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THE EMERGENCE OF NEW ISSUES & DIMENSIONS IN THE INTELLECTUAL PROPERTY RIGHTS REGIME: A CRITICAL ANALYSIS

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I. Introduction

Intellectual property law as a branch of study has seen various contributions as well as modifications, different intellectual properties have come out to being and this shift towards the evolution in various sectors marks as the matter for necessity in the times where the trends are changing. The evolution of intellectual properties has created a big loophole in the Indian framework of laws of intellectual property rights (herein referred to as 'IPR'), for instance, there is an express ousting of software from the patent protection as the scope of Indian Patents Act, 1970[1] is limited but on the same point the copyright law provides the adequate protection but on the point of invention in software, the matter becomes complicated and hence an overlapping of both the laws comes into picture. Similar is the case with the new types of intellectual properties on the rise that is, Data Exclusivity, Orphan Drug Exclusivity, Standard Essential Patents etc. Indian protection on intellectual property marks the lack of legislature and due to the mixed priorities also, it appears that the legal framework has a long way to go to integrate these issues and maintain the approach of giving precedence to the public benefit as well.

The intellectual property regime of India caters well to different forms of intellectual properties and their protection in this technologically advancing and innovation driven era. Various commonly protected intellectual properties like copyright, patents, designs, geographical indications, trademarks, plant varieties etc are given the benefit of the legislations underlying the purpose for which they were formulated. As now with the advent of newly emerging intellectual properties, those find a mention in more than one legislations as majorly appearing subject matter of more than one of them, or the ones which create an ambiguity as to which legislation in the present regime they would fall upon to become a subject matter and finally the ones which find no mention or no significance in any of the existing legislations. The main aim of the judiciary is to then apply its judicial wisdom and devise a certain way wherein an intellectual property of such description can be given protection.

It is very pertinent to learn about the emerging intellectual properties and the question as to how they should be accommodated under the garb of IPR protection in the Indian legal framework so

[1] The Indian Patents Act, 1970 (Act 39 of 1970).

as to make the Indian legal framework of protection as a robust and comprehensive system tailormade for protection and dealing of the various issues of these aforementioned intellectual properties a possible prospect. As the intellectual properties are the products of an intellectual mind and by the virtue of it, they should be protected and preserved, keeping in mind the pro-public benefit approach of the Indian regime. The various relevant criticisms around the same topic have also been covered as a part of the study and some major suggestions and recommendations from the author's side towards the conclusion is an integral segment of the same.

An approach of uncovering the various newly developed intellectual properties is employed and the various lacunas of the legal system are pointed out and what lies beyond the idea of efficacious protection and coverage of these intellectual property is underlined along with pointing out how this irregularity can be solved.

The project opens with an introduction and background information of the newly discovered intellectual properties, their genesis, origin and development, which is followed by the covering of legislative framework required by the same. This is followed by some criticisms, judicial response with the help of some select cases and the suggestions and recommendations from the author's side.

II. Intellectual Property: Meaning & Concept

The intellectual properties are creations of the human mind. They are knowledge assets created through the manifestations of ideas; they are conferred upon the people who are creators as something like as exclusive right for the intangible assets of knowledge. These rights can be used for the interaction of trade and commerce and they are also enforceable by law. They are capable of playing an important role as assets for an enterprise than physical assets; the major tools for the regulation of competition in business, it is often regarded as the 'new wealth of nations'[2].

a) Genesis and Origin

It was marked by the advent of marks and patent system of the ancient era, followed by the early history of copyrights and so on.

The usage of Marks

In the early 2700 B.C., the Chinese pots came to the surface that had two kinds of marks that would imply the name of period's emperor and name of the maker. The stamps on the bricks in the early Roman empire were also used to show the marks of identification in the 2nd century B.C. Potters mark in the times of Greek and Roman empire were also allowed on the vessels to mark the origin, destination and identification of the maker. The barber's pole was also used to indicate the location of business. In the 10th century, the use of 'merchants mark' also come up to the surface. In 1266, a law was enacted by English Parliament to affix a certain mark on the

[2] V.K. Ahuja, *Law Relating to Intellectual Property Rights*, 38 (LexisNexis Publications, Nagpur, 3rd edn., 2017).

bread by the traders to know what kind of bread was being given. The case of ***Southern v. How***[3] in the year 1617 it was held that nobody has any right to represent his goods as the goods of someone else. The British Trademark Act of 1875 also signified the registration of trademark as evidence of ownership.

The early Patent system

It was based on 'letters patent' that provided with rights, ranks or titles. The sovereign state used to provide such a right which had an exclusive privilege of supplying in the territory a certain product. There was also an example of early patent when in the Greek city Sybaris the leaders decreed that if a cook invents a delicious new dish then no other cook is permitted to make it for another year. The earliest patent in the English legal system was granted by Henry VI in 1449 of John of Utynam, a glass maker who could share his technological secrets with his apprentice without the fear of competition from them for 20 years. In Italy, the Venetian Patent Act of 1474 was formulated and it gave rise to a lot of patents being made under that. Followed by it was Statute of Monopolies by U.K. in the year 1623 as a regulator and protector for projects of new invention and discrediting those which were against the public interest. The original invention could now be used for a fixed number of years. In ***Darcy v. Allein***[4] the judiciary historically dealt with monopolies regulation.

The early history of Copyrights

In 557 AD, wherein in Ireland where Finian was robbed off his manuscript when somebody copied it, this paved way for the dictum of to every cow her calf and to every book its copy. In 1440, the printer's license by the sovereign used to work for the earliest copyright system. The guild members had monopoly over this and it was permanent whereby authors could not take part in the same, they were granted no royalties. The copyrights were also granted as 'monopolies' but this was ended after the Statute of Monopolies of 1623 took it away. The Statute of Anne, 1710, followed this development and gave exclusive rights to authors rather than publishers.

b) Development and Evolution

The development and evolution of the subject matter was marked by IPR regime under British rule, followed by the post-independence era and oncoming of various newly emerging IPRs.

Pre-independence era (IPR Regime under British rule)

In the year 1856 the Britishers had implemented the statute 'On Protection of Statutes' and the rights of exclusive use were granted to the inventors for 14 years. In the year 1888, the consolidated Act to put together 1872 Patterns and Designs Act and 1883 Patents Act in accordance with amendments in the UK law, it was called the Inventions and Designs Act. In

[3] TRADEMARK BASICS, *available at:* https://www.wipo.int/edocs/mdocs/sme/en/wipo_smes_hyd_07/wipo_smes_hyd_07_www_91793.pdf (Visited on November 28, 2021).

[4] 74 ER 1131.

1911, the Patents and Designs Act came into being and the Patent Office and Controller of Patents was installed and the period was increased from 14 years to 16 years. The Indian Copyright Act was also formulated in the year 1914 on the U.K. Copyright Act, 1911. The Trademarks Act and Registry was put up right after in the year 1940.

Post-independence era

The consolidated Indian Copyright Act, 1957 to deal with the copyright matters was put in motion, this was again followed by the Trade and Merchandise Act, 1958 which was put forth. In 1970, a consolidated Patents Act was put in force whereby 7 years protection for food and 14 years for drug was there and compulsory licensing procedures were there, in the same years Designs Act was separated from it. In 1994, the provisions of Rome Convention, 1961 and other relevant modifications were done in the Copyright law. The year 1999 saw the oncoming of new Trademarks Act and some modifications in the Patent Act according to the TRIPS obligations. The Geographical Indications of Goods (Registration & Protection) Act, 1999 was also passed. The Semiconductor Integrated Circuits Layout Design Act was enacted in the year 2000 to provide protection to semiconductor IC layout designs. The year 2001 marked the onset of Designs Act, 2000. In the year 2002, establishment of Intellectual Property Appellate Board took place and Uniform term of 20 years irrespective of the field of invention of patents was put through. In the year 2005, product patents were introduced in areas of drugs, pharmaceuticals and agrochemicals; Pre/Post- grant Opposition system was also set up. In the year 2012, provisions in conformity with the WIPO Treaty and WIPO Performances and Phonograms Treaty were added in copyright laws. The inclusion of important obligations of Madrid Protocol in Trademarks Act was done in 2013.

Oncoming of IPs (adequately) not covered & other issues and challenges

The IPR regime lacked adequate protection for certain peculiar intellectual properties like the softwares which neither a subject of copyright law, nor the patents law if an invention was involved and also various other IPs like the data exclusivity for the data of the drugs that are used was not adequately protected and it needed a refurbished system for the same to carry through. The SEPs and FRAND licensing had always been a problem, whereby the SEPs were never said to be adequately covered, it was only touched upon by the judiciary in a catena of cases, the FRAND licensing could be enforced but the major problem was that it had a loose nexus of enforcing the same. Then there were IPs were orphan drug exclusivity which are not at all covered by the present IPR regime. The other issues like ever-greening and incremental inventions still stay as the major unresolved questions and the debate of public rights vs. private rights in the aspect of compulsory licensing was never in a tilt that could contain balance.

III. The case for newly emerging IPs: current position and way ahead

The various newly emerging IPs have been coming forward in the legal regime of India, particularly that need adequate protection for the same. The ones that are the within the scope of this study are, invention in software, SEPs, FRAND Licensing, Data Exclusivity, etc.

a) Invention in Software

Whenever the question is to determine as to what is the kind of protection the particular intellectual property is seeking, it is also important to know what is 'intellectual' about the property. The question revolves around two parallels, whether the same lands in the realm of copyright law or patent law.

Legislative scope and framework

Under the Indian Copyright Act, 1957

Software, or within the words of Indian Copyright Act, 1957, 'computer programme' finds its mention and partial protection in the Act. The S. 2(ffc)[5] defines a computer programme as, *"a set of instructions expressed in words, codes, schemes or in any other form, including a machine-readable medium, capable of causing a computer to perform a particular task or achieve a particular result"*. The areas of 'literary work' in the same Act also touches upon the same as defined in the S. 2(o)[6] of the Act, *"literary work includes computer programmes, tables, and compilations including computer literary databases"*

Under the Indian Patents Act, 1970

Whether the computer programmes find a mention in the Patents Act, or not is a question more related to the patentable subject matter according to which we can find out whether a particular intellectual property falls in the ambit of patentable subject matter under S. 3[7] of the Act stating what are not inventions. S. 3(k)[8] of the Act states it as, "*a mathematical or business method or a computer programs per se or algorithms"*; and S. 3(m)[9] as, *"a mere scheme or rule or method of performing mental act or method of playing the game; expressly excludes computer programs from the patentable subject matter"*. In the year 2005, a specific clause to bring software patents within the ambit of protection was quashed in the parliament[10] but the new guidelines in the year 2016, the Office of the Controller General of Patents, Designs and Trademarks had remarked that they would accept the applications of such patents given that they are in conjunction with a novel hardware.[11] In the succeeding year, i.e. 2017 new guidelines came in whereby the untangling of the legal protection was done in this context as the major prerequisite for protection became the technical advancement and cannot be excluded in the S. 3[12] of the Patents Act.[13] In the Patents

[5] The Indian Copyright Act, 1957 (Act 14 of 1957), s. 2(ffc).
[6] *Supra* note 2, s. 2(o).
[7] The Indian Patents Act, 1970 (Act 39 of 1970), s. 3.
[8] *Supra* note 3, s. 3(k).
[9] *Supra* note 3, s. 3(m).
[10] Software patents under Ordinance face reversal, *available at*: https://www.financialexpress.com/archive/software-patents-under-ordinance-face-reversal/82155/ (Visited on November 29, 2021).
[11] Guido Noto, "Software Patents and the Internet of Things in Europe, the United States and India" 3 *EIPR* 39 (2017).
[12] *Supra* note 3.
[13] Guidelines for Examination of Computer Related Inventions (CRIs), *available at*:

(Amendment) Act, 2002, whereby the newly proposed clause (k) in the S. 3 of the Act was brought in, it was said that attaching the words 'per se' would help in the long run as to include the computer programmes within the scope of the same.

Select case laws

Accenture Global Service GMBH v. The Assistant Controller of Patents & Designs[14]

In this case, there was an application filed for a patent to be granted which was refused within the meaning of S. 3(k) of the Act as it could be found under the scope of patentability. But it had to be shown that the applicant's invention was not a software per se, but system which can be used for the enhancement of web services and software.

Nissan Motors case[15]

The Nissan Motors had filed a number of applications on the same issue which reasoned out as being under this same category, it was about a device for travel control and enabling the target avoidance technique that was the subject matter of that issue, a system that can also enable the location of the vehicle etc, Nissan took the refuge in the Guidelines for Examination of the Computer Related Inventions, though it was contended that the same subject matter is a hybrid of technology and software but it was seen as a conflict between guidelines and the Act and hence in this case the Act was made to prevail.

b) Standard Essential Patents (SEPs) and Fair, Reasonable and Non-Discriminatory (FRAND) Licensing

Meaning & Concept

When there is a patent that is used for the protection of the technology that is essential to a standard, it is called as standard-essential patent. A standard refers to as a document that puts in motion certain requirements that are needed to be fulfilled for a specific item, material, component, system or service, or it covers the details of a particular method or procedure.

Position under the Indian Patents Act, 1970 and the corollary situation

The Indian Patents Act, 1970 does not have any special provisions for the protection of SEPs but it has its mentions in the jurisprudence of the same. In the case of ***Telefonaktiebolaget lm Ericsson (publ) v. Competition Commission of India and another[16],*** a mention of the requirements of the Standard Setting Organisation (SSO) was taken forward to show that the

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https://ipindia.gov.in/writereaddata/Portal/Images/pdf/Revised__Guidelines_for_Examination_of_Computer-related_Inventions_CRI__ (Visited on November 30, 2021).

[14] 1398/DELNP/2003.

[15] Emerging trends in IP, *available at:* https://www.iiprd.com/emerging-trends-in-ip/ (Visited on December 02, 2021).

[16] 2016 SCC OnLine Del 1951.

companies that involve in the standardisation of any technology have to undergo certain guidelines and rules that are there:

- They have to put on record and incorporate the patent that is essential so as to get that standard.
- With a view of enabling themselves to use such a patent without infringing the same, they have to get a licence from the holder of such patent.

The inadequacies of SEP protection and FRAND commitments

Though in these situations, there can be a possible monopolistic outcome by the person who owns the patent as such and to control and monitor this situation so as to curb the situation the patent holder has to follow the commitments of SSOs. These particular commitments are known as FRAND commitments which are associated with the same. The fair, reasonable and non-discriminatory terms are to be decided by the parties in the question and to be treated in the same way. When there is an inability of the parties to reach the conclusion, they can go for the mediation proceedings, the Competition Commission of India (CCI) can intervene if it finds that the other party is using abusive and dominant powers, the CCI can use its jurisdiction and bring it into the matter.

c) Data Exclusivity

The genesis from Paris Convention, TRIPS and legislative scope and framework in India

The basis of data exclusivity can be traced back to the principles of unfair competition, which were established by the Paris Convention, which is governed by WIPO under Article 10 bis and includes effective defence against unfair competition. The Data Exclusivity is a type of intellectual property that has been a derivate of the TRIPs Plus element and its use is pretty much debatable as far as applicability in India is concerned. When the Article 39[17] of the TRIPS Agreement is put to use, it embodies the interpretation of the same, which is as follows: "*Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use*". As the countries like USA interpret the 'protection against unfair commercial use' as to imply that the regulatory agency should be provided the clinical data for safety and efficacy of a new drug and the generic drug manufacturers should be stopped from using such data from being used.

[17] The Trade-Related Aspects of Intellectual Property Rights, 1995, art. 39.

The possible problems and the deadlock of IP laws

In India basically, the Drugs and Cosmetics Act, 1940[18] provide for the provisions of data exclusivity of a new drug under the S. 122E[19] for a period of 4 years from the date of approval. In the year 2016, there was a proposal to increase the period from 4 years to 10 years for the reasons of keeping the data exclusive for a long period of time thus protecting the situation wherein the patent would stand invalid, the data would still be protected for a longer duration, this could not see the light of the day as it would be a huge roadblock in providing the drug to the common people for their use at reasonable prices.

d) Orphan Drug Exclusivity

Meaning & Concept

An orphan drug is referred to an agent in the pharmaceutical sector that is used for treating or curing a rare medical condition or a disease of that sort. India, specifically has no rules and regulations regarding this kind of intellectual property that could deal within itself the matters of regulation of these orphan drugs' selling or manufacturing.

The absence of laws and framework of protection

The issue lies deep in the facts and figures, which show that the treatment of rare diseases is very costly in India and more than 7 Crore people are suffering from such diseases and around 6,000-8,000 diseases can be found which include some that do not have a cure and are mostly genetic. Many countries do have the various definitions and regulations of orphan drugs. The lack of rules and regulations in India increases the burden of the patients who are suffering from such diseases and also cut down the growth of country's pharmaceutical sector. They can help to ease the revenue loss caused by the patent expiration of blockbuster drugs; the orphan drugs not only treat the disease but also gives the stability in the market. The governments all across the world, have started given an incentive to the orphan drugs as well so that they can be given a helping hand in catering the protection of such intellectual property.

IV. The current emerging issues of IPR

The newly emerging IPRs have also accounted for various newly emerging issues as well and thus, it has become important to adequately cover these issues by fine-tuning the laws.

a) Ever-greening and incremental inventions

The position under TRIPS and Indian Patents Act, 1970

Issues of ever-greening and incremental inventions in the drugs and pharmaceutical sector remain as a big problem and unresolved question. Indian Patent Act, 1970 was amended to be in line with the obligations of TRIPS Agreement[20], majorly the Article 31[21] in the year 2005, thus

[18] The Drugs and Cosmetics Act, 1940 (Act 23 of 1940).
[19] *Supra* note 14, s. 122E.
[20] Balwant Rawat, "Patenting Landscape in India" 10 *SSRN* 31 (2009).
[21] The Trade-Related Aspects of Intellectual Property Rights, 1995, art. 31.

giving the patent protection to the sectors of food, drugs, chemicals and microorganisms, the exclusive marketing rights were deleted and a provision for the compulsory licencing of the export of medicines, the modifications in both pre-grant and post-grant oppositions that could be filed were also brought in, the patenting of abroad to prevent dual use technologies was also brought in and finally the process of rationalisation of the timelines associated with the filing and applying for the patents.

The Novartis case and the problem of ever-greening

It has been held to be of little to no use as in the case of ***Novartis v. Union of India & Others***[22] which is a landmark judgement on the point whereby the Supreme Court had upheld the rejection of the patent of Novartis, the major reason on the point of rejection was that amendment which was brought in the year 2005 that discussed about the patentability of new uses for known drugs and their modification. The section whereby in the paragraph 3(d) it was specified that the inventions are patentable only if they differ significantly in properties with regard to efficacy.[23]

b) Compulsory Licensing

The legislative framework and position under the Indian Patents Act, 1970

The issue of compulsory licensing runs deep to the reasons of private rights vs. public rights debate. It has been always regarded as important provision that is sought after by the various jurisdictions for the grant of an efficacious remedy in the cases of abuse of patent protection. As it is understood that it is provided under the S. 84[24] after 3 years from the date of grant to any interested party. It has some major grounds that are, reasonable requirement of public not being satisfied, non-availability of the same to public at a reasonable price or the patent invention not being worked within the territory of India. Also, S. 92[25] states that at any time of the grant of the patent the Central Government can direct the Controller to grant such license in the matters of: national emergency, extreme urgency or public non-commercial use.

The first compulsory license grant

In the year 2012, India actually granted the Indian generic drug manufacturer Natco Pharma for Sorafenib tosylate which was particularly a cancer drug patented by Bayer.[26] Though Bayer moved against the same decision to the Intellectual Property Appellate Board (IPAB) on grounds of societal and health perspectives according to Article 21[27] of the Constitution, though it was

[22] (2013) 6 SCC 1.
[23] *Ibid.*
[24] *Supra* note 3, s. 84.
[25] *Supra* note 3, s. 92.
[26] India Grants First Compulsory Licence, For Bayer Cancer Drug, *available at*: https://www.ip-watch.org/2012/03/12/india-grants-first-compulsory-licence-for-bayer-cancer-drug/ (Visited on December 01, 2021).
[27] The Constitution of India, art. 21.

rejected and a lot of issues regarding the compulsory licences in IPR were exposed. (***Natco Pharma Ltd v. Bayer Corporation***[28])

The major problems and considerations

But the provisions of compulsory licensing do not come without the presence of some major issues that are required for consideration as far as the IPR regime is concerned. It has been a fact that the compulsory licensing is provided in the jurisdictions of various countries like USA, Europe etc. When a country is at a developing stage, it has to be seen that it ought to have a patent law that should cater to the reasons of it being of some support to the developing economy. Most of the developed countries have also incorporated these provisions in their patent laws. In the recent trends, strong oppositions are being put forth by the developed countries against the grant of compulsory licencing to least developed countries particularly in the realm of TRIPS and Doha Declaration, huge hue and cry is raised against the provisions of compulsory licensing with a view that the country's position at global level would be maligned and the invoking of economic sanctions like Super 301 which are put under threat.

V. Judicial Response

A catena of select Indian cases have been chosen to fit the scope of research in the judicial response of this study and they are as follows:

a) The absence of robust FRAND licensing framework

In re ***Ericsson v. CCI***[29], it was alleged that Ericsson had added a covenant subjecting all disputes relating to matters under their FRAND license to the jurisdiction of Swedish Courts, thereby causing unnecessary costs for Indian mobile phone companies. There are no specific guidelines as to what is fair, reasonable, and non- discriminatory, due to which big fishes in the market construe the terms in their own brackets of convenience. Considering the economic condition of the Indian market, such licensing terms can lead to the winding up of small and medium enterprises which are to be further evaluated by the Competition Commission of India.

b) Inventions in Software, a proposition welcomed but not usually granted

Electronic Navigation Research Institute v. Controller General of Patents[30]

This case was in relation with the patent application number 3624/DELNP/2005 for the invention titled "A CHAOS THEORETICAL EXPONENT VALUE CALCULATION SYSTEM" in which the application was denied by the patent office on the ground that the proposed system fell under the category of mathematical formulae even if it resulted in technical effects. The invention claimed a mathematical method to determine and evaluate the time

[28] Decision of the Controller of Patents in Compulsory License Application No. 1 of 2011 (Mar. 9, 2012), *available at*: http://www.ipindia.nic.in/iponew/compulsory_license_12032012.pdf (Visited on December 01, 2021).
[29] 2013 SCC OnLine CCI 78.
[30] IPAB, OA/26/2009/PT/DEL.

signals. In this case, section 3(k) was discussed in great detail, and the patent application was rejected owing to a business model being embodied via technology. It was implied that the business model disguised as technological innovations would not meet the criteria for the patents being granted in India.

Yahoo v. Controller of Patents & Rediff.com India Limited[31]

In the case of Yahoo, the patent claims included features of a software tool targeting search terms relevant to Yahoo's business. Accordingly, the IPAB concluded that the technical advance proposed by Yahoo was simply a method of doing business, even if it was a technically smarter way of doing business and, therefore, cannot be patented in accordance with provisions of Section 3(k) of the patents act.

c) The regulation of rare diseases indicating at the urgent need for orphan drug exclusivity

In ***State of Punjab v. Ram Lubhaya Bagga***[32]**,** the court analyzed the new policy on reimbursement of medical expenses of government employees and laid down that policies on healthcare, they should not be arbitrary, unreasonable or violative of any law or principle. In another case, ***Confederation of Ex-servicemen Associations and Ors. v. Union of India &Ors***.,[33] a public interest litigation was filed in the Supreme Court for recognition of right to free and full medical care to retired defense personnel and their families as a fundamental right, at par with serving defense personnel. The existing regulations of the armed forces related to medical care at that time excluded free treatment for serious diseases like tuberculosis, leprosy and mental disorders for ex-servicemen. While recognizing the right to medical aid as a fundamental right of all citizens and also acknowledging the services rendered by retired defense personnel, the court adopted a cautious approach, stating that the right to medical care is subject to the limitations of State financial stringencies on the health budget.

d) The non-compliance of Treaties and Conventions in the Novartis case and problem of evergreening

In ***Salmon v. Commissioner of Custom and Ellerman Lines Limited***[34] it was stated the provisions of section 3(d) were inconsistent with article 27 of TRIPS and thus against the spirit of a binding International Treaty. Thus, the Novartis AG case was decided as per that.

• That by inserting section 3 (d), the Govt. of India had violated its obligation under TRIPS agreement. Accordingly, the section should be declared null and void.

• That there is no guideline in respect of the words like “enhancement of efficacy” or “differ significantly in properties with regard to efficacy” under section 3 (d). The section confers

[31] IPAB, OA/22/2010/PT/CH.
[32] AIR 1998 SC 1703.
[33] AIR 2006 SC 2945.
[34] [1967] 2 QB 116

arbitrary powers on the Controller to refuse patent applications and hence violates the right to equality under Article 14 of the Indian Constitution.

e) The problem of shoddy mechanism for compulsory licensing and its repercussions

BDR Pharmaceuticals v. Bristol-Myers Squibb[35]

The following case illustrates licence sought for Sprycel® which is used in cancer treatment. On March 4, 2013 the Controller rejected BDR Pharmaceuticals' (BDR) application for a compulsory license for the cancer drug Sprycel®. The controller stated that BDR failed to make a prima facie case for the grant of compulsory license. Specifically, the Controller found that BDR had made no credible attempt to procure a license from the patent holder and the applicant had not acquired the ability to work the invention to public advantage. Thus, the compulsory license was denied.

Lee Pharma v. AstraZeneca[36]

The following case illustrates license sought for Saxagliptin® which is used in the treatment of Type-II Diabetes Mellitus. On June 29, 2015, Lee Pharma filed an application for compulsory license for patent covering Astra Zeneca's diabetes management drug Saxagliptin®. The application was rejected stating that no prima facie case had been made out on any of the three grounds under section 84 (1) of the Indian Patent Act. Reasonable requirements of the public had not been satisfied: Lee Pharma failed to demonstrate reasonable requirements of the public with respect to Saxagliptin® and further failed to demonstrate the comparative requirements of the drug Saxagliptin® vis-à-vis other drugs. The patented invention was not available to the public at a reasonably affordable price: It was held that all related drugs were in the same price range and that Saxagliptin® being sold at unaffordable price was not justified. The patented invention had not been worked in the territory of India: Lee Pharma also failed to show the exact quantitative requirements of Saxagliptin® in India. Therefore, it could not be concluded whether manufacturing of the drug in India was necessary or not.

VI. International comparative study with reference to U.S. and E.U.

International comparative study with reference to the newly emerging IPRs have been covered under this head in the case of EU and US jurisdictions and they are as follows:

a) Invention in Software

United States

Article 1, section 8 of the United States Constitution establishes that the purpose of intellectual property is to serve a broader societal good, the promotion of "the Progress of Science and the useful Arts":

[35] CS(OS) No. 679/2013.

[36] (C. L. A. No. 1 of 2015).

Article 1, section 8 United States Constitution:

Congress shall have Power [. . .] To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries; . . .

Section 101 of title 35, United States Code, provides:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title. However, there are restrictions on subject matter eligibility under Section 101 and in general the line between what is deemed patent eligible under Section 101 and what is ineligible changes is, as discussed below, a matter of ongoing judicial activity.

E.U.

Within European Union member states, the EPO and other national patent offices have issued many patents for inventions involving software since the European Patent Convention (EPC) came into force in the late 1970s. Article 52 EPC excludes "programs for computers" from patentability (Art. 52(2)) to the extent that a patent application relates to a computer program "as such" (Art. 52(3)). This has been interpreted to mean that any invention that makes a non-obvious "technical contribution" or solves a "technical problem" in a non-obvious way is patentable even if that technical problem is solved by running a computer program. A summary of the developments concerning patentability of computer programs under the European Patent Convention is given in as a response of the Enlarged Board of Appeal to questions filed by the President of the European Patent Office according to Art. 112(1)b) EPC.

b) Data Exclusivity

United States

In 1984, the US became the first country to enact data exclusivity legislation. Under the Hatch-Waxman Act, applications for approval of new drugs receive 5 years of data exclusivity. Applications for the approval of new indications for an existing drug receive 3 years of data exclusivity.

E.U.

In the EU, Directive 65/65 provides a period of data protection of either 6 or 10 years depending on the Member State at issue. The larger Member States provide 10 years, while the smaller provide only 6 years. However, for products which are approved through the centralized procedure, Regulation 2309/93 provides a 10-year period of data protection. The 6 to 10-year range for national registrations reflects differences between the national regulatory regimes of the EU members. The EU is considering harmonizing protection to 10 years for all national registrations under 8+2+1 formula, which has 8 years of data exclusivity with 2 years of

marketing exclusivity that can be further extended by an additionaUl one year, if during the first 8 years of those ten years, the innovator obtains authorization for one or more therapeutic indication. In the EU, Directive 65/65 provides a period of data protection of either 6 or 10 years depending on the Member State at issue. The larger Member States provide 10 years, while the smaller provide only 6 years. However, for products which are approved through the centralized procedure, Regulation 2309/93 provides a 10-year period of data protection. The 6 to 10-year range for national registrations reflects differences between the national regulatory regimes of the EU members. The EU is considering harmonizing protection to 10 years for all national registrations under 8+2+1 formula, which has 8 years of data exclusivity with 2 years of marketing exclusivity that can be further extended by an additional one year, if during the first 8 years of those ten years, the innovator obtains authorization for one or more therapeutic indication.

c) Orphan Drug Exclusivity

United States

The Orphan Drug Act (ODA) of January 1983, passed in the United States, with lobbying from the National Organization for Rare Disorders and many other organizations, is meant to encourage pharmaceutical companies to develop drugs for diseases that have a small market. In 2002, the Rare Diseases Act was signed into law. It amended the Public Health Service Act to establish the Office of Rare Diseases. It also increased funding for the development of treatments for people with rare diseases.

E.U.

In 2000, the European Union (EU) enacted similar legislation, Regulation (EC) No 141/2000, which refers to drugs developed to treat rare diseases to as "orphan medicinal products". The EU's definition of an orphan condition is broader than that of the US, in that it also covers some tropical diseases that are primarily found in developing nations. Orphan drug status granted by the European Commission gives marketing exclusivity in the EU for 10 years after approval. The EU's legislation is administered by the Committee on Orphan Medicinal Products of the European Medicines Agency (EMA). In late 2007 the FDA and EMA agreed to use a common application process for both agencies to make it easier for manufacturers to apply for orphan drug status but, while continuing two separate approval processes.

VII. Suggestions and Recommendations

- The **deleterious impacts** of these non-inclusion of IPs and various issues are multi-fold and of varied importance and hence there has to be certain handouts for the **correction of those**;
- Present IPR regime leave a **grey area open** for various aspects and that is what is **open to interpretation** since the advent of these systems are **manipulated and used for**

unfair advantages, but there are some aspects like the **evergreening of patents** which are not adequately protected in either of the instruments and hence they should be looked after;

- Cogent deliberations and negotiations should be made on that regard in a harmonious manner and decided on the basis of how it needs to resolved and redressed in the light of **present day needs of economies and markets**. They should be made more **economic, respectable of socio-political set ups of the individual states so as to accommodate their interests and make them feel included and invested in those arrangements at the same time**. There needs to be a **democratic setup of organisations** of the same and they should be looked after in a way that they **protect** the intricacies of **nationality of member states** as well;
- The interpretation of the agreements have not been able to provide a certain set of principles to comply with the cases in a **more rational approach**, also there are some **emerging areas** that need the attention of these agreements and a lot of contribution needs to be made along those lines. There are various areas of emerging dimensions where the deliberations and talks are in place but little to no such fruition has been achieved on the same.;
- Viewing these provisions in a more **all-inclusive approach** it needs to be seen that the agreements need to have an all-inclusive approach and more **balancing of interests of stakeholders** need to be ensured.

VIII. Conclusion

Intellectual Property has seen numerous modifications. Different Intellectual Properties have come about to exist, which some would say is the impact of IP Maximalism and some would regard them as a matter of necessity of changing times, which reminds me of Victor Hugo, he spoke in a speech and I quote, “no power on earth can stop an idea whose time has come.” This is very well the era of IP evolution. Where software is expressly ousted from patent protection, CRIs come to their rescue. New types of intellectual property rights are on the rise, for example, Data Exclusivity, Orphan Drug Exclusivity, Standard Essential Patents, etc. India lags behind in several of these emerging trends, partly because of the lack of legislature in several issues and partly because of its mixed priorities. The legal framework needs to substantiate these issues more coherently while maintaining India’s pro-public-benefit approach towards IP.

Intellectual Property Rights came into existence with the primary objective of promoting the progress of science. Patents are the rights that grant exclusivity to the patent holders, where they

can exclude others from exploiting their invention which they have spent their R&D upon. This creates a monopoly in the hand of the right holder; this monopoly was intended to serve as an incentive for creation. This prevailing trend is untimely exclusivity masked in the disguise of evolution. However, exclusivity is an innate part of evolution, provided, used in the solution of overlooked issues such as orphan care drugs. Exclusivity is indeed very appealing for pharmaceutical companies to invest their R&D in the production of orphan drugs. It curbs their fear of negative commerce which appears to be an obvious result of producing any product with low commercial demand. With regulations such as a fixed exclusivity period over their drug and royalty standards, a profit margin can be achieved in addition to the recovery of production costs in the aforesaid duration. The shifting trend towards exclusivity can positively shape the Indian IP regime if given the right direction.