CHAPTER 7

CONCLUSIONS & RECOMMENDATIONS

In preceding chapters, researcher traced the multi-hued, dilemmatic and bewildering perspectives around the so-labelled “biological inventions” and more specifically, pharma-bio-patenting. The tremendous breadth of possibilities and power (often scary) unleashed by pharma-bio also became, in previous chapters, very apparent. Patenting system, we assessed, is perpetually stretched, not sans dissatisfactions or troubles, to embrace or accommodate newer and ceaselessly more-dilemmatic bio-innovations. The consequence in major jurisdictions, as shown in our work and concluded herein, is labyrinth of complicated, ever-evolving, much debated and, often, non-uniform norms. We humbly attempted, in such context, *inter-alia*, analysing these and, proffering, as humbly done in this chapter, modifications or tweaking in Indian norms.

7.1. CONCLUSIONS

From researcher’s pharma-bio context, TRIPS, we pointed in our previous chapters, introduced “uniform” and “minimum” yardsticks. It mandates patents “for any inventions” and “in all fields of technology”\(^1\). More importantly, it permits (by using “may”) exclusion on parameters of “*ordre public* or morality” and includes within this, protection of “human, animal or plant life or health” and also avoidance of “serious prejudice to environment”\(^2\). This exclusion, we saw, as being reflected in both EPC and India. Surprisingly, only U.S. remains sans such so-called “morality” bar, something we termed, in chapter 3, as a “moral void” in their system, unsurprisingly allowing therein, unfettered and unbridled bio-patenting sans all ethical

\(^1\) TRIPS, 1994, Art. 27.1
\(^2\) *Id.* Art. 27.2
or moral dichotomies that EPO grappled with. Moreover, TRIPS again permits (by again using “may”) exclusion of “diagnostic, therapeutic and surgical methods”. It also likewise permits excluding monopolisation of only “plants and animals” and “essentially biological processes” for “production of plants and animals”. The former bar is utilised in both EPC (although “in vitro” techniques can be monopolised) and Indian law. USA, unsurprisingly, once again, we saw in chapter 3, doesn’t have such restriction but safeguards its “medical practitioners” from infringement of such “therapeutic and surgical method” patents- a practice we termed curious and befuddling. However, clearly, that TRIPS allows, in context of our so-called “biological inventions” so much dexterity or interpretive flexibility, is perhaps testimony to what one commentator calls “the outstanding differences among industrialized countries themselves and between them and developing countries existing” in bio-patenting contexts.

Moreover, in chapter 4, we described how, in U.S., opponents of “Patents over Life” objected on, inter-alia, ethical and philosophical grounds to Chakrabarty’s revolutionary and epochal struggle to monopolise his creation- a bacteria, very much living and non-natural one. In sweeping aside all objections thereto and laying the adage that “anything under the Sun that is made by man” is eligible, U.S. system moved on proverbial “slippery slope” of allowing virtually everything. Post-TRIPS, interestingly, “microorganisms” and “non-biological and microbiological processes” are anyway compulsorily and universally eligible. USA, however, stopped at nothing, eliciting the remark that “today, it is not clear whether the patent system has

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3 Id. Art. 27.3(a)  
4 Id. Art. 27.3(b)  
5 35 U.S.C. § 287(c)  
7 Diamond v. Chakrabarty 447 U.S. 303 (1980, S. Ct.)  
8 Supra 1 Art. 27.3(b)
any subject matter boundaries at all”\(^9\). It easily allowed, as we showed, monopolising non-natural “higher life forms”, i.e. plants and animals, and also xenotransplants, ESCs, initially even the so-termed “isolated and purified genes”, gene-testing etc.

Interestingly, its policy of “anything under the Sun that is made by man”, we saw, is being scathingly denounced. Its unabashedly “pro-patent” CAFC has been, we showed, bitterly decried by commentators, and admonished lately, by their Supreme Court itself. To again quote one author, its CAFC “has systematically eliminated time-honoured categorical exclusions from patent eligible matter”\(^10\). But their apex court since, \textit{inter-alia}, \textit{Mayo}\(^11\) and \textit{Myriad}\(^12\), brilliantly claimed back (and is still doing so), as we discussed, some subject-matter to place it back into public domain. It is exploiting, in doing so, its “Product of Nature” concept, which researcher elaborately described in chapter 3. Most importantly, \textit{Myriad} disallowed “isolated and purified genes”, altering two decades of permissive practice, shaking and shocking, as we showed in chapter 5, the biotech industry and “pro-patent” lobbyists and lawyers.

Currently, U.S. system, considered the “gold standard” or epitome of patenting, is undergoing, we humbly opine, a churning and becoming somewhat circumspect. Also, in U.S., as analysed in our chapter 5, any gene-testing (diagnostic) kits containing or relying solely on so-called “isolated and purified genes” or their synthetic counterparts and involving simplistically mental assessment or comparison


\(^10\) M. Rimmer, \textit{Intellectual Property and Biotechnology: Biological Inventions} 113 (Edward Elgar, Glos, 2008)


\(^12\) \textit{Assoc. for Molecular Pathology v. Myriad Genetics}, 133 S.Ct. 2107(2013)
between normal and diseased versions, is most-likely to remain, post _Myriad_\(^{13}\) and _Sequenom_\(^{14}\), ineligible.

Europe presented, in contrast, in its EPC and EUBD, what present researcher humbly considers, an elegantly evolved code. It left scant space for EPO’s or CJEU’s interpretive manoeuvring. Both EPC and EUBD, illustratively, expressly allow monopolising “isolated and purified genes”. And yet, by constructing “ordre public or morality” parameter, EPC invited, as we showed in chapters 4 and 5, much oppositions to be raised. Illustratively, partly because of them and partly for technicalities, even for “isolated and purified genes” of Myriad, claims were so narrowed, as researcher elaborated in chapter 5, that one author opined that “neither BRCA1 nor BRCA2 were strongly patented”\(^{15}\) there. Also, patent over the famed “Harvard Oncomouse” was, after what Rimmer called an “epic, two-decade long battle”\(^{16}\), much narrowed in ambit. Moreover, its ESC-patenting contours, because of scientific irresolution or ambiguities, underwent, till even 2014, perpetual shifting.

We also deduced, in chapter 5, that since “surgery or therapy and diagnostic methods”\(^{17}\) are, within EPC, disallowed except when “in vitro” then, logically, gene therapy, if perfected, would be ineligible. Also, over xenotransplants, this jurisdiction has, so-far, remained extremely circumspect.

Consequently, even though Rimmer laments that “there remain few taboo inventions under patent law: perhaps only human cloning and animal-human hybrids remain clearly outside the scope of patentable subject matter”\(^{18}\) but still

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\(^{13}\) _Ibid_.

\(^{14}\) _Ariosa Diagnostics v. Sequenom_ 788 F.3d. 1371(CAFC, 2015)

\(^{15}\) Jessica C. Lai, “Myriad Genetics and the BRCA Patents in Europe: The Implications of the US Supreme Court Decision” 5 _UCILR_ 1041-1075 (2015), 1063

\(^{16}\) _Supra_ 10 at 90

\(^{17}\) EPC, 2000, Art. 53(c)

\(^{18}\) _Supra_ 10 at 3
monopolisation of other “taboo inventions”, we found, clearly hasn’t been smooth. The eligibility boundaries or contours are, as our chapters showed, unceasingly erected, redrawn, perpetually fluctuate and, remain, unsettled. This also shows uneasiness with “biological inventions” and also legal tussling over pharma-bio-patents.

Coming to our main focus, i.e. India, we found that regarding conventional patentability troika of “novelty, inventive step and industrial applicability”, elaborately engaged in chapter 3, the parameters and tests across jurisdictions were largely identical. Also, from our perspective, the main grouse or conundrums, we pointed, arise not in this conventional troika’s context, but in, *inter-alia*, demarcating eligibility contours. But, indeed, the aforesaid troika must be diligently assessed. Illustratively, for ESTs, universal practice, as pointed in chapter 5, is to, *inter-alia*, assess “credible, specific and substantial use” and on this logic, research tools, lacking such “specific and substantial use” are generally disallowed. If, critically, the aforesaid troika gets diluted or lowered, then obvious or non-substantial techniques/technologies might be monopolised, rewarding the unscrupulous.

About eligibility bars, i.e. what are or “are not inventions” obviously. India specifically excludes “plants or animals in whole or any part thereof”. The parts here obviously don’t mean those at molecular (“microbiological”) or genetic level. India, as pointed above, also debars “medicinal, surgical” etc. methods and also discoveries. The last, namely, “discovery” bar, is somewhat like American “Product of Nature” parameter. We highlighted that “discovery” bar be interpreted to logically

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19 Office of CGPDTM, “Guidelines for Examination of Biotechnology Applications for Patent” 11 (March, 2013)
20 The Patents Act, 1970 (Act 39 of 1970), s. 3
21 *Id.* s. 3(j)
22 See, *id.* ss. 3(i) and 3(c)
exclude the so-termed “isolated and purified genes”, although IPO’s practice, as pointed in our chapter 5, turns faulty or confusing here. The logic is simple, anything merely “isolated” or “purified” is still natural or a discovery, till something else, some concrete modification thereof is done. Also, India’s broad “public order or morality”23 parameter is interesting. Laudably, we noted, existence of IPO’s guidelines titled, “Guidelines for Examination of Biotechnology Applications for Patent”, where several excluded matter gets mentioned under “public order or morality” assessment. But, unfortunately, the illustrations therein are copied or aped from European practice, as we showed, clause by clause, in chapter 3. This creates some anomalies because our systems aren’t identical. Also, we humbly opined, in chapter 3, that IPO officials/examiners, being technologists, are, for “public order or morality”, not the best trained or most suited assessors. Also, the policy as regards “public order or morality” clause, does need ironing out or clarification.

Moreover, unlike EPC or U.S., India lacks, as we pointed in chapter 4, in context of GM-homo-sapiens or human clones, any express patenting restriction. But within “public order or morality” rubric, such exclusion, we had pointed, can easily be inferred or deduced. Also, it would be anomalous to render transgenic “plants or animals” ineligible, as aforesaid, but monopolise transgenic humans. Consequentially, specific ineligibility-clause, we humbly opine, would be superfluous. Coming to ESCs, IPO’s positioning gets hazy. It’s sans a concrete policy and merely copies EPO by stating that “uses of human embryos for commercial exploitation” are barred under “public order or morality” bar24. Likewise, xenotransplantation is not expressly ineligible.

23 Id. s. 3(b)
24 Supra 19
Researcher noted also, in chapter 3, the unique and extremely laudable s. 3(d), also famous as “the anti-evergreening clause”, though it also disallows second-indications. The “anti-evergreening clause” is, however, unfairly getting targeted by lobbyists. Disturbingly, the world is now entering “TRIPS Plus” era. The “Plus” here means higher than TRIPS standards. Commentators opine that such “higher standards” are negotiated or imposed via “bilateral negotiations”\(^\text{25}\). Within TRIPS, negotiating such “higher standards” is too arduous, so developed world or rather “pro-IP” lobby is resorting to shenanigans of aforesaid “bilateral negotiations” or of FTAs\(^\text{26}\) to impose its will. The other party in the “bilateral negotiations” is usually a developing country, compelled as part of “quid pro quo” to enhance its IP to suit vested interests\(^\text{27}\). Disturbingly, commentators point how such “practice may soon make TRIPS obsolete”\(^\text{28}\). In our context, reportedly, U.S. “has been complaining for long that India’s IPR laws are not strong enough” and it “has been pushing India to make any changes on controversial laws such as section 3(d) of the Indian Patents Act, a prime demand of multinational pharmaceutical industries”\(^\text{29}\). So far India has maintained that “it is not ready to engage with anyone on TRIPS plus issues which could lead to evergreening of patents or blocking of compulsory licenses”\(^\text{30}\).

Coming to biopiracy, we, in chapter 6, explained concept thereof. Clearly, to foil bio-stealing, “traditional knowledge” isn’t considered “invention” in India\(^\text{31}\). Our emphasis, in this context, was on TK’s subset which we termed “traditional medicinal


\(^{26}\) Free Trade Agreements

\(^{27}\) Supra 25 at 34, Curci notes that “Bilateral treaties increasingly put pressure on developing countries to heighten standards” of IP protection.

\(^{28}\) Id. at 32


\(^{30}\) Statement by Indian Commerce Minister, quoted in Id.

\(^{31}\) Supra 20 s. 3(p)
knowledge” or TMK. In this context, we also briefly engaged (since this wasn’t within our exact ambit) with the concept called “Prior Informed Consent” and with inter-related mechanism labelled “Access and Benefits Sharing”. These modalities also help foil bio-stealing, although they aren’t directly linked to patenting. The link, however, as we mentioned in chapter 6, is that in India, within “disclosure” or specification requirement, applicants must submit NBA’s approval (the apex “National Biodiversity Authority” under the biodiversity law), if their innovation uses “biological material from India”32. We also argued that since patenting, unfortunately, facilitates bio-stealing, therefore, some basic modality to foil thereof, must be carved within patenting rubric. The aforesaid approval requirement within specification or “disclosure” is one such example. Moreover, linking TKDL database to IP offices, we again noted in chapter 6, has been an epochal exercise in spotting unscrupulous applications embracing TMK. Domestically, bio-stealing is indeed soundly negotiated. Internationally, we saw Indian attempts to have so-called “disclosure of origin of biological material” or simply “disclosure of source” to be mandated within “disclosure” requirements33. We have, in this work, considered “disclosure” of invention, often labelled as “quid pro quo” of grant, as very much a fourth patentability parameter. Sadly, India’s aforesaid negotiations on “disclosure of source” have stopped. But the same, researcher humbly opines, could be a valuable “TRIPS plus” criterion.

32 The Patent Rules, 2003, Form 1, Declaration
33 See, WTO Document No. “IP/C/W/429” of 21st Sep. 2004. This was followed by “IP/C/W/442” of 18th Mar. 2005. There were several consequent negotiations around this issue. Many countries took pro- and anti-stance. Links to these documents and background notes available at https://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm (last visited on December 7, 2016)
We engaged, also, with the dilemma called “tragedy of the anticommons”\textsuperscript{34}, which becomes more pronounced in pharma-bio context, since here, as we have noted, “inventing around” is hard. We saw, in chapter 5, that “tragedy of the anticommons” is nothing but hindrance or obstruction of downstream, follow-up or more complex inventing when too many foundational or basic techniques/tools get locked-up or monopolised. This, indeed, is against the lofty claim that “patents promote innovation”. Here, they are, rather, blocking it. Several remedies were assessed, including “experiment or research exception”\textsuperscript{35} and also “Open Source Biotechnology” or OSB, both proving inadequate. OSB is borrowed from software industry and is, we had opined in chapter 5, inadequate for, \textit{inter-alia}, pharma-bio.

Finally, for issues pointed in our chapter 1, our assessment and afore-mentioned conclusions indicate that eligibility contours, in our pharma-bio context, within India, require clarifications or tweaking. Also, IPO must be diligent in, \textit{inter-alia}, practices regarding aforesaid conventional patentability troika. Also, the afore-discussed international “disclosure of source” parameter and the “anticommons” conundrum also require urgent action. Lastly, patents over so-called “biological inventions” need not be demonized, albeit, they need clarifications. Also, to afore-discussed extent, our hypothesis is proved. We proffer, humbly, in light of highlighted lacuna, the following recommendations.

7.2. RECOMMENDATIONS

1. \textbf{Indian Morality Board:} In context of “public order or morality” clause, patent officials/IPO-examiners alone might not, we pointed above, considering their

\textsuperscript{34} It comes from, M. A. Heller and Rebecca S. Eisenberg, “Can Patents Deter Innovation? The Anticommons in Biomedical Research” 280 \textit{Sci.} 698-701 (May, 1998), 698

\textsuperscript{35} \textit{Supra} 20 s. 47(3)
technical/scientific backgrounds, be most suitable or right “public order or morality” arbiters. Also, we pointed how IPO’s guidelines regarding “public order or morality” simply aped, rather blindly, EPO’s practices. To curb this, and to reduce or obliterate subjective assessments by IPO-examiners, we proffered, in chapter 3, a non-permanent Morality/Ethics board, having features, as follows,

   a) Having 5-10 members (at least 2 biotechnologists, 2 bioethicists, and 2 IP academics/lawyers and also Sr. patent officers). This heterogeneous composition, we opine, can ensure balancing of perspectives.
   b) It must prepare reviewable guidelines/list of controversial matter/innovations to be excluded under “public order or morality” clause.
   c) Since morals/ethics vary with time and so do bio-innovations’ advancements, its guidelines/lists must be reviewable every 3-5 years.
   d) Afore-mentioned list must not offend TRIPS.

2. Rule foiling Xenotransplantation monopolies: We discussed in chapter 4, India’s positioning, generally and from patenting perspective, on Xenotransplantation. We mentioned that “public order or morality” yardstick might exclude process/methods of constructing xenotransplants or of manufacturing suitable animals therefor. But we noted, in chapter 4 and also above, suitability of incorporating specific policy/rule for IPO. We proffer, humbly, such rule’s form/content:-

   Rule: Within “public order or morality” yardstick, any procedure for creating or making xenotransplants or for enabling specifically xenotransplantation, or for altering/manufacturing animals therefor, is excluded.

3. ESCs and IPO’s Practice: We pointed above and also in chapter 5, the ever-shifting and massively obfuscating European parameters on ESC-patenting. We also
pointed that IPO’s guidelines, aping EPO rules, just exclude “uses of human embryos for commercial exploitation”\(^\text{36}\). This is too ambiguous. Illustratively, what does “human embryo” signify? European jurisprudence could, we had proffered, in chapter 5, illuminate our path. IPO’s guidelines must, borrowing therefrom, incorporate explanatory note or clarification, as worded below (words in quotes from EPC/CJEU jurisprudence):

§ Explanatory Note: The “uses of Human Embryos for commercial exploitation” is barred under the “public order or morality” clause. In this context, further, terms mean:

**Human Embryo:** It means “any human ovum” when, and “as soon as fertilised”\(^\text{37}\) and further includes “a non-fertilised human ovum” if by any process, it is rendered “capable of commencing the process of development of a human being”\(^\text{38}\).

**Eligibility of Innovations:** Anything is ineligible if “implementation of the invention requires the destruction of human embryos” as embryos are defined above, regardless of “the fact that destruction may occur at a stage long before the implementation of the invention”\(^\text{39}\).

4. Genes Patents and IPO’s Faulty Practices: We saw, in chapter 5, how another commentator exposed certain wrongly-granted Indian “isolated gene” patents. We saw there, Indian Patent “244118” titled “An isolated nucleic acid (NA) molecule comprising an allele of a genetic polymorphism linked to resistance to enterotoxigenic Escherichia coli (ETEC)” and another Patent “226034” titled “An isolated nucleic acid...”

\(^{36}\) *Supra* 19
\(^{37}\) This is rationale of *Oliver Brustle v. Greenpeace e.V.* (CJEU, C-34/10, 2011)
\(^{38}\) This is rationale of *Intl’n Stem Cell Corp. v. C.G.P.D.T.M.* (CJEU, C-364/13, 2014)
\(^{39}\) *Supra* 37
acid encoding a human AKT3 protein”. Current status of both is “ceased”\(^40\). Their very initial grant, however, we explained in chapter 5, is contrary to Indian exclusion of “discovery of any living thing or non-living substances occurring in nature”\(^41\). Hence, we proffer that IPO officials/examiners be better, more diligently trained and must strictly follow law. Such massive errors or anomalies can create an embarrassing chasm between law and IPO’s practices.

5. Genetic Research: IPO must, given aforesaid anomalies, embrace the following as policy,

a) Not just the so-called “isolated and purified genes” but any gene/DNA sequence, even when synthesized or constructed in lab (labelled “Synthetic DNA”) and which is functionally identical or constructed to resemble/mimic natural one in its informational content should be strictly ineligible. Process or modality of making such “synthetic DNA” be, all criterion being met, allowed.

b) About cDNA, although U.S. allows them but if reasoning that “messenger RNA exists in nature, and cDNA is just a translation of this sequence”\(^42\) is accepted, then monopolies thereon would cease. India must, independently, accept this reasoning.

6. Clarity on Genetic Testing: We explained, in chapter 5, that India excludes patenting “any process” for inter-alia “diagnostic, therapeutic or other treatment of human beings”\(^43\). We explained how genetic testing is such excluded “diagnostic process”. We mentioned in that chapter, how some authors, unfortunately, argue,

\(^{40}\) The details of both patents and current status can be seen at “Patent E-register” facility within “inPASS” search facility of IPO. This can be accessed through links on IPO’s website, www.ipindia.nic.in (last visited on March 15, 2017)

\(^{41}\) Supra 20 s. 3(c)

\(^{42}\) WHO “Genomics and World Health” 136 (Geneva, 2002)

\(^{43}\) Supra 20 s. 3(i)
allowing monopolisation of “in vitro” (meaning “out of body”) procedures. This is EPC practice. IPO and Indian courts must, researcher stresses, negate any such tendency or interpretation. Aforesaid interpretation or any attempt to allow “in vitro” techniques, given our social welfare goals, can be damaging and will increase costs.

7. International Criterion for “Disclosure of Source” within Specification: We noted above how India raised “issues relating to disclosure of source and country of origin of biological resource and/or traditional knowledge used in an invention” within TRIPS council. But post-2008, this cooled off. The aforesaid “disclosure of source”, we recommend, India must push, in bio-patents’ context, as a “TRIPS-plus” additional international or universal mandatory criterion. Pushing it internationally is more critical. If such internationally mandatory “disclosure of source” is missing, patent grant should be denied. Once “disclosure of origin/source” is there, even PIC and “access and benefit sharing” as “quid pro quo” for PIC can be ensured.

8. Patent-Free Basics: To resolve, in pharma-bio, the so-called “tragedy of the anticommons”, we humbly proffer, adopting, notion of Patent-Free Basics (PFB). PFB, as we outlined in chapter 5, is not “Open Source” or “OpenBio”. Rather within PFB, early-stage or fundamental techniques/tools or technologies remain absolutely unencumbered (Patent Free). Contours or rather contents thereof, i.e. what is basic or fundamental tool/procedure or innovation, and therefore, to be placed in PFB, must be determined by biotechnologists/experts. This PFB can reduce innovation-costs.

44 Supra 33