticement as well”\textsuperscript{30}. Inventing is considered arduous, long-drawn, full-of-failures, skill-intensive, patience-demanding endeavour. But once over, then sans protection or aforesaid “specific enticement”, the unscrupulous can imitate

\textsuperscript{25} Supra 18 \\
\textsuperscript{26} Supra 15 at 70 \\
\textsuperscript{27} Id. at 72 \\
\textsuperscript{28} Justice Ayyangar, “Report on the Revision of the Patents Law” 12 (Sep. 1959) \\
\textsuperscript{29} Ibid. \\
\textsuperscript{30} Supra 15 at 73
innovations. Moreover, copying or imitating is relatively brisk, relatively easier and also relatively cheaper. Hence, imitations can be sold as “low-cost” alternatives. But, damagingly, this jeopardizes innovator’s capability to profit or to recoup her costs. Consequentially, sans “specific enticement”, innovating is disincentivized, causing “sub-optimal levels of invention” which is detrimental to society. The best “specific enticement” modality is patents. Hence, “patents encourage new inventions by preventing appropriation by competitors, and we accept the deadweight loss caused by the exclusive patent grant” as price for “an increase in innovation”.

But commentators opine that “recent research has called into question” this “effectiveness of patents as a tool for stimulating innovation” and that “empirical support for any of these innovation theories is mixed, with a number of surveys indicating that outside the drug industry, patents are a less effective means of appropriating market exclusivity than secrecy or lead time”. Interestingly, Ayyangar Report had sagely cautioned that,

“The advantages accruing to a nation’s economy from rewarding inventors with the grant of exclusive privileges for a limited time are dependent on two main factors: (1) The country must be technologically advanced to maintain the rate of invention which is brought forth by the promise of the reward. This in turn would be dependent upon (a) the degree of diffusion of scientific and technological education and the number of persons reaching high proficiency by such education; (b) the massive industrial

---

31 Id. at 75
32 Ibid.
33 Lisa Ouellette, “Do Patents Disclose Useful Information?” 25(2) HJLT 531-593 (Spring, 2012), 540-541
34 Id. at 542
35 Id. at 541
production which would absorb the products of education and
develop the instinct for research” ... “(c) the amount of
speculative capital” ... “being risked in investment in new
ventures” ... “(2) The patented invention must be worked in the
country which grants the patents.”

Clearly, therefore, “Incentive to Innovate” is not an absolute truth. Other afore-quoted factors, and not just “specific enticement” of patents, are also needed to enhance or propel innovating.

4. The “Contract to Disclose” Justification: Patent is viewed as the “quid pro quo” to innovator for her “disclosure to the public of the invention and the manner of its working”

This is also related to “public benefit” accruing from patents and is called the “Information Function of the patent system”. The monopoly isn’t perpetual, and post expiry thereof, anyway, the innovation shall fall in so-called “public domain” whereupon it is free or open. Also, “patents act as incentives” given “to disclose information that might otherwise have remained secret”. Therefore, U.S. judiciary noted that,

“The primary purpose of our patent system is not reward of the individual but the advancement of the arts and sciences. Its inducement is directed to disclosure of advances of knowledge

---

36 Supra 28 at 13
37 P. Narayanan, Patent Law 3 (ELH, Kolkata, 4th Edn., 2010)
38 Supra 18
39 Ibid.
40 Ibid.
which will be beneficial to society; it is not a certificate of merit but an incentive to disclosure”.\(^{41}\)

As corollary, such “disclosure” also prevents “wasteful duplication of effort”\(^{42}\) by those others who sans such “disclosure” would strive, independently, towards identical or similar things.

5. The Developmental Justification: It is said that “patent systems are not created in the interest of the inventor but in the interest of national economy” and that they “were needed to encourage invention and afford increased opportunity for industrial development and achieving gainful and diversified employment.”\(^{43}\) Also, generally for IP, TRIPS says that,

“The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”\(^{44}\).

For us, crucial aspect is “social and economic welfare”. Also, commentators say that although “Article 7 refers to protection and enforcement of intellectual property rights in general; it only deals with innovation and technology. It thus focuses on certain types of IPR, such as patents, some categories of trade secrets, and integrated circuits’

\(^{41}\) *Sinclair & Carroll Co. v. Interchemical Corp.* 325 US 327 (S.Ct., 1945), 330-331
\(^{43}\) Supra 28 at 11-12
\(^{44}\) Supra 1 Art. 7, titled, “Objectives”
layout designs”. Hence, rephrasing it, “the protection and enforcement of” patents “should” be “in a manner conducive to social and economic welfare”. Hence, patents must operate to enhance “social and economic welfare” or, we submit humbly, to enhance development. It also points towards attainment of “higher social values”.

After surveying the above justifications, clearly, innovators’ interest or “reward” is simply not the prominent rationale. Indeed, thrust is on aforesaid “social and economic welfare” and also the “disclosure” aspect with perhaps some role for “incentive to innovate” justification also. Clearly, there is a precarious and delicate adjustment, within patenting rubric, solely necessitated to ensure afore-quoted “balance of rights and obligations”, and emphasis is equally on society, its betterment, and not solely on innovator. We now assess, before turning our gaze to pharma-bio, one last patents’ aspect, i.e. international harmonization.

2.3. PATENTS: INTERNATIONAL HARMONIZATION EFFORTS

Patented innovations are inextricably intertwined to international trade. Harmonisation of patenting system, therefore, was critical. Different jurisdictional yardsticks, parameters and technicalities are obfuscating, frustrating, and tedious for innovators or applicants and also impede free trading. Hence, unification or harmonisation was paramount need. Interestingly, it occurred not sans conflict. Also, harmonisation isn’t absolute and flexibilities, reflecting jurisdictional needs, are carved out. We engage with five major harmonizing efforts, i.e. treaties. Interestingly, amongst all, the most epochal and influential is, undoubtedly, TRIPS.

\[45\] Supra 4 at 100
\[46\] Id. at 99. This insistence on “higher social values” is further manifested in Art. 8.1 titled “Principles” which says that, “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement”. See, supra 1 Art. 8.1
2.3.1. PARIS CONVENTION

The first impetus for synchronisation came during “an international exhibition of inventions held in 1873 at Vienna” which saw lukewarm response since “many foreign visitors were not willing to exhibit their inventions” being scared by “the inadequate legal protection offered to exhibited inventions”\(^47\). This led to “Congress of Vienna for Patent Reform” which, inter-alia, “urged governments to bring about an international understanding upon patent protection as soon as possible”\(^48\). After this, “an International Congress on Industrial Property was convened at Paris in 1878”\(^49\). Then, finally, “a diplomatic conference was convened in Paris in 1883, which ended with final approval and signature of the Paris Convention”\(^50\). Paris Convention has undergone multiple revisions\(^51\). Basically, “the countries to which this Convention applies constitute a Union for the protection of Industrial property”\(^52\). Also, it has two epochal principles, i.e., “National Treatment”\(^53\) and “Right of priority”\(^54\). The former is reiterated in TRIPS, and is, therefore, shortly discussed therein. The latter means that,

“Any person, who has duly filed an application for a patent” ...

“in one of the countries of the Union, or his successor in title, shall

---

\(^48\) Ibid.
\(^49\) Ibid.
\(^50\) Ibid.
\(^51\) The Convention Text says that it has been “revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967”. It has also been “amended on September 28, 1979”.
\(^52\) Paris Convention, 1883, Art. 1.1
\(^53\) Id. Art. 2
\(^54\) Id. Art. 4
enjoy, for purpose of filing in other countries, a right of priority during the periods hereinafter established”\textsuperscript{55}.

And thereupon,

“Consequently, any subsequent filing in any of the other countries of the Union before the expiration of the periods referred to above shall not be invalidated by reason of any acts accomplished in the interval, in particular, another filing, the publication or exploitation of the invention” ... “and such acts cannot give rise to any third-party right or any right of personal possession”\textsuperscript{56}.

For patents, “the period of priority” is fixed at “twelve months”\textsuperscript{57}. It also provides that “patents applied for in the countries of the Union” are “independent of patents for the same invention in other countries”\textsuperscript{58}. So, adverse decision (e.g. revocation) in one country does not automatically lead to or trigger the same in another. Also, it says that “inventor shall have the right to be mentioned as such in the patent”\textsuperscript{59}. Also, as specified in our chapter 1, it provides for “compulsory licenses”\textsuperscript{60}.

**2.3.2. PATENT COOPERATION TREATY**

Patents are territorial. Consequentially, applicants must file “individual patent applications for each country where protection is sought”\textsuperscript{61}. It means incurring “expenses for translation, patent attorneys in the various countries and payment of fees to the Patent Offices, all at a time when the applicant often does not know

\textsuperscript{55} Id. Art. 4(A)(1)
\textsuperscript{56} Id. Art. 4(B)
\textsuperscript{57} Id. Art. 4(C)(1)
\textsuperscript{58} Id. Art. 4bis
\textsuperscript{59} Id. Art. 4ter
\textsuperscript{60} Id. Art. 5(A)(2)
\textsuperscript{61} Supra 47 at 276
whether he is likely to obtain a patent”\(^{62}\). Also, “every single patent office with which an application is filed has to carry out a formal examination of every application”\(^{63}\). Hence, a remedy was needed “to reduce the duplication of the effort both for applicants and national Patent offices”\(^{64}\). The answer was treaty titled, “Patent Cooperation Treaty” (or PCT). It is an extremely significant “agreement for international cooperation in the field of patents”\(^{65}\). Interestingly, however, it “does not provide for the grant of international patents”\(^{66}\). All it achieves is “rationalization and cooperation with regard to the filing, searching and examination of patent applications and the dissemination of the technical information contained therein”\(^{67}\). Grant, therefore, still is prerogative of national offices. Also, “the PCT does not compete with but, in fact, complements the Paris Convention” and “is a special agreement under the Paris Convention open only to States which are already party to that Convention”\(^{68}\).

Briefly, PCT requires an “international application”\(^{69}\), filed in triplicate at “Receiving Office”\(^{70}\) (or R.O.) which “will check and process it”\(^{71}\). The “international application” must mention all “the Contracting state or states in which protection for the invention is desired”\(^{72}\). Such states are labelled “designated states”\(^{73}\). Now, “one

\(^{62}\) Ibid.
\(^{63}\) Ibid.
\(^{64}\) Id. at 277
\(^{65}\) Ibid.
\(^{66}\) Ibid.
\(^{67}\) Ibid.
\(^{68}\) Ibid.
\(^{69}\) PCT, 1970, Art. 2(vii). It means “an application filed under” PCT. It comprises of “a request, a description, one or more claims, one or more drawings (where required), and an abstract”, see, Art. 3(3). It must also “be in the prescribed language”, “comply with the prescribed physical requirements” and “comply with the prescribed requirement of unity of invention” and be accompanied with “prescribed fees”, see, Art. 3(4).
\(^{70}\) Id. Art. 2(xv). It is “the national office or the intergovernmental organization with which the international application has been filed”.
\(^{71}\) Id. Art. 10
\(^{72}\) Id. Art. 4(1)(ii)
\(^{73}\) Ibid.
copy of the international application shall be kept by the receiving office (home copy), one copy (record copy) shall be transmitted to the International Bureau, and another copy (search copy) shall be transmitted to the competent International Searching Authority”⁷⁴. The last, i.e. “International Searching Authority” simply conducts “international search”⁷⁵ with aim “to discover relevant prior art”⁷⁶. On basis of this, an “International Search Report” is “transmitted by the International Searching Authority to the applicant and the International Bureau”⁷⁷. The report allows “the applicant to calculate his chances of obtaining a patent in or for the countries designated in the international application”⁷⁸. Also, “the international bureau shall publish the international application”⁷⁹. Applicant may also seek an “International Preliminary Examination”⁸⁰. Its aim “is to formulate a preliminary and non-binding opinion on the question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), and to be industrially applicable”⁸¹. This assessment “provides the applicant with an even stronger basis for calculating his chance of obtaining a patent, and the elected offices have an even better basis for their decision whether to grant a patent”⁸². All this happens in the so-called “international phase”, post which, applications enter the territorial “national phase”⁸³. This was thus the PCT overview.

2.3.3. TRIPS & INDIA

⁷⁴ Id. Art. 12(1)
⁷⁵ Id. Art. 16
⁷⁶ Id. Art. 15(2)
⁷⁷ Id. Art. 18(2)
⁷⁸ Supra 47 at 280
⁷⁹ Supra 69 Art. 21
⁸⁰ Id. Art. 31(1)
⁸¹ Id. Art. 33(1)
⁸² Supra 47 at 281
⁸³ Id. at 278
We already have dealt, in our chapter 1 and also above, with various TRIPS clauses. Some other, critical ones are mentioned here. We, thereafter, also engage briefly with some historic grouses surrounding TRIPS.

**Paris becomes Mandatory:** It, *inter-alia*, mandated that, as regards patents, “members shall comply with” relevant articles “of the Paris Convention”\(^{84}\). Also, “nothing” in TRIPS “shall derogate from existing obligations that Members may have to each other under the Paris Convention”\(^{85}\). Hence, it, in effect, rendered that convention mandatory.

**The “National Treatment” and MFN clauses:** As mentioned above, it reiterates the “National Treatment” concept, and also lays “Most-Favoured-Nation Treatment” (or MFN). The former means that,

> “Each member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention”\(^{86}\).

Likewise, MFN means, subject to exemptions, that “any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members”\(^{87}\).

**The Exhaustion Rule:** It also says that, “subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of

---

\(^{84}\) *Supra* 1 Art. 2.1  
\(^{85}\) *Id.* Art. 2.2  
\(^{86}\) *Id.* Art. 3.1  
\(^{87}\) *Id.* Art. 4
intellectual property rights”88. Commentators opine that, thus, countries have “freedom to incorporate the principle of exhaustion of rights into their domestic law with a national, regional, or international reach”89. This exhaustion is based on “First-Sale” concept and means that “once a patented product has been sold anywhere under the authority of the patent holder, the patent holder has no right to prevent further sale or importation anywhere in the world”90. Simply, first sale exhausts holder’s IPRs.

**Patent Provisions, Controversies & Indian Amendments:** Part of demonization and maligning of TRIPS is attributable to patents. Indeed, it is maintained that “the issue of patentability and the exclusion thereto was one of the main areas of controversy in the TRIPS negotiations”91. This stems from afore-discussed “uniform” and “minimum” epochal mandate that “patents shall be available for any inventions, whether products or processes, in all fields of technology”92. This caused tectonic ramifications since “at the time” allegedly “fifty countries did not confer patent protection on medicines, and in some cases, on other products such as food and beverages”93. India also gave no pharma-product monopolies. Serious fallout ensued from undoing such practices, e.g. crippling domestic generic industries, reducing so-called “access to medicines” due to increased costs etc. It is said that,

“It was quite evident from the outset” ... “extension of patentability, particularly to pharmaceuticals, in those countries that did not recognize it, was a major objective of the proponents of GATT disciplines on intellectual property. The very existence of

---

88 Id. Art. 6
89 Supra 4 at 79
91 Supra 4 at 271
92 Supra 1
93 Supra 4 at 271
the TRIPS Agreement can probably be attributed to the active lobbying of the pharmaceutical industry and its ability to convince the U.S. government to link intellectual property and trade matters⁹⁴.

In absence of product patents, earlier, India was “key supplier of low cost generic versions of drugs to other developing countries”⁹⁵. But this soon changed. Interestingly, “developing countries were given time period to make their patent law TRIPS compliant”⁹⁶. This was due to “Transitional Arrangements” wherein, firstly, “no member shall be obliged to apply the provisions of this” TRIPS “before the expiry of a general period of one year following the date of entry into force of the WTO Agreement”⁹⁷. This applies to all. Secondly, “a developing country member is entitled to delay for a further period of four years the date of application” of TRIPS, except for some clauses⁹⁸. Further, “to the extent that a developing country member is obliged by this” TRIPS “to extend product patent protection to areas of technology not so protectable in its territory” then “it may delay the application of the provisions on product patents of section 5 of part II to such areas of technology for an additional period of five years”⁹⁹. This amounted to, for India, time till 2005. Consequentially “several amendments”¹⁰⁰ got introduced, in three phases. Illustratively, in “1999”, firstly, “exclusive marketing rights (EMR) and mail box application” got “introduced”¹⁰¹. Details thereof are, from our perspective, immaterial. Next, in 2000, “term of patent” was “extended for 20 years from filing date” and “invention and

---

⁹⁴ Ibid.
⁹⁵ S. Arora and Rekha Chaturvedi, “Section 3(d): Implications and Key Concerns for Pharmaceutical Sector” 21 JIPR 16-26 (Jan., 2016), 17
⁹⁶ Id. at 16
⁹⁷ Supra 1 Art. 65(1)
⁹⁸ Id. Art. 65(2)
⁹⁹ Id. Art. 65(4)
¹⁰⁰ Supra 95 at 16
¹⁰¹ Ibid.
inventive step” got redefined\textsuperscript{102}. Also, changes saw “microorganism covered under patentable subject matter” and “incorporation of research exemption”\textsuperscript{103}. Lastly, in 2005, \textit{inter-alia} “product patent” got “introduced for invention in food, medicine and other drug substances”\textsuperscript{104}. Moving further, amongst other TRIPS articles, “disclosure of invention”\textsuperscript{105}, is, \textit{inter-alia}, dealt in our chapter 6. Also, “Rights Conferred”\textsuperscript{106}, “Term of Protection”\textsuperscript{107} and certain other aspects have been previously engaged in our chapter 1 and also in this chapter.

2.3.4. OTHER TREATIES

The treaty, titled “Patent Law Treaty” (or PLT, 2000) seeks to “harmonize and streamline formal procedures in respect of national and regional patent applications and patents”\textsuperscript{108}. It only “provides the maximum set of requirements which office of the contracting part may apply”\textsuperscript{109}. India is not member thereof. We, therefore, don’t engage with it elaborately. The fifth one is titled “Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purposes of patent procedure”. It has much relevance from our perspective, and we, therefore, extensively discuss it in our chapter 6. Now, having outlined various patenting aspects and basics, we move, as mentioned in beginning, to basics of pharma-bio.

2.4. BIOTECHNOLOGY: BREAKING TERMINOLOGICAL MYTHS

Before commencing with pharma-bio, we focus, firstly, on the broader, wider field, i.e. biotechnology (henceforth, biotech.). Curiously, numerous definitions or

\begin{thebibliography}{99}
\bibitem{102} Id. at 17
\bibitem{103} Ibid.
\bibitem{104} Ibid.
\bibitem{105} Supra 1 Art. 29
\bibitem{106} Id. Art. 28
\bibitem{107} Id. Art. 33
\bibitem{108} Supra 47 at 301
\bibitem{109} Ibid.
\end{thebibliography}
meanings are ascribed thereto. Most simplistically, it is “the use of living organisms to solve problems or make useful products”\(^\text{110}\). Also, it is defined as a “field that involves the use of biological systems or living organisms to manufacture products or develop processes that ultimately benefit humans”\(^\text{111}\). It is also described as “the manufacture of products by or from living organisms, usually involving bioprocessing”\(^\text{112}\). Interestingly, legal texts, such as the convention titled, “Convention on Biological Diversity” (henceforth, CBD) says that,

“Biotechnology means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.”\(^\text{113}\)

Our species has used aforesaid “biological systems, living organisms or derivatives thereof” for making “products or process” since ages. Indeed, it is said that,

“Biotechnology is not something new but represents a developing and expanding series of technologies dating back (in many cases) thousands of years, when humans first began unwittingly to use microbes to produce food and beverages, such as bread and beer, and to modify plants and animals through progressive selection for desired traits.”\(^\text{114}\)

It is further said that,


\(^{112}\) Ronald A. Rader, “(Re)defining biopharmaceutical” 26(7) *Nat.Biotec.* 743-751 (July, 2008), 744


\(^{114}\) John Smith, *Biotechnology* 4 (CUP, New York, 5th Edn., 2009)
“Our ancestors extended their use of living organisms to microorganisms around 8000 years ago, when they began to exploit bacteria, yeast or other fungi to convert grapes into wine, milk into yogurt and cheese, and grains into raised breads through the process of microbial fermentation. Human use and manipulation of microorganisms extend well beyond food fermentation. Virtually all antibiotics come from microbes” ... “certain vaccines are based on the use of live, but weakened, viruses or bacteria”\(^{115}\).

So naturally, it is asked that “if biotechnology is over 10,000 years old, what is it about today's biotechnology that sets it apart from ancient biotechnology?”\(^{116}\) Or, why something “10000 years old” turned dilemmatic or controversial or is suddenly evoking so much fear or conundrums now? It is due to “Modern Biotechnology”. This modern or “new biotechnology embraces all methods of genetic modification by recombinant DNA and cell fusion techniques together with the modern development of traditional biotechnological processes”\(^{117}\). The genesis of “modern biotechnology” is stated to be around “the 1960s and 1970s” when commentators say that “knowledge of cellular and molecular biology reached the point where scientists could begin to use and manipulate organisms at those levels”\(^{118}\). Hence, “new biotechnology” is defined as “the use of cells and biological molecules to solve problems or make useful products”\(^{119}\). It is also pointed that,

\(^{115}\) Supra 110
\(^{116}\) Ibid.
\(^{117}\) Supra 114 at 3
\(^{118}\) Supra 110 at 4
\(^{119}\) Ibid.
“It is unfortunate that the term biotechnology has become in some quarters, a substitute for genetic modification or genetic engineering. This originated in the USA many years ago to offset the activists who were demonising these new genetic procedures to the lay public. Using the term biotechnology” ... “was considered more friendly sounding” ... “In truth genetic modifications have been used by mankind for over 10,000 years to improve plants and animals by selective breeding. Only within the last 50 years has this process used new methods, such as polyploidisation, mutagenesis and X-rays, to achieve changes in genetic composition”\textsuperscript{120}.

Hence, two myths are dispelled. Biotech as aforesaid “is not something new”\textsuperscript{121} and, has very much been “an established industry before the impact of molecular genetics”\textsuperscript{122}. Secondly, it isn’t merely genetic engineering. Also, a distinction exists between- “classical” and “modern biotechnology”. The difference between these “classical” and “modern” demarcations is that earlier we “did not understand the mechanics underlying the life process” which we “wanted to control” and everything was “trial and error ventures”\textsuperscript{123} but now we can “alter precisely the genetic compositions of living organisms”\textsuperscript{124}. Examples of former, i.e., “classical biotechnology” also include, “herbal remedies and plant balms for treatment of wounds and ailments”\textsuperscript{125}. The latter, i.e. “modern biotechnology” enables exploitation of “biological systems at any level of complexity or organisation for useful purposes,

\textsuperscript{120} Supra 114 at 3
\textsuperscript{121} Id. at 4
\textsuperscript{123} Supra 110
\textsuperscript{124} Supra 114
\textsuperscript{125} Supra 111 at 10
from the level of molecules, tissues, organs to whole organisms”\textsuperscript{126} and includes stem cells, rDNA etc. Interestingly, legal texts define “modern biotechnology” as follows,

“The application of (a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acids into cells or organelles, or (b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection”\textsuperscript{127}.

The “New” biotechnology applications also include “genetic testing, and genetically modified organisms”\textsuperscript{128}. In context of afore-discussed “old” and “new biotechnology”, one author has opined that,

“Labelling biopharmaceuticals (and biotechnologies) as either old or new is arbitrary and unwieldy because much of what is considered new maybe old and vice versa. Recombinant proteins and mAbs are based on technologies that may now deserve to be considered old, invented in the 1970s and commercialised in the 1980s”\textsuperscript{129}.

We, consequentially, don’t follow “old” and “new” distinctions but follow, here, wider CBD definition combining and embracing both “classical” and “modern biotechnology”. Biotech is also considered “an interdisciplinary pursuit”\textsuperscript{130} and as a

\textsuperscript{126} D. Balasubramanian, C.F.A. Bryce et.al., Concepts in Biotechnology 1 (Uni. Press, Hyderabad, 2004)
\textsuperscript{127} Cartagena Protocol on Biosafety, 2000, Art. 3(i)
\textsuperscript{128} Supra 111 at 10
\textsuperscript{129} Supra 112 at 747
\textsuperscript{130} Supra 114 at 6
“science of integration”131 which draws from “molecular biology, genetics, human pathology, biochemistry, and microbiology”132. Also, it has been called “a collection of technologies”133. It, therefore, “is not a singular entity” and indeed is said to be “a set of enabling technologies used by a wide variety of industrial sectors”134. We now engage with some constituent concepts/techniques of biotech.

2.5. BIOTECHNOLOGY: CONCEPTS & TECHNOLOGIES

As said above, we describe, from our pharma-bio perspective, some foundational and frequently encountered concepts/technologies. These are common to entire biotech, and also many other techniques exist, but we focus on those most relevant for our perspective. We begin with genes.

2.5.1. GENETICS & GENES: THE VALUE OF “GENETIC INFORMATION”

Genetics is defined as “the study of heredity, the process by which characteristics are passed from parents to offspring so that all organisms, human beings included, resemble their ancestors”135. This passing of aforesaid “characteristics” occurs via genes. Genes, therefore, are “units of biological information” and “are also units of inheritance”136. Genes are, biologically, merely “a segment of DNA”137 and possess information needed “to make a protein”138. The DNA, itself, merely “holds genetic

---

131 Supra 111 at 13
132 Ibid.
133 Ibid.
134 Supra 110 at 5
135 Ibid.
137 Ibid. Brown elaborates that “genes of the parents are incorporated into the fertilized egg cell” during sexual reproduction and this implies that “the fertilized egg” has the “full complement of biological information that it needs in order to develop into a new living organism”. Clearly, the baby will have the “physical and biochemical characteristics from both its parents”.
information”139. It is perhaps, at most basic level, who we are. It is “one of the most essential components of life”140. Basically, it’s a nucleic acid. These acids “are macromolecules formed from repeating nucleotides”141. Both “Deoxyribonucleic acid (DNA)” and “Ribonucleic acid (RNA)” are such macromolecules142. Elegantly summing the science, U.S. Supreme Court said that,

“The human genome consists of approximately 22,000 genes packed into 23 pairs of chromosomes. Each gene is encoded as DNA which takes the shape of the familiar double helix that Doctors James Watson and Francis Crick first discovered in 1953. Each cross-bar in the DNA helix consists of two chemically joined nucleotides. The possible nucleotides are adenine (A), thymine (T), cytosine (C), and guanine (G), each of which binds naturally with another nucleotide, A pairs with T, C pairs with G” … “Sequences of DNA nucleotides contain the information necessary to create strings of amino acids, which in turn are used in the body to build proteins.”143

The afore-quoted “information necessary to create strings of amino acids” is called Genetic Code. It resides in “sequence of bases”144 or aforesaid “sequence of DNA nucleotides”. This, therefore, is DNA or gene’s use- “to preserve and express the genetic information”145. But how is “genetic information” communicated? It

---

139 Supra 111 at 33
140 Daniel M. Lorentzen, “Do these Genes Fit? The Gene as patentable subject matter” 60 Drake L.Rev. 933-966 (2012), 945
141 Supra 126 at 9
142 Ibid.
143 Assoc. for Molecular Pathology v. Myriad Genetics, 133 S.Ct. 2107(2013), 2111
144 Supra 126 at 57
145 Id. at 38
“involves two principal steps, known as transcription and translation”\textsuperscript{146}. From our legal perspective, details thereof are immaterial. Proteins so formed, interestingly, “provide organisms with their structure, their ability to move, and their ability to carry out biochemical reactions”\textsuperscript{147}. The overall importance of genes, therefore, is that, “The units of biological information contained in genes give rise to this multiplicity of function by encoding the amino acid sequences of all the proteins that a cell is able to make. In this way, genes are able to specify the biological characteristics of a living organism.”\textsuperscript{148}

What if an unusual or catastrophic alteration or fault arises in genes? What if so-called “genetic code” is corrupted or malfunctions? It might hamper protein’s formation. It is, indeed, said that, “The vast majority of human monogenic disorders are due to loss-of-function mutation that inactivates a particular gene. The protein coded by that gene is absent, or modified in some way that prevents its functioning correctly, and the resulting defect is manifested as the inherited disease.”\textsuperscript{149}

Now, if we grasp “the nature of mutation or mutations underlying a particular genetic disease”\textsuperscript{150}, we can find people who carry such “mutations”, vide genetic/diagnostic tests. Additionally, we may “replace the mutated gene with a non-defective

\textsuperscript{146} Supra 143
\textsuperscript{147} Supra 135 at 34
\textsuperscript{148} Id. at 34-35
\textsuperscript{149} Id. at 414
\textsuperscript{150} Supra 140 at 954
version”\textsuperscript{151}. This is Gene Therapy. This is why so-called “isolated and purified genes”, gene testing and research, and also patenting them is, as discussed in our chapter 5, so controversially lucrative.

### 2.5.2. FERMENTATION & rDNA

Fermentation is also called “bioprocess technology” and involves “the use of microorganisms for the production of foods such as cheeses, yoghurts, sauerkraut” and also “beverages such as beers” etc\textsuperscript{152}. Technically, it is process for converting “a carbohydrate such as sugar into an acid or an alcohol”\textsuperscript{153}. It is part of both “old and new biotechnology”\textsuperscript{154}.

**The rDNA**: The technology called “recombinant DNA technology” (or “rDNA”) is the soul of so-called “modern biotechnology”. It is also “widely used to create transgenic microorganisms, plants and animals”\textsuperscript{155}. So the GMOs (“genetically modified organisms”), we encounter in chapter 4, are made by this. These are nothing but organisms with so-called “foreign DNA”\textsuperscript{156}. And rDNA is most simplisticly a mixing of DNAs. It is also “popularly termed gene cloning or genetic engineering”\textsuperscript{157}. Hence, clearly this “genetic engineering” is only a subset of biotech. Interestingly, it is said that,

> “Genetic recombination, as occurs during normal sexual reproduction consists of the breakage and rejoining of the DNA molecules of the chromosomes, and is of fundamental importance

\textsuperscript{151} Supra 135 at 430  
\textsuperscript{152} Supra 114 at 49  
\textsuperscript{153} Supra 111 at 370  
\textsuperscript{154} Supra 114 at 49  
\textsuperscript{155} Id. at 40  
\textsuperscript{156} Id. at 37  
\textsuperscript{157} Id. at 35
to living organisms for the re-assortment of genetic material. Genetic manipulation has been performed for centuries by selective breeding of plants and animals"\(^{158}\).

But now, we, by doing this artificially, can recombine or mix, even species and create the non-natural. Hence, rDNA technology enables us to “isolate genes and to transfer them from one organism to another”\(^{159}\). Detailed mechanism thereof is beyond our ambit. It, however, involves using something called “enzymes”\(^{160}\). Firstly, “microbial enzymes called restriction enzymes, or strictly, restriction endonucleases” are used to “hydrolyze or cut DNA at specific places in the DNA sequence”\(^{161}\). Different species’ DNA so “cut” are then “joined together in vitro by the action of specific DNA ligases”\(^{162}\). In short, different species’ DNAs can be “cut” and later joined or recombined. And “when two pieces of DNA from different sources are joined together, the result is said to be recombinant DNA”\(^{163}\). Hence, rDNA occurs “when two DNAs of different origin are combined”\(^{164}\). We now move to industries or sectors utilising biotech, of which solely one is our ambit here, namely, pharma-bio.

2.6. BIOTECH’S APPLICATIONS: OVERVIEW OF SECTORS

Interestingly, biotech, as noted above, is not one industry but “has applications in different sectors, sometimes termed red (in pharmaceuticals), green (in agriculture) and white (in industry)”\(^{165}\). More specifically, it finds use “in a wide range of

\(^{158}\) Ibid.


\(^{160}\) These are defined as “natural proteins that catalyze chemical reactions”. See, R.B. Silverman, *The Organic Chemistry of Drug Design and Drug Action* 174 (Acad. Press, N. Delhi, 2\(^{nd}\) Indian Edn., 2004)

\(^{161}\) Supra 137 at 74

\(^{162}\) Supra 114 at 38

\(^{163}\) Supra 110 at 139

\(^{164}\) Lizabeth A. Allison, *Fundamental Molecular Biology* 181 (Blackwell, Oxford, 2007)

industrial sectors including health care and medicine, agriculture and forestry, fine and bulk chemical production, food technology, fuel and energy production, pollution control and resource recovery\textsuperscript{166}. Illustratively, GM-microbes are used in “pulp and paper manufacturing”\textsuperscript{167}. Also, reportedly, “a fat degrading enzyme”, has been produced from “genetically modified fungi”\textsuperscript{168}. Commentators also mention “use of microorganisms in preparing fibres such as flex and hemp” and for “deterioration of textiles, including cordage and ropes”\textsuperscript{169}.

Also, there exists a distinct branch named “Environmental Biotechnology” which “is the application of recognized biotechnology processes for the protection and restoration of the quality of the environment, especially with a long term perspective”\textsuperscript{170}. One of its constituents is “bioremediation” which is “a treatment technology which uses biological systems to catalyse the destruction or transformation of a large variety of classes of chemical, environmental pollutants”\textsuperscript{171}. As per FAO, it is “a process that uses living organisms to remove contaminants, pollutants or unwanted substances from soil or water”\textsuperscript{172}. It is said that “a further possibility of bioremediation is to genetically engineer microorganisms to be able to degrade organic pollutants that at present they are unable to”\textsuperscript{173}. Microorganisms are further “useful in enhanced recovery of metals, including uranium from low grade ores”, via a process called “bioleaching”\textsuperscript{174}.

\textsuperscript{166} Supra 114 at 14-15
\textsuperscript{167} H.S. Chawla, Introduction to Plant Biotechnology 513 (Oxford-IBH, N. Delhi, 3\textsuperscript{rd} Edn., 2011)
\textsuperscript{168} Ibid.
\textsuperscript{169} Supra 111 at 393
\textsuperscript{170} Supra 114 at 111
\textsuperscript{171} Supra 126 at 397
\textsuperscript{172} FAO, “Glossary of Biotechnology and Genetic Engineering” 31 (1999)
\textsuperscript{173} Supra 114 at 125
\textsuperscript{174} Supra 111 at 155
There is also something called “Agricultural Biotechnology”. This agri-bio is defined as “an advanced technology that allows plant breeders or farmers to make precise genetic changes in plants to impart beneficial traits which include size, yield, colour, taste, and appearance”\(^{175}\). Indeed “traditional breeding methods” always existed\(^{176}\). It is said that “early farmers dramatically changed the genetic make-up of crop plants long before the science of genetics was understood”\(^{177}\). However, “modern biotechnology” renders this much “more precise and selective”\(^{178}\). Detailed elaborations of these are not required. As pointed earlier, our ambit or perspective is neither aforesaid environmental biotech nor agri-bio, but it is pharma-bio, consequentially we now solely and elaborately engage with the same.

**2.7. PHARMA-BIOTECHNOLOGY**

As regards pharma-bio, it is said that “while dealing with diseases, applications of biotechnology include prevention, diagnosis, and cure of diseases”\(^{179}\). Illustratively, “biotechnology is useful in providing immunity against a disease through development of a vaccine and in diagnosis of a disease”\(^{180}\). Before elaborating these aspects, we clarify the term- “biopharmaceuticals”.

**Biopharmaceuticals:** It is said that “there is still considerable confusion over what is and what isn’t biopharmaceutical” and that “definitions of biopharmaceutical in common use vary greatly, ranging from those based on biological source and nature of products and their manufacture to those based purely on business models,

\[^{175}\textit{Id.} \text{ at 163}\]
\[^{176}\textit{Ibid.}\]
\[^{177}\textit{Ibid.}\]
\[^{178}\textit{Ibid.}\]
\[^{179}\textit{Supra} 111 \text{ at 267}\]
\[^{180}\textit{Ibid.}\]
perceptions and public relations”\textsuperscript{181}. Some authors “refer to human therapeutic products produced using biotechnology techniques” as biopharmaceuticals\textsuperscript{182}. And for such authors, biopharmaceuticals “generally have molecular weights of thousands or even tens of thousands of Daltons, and are thus considerably bigger than small molecule drugs”\textsuperscript{183}. Such authors then erroneously demarcate even “natural products, derived from compounds isolated from plants, animals or microorganisms” as drugs on basis of their “small molecular weight”\textsuperscript{184}.

Better definition however, is that “biopharmaceutical” is “a pharmaceutical inherently biological in nature and manufactured using biotechnology”\textsuperscript{185}. Also, a drug then is merely “a pharmaceutical inherently chemical (not biological) in nature and manufactured using chemical methods”\textsuperscript{186}. Another similar definition is that “biopharmaceuticals” are “similar to natural biological compounds found in the human body or they are fragments that mimic the active parts of natural compounds”\textsuperscript{187}. We follow herein these more wholesome definitions. Further, “drugs manufactured using enzymes and certain animal and plant derived natural products may” then be classified as “biopharmaceuticals”\textsuperscript{188}. The stress here is, rightly on “active parts” or “active agents”. Allegations of bio-stealing arising, \textit{inter-alia}, for such “animal and plant derived” biopharmaceuticals, we engage with, in our chapter 6. We now focus on other constituents of pharma-bio.

\textsuperscript{181} Supra 112 at 743
\textsuperscript{182} Kerry ten-Kate and S.A. Laird, \textit{The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit Sharing} 39 (Earthscan, London, 2000)
\textsuperscript{183} Id. at 40
\textsuperscript{184} Ibid.
\textsuperscript{185} Supra 112 at 744
\textsuperscript{186} Ibid.
\textsuperscript{187} Rick NG, \textit{Drugs: From Discovery to Approval} 94 (Wiley-Blackwell, New Jersey, 2\textsuperscript{nd} Edn., 2009)
\textsuperscript{188} Supra 112 at 744
2.7.1. XENOTRANSPLANTATION

In general, organ transplant is “the moving of an organ from one body to another for the purpose of replacing the recipient’s damaged or failing organ with a working one from the donor”\textsuperscript{189}. Today, such transplants are routine. However, “the need for organs has become critical”\textsuperscript{190}. Interestingly, for addressing this, there is “substantive research into xenotransplantation or transgenic organs”\textsuperscript{191}. Xenotransplantation means “the transplantation of tissue from one species to another species, typically from non-human mammals to humans”\textsuperscript{192}. It encompasses research over development of “cells and organs from non-human sources for their potential application to human medicine”\textsuperscript{193}. Another term “xenograft”, in this context, means “surgical graft of cells, tissues, or organs from one species to an unlike species, such as from pigs to humans”\textsuperscript{194}. Repulsively, pigs are selected due to their “genetic similarity to humans”\textsuperscript{195} and similar “organ size, anatomy and basic physiology”\textsuperscript{196}.

The Concerns: Expectedly, multitudinous “medical, legal and ethical issues”\textsuperscript{197} arise. Medically, there could be “rejection of organs transplanted from pigs”\textsuperscript{198}. The solution is that “animal organ, probably from pig or baboon, could be genetically altered with human genes to trick a patient’s immune system into accepting it as a part of his own body”\textsuperscript{199}. Also, pigs’ use could offend religious sensibilities. Also, there is

\textsuperscript{189} Supra 111 at 304
\textsuperscript{190} Id. at 305
\textsuperscript{191} Ibid.
\textsuperscript{192} Supra 172 at 246
\textsuperscript{193} Supra 137 at 360
\textsuperscript{194} Supra 111 at 307
\textsuperscript{195} Randall S. Prather, “Pig genomics for biomedicine” 31(2) Nat.Biotec. 122-124 (Feb., 2013), 122
\textsuperscript{196} Molly Fitzgerald-Hayes and F. Reichsman, \textit{DNA and Biotechnology} 323-324 (Elsevier, London, 3rd Edn., 2010)
\textsuperscript{197} Supra 111 at 307
\textsuperscript{198} Supra 196 at 324
\textsuperscript{199} Supra 111 at 307
“fear of new viruses being transmitted from pigs to humans”\textsuperscript{200} or an across-species “disease transmission” called “Xenozoonosis”\textsuperscript{201}. For us, however, patenting dilemmas are relevant. Illustratively, can such “xenotransplantation” or “xenograft” or the transgenic pigs/other animals for such procedures, be monopolised? In our chapter 4, we analyse these dilemmas.

2.7.2. VACCINES

Biotechnology texts say that,

“A vaccine is a biological preparation that improves immunity to a particular disease. It typically contains an agent that resembles a disease-causing microorganism and is often made from weakened or killed form of the microbe. The agent stimulates the body’s immune system to recognize the agent as foreign, destroy it, and remember it, so that the immune system can more easily recognize and destroy any of these microorganisms that it later encounters”\textsuperscript{202}.

Technically, therefore, vaccine is “a preparation of dead or weakened pathogens, or of derived antigenic determinants that is used to induce formation of antibodies or immunity against the pathogens”\textsuperscript{203}. Biotechnology texts also enumerate “several types of vaccines”\textsuperscript{204} namely,

\textsuperscript{200} Supra 137 at 360
\textsuperscript{201} Supra 111 at 307
\textsuperscript{202} Id. at 267
\textsuperscript{203} Supra 172 at 240
\textsuperscript{204} Supra 111 at 268
Attenuated Vaccines: These contain “live, attenuated virus microorganisms”\textsuperscript{205}. Here the “virulence of a pathogen” is reduced (i.e. “attenuated”)\textsuperscript{206}. Virulence means “the degree of ability of an organism to cause disease”\textsuperscript{207}.

Killed Vaccines: When “chemical and temperature treatment are normally used to kill or inactivate the pathogen”, these are made\textsuperscript{208}.

Toxoids: These “are derived from the toxins secreted by a pathogen”\textsuperscript{209}.

Other kinds: There are so-called “Sub-unit vaccines” which contain “a fragment” of the microorganism, which can also “create an immune response”\textsuperscript{210}. Reportedly, there are various “vaccines currently in the developmental stage or which are already in use, such as recombinant vector vaccines, DNA vaccines” etc\textsuperscript{211}.

Issues: As afore-discussed, since vaccines involve “living” or “killed” or even “attenuated microorganisms” some of which could invariably be transgenic consequentially there do arise, from our perspective, monopolisation or even bio-stealing dilemmas, as analysed in our chapters 4 and 6.

2.7.3. ANTIBIOTICS

Technically, these are “antimicrobial compounds produced by living microorganisms, and are used therapeutically and sometimes prophylactically in the control of infectious diseases”\textsuperscript{212}. They are also defined as “a class of natural and synthetic compounds that

\textsuperscript{205} Ibid.
\textsuperscript{206} Supra 187 at 97
\textsuperscript{207} Supra 172 at 243
\textsuperscript{208} Supra 187 at 97
\textsuperscript{209} Ibid.
\textsuperscript{210} Supra 111 at 269
\textsuperscript{211} Ibid.
\textsuperscript{212} Supra 114 at 193
inhibit the growth of, or kill some microorganisms”\textsuperscript{213}. Interestingly, commentators mention that “antibiotics have been extensively used in medicine since about 1945 with the arrival of penicillin”\textsuperscript{214}. Further, today, due to “increasing knowledge of the biosynthetic pathways in microorganisms it is increasingly possible to involve genetic manipulation” and use this in “antibiotic production”\textsuperscript{215}. GM-microbes, again, therefore, prove useful. Consequentially, here also, patenting thereof, can be, from our perspective, an important aspect, as explored in our chapter 4.

2.7.4. GENE THERAPY

We described above, inter-alia, genes and the so-called “genetic code” and role thereof. We pointed also, briefly, how mutations or alterations to the “genetic code” can trigger disease. Interestingly, this “knowledge of genetic basis of an inherited disease is important for two reasons”\textsuperscript{216}. These are, as follows,

“First, it provides the information needed to devise a screening program so that the defective gene can be identified in individuals who are carriers or who have not yet developed the disease” ... 

“Genetics can also lead to strategies for treating an inherited disease”\textsuperscript{217}.

The former, basically is genetic/diagnostic testing. Indeed “early identification in individuals who have not yet developed the disease allows appropriate precautions to be taken to reduce the risk of disease becoming expressed”\textsuperscript{218}. But afore-quoted second aspect, i.e. “treating an inherited disease”, is said to be “different from cure”...
and that “only way of curing an inherited disease is to replace the mutated gene with a nondefective version”\textsuperscript{219}. The cure, therefore, is “gene therapy”\textsuperscript{220}. It is defined as “the transfer of normal, functional genes to replace genetically faulty ones so that proper control of protein expression and biochemical processes can take place”\textsuperscript{221}. Its crux is “to replace or repress defective genes with sequences of DNA that encode a specific genetic message”\textsuperscript{222}. The essence, therefore, is “replacing a defective gene with a normal gene, thereby restoring the lost gene function in the patient’s body”\textsuperscript{223}. 

Gene Therapy has two types- “germ-line therapy and somatic cell therapy”\textsuperscript{224}. Simplistically, when “a fertilized egg is provided with a copy of the correct version of the defective gene and reimplemented into the mother”, it is termed “germ-line therapy”\textsuperscript{225}. This “correct version” will get manifest “in all cells of the individual which develop from that egg”\textsuperscript{226}. It means that changes “can be passed onto offspring”\textsuperscript{227}. This is fountain-head of conundrums. It is asked that “should gene therapy be considered in humans for non-therapeutic purposes, e.g. genetic enhancement to increase human physical or mental capabilities over what is considered normal? Should this technology be used to make body better?”\textsuperscript{228} Because of such misuse, it is said that, “theoretically, germ-line gene therapy could be used to treat any inherited disease, but it is considered ethically unacceptable to manipulate the human germ line in this way”\textsuperscript{229}. Interestingly, India has placed “research related
to germ line gene therapy” within “Prohibited Areas of Research”\textsuperscript{230}. In the second kind, i.e. “in somatic cell therapy, functioning genes are introduced into body cells that lack them” and its benefits “are confined to the person undergoing the treatment and are not passed onto the offspring” but here unfortunately “the treatment will have to be repeated for the person’s lifetime”\textsuperscript{231}. But it is labelled as “less controversial” with possible applications in “treatment of inherited blood disease, such as haemophilia and thalassemia”\textsuperscript{232}.

**Issues in Genetic Testing and Therapy:** Scientifically, however, both “germ-line therapy” and “somatic cell therapy” perhaps remain unperfected. Illustratively, one “hurdle surrounding gene therapy is the identification of genes causing the disease”\textsuperscript{233}. It is said that “gene therapy has not yet lived up to its original promise” and is restricted to “correcting single gene defects”\textsuperscript{234}. More importantly, it is admitted that “the coming genomics era will raise important ethical issues and challenges”\textsuperscript{235}. Moreover, regarding genetic testing, it’s cautioned that,

> “Since genetic information about individuals can be highly predictive of their future health, it has the potential to both stigmatize them and to be used by others such as potential employers and insurers as a basis for discrimination. These issues provide grounds for strong confidentiality protections. In the different context of families, however, there may be reasons to put special limits on confidentiality, since genetic information about an

\textsuperscript{230}ICMR, “National Guidelines for Stem Cell Research” 10 (N. Delhi, Dec. 2013)
\textsuperscript{231}Supra 114 at 208
\textsuperscript{232}Supra 135 at 431
\textsuperscript{233}Supra 187 at 125
\textsuperscript{234}Supra 114 at 208
\textsuperscript{235}WHO, “Genomics and World Health” 147 (Geneva, 2002)
individual is often equally relevant to his or her family members.\(^{236}\)

Further when “there is deep-seated bias and discrimination against women, genetic information can be withheld or used in ways deeply prejudicial to them.”\(^{237}\) These non-scientific conundrums need ironing out. Unsurprisingly, such “genetic information” is labelled “ultra-sensitive” and “highly predictive.”\(^{238}\) Hence, even a “Right to Genetic Privacy” is proffered.\(^{239}\) It is also said that “interventions to prevent genetic transmission of serious disease to children often involve abortion which does not simply prevent the disease” rather it “prevents the birth of a child.”\(^{240}\) This has been condemned.\(^{241}\) Also, for testing and research “free and informed consent” is paramount.\(^{242}\) But given our limited ambit, i.e. patenting conundrums alone, aforesaid regulatory dilemmas remain, humbly submitted, beyond our purview. They do, however, exhibit, in context of “biological inventions” and of genetic researches, the myriad and obfuscating troubles. For us, however, patenting feasibility, being relevant, is described in our chapter 5.

2.7.5. CLONING

Biotechnology texts say that, “In biology, cloning is the process of producing populations of genetically-identical individuals and occurs in nature when organisms such as bacteria, insects or plants reproduce asexually.”\(^{243}\) Hence, clearly, aforesaid “genetically-identical individuals” or duplicates are so manufactured. Also, clearly

\(^{236}\) Id. at 147-148  
\(^{237}\) Id. at 160  
\(^{238}\) Kshitij K. Singh, “Human Genome and Human Rights: An Overview” 50(1) JILI 67-80 (2008), 69  
\(^{239}\) Id. at 70  
\(^{240}\) Supra 235 at 148  
\(^{241}\) Ibid.  
\(^{242}\) Id. at 149  
\(^{243}\) Supra 111 at 307
since it “occurs in nature”, it isn’t new. Moreover, “in biological parlance, the term cloning refers to producing a copy of a gene, an organism, or a cell”\(^{244}\). Illustratively, “molecular or gene cloning” involves “creating genetically identical DNA molecules” while “cellular cloning produces cell lines of identical cells” and both are “fundamental tool of biotechnology research”\(^{245}\). Admittedly, “all applications of recombinant DNA technology” discussed above by us, and also “pharmaceutical manufacturing” and “production of transgenic crops, depend on molecular cloning”\(^{246}\). And yet, the term “cloning” evokes fear. Perhaps, the third aforesaid aspect, namely “organism cloning” particularly when such “organism” is homo sapien, is, we humbly opine, genesis of all obfuscations and fears. There exists “wide spread alarm” and more importantly several “ethical, legal and moral questions relating to human cloning”\(^{247}\). These, we discuss, in our chapter 4. But, here, presently, researcher simply emphasises, to contextualize the conundrums, the cloning techniques or science thereof.

Interestingly, several “animals have now been cloned using somatic cell nuclear transfer (SCNT) including goats, cattle, mice, pigs, cats, rabbits, horses, and dogs”\(^{248}\). These can be used in, *inter-alia*, “commercial agriculture”\(^{249}\). But, admittedly, “the process is very inefficient, the frequency of live births is generally low and many of the animals born using the procedure have developmental challenges”\(^{250}\). Hence, it is imperfect. Further, the highly dilemmatic “human cloning”, within our ambit here, means “the creation of a genetically identical copy of an existing or previously

\(^{244}\) *Supra* 137 at 222  
\(^{245}\) *Supra* 110 at 15  
\(^{246}\) *Ibid.*  
\(^{247}\) Ajai Kumar, “Human Cloning: A Socio-Legal and Ethical Appraisal” 52(1) *JILI* 92-109 (2010), 92  
\(^{248}\) *Supra* 196 at 325  
\(^{249}\) *Ibid.*  
\(^{250}\) *Supra* 196 at 326
existing human". It has two kinds, namely “therapeutic cloning and reproductive cloning”. The latter means “creation of an identical genetic copy of an individual human” and, unsurprisingly, “is widely viewed by scientists and most of the public as dangerous and unethical”. The former, i.e. “therapeutic cloning allows scientists to produce genetically matched embryonic stem cells by somatic cell nuclear transfer”. We now describe this controversial “somatic cell nuclear transfer” (or “SCNT”). A somatic cell is “any cell of a multicellular organism that composes the body of that organism but does not produce gametes”. This is also called “adult cell”. From such “adult cell”, its “nucleus is removed” and then “transferred into an empty oocyte (an enucleated egg cell) which no longer contains a nucleus”. So now “egg cell” has the nucleus. Now this “oocyte begins to undergo cell division when activated with a pulse of electricity (or similar trigger). After a period of growth in culture” this is “transferred into the uterus of an appropriate female animal” leading to “reproductive cloning”. However, “such clones”, for technical reasons, “are not strictly identical”. Technicalities, however, given our ambit, are immaterial. Patenting feasibility of “reproductive clones”, our real perspective here, we analyse, in our chapter 4.

2.7.6. STEM CELLS

\[\text{\textsuperscript{251} Supra 111 at 310}\]
\[\text{\textsuperscript{252} Ibid.}\]
\[\text{\textsuperscript{253} Supra 196 at 326}\]
\[\text{\textsuperscript{254} Id. at 327}\]
\[\text{\textsuperscript{255} Supra 172 at 217, a gamete is a “mature reproductive cell”, e.g. sperm or egg}\]
\[\text{\textsuperscript{256} Supra 196 at 327}\]
\[\text{\textsuperscript{257} Ibid.}\]
\[\text{\textsuperscript{258} Supra 111 at 309}\]
A stem cell is an “undifferentiated cell of a multi-cellular organism which is capable of giving rise to indefinitely more cells of the same type, and from which certain other kinds of cells arise by differentiation”\(^{259}\). Biotechnology texts say that,

“Stem cells are distinguished from other cells types by two important characteristics. First, they are unspecialized cells capable of renewing themselves through cell division, sometimes after long periods of inactivity. Second, under certain physiologic or experimental conditions, they can be induced to become tissue or organ specific cells with special functions”\(^{260}\).

Illustratively, our skin cells won’t convert or transform into our liver cells. But the so-called “stem cells” are different. As quoted above, they are “undifferentiated” or “unspecialized”. These can, *inter-alia*, “generate all the cell types of the organ from which they originate, potentially regenerating the entire organ from a few cells”\(^{261}\).

For e.g., “pluripotent haematopoietic stem cell (HSC) in the bone marrow” can turn into “a red blood cell, a neutrophil, a basophil, a lymphocyte, a macrophage or a mast cell”\(^{262}\). Simply, these can convert into anything. They “can be divided into two major types, adult stem cells and embryonic stem cells”\(^{263}\). The “adult stem cells” (henceforth, ASCs) “also known as somatic stem cells” are “not considered to be controversial as they are derived from adult tissue samples rather than destroyed human embryos”\(^{264}\). They “are multipotent, which means they have limited
developmental potential. Regardless of their source, adult stem cells can differentiate only into cells of the same type as the tissue from which they originated”

**ESCs & Conundrums:** The other category, i.e. “embryonic stem cells” or ESCs, is truly bewildering and dilemmatic. They come “from the inner cell mass of an early-stage embryo, known as blastocyst” which stage comes “4-5 days post fertilization”\(^{266}\). These possess “pluripotency”\(^ {267} \). In short, the ESCs obtained “from human embryo will generate all of the 200 or so different types of cells required to grow a human body”\(^{268} \). Medically, these ESCs “may be able to produce replacement cells to treat diabetes, Parkinson’s disease, and heart disease, among others”\(^{269} \). Also, ESCs are applicable for “regenerative medicine and tissue replacement for a number of blood and immune system related genetic diseases, cancers, and disorders”\(^{270} \). But, obtaining them obliterates the “early-stage” embryo. This raises, within patenting, the “ordre public or morality”\(^ {271} \) dilemmas. Therefore, hunt for “alternative methods” of “generating ES cells without killing the embryos” is there\(^{272} \). Illustratively, ESCs might come from “amniotic fluid”\(^ {273} \). We trace, in our chapter 5, *inter-alia*, more such “alternative methods” and also patenting conundrums.

Now, we discussed herein, from our perspective, the science of pharma-bio and also persistent conundrums surrounding afore-noted relevant pharma-bio-innovations. We also clarified certain myths, generally surrounding biotech and saw also how it finds applicability in several afore-noted areas. We also discussed certain basic aspects of

\(^{265}\) *Supra* 196 at 271  
\(^{266}\) *Supra* 111 at 286  
\(^{267}\) Alan Trounson, “A fluid means of stem cell generation” 25(1) *Nat.Biotec.* 62-63 (Jan., 2007), 62. It is “the ability of a cell to form all the cells of the body”.  
\(^{268}\) *Supra* 196 at 267  
\(^{269}\) *Supra* 110 at 11  
\(^{270}\) *Supra* 111 at 287  
\(^{271}\) *Supra* 1 Art. 27.2  
\(^{272}\) *Supra* 111 at 288  
\(^{273}\) *Supra* 267
patenting, including, *inter-alia*, harmonization and justifications thereof. This shall contextualize our work in ensuing chapters, especially our exploration of the intersections of patents and hereinabove described pharma-bio-innovations.