ENABLEMENT AND PLAUSIBILITY IN BIOTECH PATENTS

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ABSTRACT

The entire patent system revolves around the concept of the grant of monopoly over the sufficient disclosure of an invention. Enablement and plausibility are extended branches to the test of sufficiency, particularly when dealing with biotech patents. The concept of plausibility got its origin from EPO and later got flourished to various jurisdictions through well-established case laws. The quantum of experimental evidence needed is one of the most important considerations on patent filing decisions in the biotech sector, which in turn points to the prominence of plausibility and enablement in the sector. Patentees must be capable of striking a balance between the fact that trial studies can take an extensive stretch of time against the first to file criteria of patents and thereby self-analyse how early to file a patent application. It's a challenge for the patentee to sufficiently describe the inventions so that the issue of plausibility does not arise, knowing the fact that deficiency in enablement cannot be resolved after the effective filing date. Further limiting the undue broadness of claims, passing the threshold test for plausibility is a major issue in biotechnology patents. In this context, this paper covers issues related to enablement and plausibility in biotech patents by analysing case laws evolved across various jurisdictions over the years.

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I. INTRODUCTION

A monopoly over the exclusive rights of a patent in lieu demands for a sufficient and complete disclosure of the invention. Enablement and plausibility are intended to guarantee that the patentee sufficiently discloses the invention in exchange for the patent granted. A patent must depict the invention clearly enough so that a person skilled in the field can reproduce the innovation without performing tests to decide how to make and utilise the development. This is called "enablement" of the patent application. In the field of "unpredictable" arts mainly for biology and chemistry, enablement is particularly important. A deposit in such a field shall encourage or ensure performing ability or a plausible disclosure. The need for such a 'deposit' is mandated by the Budapest Treaty to strengthen and support the patent specification. For example, India is a member country of the Budapest Treaty which requires an applicant to deposit the biological material used in the invention with an International Depository Authority ["**IDA**"]. Thus, for the completion of the patent specification, deposition is important.

'Plausibility' is an intriguing issue which emerges frequently in case of both enablement and sufficiency, especially in the life sciences sector. Plausibility is one of the factors judging the sufficiency of a biotech patent rather than a separate test for striking patent validity. 'Plausibility' got its origin from the European Patent Office ["**EPO**"] in reaction to excessively broad claims and to forestall speculative claiming. It isn't central that the specification contains trial information or results, given that the nature of the innovation is with the end goal that it depends on a technical impact which is either plainly obvious or predictable or dependent on a decisive theoretical idea, i.e. plausible.

In the biotech sector, there is a dilemma between the quantum of experimental evidence required and the first to file requirement. Plausibility ought to be viewed based on the specification as on the patent filing date. Deficiency in enablement can't be rectified later by post filed information. Also, the advent of plausibility tackles patents of broad and speculative claims and those patents which lack strong experimental proof that the technical effect claimed is achieved.[1] The emerging numbers of second medical use patents leave more space for plausibility and enablement. Generally, in second medical use, patents claim patentability over a new use of an already known compound. Such patents provide the holder with an extended life of the claimed compound with

[1] Dr. Sven J.R Bosytn, *Plausibility in Life Science Patents*, GENOME EDITING - CRISPR ALS HERAUSFORDERUNG FÜR DAS LIFE SCIENCES-RECHT (2018), https://ius.unibas.ch/fileadmin/user_upload/ius/09_Upload_Personenprofile-/01_Professoren/Zech_Herbert/Konferenzmaterial/Plausibility_in_Life_Sciences_Patents_Bostyn.pdf.

an additional protection and thereby preventing the entry of generic drugs. Several jurisdictions enable such patenting, one of them being Europe. Article 54(5)[2]of European Patent Convention calls for the kind. The threshold of plausibility differs with respect to jurisdictions. In this context, the present study aims to analyse the enablement and plausibility requirements in biotech patents in different jurisdictions like EU, US and India and highlights the recent development in this sector.

A. ENABLEMENT AND PLAUSIBILITY

'Invention' in the context of patent law must solve a technical issue and necessitates to be made plausible by the specification disclosure that the problem is solved. It is not the claims alone to be assessed for satisfying the test of enablement, but the description and claims together *i.e.* the patent application as a whole.[3]

'Plausibility' had its origin in the EPO *AgrEvo* decision.[4] This decision didn't explicitly allude to the term plausibility. *AgrEvo* set out that while testing the 'inventive step', the technical issue comprehended over the entire extent of the claim must be reasonable or credible. In this case, the court noted that the claim for a group of chemical compounds cannot be objected to solely on the ground that the description does not contain sufficient information in order to make it credible that an alleged technical effect is obtained by all the compounds so claimed. The term "plausibility" was coined in the case of *Johns Hopkins*.[5] The decision sets out that a technical impact depended on to show inventive step must be made conceivable by the description.

The case of *Conor Medsystems Inc. v. Angiotech Pharmaceuticals Inc.*,[6] concerned a patent asserting the utilisation of taxol-covered stents to forestall restenosis. The traditional method for stent implant will result in proliferation of muscle cells which block the artery, leading to the condition of 'Restenosis'. An anti-angiogenic agent was claimed which can be used to prevent tissue growth in the said condition. The court analysed the case and cited that there was no dispute

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[2]Convention on the Grant of European Patents (European Patent Convention) art. 54(5), Oct. 5, 1973, 1065 U.N.T.S. 199.("Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art.") [hereinafter "**European Patent Convention**"]

[3]*European Patent Convention*, art.83. ("The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.")

[4]Case T-0939/92, AGREVO/Triazole herbicides, 1995,ECLI:EP:BA:1995:T093992.19950912.

[5] Case T-1329/04, Factor-9/John Hopkins,2005, ECLI:EP:BA:2005:T132904.20050628.

[6] Conor Medsystems Inc v. Angiotech Pharmaceuticals Inc., [2008] RPC28.

about the expert's way of teaching the patent and the claims can be substantiated even in the absence of experimental data. The case put forward the term 'plausibility' before the UK courts. The court validated the patent as the specification didn't need to contain data to support this invention if it made the invention plausible, which it did. The decision lead to a two-stage test: (i) first the court will check if the plausibility test is satisfied, and then (ii) the court will proceed to determine whether the patent is obvious according to established UK law.

B. PLAUSIBILITY IN THE CONTEXT OF ENABLEMENT

The most interesting developments regarding plausibility in relation to pharmaceutical patents have been in the context of enablement. To meet the criteria of enablement, the specification must sufficiently disclose the invention for it to be performed by a person skilled in the field. The leading case on plausibility in context of enablement is the *Regeneron case*[7] traced from England and Wales. In this case, the Court held that a patentee doesn't need to show that an invention works over the full extent of the claim; rather, it must be conceivable or plausible that it works considerably across the claim to the full extent. If it is possible to predict that the invention works across the claim by trying to club the products and methods claimed by a common principle, then the patentee need not demonstrate the working of the invention in every case. If such a forecast is not possible, then the claim will be insufficient.

The same was later summarised into a two-stage test by Mr. Justice Arnold[8] as follows:

> "*The first stage is to determine whether the disclosure of the Patent, read in the light of the common general knowledge of the skilled team, makes it plausible that the invention will work across the scope of the claim. If the disclosure does make it plausible, the second stage is to consider whether the later evidence establishes that in fact the invention cannot be performed across the scope of the claim without undue burden. In some cases, it is convenient to divide the second stage into two, first considering whether the invention can be performed without undue burden at all and then whether the claim is of excessive breadth*."

Therefore, whether a specification makes the claimed invention plausible is a threshold test where it enables the person skilled to "make a reasonable prediction that the invention will work with substantially everything falling within the claim."[9]

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[7]Regeneron Pharmaceuticals Inc., Bayer Pharma AG v. Genentech Inc., [2013] EWCA (Civ) 93.
[8]Warner-Lambert Company LLC v. Generics (UK) Ltd and Ors., [2006] EWCA (Civ) 1006.

II. ENABLEMENT AND PLAUSIBILITY IN BIOTECH SECTOR

Enablement and Plausibility are topics that are frequently debated within the biotech sector. Some precedents in the pharma sector have built up the current status around how plausible the technical effect of an invention must be at the filing date of the patent application. In relation to medical use patents, the Technical Board of Appeal held in *Salk*[10] that the claimed medical effect must be made plausible by the disclosure of the patent.

What level of disclosure satisfies the plausibility threshold is an important point to be considered. To this end, the threshold of plausibility might be fulfilled by the exposure of *in vitro* information, where such disclosure shows a clear and acknowledged connection between the impacts of the asserted compound and the target disease being referred to. The Court of Appeal agreed with the TBA and confirmed that a patentee must show, for example by appropriate experiments, that the product has an effect on a disease process so as to make the claimed therapeutic effect plausible.[10] It would be a burden for the patentee to show that the referred compound has endorsement as a medication.

In the Regeneron case, the issue was concerned with the application of revocation of Genetech's patent and a declaration of non-infringement on the product of Regeneron i.e. VEGF Trap Eye, which was intended to treat age-related macular degeneration of eye. The patent was attacked on the basis of insufficiency in two ways: that the claims extended to a very wide class of diseases, namely all non-neoplastic neo-vascular diseases which made it impossible for a reasonable prediction that anti-VEGF therapy may be efficient in the full range of diseases (insufficiency for excessive claim breadth); and that the patent claimed all known VEGF antagonists which made it burdensome to identify which antagonist worked for which disease (classical insufficiency). When read in light of the basic general information, the patent was held to disclose a guideline of general application, which VEGF was important for neurotic angiogenesis, and it was sensible to foresee it. Therefore, the principle of general application disclosure made it plausible that the claimed VEGF inhibitors could be used to treat the wide range of non-neoplastic diseases referred to in the patent. As a result, the patent was held valid.

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[9]Regeneron Pharmaceuticals Inc., *supra* note 7, p 100.

[10]Case T-0609/02, AP-1 Complex/ Salk Institute, 2004,ECLI:EP:BA:2004:T060902.20041027, p 9("The boards of appeal have accepted that for a sufficient disclosure of a therapeutic application, it is not always necessary that results of applying the claimed composition in clinical trials, or at least to animals are reported.")

III. COMPARISON OF ENABLEMENT AND PLAUSIBILITY REQUIREMENTS ACROSS DIFFERENT JURISDICTIONS

A. ENABLEMENT AND PLAUSIBILITY STANDARDS AT EUROPEAN PATENT OFFICE ["EPO"]

EPO sees the prerequisite of "plausibility" which arises during both the evaluation of 'sufficient disclosure' of the invention and 'inventive step' in proceedings before it, especially according to developments in the pharma and life sciences field. The requirements of sufficiency of disclosure may get invalidated if the invention claimed lacks reproducibility as per EPO guidelines. An innovation lacks reproducibility either in light of the fact that its ideal technical impact as communicated in the claim isn't accomplished,[11]or if the technical effect isn't expressed within the claim but is an element of the problem to be solved.[12]

EPO considered the requisite of 'plausibility' for sufficiency of disclosure in the case of *AgrEvo*. For this case, the Board held that the application gave information just for a few compounds to demonstrate the technical effect and that it was not plausible regardless of whether the technical effect was accomplished by all the compounds, and thus refused the application as not inventive. The EPO Board of Appeal additionally expressed that issue of plausibility when evaluating sufficiency emerges just when the technical effect is part of the claim.

In John Hopkins,[13] the Board of Appeal stated that an invention should necessitate in any event, the technical problem is made conceivable by the disclosure that it's instructing to be sure takes care of the problem it implies to solve. Without any information in the application, the Board of Appeal took the view that post-published proof to illustrate that the specific technical issue is tackled, can be taken into consideration only if it is made plausible from the original disclosure that the problem is indeed solved.

In this way, for post-published evidence to be considered, it is important to set up whether the declared invention has been made adequately conceivable at the effective date of filing the patent. The reason for this appraisal is the application as filed and the regular general

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[11] European Patent Convention, art.83 ("The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.")

[12] *Id.* at art 56 ("An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. If the state of the art also includes documents within the meaning of Article 54, paragraph 3, these documents shall not be considered in deciding whether there has been an inventive step.")

[13] John Hopkins, *supra* note 5.

information on the individual skilled in the art at the priority date. The various precedents reinstating this principle include *Pancreatic cells/IPSEN*,[14] Arch Development *et al.*,[15]*Conju Chem Biotechnologies Inc.*,[16]*Dasatinib/ Bristol-Myers Squib*.[17] It appears that regardless of whether a claim is non-obvious as for or without any prior art, the EPO could still reject a case on the off chance that it isn't conceivable at the date of filing that the invention does solve the problem it intends to solve.

The EPO gives off an impression of being more exacting with the prerequisite of plausibility and thus it is advisable to provide as much information as possible with respect to technical advantage, including any trial information, at the date of documenting.

B. ENABLEMENT AND PLAUSIBILITY STANDARDS AT UK PATENT OFFICE

Plausibility here pops in the context of sufficiency, inventive step, novelty, entitlement to priority and industrial applicability. Plausibility is especially pertinent to patents of medical use. Two flavours of insufficiency exist here: classical insufficiency and excess claim breadth insufficiency. The former crops up if the claimed invention cannot be performed without an excessive burden and the latter type of insufficiency relates to whether the specification enables the invention to be performed.[18]

In *Regeneron Pharmaceuticals Inc.* and *Bayer Pharma AG v. Genentech Inc*,[19] Kitchen LJ summarised that the assertion that the invention will work across the scope of the claim must be plausible or credible. If it is possible to predict that the invention works across the claim by trying to club the products and methods claimed by a common principle, then the patentee need not demonstrate the working of the invention in every case. If such a forecast is not possible, then the scope of the monopoly will exceed the technical contribution the patentee has made to the art and the claim will be insufficient.

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[14] Case T-0578/06, Pancreatic Cells/IPSEN, 2011, ECLI:EP:BA:2011:T057806.20110629.

[15]CaseT-1642/07, Viral Enhancement Of Cell Killing/ Arch Development Corporation et al., 2010,ECLI:EP:BA:2010:T164207.20101202.

[16]Case T-433/05, Fusion Peptide Inhibitors/CONJUCHEM, 2007,ECLI:EP:BA:2007:T043305.20070614.

[17]Case T-0488/16, Dasatinib/Bristol Myers Squib, 2017,ECLI:EP:BA:2017:T048816.20170201.

[18]Zack Mummery, *Plausibility in UK*, REDDIE& GROSE (June 16, 2016), http;//www.reddie.co.uk/2016/06/27/plausibility-in-the-uk.

[19] Regeneron Pharmaceuticals Inc. v. Genentech Inc [2012] EWHC (Pat) 657.

With respect to patents of second medical use, while thinking about plausibility and enablement, the specification must make it believable that a specific medication is viable for claimed condition's treatment.

In *Generics (UK) Ltd (t/a Mylan) v. Warner-Lambert Company*,[20] a claim pointed to Pregabilin for use in treating torment was inadequate in light of the fact that there was no premise that made it conceivable that Pregabilin can be used for a wide range of pain.

In *Actavis v. Eli Lilly*,[21] plausibility was brought by Actavis in regard to adequacy and inventive step. Actavis contended that the test for credibility with regards to adequacy is equivalent to the test for 'reasonable expectation of success'. The court held that plausibility doesn't form a separate ground of issue with the legitimacy of patents. The same is restored in the case of *GlaxoSmithKline UK Ltd. v. Wyeth Holdings LLC.*[22]In this case, plausibility was considered with respect to insufficiency and the test of credibility was reinstated.

C. ENABLEMENT AND PLAUSIBILITY STANDARDS AT US PATENT OFFICE

The enabling requirement of specification is set forth in 35 U.S.C. §112. The US patent office requires that an application must contain a written description of the invention and an enabling disclosure so that a person skilled in the art can carry out the invention without undue experimentation. It is also desirable that the applicant/inventor provides a disclosure of the best mode as contemplated by him at the time of filing.

The US jurisprudence shows many instances where the questions of enablement and plausibility have been raised in conjunction with robust written description requirements particularly in cases of patents from biopharmaceuticals and diagnostics sectors. In *Promega Corp. v. Life Technologies Corp.*,[23]the court emphasised the fact that it must be sensible or conceivable for the individual of average skill in the pertinent zone of innovation to expect that the invention works depending on the data contained in the patent application. In *Amgen, Inc. v. Hoechst Marion Roussel Inc.*,[24] and *Regents of the University of California v. Eli Lilly*,[25]it was held that an enabling disclosure of how to make a product must be sufficiently described in the complete specification. In the case of

[20]Generics (UK) Ltd (t/a Mylan) v. Warner-Lambert Co., LLC [2015] EWHC (Pat) 2548.
[21]Actavis v. Eli Lilly, [2015] EWHC (Pat) 3294.
[22]GlaxoSmithKline UK Ltd. v. Wyeth Holdings LLC [2016] EWHC (Ch) 1045.
[23]Promega Corp. v. Life Techs. Corp., 875 F.3d 651 Fed. Cir. (2017).
[24]Amgen, Inc. v. Hoechst Marion Roussel Inc., 314 F.3d 1313, 1330 (2003).
[25]Regents of the University of California v. Eli Lilly, 119 F.3d 1559, 1568 Fed. Cir. (1997).

proteomics (the study of proteomes or proteins on a large scale) and genomics (the study of genomes or genes) inventions, the written description and enablement requirement has emerged as a major constraint. In a biopharmaceutical patent, the amino acid sequence for a protein corresponding to a gene and cloning procedure may satisfy the enabling requirement but not the written description standard. Similarly, patent applications with indefinite, undescribed or insufficiently described and non-enabling steps directed towards correlating the test results for establishing a basic scientific relationship is not allowed.[26] To address all those issues the USPTO has issued several guidelines and training manuals for examiners. For instance, the MPEP 2164 cites the enablement requirement, wherein 2164.04 particularly cites the role of the examiner. The said guidelines separately point out the case of unpredictable arts. The question of undue experimentation is one consideration where it states that it can be replaced by several factors in the case of unpredictable arts. The quantity of examples used to support the enablement is one such factor.[27]

D. ENABLEMENT AND PLAUSIBILITY REQUIREMENTS AT INDIAN PATENT OFFICE

The Indian Patents Act, 1970 does not mention about plausibility requirement directly. However, there are certain aspects of the Indian Patent Law that indirectly hint the plausibility-related issues, such as sufficiency, industrial application and inventive step requirements as laid down in Section 2 of the Indian Patent Act.[28] Similarly, Section 10,[29] which describes the requirements of complete specifications and claims and Section 3(d)[30] have implicit effects on the concept of plausibility. In India, when a patent claims more than one form of compounds, all the compounds should have some technical relationship explicitly described in the specification. A claim directed towards a new form of known substance must be supported by experimental evidence and comparative studies proving its enhanced efficacy. In India, methods of treatment and second use of therapeutics are not allowed. So, while claiming any protein or modified gene not only the functional features but also their structural and technical features which confers the novelty and non-obviousness to the invention becomes important. There are many instances

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[26] Laboratory Corporation of America Holdings v. Metabolite Laboratories Inc, 548 U.S 124 (2006).

[27] In Re Wands, 858 F.2d 731, 737 Fed. Cir. (1988). (In this case, the court concluded that undue experimentation would not be required to practice the claimed immunoassay using monoclonal antibodies to detect hepatitis B-surface antigen as the invention seemed plausible.)

[28] §2, Patents Act, No. 39 of 1970, INDIA CODE (1970), Act ID 197039, https://www.indiacode.nic.in/handle/123456789/1392?locale=en.

[29] *Id.* §10.

[30] *Id.* §3(d).

where Indian patent office has rejected patent applications as the technical and structural effect of the claimed sequences are not described in the specifications (Forexample, in Application nos. 3411/DELNP/2006, 6845/CHENP/2010, 1161/KOLNP/2011).

In order to simplify the process of examining biotech patents, the extent of disclosure and clarity in claims the IPO had issued guidelines for examining biotech patents.[31] As per Indian patent examining practice, the claims and disclosure should be mutually supportive. While evaluating the sufficiency of disclosure, the examiner checks the presence of at least one complete disclosure for enabling the invention as portrayed in the claims, and not just a piece of it. The disclosure should enable a skilled individual in the pertinent art to work out the same invention without the undue burden of experimentation or the utilisation of innovative inventiveness. On the off chance, the disclosure is insufficient if the skilled person going by the specification needs to discover something new to enable the innovation. An inventor cannot claim an array of unrelated diseases/ailments as potential future diagnostic targets against a claimed gene or protein without experimenting or characterising that protein against the diseases. Even if the gene's association with one disease is ascertained, it is unlikely that that gene will have a role in all other claimed diseases. In absence of proper evidence to support the use of the gene in the other unrelated diseases claimed, the specification would be treated as insufficient. When claims seek to protect things that are in the scope of potential future discoveries and not yet into being at the time of filing, such claims are not patentable on the ground of insufficiency. There can be innumerable variants of polynucleotides or polypeptide sequences, in the form of additions, substitutions or deletions. A claim towards polynucleotides must be restricted to variant sharing common specificity as described in the specification. For DNA sequences hybridising with a particular probe and possessing certain activity, the specification must disclose the hybridisation conditions. The absence of the conditions may render the application to be cancelled.

In *Raj Prakash v. Mangatram Chowdhury*,[32]it was observed that a complete specification must describe 'an embodiment' of the invention claimed in each of the claims and the description must be sufficient to enable those in the industry concerned to carry it into effect without their

[31] Office Of The Controller General Of Patent, Design And, Trade Marks, *Guidelines for Examination of Biotechnology Applications of Patents* (Mar. 2013), available at: http://www.ipindia.nic.in/writereaddata-/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf.

[32]Raj Prakash v. Mangatram Chowdhury, AIR 1978 Del 1 (India).

making further inventions "and the description must be fair, i.e. it must not be unnecessarily difficult to follow."[33]

The IPO has also issued guidelines for the examination of pharmaceutical patents where the scope or ambit of claims is generally broader than the other fields of technology.[34] In pharmaceutical patents, the specification ought to contain at least one model covering the whole scope of the invention as claimed which empowers the skilled individual in the pertinent art to perform the innovation. In the event that the invention is related to the product per se, portrayal will be upheld with models for all the compounds claimed techniques for planning or trial information incorporated. Test boundaries, method of medication conveyance, results with clarification and derivation can be given. On the off chance of more than one pharmaceutical use for an application, the significant test ought to be supplemented.

Plausibility *per se* a requirement has not been considered by Indian courts. However, in other jurisdictions, it is a matter of contention in many cases. Some of the major cases and the plausibility definitions given in those are listed below.

IV. EVOLUTION THROUGH CASES

In the case of *Human Genome Sciences, Inc. v. Eli Lilly & Co.*,[35]it was held thatthe patent must uncover a practical application for the asserted item and that a conceivable or sensibly dependable claimed use or even an educated guess as to such a utilisation could be adequate for that reason. A separating line between "plausibility" and "educated guess" as against "speculation" attracted the case.

The case emphasised the need of a plausible disclosure in terms of industrial applicability. The degree of plausibility varies with regard to the facts and circumstances of each case. The case foresees the problems with respect to speculative or upstream patenting. This case is anapt guide of the "don'ts" to patentees who put forward speculative claims as of the compound's future use. The case cited that if the patentee fails to give plausible disclosure of industrial application, then the patent may be invalidated.

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[33]*Id.* at 9.

[34] Office of the Controller General of Patent, Design and, Trade Marks, *Guidelines for Examination of Patent Applications in the field of Pharmaceuticals* (Oct., 2014), http://www.ipindia.nic.in/writereaddata/Portal-/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf.

[35]Human Genome Sciences Inc. v. Eli Lilly & Co. [2010] EWCA Civ. 33.

In the case of *Warner-Lambert Company LLC. v. Generics (UK) Ltd. (trading as Mylan) and Ors.*,[36] it was established that the requirement of plausibility is a low threshold test, which is intended to prohibit speculative claiming. The patentee should illustrate that the claimed efficacy is credible with help of scientific reasons rather than mere assertions. This calls for the need to support second medical use claims with adequate disclosure. Unless a reasonable amount of plausibility is proved with respect to the new use, the patentee cannot claim a monopoly over it.

The Court, in *Merck v. Shionogi*,[37] laid a two-phase enquiry. The principal step is to decide if the specification, read in the light of the common general information of a skilled person, makes it conceivable that the creation will work over the extent of the claim. At this stage, it is not permissible for the patentee nor the opponent to depend upon proof which post-dates the patent. On the off chance that the disclosure makes it plausible, the subsequent stage is to consider whether the proof sets up that in certainty the innovation can't be performed over the extent of the claim without undue burden. At times, it is advantageous to isolate the second stage into two sections, first thinking about whether the innovation can be performed without unnecessary burden at all and afterward whether the claim is of exorbitant broadness. At this stage, proof which postdates the patent is permissible.

It was observed in the case of *Salk*,[38]that it is necessary that the patent gives some information as to the profit that the asserted compound directly affects a metabolic instrument explicitly engaged with the disease. When this proof is accessible from the patent application, at that point post-published expert evidence might be considered. However, it can't be only looked into the 'adequacy of disclosure' test, but as to back-up the discoveries in the patent application in relation to the use of the ingredient as a pharmaceutical.

In the *John Hopkins* case,[39] the term 'plausibility' was in the limelight. Here, plausibility was seen as a threshold for the test of both, the inventive step and sufficiency. It was viewed in the context of technical contribution and had set a standard to plausibility. The emerging standard in the case is that the application must make it at least plausible that it's teaching indeed solves the technical problem it purports to solve. The court in this case emphasised the importance of post published evidence to support the claimed subject matter. Such evidence can serve valid only in

[36]Warner-Lambert Company LLC v. Generics (UK) Ltd. (trading as Mylan) and Ors. [2016] EWCA (Civ)1006.
[37] Merck v. Shionogi [2016] EWHC (Pat) 2989.
[38] Salk Institute, *supra* note 10.
[39] John Hopkins, *supra* note 5.

the absence of any supporting data demonstrating the technical effect and if it is already credible from the original disclosure that the problem is indeed solved. In such cases, it may still be possible to demonstrate plausibility based on prior art or common general knowledge.

In *Regeneron Pharmaceuticals Inc. and Anr. v. Genentech Inc.*,[40] it was held that it must be conceivable to make a reasonable expectation the invention will work with considerably everything falling inside the extent of the claim. If it is possible to predict that the invention works across the claim by trying to club the products and methods claimed by a common principle, then the patentee need not demonstrate the working of the invention in every case. If such a forecast is not possible, then the scope of the monopoly will exceed the technical contribution the patentee has made to the art and the claim will be insufficient.

The Court, in *Actavis v. Eli Lilly*,[41] held that plausibility is a threshold test that is fulfilled by a disclosure which is "credible" as opposed to speculative. A conceivable invention may in any case be demonstrated to be inadequate. The norm for appraisal of plausibility isn't the equivalent to the norm for evaluation of expectation of success in the context of obviousness. The case laid the standard that, the test of plausibility is different from the test of sufficiency and inventive step and can be used in aid for the test of the latter two.

V. CONCLUSION

Plausibility is not a new requirement. It is a test that assists granting/judicial instances to evaluate whether and to what extent the patent applicant/holder is in possession of the invention. It is something different from the written description requirement. It seems to have become a useful instrument to tackle patents that are unduly broad, speculative, lack experimental support for effects allegedly achieved. It seems to discourage "armchair patents". It is likely to force patent applicants to provide more detail and evidence in patent applications for scope and effects claimed. It is a useful instrument to make the scope of the patent commensurate with what is disclosed. It is likely to cast doubt over practices where one relies heavily on post-published evidence without much more in the application as filed.

Even though for active substances per se, less evidence needs to be provided, if it is not plausible that the compound has the purported therapeutic activity, the objective technical problem to be solved may have to be redefined. But in doing that, there is a risk of falling into the lack of

[40] Regeneron Pharmaceuticals Inc., *supra* note 7.
[41] Actavis v. Eli Lilly [2015] EWHC (Pat) 3294.

inventive step trap. It can present difficulties for some early-stage patents, where there is not yet a lot of experimental evidence, but it is equally not warranted to wait longer with patent filing. The concept of plausibility is seemingly being developed as a separate test, be it or not as part and parcel of already existing patentability requirements, or as an emerging separate patentability requirement.

With increasingly more patents of second medical use currently being disputed, plausibility will stay a popular assault for claiming insufficiency or lack of inventive step. Recent decisions have perhaps begun to get control over the degree to which plausibility can be utilised to assault patentability. Further advancements are probably going to follow, so watch this space. It would also appear that the hurdle for plausibility is not as high as many feared it had become. The authors hope that a relatively low or justifiable threshold test for plausibility continues to be applied by the court going forward. A balance must be struck between plausibility and enablement requirements given that new research, particularly new medical uses of existing pharmaceuticals need to be encouraged in light of the difficulties that currently the pharmaceutical industry faces in the identification of new (bio)chemical compounds suitable for drug development .