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Substantive Requirements of Patentability in terms of Pharmaceuticals and Environmentally Sound Technologies : A Comparative Study

Bhavya Singh,
Research Scholar (Faculty of Law), Jamia Millia Islamia, India.

Dr. Eakramuddin,
Associate Professor (Faculty of Law), Jamia Millia Islamia, India.

Abstract

The genesis of the present work comes from unclear, insufficient and vague patent laws that are there in the case of environmentally sound technologies. So, in the path of carving a set of proper rules and laws for them, pharmaceutical sector often tops the comparison debate. It will not obviously be a sound decision to pick the patent laws that pertain to drugs and apply them as it is to the EST sector as well. It is a long route to the destination and this paper forms a small part of that route. The principal objective of this paper is to understand what patentability means in terms of pharmaceuticals and ESTs and how are they similar or different from each other. Only when this paper decently achieves this objective, can the journey be continued of studying pharmaceutical patent laws and bringing them in use in the case of ESTs in the future works.

The authors in the paper, therefore, establish the commonality that exists in between pharmaceuticals and environmentally sound technologies, more so linking public health crisis with the climate change crisis. When it gets clear why this work orbits around drugs and ESTs and their correlation with each other, the authors then dive into the concept of patentability, which has been discussed from the general point of view, which offers an understanding at the foundational level, as well as in relation to drugs and ESTs specifically, in order to have a more nuanced approach.

In this doctrinal study, the authors attempt to accentuate the contradiction that persists between the public interest in terms of patented pharmaceuticals and ESTs on one hand and the exclusive patent rights on the other. There is a certain balance that should strive to be maintained between the protection that comes by virtue of patenting inventions and at the same time the accessibility of pharmaceuticals and ESTs to the community at large. So, to draw any sort of analogy between pharmaceuticals and ESTs, in order to present some lessons for consideration of the harmonisation between access to ESTs and international patent protection by using the advantages of the global reconciliation between public health and patents relating to pharmaceuticals, it is necessary to first understand the substantive requirements of patent

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protection that are intrinsic to them.For any invention to qualify as patentable, mostly three factors are essential, novelty, inventive step and industrial application. Before digging into the lessons learnt from the analogy between the two, it becomes pertinent to understand what novelty, inventive step and industrial application means in terms of pharmaceuticals and ESTs and only then can some clarity be expected to move further and make various other suggestions.

1. Introduction

Often the parallels are drawn between the debate over Environmentally Sound Technologies and pharmaceuticals and the debate over the effect that TRIPS has, particularly within developing nations, on the accessibilityof essential medicines. Many developing nations found, soon after the taking effect of TRIPS, that there were a lot of difficulties that they were facing in the procurement of the patented pharmaceuticals in order to combat the problems relating to public health in an adequate manner. These health problems were ranging from malaria, tuberculosis, HIV/AIDS and various other epidemics.

A worldwide public health crisis presents an opportunity to draw attention to public interests globally by mirroring the conflict that persists between drug patents and the human right to life. Similar to this, strict patent protection is defended by the EST owners while the countries that importexpect to receive technology at a fairly affordable cost. Both parties are confronted with the double dilemma of energy crisis and climate change.

An invention, whether it is patentable or not, is evaluated by certain standards and these are what come to be known as the substantive requirements of patentability. These standards although, vary from country to country depending upon the laws and policies of each specific one, however TRIPS provides a somewhat uniform standard. Invention in all technological fields can be granted patent under Article 27 of TRIPS, if they happen to be new, involve an inventive step and at the same time possess the capability of industrial use. This has been discussed at length in the subsequent paragraphs.

The purpose of this doctrinal study is to present some lessons for consideration of the harmonisation between access to ESTs and international patent protection by making optimum utilisation of the advantages of the global reconciliation that exists in between patents relating to drugs and public health.

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The objectives that the paper aims to achieve are to first examine the commonality between pharmaceuticals and ESTs. Then to understand briefly the concept of patentability as mentioned under TRIPS. The other objective is to amplify on each substantive requirement of patentability specifically and finally to explore these substantive requirements in the context of pharmaceuticals and ESTs.

The research questions that authors aim to answer through this work are; what is the common thread in between pharmaceuticals and ESTs, how has patentability been explained under TRIPS, what is the conceptual understanding of the substantive requirements of patentability in general and universal terms and finally the understanding of these requirements specifically in the context of drugs and ESTs.

The paper has been divided into three parts. The first part establishes the correlation between drugs and ESTs, which is the foundation of the whole paper and hence becomes necessary to highlight the common thread that runs through the work. The second part gives a brief overview of patentability under the TRIPS agreement. Before moving into the details, understanding patentability as mentioned under the TRIPS, helps develop a clarity. In the third part, the authors discuss patentability in a much deeper level. The part has two divisions itself. First section of each criterion (criterions being novelty, inventive step and industrial application) elaborates patentability in general terms, so as build a strong conceptual framework. However, in the second section of each criterion, patentability specifically in terms of drugs and ESTs is explored, in order to understand the complexities of each domain, i.e., drugs and ESTs, in light of these criterions. How novelty, inventive step and industrial application, as substantive requirements of patentability, translate specifically with reference to drugs and ESTs, has been explored in this part of the paper.

2. Correlation of Pharmaceuticals with ESTs

Public health and climate change have a very strong common factor as both of them qualify to be urgent issues. The dichotomy that exists between public interest at large and the exclusive rights of patents, is something which is common to both drugs and ESTs, one tapping the domain of public health crisis and the other tapping climate change crisis. It is not possible to see any of the two from purely a commercial lens.

Pharmaceuticals and ESTs having characteristics ofpublic and as well as private goods are under the category of imperfect public goods. These also include some components of public goods. These goods are produced by a small group of individuals using intricate, expensive, and time-

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consuming production procedures, and they are not naturally occurring goods or inexhaustible resources. Concerns over the human-caused public health issue and climate change are growing because there are fewer efficient market or governmental structures in place to distribute ESTs or drugs.[1] This is deemed to be a really bad case of a market failure in the supplying of a global good. It is because of certain very similar characteristics that these two possess, is why correlation is made or parallels are drawn between ESTs and Drugs.

3. Patentability under TRIPS Agreement

The TRIPS Agreement's implementation in 1995 marked a special turning point in the field of international intellectual property law. The agreement established minimum standards for intellectual property protection that all member countries had to adhere to. The TRIPS Agreement evolved into the international code of conduct for intellectual property law. All countries are required by it to make sure that their domestic legislation complies with the TRIPS requirements or face penalties under the WTO system.[2]

The Paris Convention is essentially the source of the TRIPS Agreement's patent clause.[3]The TRIPS Agreement mandates that member nations grant patents without discrimination for "any invention, whether products or processes, in all fields of technology," subject to the standard patentability requirements, which include novelty, inventiveness, and industrial applicability.[4]According to this broad concept, patentability may also cover the pharmaceutical industry, a crucial one for developing nations.[5]

Additionally, it is necessary that patents be available and that patent rights be exercised without discrimination as to the place of the invention or the origin of the products, i.e. whether they are locally produced or imported.[6]The standard patentability test criterion largely mirrors the provisions of the European Patent Convention. It stipulates that the innovation must be new, incorporate an inventive step, and possess the capability for industrial application.

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[1] Frederick M. Abbott, "Innovation and Technology Transfer to Address Climate Change: Lessons from the Global Debate on Intellectual Property and Public Health" *ICTSD's Programme on IPRs and Sustainable Development, Issue Paper No. 24*, 18 (June 2009).

[2] Donald S. Chisum, "Patentability under TRIPS: the need for uniformity". The *Indian Journal of Law and Technology, 2*, p.1. (2006).

[3]Paris Convention for the Protection of Industrial Property, Stockholm Act of July 14, 1967.

[4] Trade Related Aspects of Intellectual Property Rights, 1994, art. 27.1.

[5]HualaAdolf, "Trade- Related Aspects Of Intellectual Property Rights And Developing Countries" 56 *The developing economies*, *39*(1) (2001).

[6] Trade Related Aspects of Intellectual Property Rights, 1994, art. 27.1 (last sentence).

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4. Patentability criterions vis-a-vis Pharmaceuticals and Environmentally Sound Technologies

4.1 Novelty

a) In General Terms

The patent owners, by virtue of the patent system, acquire the exclusive right to prevent all the other people from using the invention that is patented in a commercial manner. In return to this right, a public disclosure is required of their invention so as to enrich the body of technical knowledge that at the time exists in the world. This public disclosure part in the patent system is what can be considered as its fundamental objective, meaning that nothing that already belongs to the society should be alienated from it. The notion of novelty, to a large extent, draws the line between what can be withheld from the society and what belongs to the society. The requirement of novelty, is therefore, internally recognized as one of the most important principles of the law of patent.

The meaning of the term "novelty" might not necessarily be exactly the same as understood in the general usage. Under patent law, an invention is required to be new and this newness is seen from the perspective that it does not form part of the prior art. Therefore, the rule of thumb is that an invention is not novel if it is same as prior art or contents in disclosure already have been found in the prior art before. The two things that are important here are, information disclosure in entirety on the part of the applicant and expertise of information on the part of the patent authorities. These two elements are crucial to the outcome of the novelty examination.[7]

Prior art can be understood as referring to those information, that in some way or the other, have been made available to the public. Moreover, combining separate items of prior art is not allowed since in determining novelty, the factual question has to be dealt with, which is whether before the priority date or before the filing, that invention has been made available to the public or not. Two questions that have to be addressed in the context are that, firstly, what constitutes as "prior art" and secondly, what is the meaning of the expression "form part of the prior art".

The first question has a dual aspect to it. In a number of national as well as regional patent systems, the prior art constitutes any sort of information that is made available to the public in any form, including by use, by the oral or written disclosures, before the filling or the priority date, anywhere in the world. There are many other systems wherein the public disclosures that are not in the written form are not considered as prior art in many foreign countries. Then there are

[7] Trade Related Aspects of Intellectual Property Rights, 1994, art. 29 para 1.

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certain countries and regions where earlier applications having earlier filling or priority date than the filling or priority date of the claimed invention, but after the latter date are published, are the ones also forming part of the prior art.

The second question draws a comparison between the invention that has been claimed and the prior art. It has to be determined that to what extent of public disclosure, by use, through oral disclosure, publication or in any other way, is needed in order to trigger anticipation of the invention claimed.[8]

Most of the countries tend to apply the universal requirement of novelty which restricts the patentability of an information belonging to the 'prior art'. The evaluation of prior art forms the foundation of the standard of novelty in contemporary patent laws.[9] TRIPS does not contain a comprehensive definition or explanation of the standard of novelty, which makes it possible for member states to implement the criteria of novelty in their own creative ways.[10]

Therefore, WTO members are not confined to a specific idea of the requirements of the patentability.

This flexibility in the context of novelty has, for instance, permitted the United States to maintain a standard of double novelty depending on the fact that whether the invention's disclosure has taken place outside the territory or within that of the US.[11] It was held by the US that its legislations were perfectly consistent with the TRIPS provisions as there are no specific prescriptions as to how the members in their domestic laws are supposed to define what could be considered as 'new' invention.

One of the necessary condition for patent grants happens to be the information disclosure. This information disclosure has its direct relations to the extent of protection of the patent which has been described in the claims. Generally, the scope of patent protection is somewhat the same as the range of information disclosure and not wider than that. Where the information angle is

[8] "Enlarged" Concept Of Novelty: Initial Study Concerning Novelty And The Prior Art Effect Of Certain Applications Under Draft Article 8(2) Of The SPLT prepared by the International Bureau, available at <https://www.wipo.int/export/sites/www/scp/en/novelty/documents/5prov.pdf> (last visited on 17.02.2023).

[9]Daniele Archibugi and Andrea Filippetti, "The Globalization of Intellectual Property Rights: Four Learnt Lessons and Four Theses" 1 *Global Policy* 146 (2010).

[10] Mohammed K El Said, Public health related TRIPS-plus Provisions in Bilateral Trade Agreements: a policy guide for negotiators and implementers in the Eastern Mediterranean Region (World Health Organization Regional Office for the Eastern Mediterranean and ICTSD 2011) 90.

[11] 35 U.S. Code section 102(a).

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sorted, in those cases the patent would be granted to the inventions that meet the novelty standard. Reality, although, might be a little different as applicants as well as patent authorities. Former at the time of application and latter at the time of reviewing of patent applications, are unable to exhaust the disclosed information in one technological field. This is especially more apt in the fields of complex technologies.

b) In Terms of Pharmaceuticals and ESTs

The industry of pharmaceuticals and drugs provide some potent as well as powerful treatment for a number of diseases by mass drugs production. This industry associates itself with the high tech sector and is divided primarily into the categories of 'biological' and 'synthetic organic chemistry-based' pharmaceutical products. The intensity of the manufacturing sector forms the basis of these classifications, which is in tune with the international standard set by the European Union. Substantially different types of processes of production and materials are used from the latter category, which are seen as traditional pharmaceuticals, are used to develop the former category. The latter, however, are dominated by low molecular compounds and without putting humongous amount of effort these can be imitated to produce similar structure products by controlling the chemical formulas. The standard of novelty, in the industry of pharmaceuticals, is not examined by all the chemicals contained in the new drug but rather by testing the active pharmaceutical ingredients. The electrical, mechanical and chemical technologies, in the diagnostic areas, may have the involvement of separate patents and because of this the disclosure of active ingredients in detail becomes complicated. Now, in order to protect the information from the competitors, patent holders are generally not very inclined to disclose the active ingredients.

Comparatively, ESTs that can be distinguished by a wide variety of sectors cannot be grouped using a clear classification system, despite there being international patent classification which was introduced on the basis of different areas of technology specifically. This has the effect of making it difficult to filter or search for such ESTs using the current classification criteria. ESTs and projects that are closely related to them are managed as a complex industrial system made up of intricate procedures including environmental engineering and a substantial amount of general purpose machinery.

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The flue gas desulfurization (FGD) system is an illustration of this. A number of patents inside an FDG unit are held by multiple patent owners, making it more difficult to disclose information. For instance, 300MW FGD plant will consist of number of parts, like boost fan, high velocity horizontal flow spray absorber, a milling system, and so many similar parts. It is pertinent to know that within a particular field of ESTs also, it is not always possible to conduct a thorough and methodical search of the prior art. Taking the example of carbon capture technologies, their classification is not easily found under the International Patent Cooperation and the United States Patent Classification. The reason behind this is that there is an involvement of various separation technologies that are widely used, including biological and chemical technologies of purification as well. All this mix up makes it quite an impossible task to retrieve all the technologies relating to carbon dioxide from the patent database that exists currently.[12]

Even with the most thorough EST patent classification, commonly the impossibility to exhaust all pertinent patent documents is witnessed, which shows that incomplete information makes it more difficult for patent authorities to meet the threshold of novelty. The expense of decreasing errors and the advantage of unrestricted competition must be balanced by patent authority. If mistakes are made, a suck cost and monopoly cost will result, and there are many additional market uncertainties that undoubtedly impair the impartial evaluation of the advantages of open competition.[13]It is important to establish a novelty standard on the lines of strict disclosure and reasonableness,given the usage of prior art as a critical reference to distinguish between filings and prior art. This would result in bringing down the cost of monopoly which is often a by-product of information which is incomplete.

The advancement of pertinent technological domains and industrial sectors is intimately related to the standard of novelty, which assures that patents won't be granted for inventions that are already in the public's hands.[14]The extent of the protection of patent, which determines the advantages that the owners of the patents can recuperate during the course of their patents, is likewise closely

[12]USPTO, Patent Classification: Environmentally Sound Technology Concordance <https://www.uspto.gov/web/patents/classification/international/est_concordance.htm> (last visited 14.02.2023).

[13] H-Holger Rogner, Dadi Zhou, et.al.,Chapter 1 Introduction in B. Metz, O.R. Davidson, et.al. (eds), *Climate Change 2007: Mitigation of Climate Change* 102 (Cambridge University Press, 2007).

[14] Sean B. Seymore, "Rethinking Novelty in Patent Law" 60 *Duke Law Journal* 919, 922-924 (2011).

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linked to it.[15]Although a threshold of novelty, which is quite stern in nature, is advantageous for early researchers, in the sector of pharmaceuticals, where significant resources have been invested in basic research, competitive excess may arise, leading to underinvestment in later stages. Schtchmer and Green contend that lax novelty review policies encourage prompt disclosure, which has a substantial positive externality and increases benefits to closely connected businesses.[16] Spence, on the other hand, is adamantly opposed to this idea, contending that while the strong externality of information may reduce competitor's production costs and the cost of industry-wide R&D, it will also lead to free-riding issues and a weaker incentive for private innovation.[17]

4.2Inventiveness or Non-Obviousness

a) In General Terms

The most valuable element of an invention is inventiveness. It requires more technological upgradation than novelty, which is more concerned with the differences between patent filings and prior art.[18] "Inventive" is a term which is synonym for "non-obvious", as interpreted by TRIPS. It can be construed to say that the progress made by the invention, while drawing parallels with the prior art, is a significant and substantial one.[19]

So, as far as the concept of 'inventive step' is concerned, again there is ample of space to maneuver. Members have been given the freedom to use the terms 'inventive step' and 'non obviousness' in a synonymous manner, the former finding its applicability, for instance, in Europe and latter in the USA. Although, the terms are considered synonymous by the Members, there do lie certain differences between them. "Inventive Step' reflects that in order to develop a product or process which is new, there has been an intellectual process behind it. 'Non-obviousness' on the other hand can be interpreted regarding the subject matter, even if it has not been 'invented' and only been found.

[15] Richard Gilbert and Carl Shapiro, "Optimal Patent Length and Breadth" 21 (1) *RAND Journal of Economics* 106 (1990).

[16] Jerry R. Green and Suzanne Scotchmer, "On the Division of Profit in Sequential Innovation" 26 (1) RAND Journal of Economics 20 (1995).

[17] Andrew M. Spence, "Cost Reduction, Competition, and Industry Performance" 52 (1) *Econometric Society* 101 (1984).

[18] Eric L. Lane, "*Chapter 1: Clean Tech IP Is for Real, Clean Tech Intellectual Property: Eco-Marks, Green Patents, and Green Innovation*" 9 (Oxford University Press, 2011).

[19] Ibid.

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Possibilities as well as opportunities for technological innovation show immense difference, and the reason that can be identified behind it would be the lack of balance in the technological development stages within numerous areas of technology, national state and sectors of industries.[20] As a result, there cannot be one particular benchmark, as far as inventiveness is concerned, for all types of technology.

Members can decide on the policies that they are willing to apply and there exists a lot of room to establish the standard of 'inventive step/non-obviousness'. A relatively low standard can be opted, as in the case of the USA at present, in order to allow patenting of a wider range of incremental, minor, developments. The US Federal Circuit, which specializes in the matters of intellectual property, has adopted this lax approach.[21] On the other hand, a considerably strict standard can also be adopted, which aims at rewarding the substantive departures from what is called the prior art. This was the scenario of the USA in the past.[22]

As both the minor and major innovations could be covered under the patents, it can be argued that a low inventive threshold-based patent regime could prove to be functional in the case of the innovation path present in the developing countries.

However, this liberal approach of patentability might backfire. On the one hand, as demonstrated by the example of pharmaceuticals, there is a risk of stifling innovation and competition rather than fostering it because large companies with competent patent attorneys are much better equipped, technically and financially, so as to exploit a patent regime with a considerably low patentability threshold than the firms that are domestic. Additionally, the general people will be required to pay monopolistic pricing in order to access information and products that ought to be and should continue to be in the public domain.On the other hand, most local innovators, typically small and medium enterprises(SMEs), find it hard to afford the cost of acquiring and, in particular, exercising patent rights. While SMEs may choose to pursue patent protection in many circumstances, they have to be responsible for paying the filing, registration, and maintenance costs. If there is litigation, whether it be to defend the patent from validity challenges or to enforce it against infringers, winning in court is not guaranteed. Damage claims by counterparts may be huge, and the cost of the litigation may be prohibitive.

[20] Stefano Breschi, Franco Malerba and Luigi Orsenigo, 110 (463) "Technological Regimes and Schumpeterian Patterns of Innovation" *The Economic Journal* 388 (2000).

[21] Carlos M. Correa, *Trade related aspects of intellectual property rights: a commentary on the TRIPS agreement* 277 (Oxford University Press, 2020).

[22] Donald S. Chisum and Michael A. Jacobs, *Understanding intellectual property law*, (Matthew Bender, New York, 1995).

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b) In Terms of Pharmaceuticals and ESTs

Pharmaceutical technologies fall under the matured technology group, whose application addsonly a small amount of value to products at the maturation stage.

These mature technological group require a comparatively high standard of inventiveness. ESTs are classified as new and emerging technologies under the same grouping criteria, which correlates to products in the growth phase of their life cycles and moreover the implementation of which will significantly affect the value chain, enabling the similar related new products to develop rapidly.[23]

Additionally, ESTs are categorised as complex technologies, relying on the study of von Graevenitz , Wagner, and Harhoff, which reflects that it is harder to imitate ESTs which in turn could affect their rate of diffusion adversely.[24]

Compounds that are innovated are mostly closely linked to the compounds that are already known, in terms of structure, in the field of pharmaceuticals.[25]Now, to evaluate the fact that whether there exists a certain amount of difference in their structureand change in the effects as well, the new compound has to pass a more rigorous review because of similar properties and uses and common structures of those preceding it.[26] So, a compound having substantial amount of structural difference has a possibility of being qualified as inventive and in cases where there is a similarity in the structure to the prior art, the difference in the effect shall be taken into consideration.

Understanding from the example of China, there, the assessment of inventiveness is done by testing whatever the positive, useful, beneficial, etc effects were claimed, and these effects being the outcome of the new functions involved in the invention. This is in the cases where the new compound has a similar structure to the previous ones.

The bar of inventiveness is extremely high when it comes tothe kind of pharmaceuticals that are resource intensive in nature and face quite a lot of obstacles and challenges in the research and development stage. Although, this was the scenario some years back, in the recent years what has been noticed is that the standard of non-obviousness or inventiveness is somewhat declining as a

[23] Ibid.

[24] Georg von Graevenitz, Stefan Wagner and Dietmar Harhoff, "Incidence and Growth of Patent Thickets: the Impact of Technological Opportunities and Complexity" 61 (3) *The Journal of Industrial Economics* 521 (2013).

[25] Frederick M. Abbott, "Innovation and Technology Transfer to Address Climate Change: Lessons from the Global Debate on Intellectual Property and Public Health" *ICTSD's Programme on IPRs and Sustainable Development, Issue Paper No. 24*, 9 (June 2009).

[26] Ibid.

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number of discoveries which might consist of the new uses or combinations or any sort of new dose forms, etc can be seen to be patented.[27]

Innovation in the case of Environmentally Sound Technologies include primarilythe creation of design patterns, integrated systems, and the key equipment.[28]

The essence of ESTs can be said to lie in their functions, reducing the amount of emissions, amplifying energy efficiency, etc. Hence, function can be considered as the one playing one of the most important roles in establishing the innovation standard in ESTs.For instance, the gas desulfurization technology removes sulphur from gas emissions in an effort to reduce air pollution. Theoretically, a function based standard is not something that is commonly accepted, but in exceptional situations where the principle determinant for inventiveness is the functional characteristic itself and in the absence of which it would be impossible to describe the inventions, in those cases they can be accepted as a standard of inventiveness.[29]

These functional features, although, need to be employed in extremely cautious ways as there are a number of things that can go wrong and ultimately would impede innovation as a result of it. This can happen, for instance, when in a certain technical solution, a particular function has been claimed, and this is on which the patent has been sought. If in case it gets recognized, then there will be no protection given to the other technical solutions having similar functions.[30]

Effects, as a standard of inventiveness, are limited too in the same manner as the functions. Although, what constitutes as one part of claim is function rather than effects.[31]

Effects have nevertheless grown in importance for inventiveness reviews as one of the factors utilised to compare against prior art. The introduction of effect-based standards has special implications for assessments of inventiveness of ESTs and pharmaceuticals innovation.

One of the primary factors on which the inventiveness is judged in the case of new pharmaceuticals, would be the non-obvious progress of the drug or in other terms, its efficacy.

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[27] Marcia Angell, *The Truth about the Drug Companies* (128) (Random House Group, 2005).

[28] Keqin Sun, Kai Shen, Haitao Xu, Changcheng Chou, Yanzhong Xu, "The Study on Emission Reduction during the Innovative Process of ESTs" *The Fourth China's International Forum on Environment and Development*, (Beijing China, October 2008).

[29] Andrew Beckerman-Rodau, "The Problem with Intellectual Property Rights: Subject Matter Expansion" 13 *Yale Journal of Law & Technology* 35 (2010).

[30]Jeanne C. Fromer, "The Layers of Obviousness in Patent Law" 22 *Harvard Journal of Law & Technology* 75, 84 (2008).

[31] Michelle L. Johnson, "In re Brana and the Utility Examination Guideline: A Light at the End of the Tunnel?" 49 *Rutgers Law Review* 285 (1996).

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Now, these factors are not the ones that could readily be deduced from compositions of the previous drug or their structures. These are the cases where there is slight difference from the prior art in the technical solutions of the pharmaceuticals.[32] The ability to produce the purported efficacy will also have a significant impact on whether patent infringement is found to have occurred.

The design, implementation, and debug phases make up the EST innovation process.[33] The core innovative component of ESTs is designed during the traditional initial stage of invention, where energy-saving goals are only seen as design constraints. Energy conservation and emission reduction are now objectives, just as essential as economic ones, large credit of which goes to the present worldwide agreement on required emission reduction targets.[34] Therefore, another crucial factor in assessing the inventiveness of ESTs is their actual effect on energy conservation and emission reduction.[35]

4.3 Industrial Application or Utility

a) In General Terms

The industrial applicability of the invention is the third prerequisite for patentability. It refers to a practical application that might allow regular technicians in relevant domains to implement these technologies with positive outcomes.[36] It highlights that inventions are frequently operational, as opposed to being entirely theoretical.According to current patent examination procedures, applications are less likely to be rejected on being short of industrial applicability than due to the lack of novelty or inventiveness.[37]

"Industrial" must be construed in accordance with the Paris Convention's Article 1(3):

Industrial property shall be understood in the broadest sense and shall apply not only to industry

[32] Jerome H. Reichman and Frederick M. Abbott, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions" 10 (4) *Journal of International Economic Law* 921 (2007).

[33] Keqin Sun, Kai Shen, Haitao Xu, Changcheng Chou, Yanzhong Xu, "The Study on Emission Reduction during the Innovative Process of ESTs", *The Fourth China's International Forum on Environment and Development,* (Beijing China, October 2008).

[34] Michael A. Gollin, "Using Intellectual Property to Improve Environmental Protection" 4 *Harvard Journal of Law & Technology* 193, 226 (1991).

[35] Naoki Yoshida, David Albagli, "The Fastest Routes for Green Patents-Japan" 222 *Managing Intellectual Property* 60 (2012).

[36]Trade Related Aspects of Intellectual Property Rights, 1994, art. 27.

[37]European Patent Office, Guidelines for Examination in the European Patent Office (Amended 2014) <https://www.epo.org/law-practice/legal-texts/guidelines.html> (last visited 15.02.2023).

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and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.

According to footnote 4 to Article 27.1, a Member may consider the terms "capable of industrial application" and "useful" to be interchangeable for the purposes of this Article. But the definition of "useful" goes much beyond industrial applicability. Thus, while they may not satisfy the industrial patentability criteria, research tools, business and other methods, and computer programmes may be patentable under the former. This distinction is one of the things that explains why there has been a noticeable increase in the number of patents in the United States compared to other countries, such as those in Europe.[38]

Members may decide when an innovation is regarded to be useful or capable of industrial application given the flexibility of Article 27.1. When an invention can be used in any industry, many national laws consider the requirement of industrial application to be satisfied. Other laws, however, restrict this use and more specifically demand that the invention be capable of industrial use, either by materialising into an industrial product or through an industrial manufacturing process. As in the instance of Section 3(d) of the Indian Patent law, "useful" may be construed to entail an assessment of "efficacy."

Numerous patents on computer programs have been issued in the US based on the expansive definition of utility. The US Supreme Court adopted a liberal rule allowing the patenting of software algorithms after the 1981 decisions in Diamond v. Diehr and Diamond v. Bradley. This wasn't the case before. As a result, patents have frequently been granted in the US even when only data manipulation is taking place and no physical substances are being changed into a different physical state. The permissive approach of the US has on software patents somewhere influenced the European law as well.[39]

[38] Carlos M. Correa, *Trade related aspects of intellectual property rights: a commentary on the TRIPS agreement* 278 (Oxford University Press, 2020).

[39] Id. at 280.

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b) In Terms of Pharmaceuticals and ESTs

The fact that most of the patenting, of biological and chemical compounds, happens during the phase of clinical trials itself, despite the fact that their industrial applicability is still being examined, suggests that the pharmaceutical sector operates under a lax criterion of utility.[40]

There are two additional factorsin the utility of a novel drug or therapywhich are not common in other technical sectors. These are reliability and safety.[41] In the United States, pathological, therapeutic, and prophylactic findings are used to determine the utility of new drugs and therapies. The drug undergoes clinical trials after pre-clinical animal testing and cell cultivation, during which its utility is carefully evaluated to see if it is suitable for human usage.[42]

The positive effects ESTs have on the environment are essential to their utility.Patent claims for ESTs should address technical solutions to specific environmental problems. The reason behind is that, then the employment of these technologies could be done extensively in manufacturing as well as in the daily lives.[43] According to OECD-published data on patent applications, the environmental issues related to climate change that ESTs aim to solve include primarily air pollution, energy efficiency of fossil fuels and the generation of energy from sources that are primarily non fossil fuel and renewable.[44]

However, it is asserted that the evaluation of the utility of EST has more to do with the presence and absence and less with the technical usefulness or strength in respect to environmental challenges.[45]There lies a difference between technical usefulness mentioned above and the technical effect, latter being demonstrated through evaluation of the application of ESTs. The design of ESTs, on the other hand, reflects their technical usefulness. Despite official commissioning, there remains a gap between anticipated technical effects and actual outcomes.

Industrial uses can result in inventions that are worthless or unprofitable, such as those that defy

[40] Jerome. H. Reichman, "Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: the Case for Public Good Approach" 13 (1) *Marquette Intellectual Property Law Review* 1, 23 (2009).

[41] Mohammed K El Said, Public health related TRIPS-plus Provisions in Bilateral Trade Agreements: a policy guide for negotiators and implementers in the Eastern Mediterranean Region (World Health Organization Regional Office for the Eastern Mediterranean and ICTSD 2011) 133.

[42] Sean B. Seymore, "Making Patents Useful" 98 *Minnesota Law Review,* 1046, 1057-1058 (2014).

[43] Mohammed K El Said, Public health related TRIPS-plus Provisions in BilSateral Trade Agreements: a policy guide for negotiators and implementers in the Eastern Mediterranean Region (World Health Organization Regional Office for the Eastern Mediterranean and ICTSD 2011) 171.

[44]OECD Patent Statistics ISSN: 2077-7809 DOI: 10.1787/data-00508-en.

[45] Michelle L. Johnson, "In re Brana and the Utility Examination Guideline: A Light at the End of the Tunnel?" 49 *Rutgers Law Review* 285 (1996).

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established natural laws, seriously pollute the environment, waste resources, or seriously veer away from social progress.[46] Unfortunately, there are also a lot of environmentally damaging technologies that are fully applicable to industry.[47] Many environmentally harmful technology are patented and widely used in industrial production as a result of industrial strategies and economic growth. The requirement of utility conflicts with the public interest when the practical benefit produced by the employment of patented technologies is less than the expense incurred for environmental repair.[48]Along with utility, public interest should also be taken in the law of patent as the fundamental tenet, in light of the overwhelming number of patent applications.[49]

5. Conclusion

Health crisis and climate change are two things that certainly qualify to be urgent. There does not happen to be much time to sit comfortably on the issue and ponder ways and methods to deal with climate change. Quick and efficient steps have to be taken collectively to save the planet. It won't be entirely fair to let the pockets of people or nations decide if they should have a chance to fight the crises. Just like when any epidemic or pandemic happens, the exclusive patent rights given to the owners of related drugs need to be eased from purely commercial approach to a more humanistic one, similarly it is the case of environmentally sound technologies that help in fighting the crises of climate change at both the mitigation as well as adaptation stage.

So, after establishing the commonality between drugs and ESTs, often the analogy is drawn because as far as ESTs are concerned, there are no established rules to govern them, there are multiple lacunas and loopholes in international as well as national regimes. Pharmaceuticals, however have been in the debates for considerably longer time, there has been much more research that has been done on them as compared to ESTs. There have been certain milestones like Doha Declaration in the case of drugs whereas for ESTs, much discussions have happened, agendas have been set, but the whole EST domain lies in a lot of vagueness at present still.

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[46] Sean B. Seymore, "Making Patents Useful" 98 *Minnesota Law Review*, 1046, 1049 (2014).

[47] Andrew Beckerman-Rodau, "The Problem with Intellectual Property Rights: Subject Matter Expansion" 13 *Yale Journal of Law & Tech*, 42 (2010).

[48] Michael A. Gollin, "Using Intellectual Property to Improve Environmental Protection" 4 *Harvard Journal of Law & Technology* 194 -195 (1991).

[49] Joshua D. Sarnoff, "The Patent System and Climate Change" 16 (02) *Virginal Journal of Law and Technology* 302, 336 (2011).

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So, there are some voices that suggest that if we move in the lines of drug patents, we might get certain concrete solutions to deal with ESTs as well.

The primary objective that was there in the minds of the authors behind writing the paper, as established before, was to find what substantive requirements of patentability mean in terms of pharmaceuticals and ESTs and if they are somewhat similar or entirely different, because if they happen to be quite different then drawing any sort of comparison would not be a very prudent approach in the path of establishing clear patent laws in the context of ESTs. So, some of the observations that have been made in the paper have been summarized and highlighted in the subsequent paragraphs.

The first substantive requirement of patentability being novelty, has a slight difference in terms of pharmaceuticals and ESTs, as identified in the paper. The pharmaceutical products are classified into very specific categories thereby it becomes easier to check their novelty. Whereas in ESTs, it becomes difficult to group them by using a clear system of classification. Therefore, to filter and search for ESTs is a task in itself. Although there is a slight similarity as well that, number of times in pharmaceutical sector, the patent holders do not want to disclose the active ingredient, with an intention to protect the information from any of the competitors. And as has been explained in the paper, novelty is examined by that very active ingredient and not by all the chemicals in the drug. So, in these cases also, it becomes difficult to check for novelty.

The second patentability criterion is inventiveness. It is the matured technology group that pharmaceuticals fall under. These groups are known to have a high standard of inventiveness comparatively. The new compound in the drugs, have to pass a rigorous scrutiny, as the new innovated compounds are quite often related to the compounds that are already known.
In the case of ESTs, function has been identified to play a major role. Although this feature of function has to be used in a very cautious manner as has been explained in the paper. So, it is at the very initial stage itself that the main innovative component is developed in the case of ESTs. Another important factor in the assessment of EST inventiveness is the effect that they actually have on reducing emission and the conservation of energy.
The commonality between analysing inventiveness in the case of pharmaceuticals and ESTs is that the standards that are effect based have a special place.
As far as utility is concerned, as has been explained in the paper, that drugs normally work under

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lax criterions as most of the compounds are patented at the stage of clinical stage itself. Also. safety and reliability are two factors which have an additional importance in the sector of pharmaceuticals which might not be the case when utility is assessed in other sectors than this one.

In the case of ESTs, the positive effect that they have on the environment holds a great amount of importance in utility. It has been identified in the paper that while evaluating utility in the case of ESTs, what matters is their absence or presence rather than any sort of technical strength in the case of environment or technical usefulness. Although it has been noticed that since this utility factor sometimes stands in contradiction with the public interest, ideally both these factors of utility and public interest should be combined in a decent proportion so that the pendulum doesn't get stuck in one extreme direction itself.

So, as can be understood by these findings, that there do lie certain differences, which are not extreme enough so as establish and say that any comparison drawn between the two fields would certainly be a waste of time and result in failure, but at the same time these differences are significant enough to be kept in mind while drawing an analogy between the two fields of drugs and ESTs and be very cautious while applying the set of principles of drugs in the EST scenario. Then there are enough similarities which give green signal to all the future works in the context of these two fields.

This is what the purpose of the paper has been. Before jumping to a much-advanced stage, it was extremely important to understand the intrinsic requirement of patentability in terms of both drugs and ESTs. Looking at the findings of the paper, it is safe to saythat further studies should be done to come up with more of such lessons so as to contemplate the harmonization between EST's accessibility and protection offered by virtue of patents by utilizing the reconciliation reflected in the dynamics of pharmaceuticals and public health.

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