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# Comparative Study of Patentable and Non-Patentable Subject Matters in India, United States of America and Europe

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## ABSTRACT

*IP protection is a negative right as it stops people from infringing the granted IP and let the innovator enjoy the monopoly for certain period. With the emerging competitive world, the importance of protecting the ideas, innovation, and creation is imperative. Companies, Universities, Inventors all over the world are investing lot of time and money to protect their intellectual properties. Companies are driven with the thought of enjoying monopoly and ultimately the monetary benefit, but what goes behind this is a huge process. The process of bringing that product from Lab to market with Patent and trademark is not easy. With all the technical knowledge playing important role in the process, the main aspect will always be the protection of the innovation and research outcomes. The study below will put a clear construal especially for the scientific community as it can be very hard on them considering the intricacies. The study's focus is on and for the researchers, scientist, and academicians to make them appreciate their inventions and its patentability scope in different jurisdictions (India, US and Europe). The study focuses on grey subject matters in the field of Patent Law: living organisms, medical devices and procedures, software in above mentioned jurisdictions.*

*The study aims to make it easy for all those aspiring filers (willing to file a patent application) to better understand the patentable and non-patentable subject matters in India, US, and Europe. Here, the study will compare the set laws in these countries and read between the lines to understand the inference and construction in detail.*

## I. INTRODUCTION

Before getting into analysis, it is important to understand 'Patent' as a term. A special right given to the inventor for the invention can be termed as a 'Patent' which is typically granted for a product or process where such product or process is a solution to some technical problem or provides an innovative technique of doing something.<sup>2</sup> To get such product or process granted

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<sup>2</sup> WIPO, (August 4, 2022, 2:18 PM), <https://www.wipo.int/patents/en/>.

it must pass the triple test, the product or process should be 1) Novel 2) Non-obvious 3) Useful.<sup>3</sup> Patenting any product or process means no other person can use such patented innovation, technique without the consent of patentee (person/organisation that holds the patent). As a matter of research here, the patentable subject matter differs from jurisdiction to jurisdiction. For instance, in the US patentable subject matter carries a wider scope as compare to that of in India; business ideas, softwares can be patented whereas the Indian law does not accept the same. In cases of living matters and its patentability the countries have taken different routes and decisions. In case of software patents, US have much liberal grounds, a patent for software is granted if the software is proficient to transform the given input into a useful output. Whereas, Europe have stringent rules for software patent applications, it must go through the test of non-obviousness and should have a 'technical effect'. In India, the software patents are not approved built on the programming of it but based on technical output of the same.<sup>4</sup>

Therefore, it is understood that patents grant negative rights as it prohibits other people from using the patented innovation.<sup>5</sup> Now as we know that this protection can be sought in different jurisdictions. It becomes important to file it in different jurisdictions to get protection worldwide which means different Patent Offices of the respective nations. Nations have their own Law of Land and set of rules and regulations, procedure to be followed, here the convolution comes in the picture for the filers; their invention patentable in one country may not be patentable in other country. This can be exasperating at a time especially for those with the plan of commercial exploitation.

Hence, the study shows the comparison between the existing laws of the countries, along with some case laws judgements in these jurisdictions (India, US and Europe). Study is conducted using Comparative Analytical Research Methodology here as it is comparing the laws, regulations, judgements, rules, ethics and principles followed in India, US and Europe. The study used the sources available to analyse the facts and information at hand.

## CHAPTER OVERVIEW

Due to globalisation and effect of increasing competition it has become very important to protect IP from commercial exploitation in all possible jurisdiction. Patent grant is complex,

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<sup>3</sup> V K Ahuja, Law Relating to Intellectual Property Rights, 482 (V K Ahuja ed., 2<sup>nd</sup> ed. 2013); *see also* [https://www.wipo.int/sme/en/obtain\\_ip\\_rights/patents.html](https://www.wipo.int/sme/en/obtain_ip_rights/patents.html) (Sept. 28, 2022, 12:01 PM), [https://ipindia.gov.in/writereaddata/Portal/Images/pdf/Final\\_FREQUENTLY\\_ASKED\\_QUESTIONS\\_-\\_PATENT.pdf](https://ipindia.gov.in/writereaddata/Portal/Images/pdf/Final_FREQUENTLY_ASKED_QUESTIONS_-_PATENT.pdf).

<sup>4</sup> Kailash Choudhary & Rangoli Nigam, *Patentability of software: a comparative analysis in various jurisdictions*; VII Issue I, Indian Legal Impetus 4, 6 (2014).

<sup>5</sup> Richard H. Shear & Thomas E. Kelley, *A researcher's guide to patents*, 132 Plant Physiol. 1127,1127 (2003); *see also* Arnold B Silverman, *The Relationship Between Basic and Improvement Patents*, 47 (1) p.50 JOM (1995).

time-consuming, and expensive procedure. It can be tedious to understand the working and practice of it, especially if you see the patentability criteria and subject matters, even though they might appear very straight but are subjective to infer. Here, I am undertaking a nuanced perspective on the patentable and non-patentable subject matter with the help of existing law and how it can be interpreted by the courts with a explicit focus on India, United States and Europe.

This dissertation is divided into three parts (jurisdictions) and each such jurisdiction is further sub divided and deals with different area of patenting innovations like 1) Living organisms 2) Medical devices and procedures and 3) Softwares. The dissertation entails the take of different jurisdictions (India, US, and Europe) in above mentioned areas of innovation.

## RESEARCH QUESTIONS

- 1) Where the patentable subject matters contradict each other in the jurisdiction of India, US, and Europe?
- 2) What is the take of India, US and Europe on patenting living organisms, medical devices and procedures, software?

## II. INDIA

The Indian Patent system has been influenced and driven by many factors. A strong influence of Indian culture, Indian Colonial History, TRIPS Agreement, WTO membership and all the recent treaties can be seen in the Indian Patent System.<sup>6</sup> But recently India has been very actively transfiguring its patent system, India has revamped its manual of Patent Office Practice and Procedure in 2019 November. The manual directs the examiners to use the search and examination system of WIPO for patent search. Further, Govt. of India set up an IP division in the mid of 2021 to speed up the disposal of cases in the area of IP.<sup>7 8</sup> India is also working to spread IP awareness amongst people and help them understand the importance of the same. Further lot of collaborative work plans are undertaken by India and US in seriatim.<sup>9</sup>

To understand Indian Patent System in detail with regards to Living organisms, Medical devices and procedures and Softwares, below are the findings of analytical research.

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<sup>6</sup> Johanna Sheeche, *Indian Patent Law: Walking the Line*, 29 Nw. J. Int'l L. & Bus. 577, 577-582 (2009).

<sup>7</sup> Creation of IP division by the High Court of Delhi, iPLEADERS (July 26, 2022, 12:44 PM), <https://blog.ipleaders.in/creation-of-ip-division-by-the-high-court-of-delhi/>.

<sup>8</sup> Sruthi Dharbhamulla, Explained | The Indian patent regime and its clash with the U.S. norms, THE HINDU (July 26, 2022, 12:49 PM), <https://www.thehindu.com/news/national/explained-the-indian-patent-regime-and-its-clash-with-the-us-norms/article65464988.ece>.

<sup>9</sup> *Id.*

### a) Living Organism

India allows grant of patent for process and product which should be novel, useful and must include inventive step.<sup>10</sup> The Indian Patent code lists down the non-patentable subject matters some of which are related to biotechnology. The IP act does not allow patenting of Discovery of living creature already existing in nature, Plants or animals or any part of plants and animals except for micro-organism; its species, varieties or any process for breeding or production of plants and animals.<sup>11</sup>

In the landmark case of *Dimminaco*<sup>12</sup> the High Court of Calcutta averred that the criteria of patentability should be based on the test of novelty and its industrial application, the certitude that the claimed matter has living organism should not be considered as a ground to decide the process of manufacturing as non-patentable. Further the court did a vendibility test to understand if the end result i.e., the product can be transferred from one person to another through sale or purchase transaction. After applying the test of vendibility the Hight Court concluded that the process claimed in the current case ultimately gives a vendible outcome as an end product and hence the process is an invention.

Later in the year 2002 the Patent act was amended to bring it in line with TRIPS Agreement which allowed patenting the microorganism, this amendment took effect in May, 2003.<sup>13 14</sup>

One more case that is considered as important in India when it comes to patenting the biotechnology was the case of *Monsanto*<sup>15</sup> the Appellate Board here inverted the IPO's rejection of patent application by stating that the process of growing the transgenic plant is a biological process. The Board settled with Monsanto's claim that transformation of cell as asserted in the process is an outcome of human intervention.

Therefore, the protection for the process of genetically modifying plant can be protected but not the plant itself.

After considering the above judgments, Indian Patent Act and even TRIPS, it is understood that it can be very difficult to establish novelty in case of living organisms, also, in case of genes as it is naturally occurring it becomes a discovery; then to defend obviousness in case of procedures used to isolate these living organisms is another hurdle. Then the second/new use of

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<sup>10</sup> Indian Patent Act, 1970, § 2(1).

<sup>11</sup> Indian Patent Act, 1970, § 3(c) & (j).

<sup>12</sup> *Dimminaco A.G. v. Controller of Patents and Designs*, (2002) I.P.L.R. 255 (Cal).

<sup>13</sup> TRIPS Agreement, 1994, Article 27.3.

<sup>14</sup> Indian Patent Act, 1970, § 3(j) (w.e.f. 20-5-2003).

<sup>15</sup> *Monsanto Technology LLC v. Nuziveedu & Ors* AIR 2019 SC 559.

known substance is also not patentable<sup>16</sup> which makes it even more complex.

### **b) Medical devices and procedures**

Considering Medical devices, the protection can be pleaded three ways 1) the device itself 2) method for diagnosing or treating 3) software used in the device. Indian IP act prohibits patenting of any process used to treat any disease in humans and animals, including but not limited to, diagnostic and therapeutic.<sup>17</sup> Hence 3 (i) makes it clear that any medical device used in diagnosing disease or treating disease cannot be patented. But the 3(i) blanket does not cover medical devices as such. After conducting thorough research, it is safe to say that there are few to no case laws contesting the patentability of medical devices under section 3(i) of IP act.

But the next two challenges for a medical device could be section 3(f)<sup>18</sup> which excludes the mere re-arrangement of known devices for the purview of patentability. In the famous case of *Biswanath Prasad Radhey Shyam*<sup>19</sup> the court averred that the device claimed should clear the test of inventive step, “mere workshop improvement” would not serve the protection under Patent act. Further, the court stated that the protection can be given in case there is a significant improvement or the combination resulted in better and cheaper product. And the another to overcome is section 3(k)<sup>20</sup> applicable if the device uses some specialised software for functioning as this section disallows patenting of computer programmes and algorithms. The detail is discussed in part (c) of this jurisdiction.

As discussed above section 3(i) the medical procedures cannot be patented but the interpretation of this section is wider. It covers apparatus and medical devices used to perform medical surgeries and procedures.<sup>21</sup> The reason behind including such clause and not permitting the protection is always repeated stating that it will disrupt the medical practise of doctors and their freedom to practice may get affect adversely. In the India there are not lot of judicial commentaries on this issue but it is silently agreed that the patenting of medical procedures will act as sin to common man as it will lead to costly medical treatments and procedures and accessibility concern.<sup>22</sup> Therefore, it can be said that the purpose of such section is higher and the comprehensive interpretation shows a bigger picture.

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<sup>16</sup> Indian Patent Act, 1970, § 3(d).

<sup>17</sup> Indian Patent Act, 1970, § 3(i).

<sup>18</sup> Indian Patent Act, 1970, § 3(f).

<sup>19</sup> *Biswanath Prasad Radhey Shyam Vs. Hindustan Metal Industries* (1979) 2 SCC 511.

<sup>20</sup> Indian Patent Act, 1970, § 3(k).

<sup>21</sup> Nishanth Mohanty, *Patentability of Methods of Medical Treatment in India*, DSNLU (July 27, 2022 9:12 PM) <https://dsnlu.ac.in/wp-content/uploads/2022/02/16.-NISHANTH-MOHANTY.pdf>.

<sup>22</sup> *Id.*

### c) Softwares

As discussed earlier in the topic of medical devices the computer programmes cannot be patented in India.<sup>23</sup> But the courts of India in the case of *Ferid Allani*<sup>24</sup> made it clear that the section 3(k) does not apply to all the computer programming-built inventions. The court further observed that most of the modern devices are now run through such programming and disallowing such invention would rather be retrogressive. The court stated that if the invention is capable of exhibiting “technological effect or contribution” then the protection can be granted under IP act even to a computer programme and the similar approach was taken by the court in the case of *Telefonktiebolaget LM Ericsson (Publ)*.<sup>25</sup> Later in the year of 2016 in one more case of *Telefonktiebolaget LM Ericsson*<sup>26</sup> in context of algorithms the court held that if it is showing “technological or practical effect” and the presentation of the same is seen on hardware then it doesn’t come under purview of non-patentable subject matter.

To get the grant of software it does not necessarily need to clear novelty and non-obviousness test and also without showing adoption or moderation to the hardware the invention may qualify for patent under IP Act, this was well established in the case of *Accenture Global Service*.<sup>27</sup>

From the above case laws and the judgement by the courts it can be supposed that the India is taking a broader approach while analysing the software related inventions and the courts have identified the role of softwares and its importance in technology and future development.

## III. UNITED STATES

The act governing the Patents in United State is Patent Act (35 U.S. Code) and body governing this act and office of registration for patent is United States Patent and Trademark office (USPTO).<sup>28</sup> In the recent years the USPTO and US courts made some very important comments be it rejection of application on the ground that the applicant was not a natural person<sup>29</sup> which is the requisite under US Patent Law or an interesting observation was made when federal court allowed the evidence provided by the competing party as to counter the objection of obviousness.<sup>30</sup>

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<sup>23</sup> Indian Patent Act, 1970, § 3(k).

<sup>24</sup> *Ferid Allani v. Union of India* 2008 (37) PTC 448 (Del).

<sup>25</sup> *Telefonktiebolaget LM Ericsson (Publ) v. Intex Technologies (India) Ltd.* 2015 (62) PTC 90 (Del).

<sup>26</sup> *Telefonktiebolaget LM Ericsson (Publ) v. Lava International Ltd.* 2016 (67) PTC 596 (Del).

<sup>27</sup> *Accenture Global Service Gmbh v. The Asst. Controller of Patents & Designs & Ors* (2012) 28 (Del). OA/22/2009/PT/DEL.

<sup>28</sup> USPTO, <https://www.uspto.gov/web/offices/pac/mpep/mpep-0020-introduction.html> (July 29, 2022, 10:17 AM).

<sup>29</sup> 35 U.S.C. § 115 (a).

<sup>30</sup> Richard Stim, *What's New in Patent Law, 2018 to 2021*, NOLO (30 July, 2022, 2:36 PM) <https://www.nolo.com/legal-updates/what-s-new-in-patent-law-2018-to-2021.html>.

Now, to get to the subject matter of the study below is the analysis and recent take of USPTO and US Courts.

### a) Living Organisms

As per the US Patent Law living organisms are not covered under patentable subject matters.<sup>31</sup> Below are few case laws explaining the section and its interpretation.

Patenting of living organism in United States is the outcome of a very renowned case of *Diamond*<sup>32</sup> where the Supreme Court avowed that whether the invention is living thing or not, is not pertinent to decide the patentability of the invention. In the celebrated case of “Dolly the Sheep”<sup>33</sup> the US federal circuit court affirmed the decision of the board stating that the subject matter does not show any different characteristic than the existing. The federal court further observed that the cloned animal, here the sheep, cannot be patented as it has identical genetics that of its parents which makes it naturally existing. But, the patent for the method of cloning was granted.<sup>34</sup> The court took the support of *Myriad*<sup>35</sup> case where the court held that BRCA genes are already in existence and cannot be patented. Similar approach was taken in the case of *Funk Bros.*,<sup>36</sup> where the court denied protection under patent law as there was no addition or alteration done to naturally occurring bacteria.

The history of protecting plants started back in 1930 in USA with a breakthrough in the year of 1970 when Plant Variety Protection Act was enacted. Later when the research started advancing and the verdict on the case of *Chakrabarty* came out, same question to mutated plants patentability was questioned. Later in the year 2001 in the case of *J.E.M AG Supply*<sup>37</sup> the Supreme Court included plants that are sexually and asexually produced under the protection of utility patent.<sup>38</sup> Now, the US Patent Act grants the protection for only asexually reproduced plants<sup>39</sup> and the sexually reproduced plants are protected under Plant Variety Protection Act.<sup>40</sup>

So, it is clear that the US does not allow patenting the living organisms but allowed the process of genetically modifying the living organisms as learned from the cases above. Even though the courts decisions are purely based on the interpretation of the patent law but there can be a lot to

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<sup>31</sup> 35 U.S.C. § 101.

<sup>32</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

<sup>33</sup> *In Re Roslin Institute (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014).

<sup>34</sup> U.S. Patent No. 7,514,258 (Granted on April 7, 2009).

<sup>35</sup> *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

<sup>36</sup> *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 128–129, 132 (1948).

<sup>37</sup> *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 145-46 (2001).

<sup>38</sup> Elizabeth A. Rowe, *Patents, Genetically Modified Foods, and IP Overreaching*, 64 S.M.U. L. Rev. 859, 864-865 (2011).

<sup>39</sup> 35 U.S.C. § 161 (2011).

<sup>40</sup> 7 U.S.C. §§ 2321-2582.



it. Moral and ethical implications of allowing patents for such inventions was not clearly discussed in any of these cases. That is another very important area where the law, science, and ethics (common to all) intersects to decide the depth and effect on the society of various inventions. Lastly the intention of the law makers plays vital role in interpreting the set codes, but how and to what extent the interpretation is carried is a subjective matter.

### **b) Medical devices and procedures**

Like any other invention, the medical device should be novel, non-obvious and useful to the industry to be eligible for protection. Medical devices can be applied for protection as Utility Patent which requires to disclose the functioning of the medical device, the other way is to apply for design patent which is for the silhouette of the device, interface design and features limited to appearance.<sup>41</sup>

The machines are patentable subject matter as per the US Patent Act<sup>42</sup>, rather the court in the famous case of *Chakrabarty*<sup>43</sup> held that “anything under the sun that is made by man” can be subject to patent protection.

The main hindrance for the medical devices is the existing prior art which means establishing the novelty can be a little tricky; as discussed above in Indian jurisdictions as well; the pre-existing mechanisms can be used in medical devices making the patentability difficult. Another struggle is the FDA rule book, which takes up the initial grant period of the applicant. The medical devices to commercialise and make it market ready need to undergo FDA stringent rule which takes first important years of monopoly.<sup>44</sup>

To understand patenting of medical procedures in the US the judgment of the court in the *pallin*<sup>45</sup> case is very important, here the plaintiff that is Dr. Pallin filed a case for infringement of his invention which was a surgical procedure for cataract removal. This was the first case in which the court discussed and questioned the patentability of medical procedures and its impact on the public health.<sup>46</sup> However, the district court annulled<sup>46</sup> the claims and forbade Dr. Pallin from administering his rights against medical fraternity.<sup>47</sup> This case created a lot pandemonium in

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<sup>41</sup> Larry Bischoff, Types of Medical Device Patents: What You Need to Know, STERLING MEDICAL DEVICES (July 31, 2022, 02:35 PM), <https://sterlingmedicaldevices.com/thought-leadership/medical-device-design-industry-blog/types-of-medical-device-patents-what-you-need-to-know/>.

<sup>42</sup> 35 U.S.C. § 101.

<sup>43</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

<sup>44</sup> Adam Lewin, *Medical device innovation in America: The tensions between food and drug law and patent law*, DASH.HARVARD.EDU (July 1, 2022, 04:48 PM), <https://dash.harvard.edu/handle/1/11940217>.

<sup>45</sup> *Pallin v. Singer*, 36 U.S.P.Q.2d (BNA) 1050 (D. Vt. 1995).

<sup>46</sup> *Id.*

<sup>47</sup> *Patent Policy In Medical Terms | Understanding The Relationship Between Medical Procedures and Patent Policy*, IIPRD (July 2, 2022, 01:04 PM), <https://www.iiprd.com/patent-policy-in-medical-terms/>.

the medical community and the outcome of which was introduction of § 287(c)<sup>48</sup> which shields the physicians against the infringement suits in case of medical procedures.

The US Patent law does not disallow patenting of the medical procedures *per se* but it does restrict the enjoyment of monopoly as seen in the case of *Pallin*. One school of thought believed that the patent protection in form of monopoly is important for innovation and progress while the other school debated more on the ethics where such negative rights may deprive the patients from the best available treatment.<sup>49</sup>

### c) Softwares

The fashion of patenting the softwares and the competitive companies put all of us in dilemma. Comparatively new and now well versed yet always evolving field for humans had a lot of impact on industry along with the IP field.

The history can be traced from the famous case of *Diamond v Diehr*<sup>50</sup> where the issue in hand was whether process using mathematical formula and computer programme is a patentable subject matter under 35 U.S.C. § 101. The court held that the use of computer in the process does not make the subject matter unpatentable. Later the *Freeman Walter Abbe Test*<sup>51</sup> was devised which involved two checkpoints to analyse the patentability i) whether the mathematical algorithm is “directly or indirectly recited” in the claims ii) whether the application of mathematical algorithm is impacting the process or physical features. If the answer to above two is yes then the innovation is patentable.<sup>52 53</sup>

Again, in the case of *Alappatt*<sup>54</sup> the court took *Diehr* into consideration and held that computer programme is a patentable subject matter if it provides with a solid, palpable, and useful result.

In one of the recent and famous case *Alice*<sup>55</sup> the court held that,

“merely requiring generic computer implementation fails to transform [an] abstract idea into a patent eligible invention; mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent- eligible matter”

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<sup>48</sup> 35 U.S.C. § 287(c) (2006).

<sup>49</sup> Leisa Talbert Pesche, *Revisiting the Compromise of 35 U.S.C. § 287(C)*, 16 Tex. Intell. Prop. L.J. 299, 304, 321, 322 (2008).

<sup>50</sup> *Diamond v. Diehr* - 450 U.S. 175, 101 S. Ct. 1048 (1981).

<sup>51</sup> This test was outcome of three cases *In re Freeman*, 573 F.2d 1237, 197 USPQ 464 (CCPA 1978), *In re Walter*, 618 F.2d 758, 205 USPQ 397 (CCPA 1980), *In re Abele*, 684 F.2d 902, 214 USPQ 682 (CCPA 1982).

<sup>52</sup> Testing Parameters for Software Patentability, BANANAIP (August 02, 2022, 04:22 PM), <https://www.bananaip.com/ip-news-center/testing-parameters-for-software/>.

<sup>53</sup> Abhishek Kumar Singh & Suryakant Kashyap, *Software Patentability: A Comparative Analysis*, MANUPATRA (August 02, 2022, 04:24 PM), <http://www.manupatra.com/roundup/323/Articles/Software%20Patentability.pdf>.

<sup>54</sup> *In re Alappatt*, 33 F.3d 1526 (Fed. Cir. 1994).

<sup>55</sup> *Alice Corp. v. CLS Bank* 134 S. Ct. 2347 (2014).

“We must distinguish between patents that claim the building blocks of human ingenuity and those that integrate the building blocks into something more, thereby transforming them into a patent- eligible invention”.<sup>56 57</sup>

In the case of *Rosenberg*<sup>58</sup> the court disallowed the claims of gathering a data collection under a clinical trial. The Federal Court here took in consideration *Alice*<sup>59</sup> judgment that a mere improvement using technology to human’s basic ability cannot be patented. Further, the court cited *Allapat*<sup>60</sup> case to embed that the application of computer programmes which results into some use or purpose, is not applicable anymore.

It is interesting to note that the Court of Appeals for the Federal Circuit in the year of 2020 decided 27 cases in shadow of *Alice* with software as subject matter. Out of which 4 were either partially or fully decided as patent eligible, 1 was sent back to lower court and 22 were declared ineligible.<sup>61</sup>

For now, it can be concluded that the US Courts are taking the *Alice* case judgment into consideration and the framework set in the case is used.

#### IV. EUROPE

To protect innovation in Europe one needs to file and apply to the European Patent Office (EPO). Now the Europe is making strong efforts to bring in the Unitary Patent concept, which will give the inventor protection in at least 25 member nations through one application. This will make the process easy and economical.<sup>62</sup> Like other countries, patentability of certain subject matters is grey in Europe too. Below is Europe for you on Living organisms, Medical devices and procedures and Softwares.

##### a) Living Organisms

Any innovation in the field of technology which is novel, includes inventive step and has industrial application is patentable in Europe.<sup>63</sup> It is understood that EPC does allow patenting

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<sup>56</sup> *Id.*, at 2358.

<sup>57</sup> *Id.*, at 2354.

<sup>58</sup> *In re Rosenberg*, No. 19-2251 (Fed. Cir. 2020).

<sup>59</sup> *Alice Corp. v. CLS Bank* 134 S. Ct. 2347 (2014).

<sup>60</sup> *In re Alapat*, 33 F.3d 1526 (Fed. Cir. 1994).

<sup>61</sup> Theodore Rand, *Alice in 2020: Slashing Software Patents and Searching for Functional Language at the Federal Circuit (Part I)*, IPWATCHDOG (August 03, 2022, 01:15 PM), <https://www.ipwatchdog.com/2021/01/07/alice-in-2020-slashing-software-patents-and-searching-for-functional-language-at-the-federal-circuit-part-i/id=128802/#>.

<sup>62</sup> EUROPEAN PATENT OFFICE, <https://www.epo.org/applying/european.html> (last visited August 3, 2022).

<sup>63</sup> European Patent Convention, Article 52 (1).

of biotechnological invention if the bio material is separated from its natural habitat or if it is produced by some human intervention with the help of technology or if the application of the subject matter is extensive and not limited to specific plant and animals or a product or process procured by a technical or microbiological process which is not plant or animal variety.<sup>64</sup> When it comes to patenting plants and animal varieties, the EPC is very clear that no patent will be granted to plant and animal varieties including the process of biologically reproducing them.<sup>65</sup>

There is one more restriction to patenting life in Europe and it is exclusive to Europe which prohibits patenting of human clones, genetically modified animals if the outcome is suffering, alteration to human germ line and use of human embryo for commercial and industrial use.<sup>66</sup>

The current situation of patenting living organisms in Europe can be understood from a 2020 patent application<sup>67</sup> where the Enlarged Board of Appeals (EBoA) explained the term “*essentially biological process*” under Article 53 (b) of European Patent Convention, it excludes microbiological process and includes cross breeding of the plant genes as process and this cross breeding is fashioned with some technique and that technique is standalone but also helps in breeding.

At this point the basic understanding is that the products procured by altering the gene of plants or animals using some technology which are not just some technical support for breeding is patentable.<sup>68</sup> It is safe to say that the EPC articles are crisp and gives a strong impression of non-patentability.

### **b) Medical devices and procedures**

The EPC does not give protection to the process or procedure of treating a human or animal including diagnostic and therapeutic methods.<sup>69</sup> It is important to discuss here the patent application<sup>70</sup> where the BoA stated that to create rate responsive pacing system the prerequisite is to sense the activity done by human body and adjust heart rate according to human body's demand, to carry out this special task which has therapeutic value the specific pressure measurement from a particular body part could be useful to predict and deliver the needed heart

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<sup>64</sup> European Patent Convention R. 27, Article 52.

<sup>65</sup> European Patent Convention, Article 53 (b).

<sup>66</sup> EU Directive 98/44/EC read with Rules 23b-e of European Patent Convention.

<sup>67</sup> G 0003/19 (Pepper (follow-up to Tomatoes II and Broccoli II) of 14.5.2020.

<sup>68</sup> Axel B. Berger & Kerstin Galler, *Germany: Regarding The Patentability Of Plants And Animals In Europe – The G 3/19 Decision (“Pepper”) Of The European Patent Office*, MONDAQ (August 4, 2022, 03:24 PM), <https://www.mondaq.com/germany/patent/970084/regarding-the-patentability-of-plants-and-animals-in-europe-the-g-319-decision-pepper-of-the-european-patent-office>.

<sup>69</sup> European Patent Convention, Article 53 (c).

<sup>70</sup> T 0082/93 (Cardiac pacing) of 15.5.1995.

rate as this involves input from human body to perform needed task by pacemaker and hence it cannot be patented and the patent was revoked.

In another case <sup>71</sup> concerning medical pumping system where the finding derived from the medical pumping system was not applied to plan the therapy or to alter the ongoing therapy and it just indicated the possibility of occlusion without establishing any connection with the device injected. In this case the Board denied appeal to revoke the patent and forwarded for prosecution. In the case <sup>72</sup> where the subject matter was apparatus the board denied patent application stating that to arrive at the apparatus a surgical step is mandatory.

Therefore, it can be concluded that the apparatus cannot be patented if its use is subject to a surgical procedure and the invention relating to the technique of use of a medical device may or may not be patented subject to the relation amongst the device and its therapeutic effect on human body.

Europe made it very clear through its case <sup>73</sup> that EPC's attitude towards non patenting medicine, it is to encourage and assure the free flow of skill and knowledge and the medical practitioners should never practice under the fear of infringing others' rights and patent. Even though article 53 (c) prohibits patenting method of treatments there is some leverage provided by EPC which allows use of certain '*substance or composition*' in the method of treatment. <sup>74</sup> It is to be noted that even if the composition or substance is not novel but the same is not used prior for any medical purpose then the patentability of such composition is still possible under "*first medical use*".<sup>75</sup> Similarly, patenting the second use of the known substance or composition is also possible.<sup>76 77</sup>

So, it can be inferred that the medical methods are not granted protection under EPC in the method form but the same can be protected and granted if converted into "*purpose limited product claim*" or the product itself. And if the medical device relates to diagnostic, therapeutic or any surgery then the claim can be made to the device rather the method of using the device.<sup>78</sup>

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<sup>71</sup> T 0044/12 () of 11.1.2017.

<sup>72</sup> T 1731/12 (Implantat/Forschungszentrum Jülich) of 15.2.2019.

<sup>73</sup> G 0001/07 (Treatment by surgery/MEDI-PHYSICS) of 15.2.2010.

<sup>74</sup> European Patent Convention, Article 54 (5).

<sup>75</sup> European Patent Convention, Article 54(4).

<sup>76</sup> European Patent Convention, Article 54 (5).

<sup>77</sup> G 0002/08 (Dosage regime/ABBOTT RESPIRATORY) of 19.2.2010.

<sup>78</sup> Hazel Ford, *Patentability of Medical Methods in Europe*, FINNEGAN (August 4, 2022, 05:19 PM), <https://www.finnegan.com/en/insights/blogs/european-ip-blog/patentability-of-medical-methods-in-europe.html>.

### c) Softwares

EPC disallows patenting of softwares<sup>79</sup>; the protection in Europe is available under Copyright.<sup>80</sup> It is important to state the famous case of *Comvik*<sup>81</sup> here which assessed that the innovative step in the invention should provide some advance and technical offering to the existing knowledge in the field to be considered for patenting. This was the case of 2002, in the recent case<sup>82</sup> of 2021 which was related to the simulation, confirming the *Comik* case the EBoA made it clear that any invention which is computer implemented should be decided on the result, if it can be directly associated with the claimed technical advancement and features.

As discussed above, the software can be protected as a copyright and as patent but there is a catch, under copyrights the work is only protected if infringed but not against any further advancement or development of work by third party. Whereas, patent gives a wider shield by securing the technical features.<sup>83</sup>

## V. CONCLUSION

It can be concluded that the patentability of the above discussed subject matter is very different in different jurisdictions and at the same time very subjective. It becomes important for the inventors to understand the nuances of the patentability and stand taken by the courts, boards, governments from time to time. As the purpose of the study is to help the inventors to better understand the patentability of their inventions, it is safe to conclude that the inventors should not only take into consideration the laws of land to understand the concepts on the novelty, inventive step and usefulness and the patentable and non-patentable subject matter but should also look into the inferences drawn by the patent offices and examiners along with the courts of the country. Intellectual property rights and laws is still evolving all over the world, the concoction of all the above is safest option to understand to keep up with the maturation.

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<sup>79</sup> European Patent Convention, Article 52 (c).

<sup>80</sup> Samuel Denis, *Obtaining patent protection for software in Europe*, LEXOLOGY (August 4, 2022, 05:38 PM), <https://www.lexology.com/commentary/intellectual-property/european-union/gevers/obtaining-patent-protection-for-software-in-europe>.

<sup>81</sup> T 0641/00 (Two identities/COMVIK) of 26.9.2002.

<sup>82</sup> G 0001/19 (Pedestrian simulation) of 10.3.2021.

<sup>83</sup> Sylvain Chaffraix, *European Union: Patentability Of Software In Europe*, MONDAQ (August 7, 2022, 02:46 PM), <https://www.mondaq.com/france/patent/1210460/patentability-of-software-in-europe>.

**VI. BIBLIOGRAPHY****PRIMARY SOURCES – Legislation and Case Laws**

1. Indian Patent Act, 1970,  
[https://ipindia.gov.in/writereaddata/Portal/IPOAct/1\\_31\\_1\\_patent-act-1970-11march2015.pdf](https://ipindia.gov.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf)
2. *Dimminaco A.G. v. Controller of Patents and Designs*, (2002) I.P.L.R. 255 (Cal)
3. TRIPS Agreement, 1994, Article 27.3
4. *Monsanto Technology LLC v. Nuziveedu & Ors* AIR 2019 SC 559
5. *Biswanath Prasad Radhey Shyam Vs. Hindustan Metal Industries* (1979) 2 SCC 511
6. *Ferid Allani v. Union of India* 2008 (37) PTC 448 (Del)
7. *Telefonktiebolaget LM Ericsson (Publ) v. Intex Technologies (India) Ltd.* 2015 (62) PTC 90 (Del)
8. *Telefonktiebolaget LM Ericsson (Publ) v. Lava International Ltd.* 2016 (67) PTC 596 (Del)
9. *Accenture Global Service Gmbh v. The Asst. Controller of Patents & Designs & Ors* (2012) 28 (Del). OA/22/2009/PT/DEL
10. United States Code Title 35 – Patents,  
[https://www.uspto.gov/web/offices/pac/mpep/consolidated\\_laws.pdf](https://www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf)
11. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)
12. *In Re Roslin Institute (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014)
13. U.S. Patent No. 7,514,258 (Granted on April 7, 2009)
14. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013)
15. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 128–129, 132 (1948)
16. *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 145-46 (2001)
17. Elizabeth A. Rowe, *Patents, Genetically Modified Foods, and IP Overreaching*, 64 S.M.U. L. Rev. 859, 864-865 (2011)
18. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)
19. *Pallin v. Singer*, 36 U.S.P.Q.2d (BNA) 1050 (D. Vt. 1995)

20. Leisa Talbert Pesche, Revisiting the Compromise of 35 U.S.C. § 287(C), 16 Tex. Intell. Prop. L.J. 299, 304, 321, 322 (2008)
21. *Diamond v. Diehr* - 450 U.S. 175, 101 S. Ct. 1048 (1981)
22. *In re Freeman*, 573 F.2d 1237, 197 USPQ 464 (CCPA 1978)
23. *In re Walter*, 618 F.2d 758, 205 USPQ 397 (CCPA 1980)
24. *In re Abele*, 684 F.2d 902, 214 USPQ 682 (CCPA 1982)
25. *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994)
26. *Alice Corp. v. CLS Bank* 134 S. Ct. 2347 (2014)
27. *In re Rosenberg*, No. 19-2251 (Fed. Cir. 2020)
28. European Patent Convention 1973, [https://www.epo.org/law-practice/legal-texts/html/epc/2020/e/EPC\\_conv\\_20210401\\_en\\_20210325.pdf](https://www.epo.org/law-practice/legal-texts/html/epc/2020/e/EPC_conv_20210401_en_20210325.pdf)
29. EU Directive 98/44/EC read with Rules 23b-e of European Patent Convention
30. G 0003/19 (Pepper (follow-up to Tomatoes II and Broccoli II) of 14.5.2020
31. T 0082/93 (Cardiac pacing) of 15.5.1995
32. T 0044/12 () of 11.1.2017
33. T 1731/12 (Implantat/Forschungszentrum Jülich) of 15.2.2019
34. G 0001/07 (Treatment by surgery/MEDI-PHYSICS) of 15.2.2010
35. G 0002/08 (Dosage regime/ABBOTT RESPIRATORY) of 19.2.2010
36. T 0641/00 (Two identities/COMVIK) of 26.9.2002.
37. G 0001/19 (Pedestrian simulation) of 10.3.2021

## BOOKS

1. V K Ahuja, *Law Relating to Intellectual Property Rights*, 482 (V K Ahuja ed., 2<sup>nd</sup> ed. 2013)

## ONLINE JOURNALS/WORKING PAPERS

1. Kailash Choudhary & Rangoli Nigam, *Patentability of software: a comparative analysis in various jurisdictions*; VII Issue I, *Indian Legal Impetus* 4, 6 (2014).
2. Richard H. Shear & Thomas E. Kelley, *A researcher's guide to patents*, 132 *Plant Physiol.* 1127,1127 (2003).
3. Arnold B Silverman, *The Relationship Between Basic and Improvement Patents*, 47 (1) p.50 *JOM* (1995).



4. Johanna Sheeche, *Indian Patent Law: Walking the Line*, 29 Nw. J. Int'l L. & Bus. 577, 577-582 (2009).

#### WEBSITES/BLOGS AND NEWSPAPER ARTICLES

1. WIPO, (August 4, 2022, 2:18 PM), <https://www.wipo.int/patents/en/>
2. WIPO, (Sept. 28, 2022, 11:54 AM), [https://www.wipo.int/sme/en/obtain\\_ip\\_rights/patents.html#:~:text=In%20order%20to%20obtain%20a,you%20filed%20your%20patent%20application](https://www.wipo.int/sme/en/obtain_ip_rights/patents.html#:~:text=In%20order%20to%20obtain%20a,you%20filed%20your%20patent%20application)
3. IPINDIA, (Sept. 28, 2022, 12:01 PM), [https://ipindia.gov.in/writereaddata/Portal/Images/pdf/Final\\_FREQUENTLY\\_ASKED\\_QUESTIONS\\_-PATENT.pdf](https://ipindia.gov.in/writereaddata/Portal/Images/pdf/Final_FREQUENTLY_ASKED_QUESTIONS_-PATENT.pdf)
4. Creation of IP division by the High Court of Delhi, iPLEADERS (July 26, 2022, 12:44 PM), <https://blog.ipleaders.in/creation-of-ip-division-by-the-high-court-of-delhi/>
5. Sruthi Dharbhamulla, Explained | The Indian patent regime and its clash with the U.S. norms, THE HINDU (July 26, 2022, 12:49 PM), <https://www.thehindu.com/news/national/explained-the-indian-patent-regime-and-its-clash-with-the-us-norms/article65464988.ece>
6. USPTO, (July 29, 2022, 10:17 AM), <https://www.uspto.gov/web/offices/pac/mpep/mpep-0020-introduction.html>
7. Nishanth Mohanty, Patentability of Methods of Medical Treatment in India, DSNLU (July 27, 2022 9:12 PM) <https://dsnlu.ac.in/wp-content/uploads/2022/02/16.-NISHANTH-MOHANTY.pdf>
8. Richard Stim, *What's New in Patent Law, 2018 to 2021*, NOLO (30 July, 2022, 2:36 PM) <https://www.nolo.com/legal-updates/what-s-new-in-patent-law-2018-to-2021.html>
9. Larry Bischoff, Types of Medical Device Patents: What You Need to Know, STERLING MEDICAL DEVICES (July 31, 2022, 02:35 PM), <https://sterlingmedicaldevices.com/thought-leadership/medical-device-design-industry-blog/types-of-medical-device-patents-what-you-need-to-know/>
10. Adam Lewin, *Medical device innovation in America: The tensions between food and drug law and patent law*, DASH.HARVARD.EDU (July 1, 2022, 04:48 PM), <https://dash.harvard.edu/handle/1/11940217>

11. Patent Policy In Medical Terms | Understanding The Relationship Between Medical Procedures and Patent Policy, IIPRD (July 2, 2022, 01:04 PM), <https://www.iiprd.com/patent-policy-in-medical-terms/>
12. Testing Parameters for Software Patentability, BANANAIP (August 02, 2022, 04:22 PM), <https://www.bananaip.com/ip-news-center/testing-parameters-for-software/>
13. Abhishek Kumar Singh & Suryakant Kashyap, Software Patentability: A Comparative Analysis, MANUPATRA (August 02, 2022, 04:24 PM), <http://www.manupatra.com/roundup/323/Articles/Software%20Patentability.pdf>
14. Theodore Rand, *Alice in 2020: Slashing Software Patents and Searching for Functional Language at the Federal Circuit (Part I)*, IPWATCHDOG (August 03, 2022, 01:15 PM), <https://www.ipwatchdog.com/2021/01/07/alice-in-2020-slashing-software-patents-and-searching-for-functional-language-at-the-federal-circuit-part-i/id=128802/#>
15. EUROPEAN PATENT OFFICE, (August 3, 2022, 01:58PM), <https://www.epo.org/applying/european.html>
16. Axel B. Berger & Kerstin Galler, *Germany: Regarding The Patentability Of Plants And Animals In Europe – The G 3/19 Decision ("Pepper") Of The European Patent Office*, MONDAQ (August 4, 2022, 03:24 PM), <https://www.mondaq.com/germany/patent/970084/regarding-the-patentability-of-plants-and-animals-in-europe-the-g-319-decision-pepper-of-the-european-patent-office>
17. Hazel Ford, *Patentability of Medical Methods in Europe*, FINNEGAN (August 4, 2022, 05:19 PM), <https://www.finnegan.com/en/insights/blogs/european-ip-blog/patentability-of-medical-methods-in-Europe.html>
18. Samuel Denis, *Obtaining patent protection for software in Europe*, LEXOLOGY (August 4, 2022, 05:38 PM), <https://www.lexology.com/commentary/intellectual-property/european-union/gevers/obtaining-patent-protection-for-software-in-europe>
19. Sylvain Chaffraix, *European Union: Patentability Of Software In Europe*, MONDAQ (August 7, 2022, 02:46 PM), <https://www.mondaq.com/france/patent/1210460/patent-ability-of-software-in-europe>

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