

**INTERNATIONAL JOURNAL OF LAW
MANAGEMENT & HUMANITIES**
[ISSN 2581-5369]

Volume 3 | Issue 3

2020

© 2020 *International Journal of Law Management & Humanities*

Follow this and additional works at: <https://www.ijlmh.com/>

Under the aegis of VidhiAagaz – Inking Your Brain (<https://www.vidhiaagaz.com>)

This Article is brought to you for “free” and “open access” by the International Journal of Law Management & Humanities at VidhiAagaz. It has been accepted for inclusion in International Journal of Law Management & Humanities after due review.

In case of **any suggestion or complaint**, please contact Gyan@vidhiaagaz.com.

To submit your Manuscript for Publication at **International Journal of Law Management & Humanities**, kindly email your Manuscript at editor.ijlmh@gmail.com

The Use of Secondary Indicia in Assessing Obviousness in the United States of America and Europe, a Comparative Study

SHANTANU RAHUL KULKARNI¹

ABSTRACT

Secondary-indicia are fundamental to the non-obviousness test undertaken to ascertain the patentability of an invention. It includes other subjective elements such as the existing state of the art, the presence of a novel step and if a person of ordinary skill in the art will find it obvious. While the test is termed differently in distinct jurisdictions, the aforementioned elements are common. This paper presents a comparative analysis of the United States of America (US) and the European States (EU) jurisdictions and their non-obviousness tests. The paper finds that the subtle difference between the two pertains to the way secondary-indicia is considered.

Subsequently, it is argued that the status of secondary-indicia is ambiguous in the US due to the recent “KSR vs. Teleflex” judgment, whereas, the EU presents a more certain approach. Further, a critique of the aforementioned approaches is undertaken to highlight the constant undermining of secondary-indicia. Resultantly the same has diluted the non-obviousness test and increased the possibility of hindsight bias.

The paper emphatically recommends that secondary-indicia are an objective sub-test which complements the subjective sub-test contained within the non-obviousness test. Lastly, the paper establishes the need to treat secondary-indicia as a mandatory element in the non-obviousness test.

Keywords: *Secondary Indicia, Non-obviousness test, Hindsight bias, KSR vs. Teleflex, and Secondary Considerations*

I. INTRODUCTION

A patent confers an inventor with “exclusive rights”². “A patent provides its owner with the right to prevent the manufacture, sale, use, importation, or offer for sale of the patented product,

¹ Author is a student of L.L.M. in Intellectual Property and Information Technology Law at Trinity College Dublin, University of Dublin, Ireland.

²Rebecca S. Eisenberg, *Patent and the Progress of Science: Exclusive Rights and Experimental Use*, 56 THE UNIVERSITY OF CHICAGO LAW REVIEW 1017 (1989)

process, or composition”.³ The objective behind patent law is to incentivise inventors to continue to innovate and discover.⁴ There are several requirements that an inventor and the invention need to satisfy to be protected by way of a patent.

Several fundamental principles of patent law are common across jurisdictions. These principles are “Novelty”⁵, “Inventive Step/ non- obviousness”⁶ and “Industrial applicability/ Utility”⁷. Depending upon the jurisdiction within which the patent is filed the aforementioned terminologies differ. For a patent to be granted each of the principles mentioned above must be satisfied; however, the threshold of satisfaction for these elements differ depending on the jurisdiction.

To achieve the objectives of this paper we shall restrict ourselves to the second principle i.e. “Inventive Step/ Non- obviousness”. To satisfy this principle the invention in question must first be novel and not similar or derived or a part of the prior art. Prior art is defined as anything available in the public domain.⁸ If the invention fails to be considered novel the patent application fails. If the invention is indeed novel, the subsequent hurdle for a patent application is that of “Inventive Step/ Non- obviousness”.

Once the “*sine qua non* of Novelty”⁹ is satisfied, the next step is assessing whether the invention showcases an inventive step or the invention is not obvious. Once again depending upon the jurisdiction of filing, the tests to examine the invention on the touchstone of inventive step or obviousness differs. Regardless of the jurisdiction one component is common across jurisdictions and it is Secondary Indicia (“SI”) or Secondary Considerations. Several SI can be considered before the grant of a patent, with some of the most frequently referred ones being chances of commercial success, long felt and unsatisfied need or want, and failures of others to present a similar invention.¹⁰

SI are considered important for the determination of the obviousness of an invention. In most

³ Richard H. Shear and Thomas E. Kelley, *A Researchers Guide to Patents*, 132 PLANT PHYSIOLOGY 1127 (2003)

⁴ Tom Nicholas, *Are Patents Creative or Destructive*, 79 ANTITRUST LAW JOURNAL 405 (2014) <https://www.hbs.edu/faculty/Publication%20Files/14-036_88022f59-a293-4a6f-b643-b205304bce91.pdf> accessed October 9, 2019

⁵ Toshiko Takenaka, *The Best Patent Practice or Mere Compromise? A Review of the Current Draft of the Substantive Patent Law Treaty and a Proposal for a ‘First-To Invent’ Exception for Domestic Applicants*, 11 TEXAS INTELLECTUAL PROPERTY LAW JOURNAL 259 (2003)

⁶ *Ibid*

⁷ *Ibid*

⁸ WORLD INTELLECTUAL PROPERTY ORGANIZATION, STATUS AS OF OCTOBER 2019 CERTAIN ASPECTS OF NATIONAL/REGIONAL PATENT LAWS (2019), https://www.wipo.int/export/sites/www/scp/en/national_laws/novelty.pdf.

⁹ INDIGENOUS STUDIES : BREAKTHROUGHS IN RESEARCH AND PRACTICE (INFORMATION SCIENCE REFERENCE), (Information Resources Management Association ed., 2020)

¹⁰ James M. Emery, *Obviousness, Secondary Considerations, and The Nexus Requirement*, 1 ANNUAL SURVEY OF AMERICAN LAW 117 (1986)

jurisdictions, SI are known as ‘objective contributors’. They are referred to as ‘objective contributors’ because the test for inventiveness/non-obviousness is a subjective analysis of the invention uses two or maybe three prior art references, whereas the tests for SI are common across all inventions. By way of an analysis of SI, the examiners try to assess the industrial reaction to the invention to ascertain the inventiveness/ non – obviousness.

The analysis of SI also helps in curing the effects of ‘Hindsight Bias’ (“**HB**”)¹¹, which is one of the worst nightmares for inventors. It is when the examiners perceive the majority of the invention to be obvious based upon an analysis of the prior art.¹² This is increasingly becoming a problem in view of the judgment in of Hon’ble Supreme Court of the United States of America (“**SCA**”) in the “*KSR International Co. v. Teleflex Inc.*”¹³ (“**KSR Case**”) wherein the SCA has held that common sense should guide the Courts in ascertaining whether a person of ordinary skill in the art would have perceived to combine the existing prior art. The said Judgement is discussed at greater lengths in the subsequent parts of this paper.

At a time when the drive for innovation, novelty and scientific discovery is being stifled by HB, the analysis of the SI presents itself as the solution.¹⁴ The question that remains is how willing are we to accept and frame rules to adopt this solution by giving it statutory force and precedent colour.

II. SECONDARY INDICIA AND THE TEST FOR NON OBVIOUSNESS IN THE UNITED STATES OF AMERICA

Similar to other jurisdictions, US law also requires a patented invention to be non-obvious. The provision that deals with this requirement is enshrined within USC 103¹⁵. This section only came into existence in the year 1952 when US congress enacted the Patent Act. Before the existence of the Patent Act, the SCA, in 1850 while deciding the “*Hotchkiss v. Greenwood*”¹⁶ (“**Hotchkiss Case**”), had propounded the imminent need to codify the requirement of non-obviousness. The SCA held that the invention described in the *Hotchkiss case* is merely an improvement, which was stumbled upon by a skilful mechanic and not an invention in its true sense.¹⁷ Although the SCA never made any specific reference to the term “non-obvious”, the

¹¹Ashley Allman Bolt, *Combating Hindsight Reconstruction in Patent Prosecution*, 64 EMORY LAW JOURNAL 1137 (2015)

¹²*Ibid*

¹³*KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007)

¹⁴DONALD S. CHISUM, CHISUM ON PATENTS: VOLUME 2 (1997)

¹⁵ 35 U.S.C. § 103

¹⁶*Hotchkiss v. Greenwood*, 52 U.S. 248, (1851)

¹⁷Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CALIFORNIA LAW REVIEW 803 (1988)

mention of words such as “merely an improvement” and “invention” enunciated the role of knowledge and skill in construing the meaning of a patentable invention.¹⁸

More than a “decade later”¹⁹, the US Congress took notice of the *Hotchkiss Case* and enacted section 103 of the Patent Act, which codified the requirement of an invention to be non-obvious.²⁰ Over time the SCA felt the need to further refine the understanding of the term ‘non-obvious’ and in furtherance of the same stipulated a test in the “*Graham v. John Deere Co. of Kan. City*”²¹ (“**Graham Case**”).

In the *Graham Case*, the SCA noted that the US Patent and Trademarks Office (“USPTO”) followed a three-pronged test to ascertain the non-obviousness of an invention.²² The SCA felt a need to include a fourth prong in the form of an analysis of the SI to the test being applied by the USPTO. This was driven by SCA’s statement that the three-pronged test followed by the USPTO is immensely technical and fails to consider the market-related viability of an invention. The SCA appreciated the fact that the test of non-obviousness is subjective to the invention and relies on “technical/scientific evidence which the SCA may not be able to interpret”.²³ The SCA also propounded on the importance of avoiding HB; however, the SCA found that it is the person skilled in the art whose opinion affects the question of patentability of an invention. This “person skilled in the art” may tend to oversimplify and assess the invention to be obvious due to his or her immense knowledge in the field. To add a check on the probability of HB the SCA felt the necessity to introduce the requirement of analysing the SI.²⁴

The *Graham Case* was not the first instance of the SCA propounding on the need of SI. The “*Smith v. Goodyear Dental Vulcanite, Co.*”²⁵ (“**Smith Case**”) was the first time that the SCA relied on the SI to ascertain the non-obviousness of an invention. The SCA found that the invention in the *Smith Case* may be merely an improvement in the material being used; however, the ratio of the *Hotchkiss Case* does not apply to the *Smith Case*. The SCA distinguished the *Hotchkiss Case* from the *Smith Case* by stating that the invention in the latter case created an economically viable treatment in the field of dental medical science.²⁶

¹⁸*Ibid*

¹⁹Eli M. Sheets, *Arguing Secondary Considerations After KSR: Proceed with Caution*, 21 THE FEDERAL CIRCUIT BAR JOURNAL 1 (2011)

²⁰*Ibid*

²¹*Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, (1966)

²²*Supra* note 18

²³Jonathan J. Darrow, *Secondary Considerations: A Structured Framework for Patent Analysis*, 74 ALBANY LAW REVIEW 47 (2010)

²⁴*Supra* note 12

²⁵*Smith v. Goodyear Dental Vulcanite Company*, 93 U.S. 486 (1876)

²⁶*Supra* note 18

Therefore, the invention in the *Smith Case* fulfilled a long-felt need for an unresolved problem in the Dental Treatment field. The SCA held that the invention in the *Smith Case* was non-obvious and thereby worthy of patent protection. It is clear that the analysis of the SI is integral to the test of ascertaining non-obviousness. It is interesting to note that SI finds no place within the section,²⁷ but is a concept that has evolved through judicial precedents. The fact that the court has never pondered upon the comparative evidentiary value of SI has created a tremendous cloud of ambiguity. In fact, SI lack statutory force and the result is the absence of a uniform standard to assess the value of SI in the determination of non-obviousness.

The SCA had an opportunity in the *KSR Case* to resolve this controversy. However, rather than strengthening the value of SI the court diluted the test for ascertaining the non-obviousness of an invention. In the *KSR Case* the SCA found that the Federal Circuit Court (“FCC”) was applying a rigid construction of the teaching, suggestion and motivation test.²⁸ Therefore, the SCA held that it is appropriate to follow a more flexible approach in the quest to ascertain the motivation involved in combining the two inventions to create a third more novel invention with a degree of common sense.²⁹ These findings by the SCA implied that common sense is a possible contributor that motivates an inventor to combine two prior art references. By doing so the SCA has exposed the FCC to flood of litigation cantered around common sense related arguments proposing invalidation of patents already granted.³⁰

This approach by the SCA, which used an ambiguous non-quantifiable term like ‘common sense’,³¹ has led to unceasing patent infringement litigation. Another criticism of the *KSR judgment* is that the SCA directed the FCC to consider any problem that could be solved by the invention.³² This is completely contrary to the pre-*KSR* notion of ascertaining a specific problem that can be solved by the invention. The new flexible approach leads to absurdity as patent application examiners have a wider pool from which they can ascertain the teaching

²⁷Robert W. Harris, *The Emerging Primacy of Secondary Considerations as Validity Ammunition: Has the Federal Circuit Gone Too Far*, 71 JOURNAL OF PATENT AND TRADEMARK OFFICE SOCIETY 185 (1989)

²⁸Jasper L. Tran, *Timing Matters: Prior Arts Age Infers Patent Non-Obviousness*, 50 GONZAGA LAW REVIEW 189 (2014)

²⁹SHELDON W. HALPERN, KENNETH L. PORT AND SEAN B. SEYMORE, FUNDAMENTALS OF UNITED STATE INTELLECTUAL PROPERTY LAW : COPYRIGHT, PATENT AND TRADEMARK (5th ed. 2015)

³⁰Ron A. Bouchard, *KRS v. Teleflex Part 1: Impact of U.S. Supreme Court Patent Law on Canadian Intellectual Property and Regulatory Rights Landscape*, 15 HEALTH LAW JOURNAL 221 (2007); Also See: Sughrue Mion, U.S. SUPREME COURT HEARS ORAL ARGUMENTS IN KSR V. TELEFLEX | RESOURCES | SUGHRUE MION, PLLC SUGHRUE.COM (2019), <http://www.sughrue.com/US-Supreme-Court-Hears-Oral-Arguments-in-KSR-v-Teleflex-11-28-2006/>

³¹*Supra* note 18

³²C Dylan Turner, *In Cyclobenzaprine, an Objective Failure to Reach a Long-Felt Need in Secondary Considerations Jurisprudence*, 13 NORTH WESTERN JOURNAL OF TECHNOLOGY AND INTELLECTUAL PROPERTY 359 (2015)

suggestions and motivation. This fuels the problem of HB.

Although the SCA did not explicitly comment upon the status of SI, there is an implied downplay.³³ By using phrases such as “primary considerations and *prima facie* opinion” the SCA has inculcated a balancing scale test.³⁴ Primary considerations such as novelty, prior art and opinion of a person skilled in the art are utilized to formulate a *prima facie* opinion regarding the obviousness of the invention before the Court considers the SI evidence. If the SI evidence tilts the scales in favour of the inventor, the Court may establish a case of non-obviousness. This is against the pre-KSR standard whereby SI was considered an integral part of the test laid down by the *Graham Case*.

Further complicating the issue, the SCA hasn't yet given the evidentiary weight of primary considerations to SI.³⁵ Regardless of a strong case of non-obviousness being established through SI, the Courts are of the opinion that *prima facie* opinion based on primary considerations cannot change.³⁶ This was first exhibited in “**Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.**”³⁷ (“**Leapfrog Case**”) at the Trial Court. The inventor had presented a strong case based on SI for non-obviousness and the court appreciated the fact that substantial evidence has been brought on record; however, the inventor failed to convince the court that the invention in question was non-obvious.³⁸ *Leapfrog* preferred an appeal in the FCC, whereby the FCC affirmed the finding of obviousness recorded by the Trial Court despite substantial evidence of SI establishing non-obviousness. Without evaluating the weight and relevance of secondary considerations the FCC affirmed the decision of the Trial Court in complete disregard to the fact that analysis of the SI are an integral part of the test prescribed by the *Graham Case*.

This trend set by *Leapfrog Case* has been carried forward by the FCC in the case of **Apple Inc. v Samsung Electronics Co. Ltd. LLC**³⁹ (“**Apple Case**”). Here the dispute was pertaining to the “slide to unlock mechanism”.⁴⁰ The FCC has once again found evidence of SI but it has held that the evidence is not sufficient to dislodge a “strong case of obviousness found on primary considerations”.⁴¹ Here it is apparent that the FCC has appreciated SI evidence without

³³Timothy J Le Due, *The Role of Market Incentives in KSR's Obviousness Inquiry*, 11 WAKE FOREST JOURNAL OF BUSINESS AND INTELLECTUAL PROPERTY LAW 33 (2010). Also see: *Supra* Note 19.

³⁴*Supra* note 9

³⁵*Supra* note 15

³⁶Jay Jongjitirat, *Leapfrog Enterprises v. Fisher-Price: Secondary Considerations in Non-obviousness Determinations*, 42 UNIVERSITY OF CALIFORNIA, DAVIS LAW REVIEW 599 (2008)

³⁷*Leapfrog Enter. v. Fisher-Price Inc.*, 485 F.3d 1157 (2007)

³⁸*Supra* note 35

³⁹*Apple, Inc. v. Samsung Elec. Co., Ltd.*, No. 15-1171 (Fed. Cir. 2016)

⁴⁰*Ibid*

⁴¹*Ibid*

there being a uniform standard. This is indeed a worrisome stance taken by the courts with regards to the importance of SI in ascertaining non-obviousness of an invention and the absence of clarity with regards to the evidential value of SI still prevails.⁴²

III. SECONDARY INDICIA AND THE TEST FOR NON-OBVIOUSNESS IN THE EUROPEAN STATES

An inventor can seek patent protection in multiple national jurisdictions by applying with the European Patent Office (“EPO”). It is essential to note that the EPO is merely a body that sanctions patent protection to an invention.⁴³ As there is no European Court of patent law, the EPO can merely adopt a modest standard by ascertaining the standards in the domestic jurisdictions of its member states. The most crucial issue in European patent law jurisprudence is the absence of a definition to the term inventive step or a method of quantification for the degree of the inventiveness of an invention⁴⁴; however, the standard to ascertain whether an invention is inventive is prescribed by “Article 56 of the European Patent Convention”⁴⁵ (“EPC”).⁴⁶

Based upon the reading of Article 56 of the EPC it is apparent that the EPO follows a problem-solving test.⁴⁷ There are three prongs to this test: to check “whether the invention is novel compared to the closest prior art reference, assess the objective technical problem attempting to be solved by the invention, and to seek the opinion of a person of ordinary skill in the art about the inventiveness of the invention.”⁴⁸

The European Law on the question of SI or objective criteria is very clear. The European jurisprudence states that objective criteria cannot overrule the technical criteria prescribed by Article 56 of the EPC and are to be assessed in a complimentary manner to help crystallize an opinion on the inventiveness of an invention.⁴⁹

⁴²Amanda Wicker, *Secondary Considerations Should Be Given Increased Weight in Obviousness Inquiries under 35 U.S.C. Sec. 103 in the Post-KSR v. Teleflex World*, 17 THE FEDERAL CIRCUIT BAR JOURNAL 665 (2008)

⁴³Zachary Quinlan, *Hindsight Bias in Patent Law: Comparing the USPTO and the EPO*, 37 FORDHAM INTERNATIONAL LAW JOURNAL 1787 (2014)

⁴⁴Lisa Almgren, *Inventive Step*, 2000, <https://lup.lub.lu.se/luur/download?func=downloadFile&recordId=1555589&fileId=1563707>; Also See: BARDEHLE PAGENBERG, ASSESSMENT OF INVENTIVE STEP UNDER THE EPC (2010), http://www.bardehle.com/uploads/tx_toco3bardehle_files/Inventive_Step_en.pdf

⁴⁵Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973

⁴⁶Paul England, *Inventive Step in Europe and the UPC*, 13 JOURNAL OF INTELLECTUAL PROPERTY LAW AND PRACTICE 534 (2018)

⁴⁷EUROPEAN COMMISSION, ALAIN STROWEL AND DR. SINAN UTKU, THE TRENDS AND CURRENT PRACTICES IN THE AREA OF PATENTABILITY OF COMPUTER IMPLEMENTED INVENTIONS WITHIN THE EU AND THE US. (2016)

⁴⁸MARGARETE SINGER AND DIETER STAUDER, 1 THE EUROPEAN PATENT CONVENTION: A COMMENTARY (3rd ed. 2003)

⁴⁹*Supra* note 45

Despite the precedence that technical criteria hold over objective criteria, it is apparent from a perusal of “*Monsanto/Milk Production Case*”⁵⁰, that the EPO is keen on considering objective criteria as a primary indicator of inventiveness in DNA related patent applications.⁵¹ This is an industry-specific trend and has not been applied elsewhere. The main factor driving this trend is that structural modification in a DNA related patent application is inadequate to establish inventiveness; therefore, the inventor has to establish objective criteria identifying an unexpected beneficial result associated with the said structural modification.⁵² An attempt to curb the issue of HB has been made through this approach. As technology has advanced at a rapid rate, alienation, deconstruction and reassembling of DNA has become easier and it is apparent that to a person of ordinary skill in the field a mere structural change may not seem inventive.⁵³ Consideration of objective criteria will provide a nuanced and objective approach to this issue by considering factors such as long felt and unsolved need, unexpected beneficial results and commercial success.

IV. COMPARATIVE ANALYSIS

In view of the aforesaid, it is apparent that the European Countries (“EU”) have a clearer understanding of objective criteria (i.e. SI). As the name suggests, EU have given SI less importance than the primary considerations of novelty, inventive step and prior art.⁵⁴ European courts have uniformly stated that the SI will be of significant value only if there is an ambiguity after accounting for the primary considerations.⁵⁵ Thus, it is unambiguous that Europe strictly follows the balance scale approach.

The European Courts through precedents⁵⁶ have established that SI individually cannot determine the inventiveness of an invention. The role of SI in the EU is always to substantiate the *prima facie* findings of inventiveness, which are decided by considering the primary considerations.

⁵⁰Case T 249/88 “Monsanto/Milk Production”, (1996) E.P.O.R.

⁵¹Timo Minssen, *Meanwhile on the Other Side of the Pond: Why Biopharmaceutical Inventions That Were Obvious to Try Still Might Be Non-Obvious -- Part I*, 9 CHICAGO-KENT JOURNAL OF INTELLECTUAL PROPERTY 60 (2010)

⁵²Christopher M. Holman, Timo Minssen and Eric M. Solovy, *Patentability Standard for Follow-On Pharmaceutical Innovation*, 37 BIOTECHNOLOGY LAW REPORT 131 (2018)

⁵³*Supra* note 51

⁵⁴Standing Committee on the Law of Patents, WIPO, FURTHER STUDY ON INVENTIVE STEP (PART II) SCP/29/4 WWW.WIPO.INT (2018), https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=423210 (last visited May 14, 2020)

⁵⁵*Supra* note 45

⁵⁶*Ibid. Also See*: “France: Tribunal de Grande Instance, Paris, Hutchison Gomma, Barre Thomas, 10 March 2009; Germany: Pagenberg, ‘Beweisanzeichen auf dem Prüfstand – Für eine objektive Prüfung auf erfinderische Tätigkeit’, GRUR Int. 1986, 83 ff”

In contrast, the understanding of SI in the US is clouded by ambiguity as the SCA and the FCC have given diverging decisions. There is an absence of a uniform understanding of the importance of SI. In numerous cases such as *Smith, Graham and “Stratoflex, Inc. v. Aeroquip Corp.”*⁵⁷ (“**Stratoflex Case**”) the SCA has succinctly stated that SI are an integral part of the ‘Obviousness Test’.⁵⁸ The *Graham Case* introduced a four-pronged test to ascertain the non-obviousness of an invention and required that SI be analysed meticulously.⁵⁹ A combined interpretation of the abovementioned cases suggests that cogitation of SI is mandatory.

This interpretation is confused by cases such as *KSR* and *Leapfrog*. In the *KSR Case*, the SCA had an opportunity to lay down a clear interpretation for considering SI; however, it refused to interfere and summarily stated that Teleflex did not present any SI factors. This interpretation by the SCA is contrary to the previous cases, which mandated a critical consideration of SI.

As a result of the *KSR Case*, the FCC refused to consider SI in the subsequent *Leapfrog Case*. The *Leapfrog Case* will have drastic consequences because the Court noted that substantial SI evidence has been presented, but without analysing that evidence the Court found that it is insufficient to dislodge the *prima facie* view of obviousness ascertained from the primary considerations. Another complexity created by *Leapfrog* and other similar cases is the use of phrases such as ‘prima facie finding of obviousness based on primary consideration’ and ‘strong case of obviousness’. These phrases suggest that the Courts in the US follow a balance scale approach like in the EU; however, the ratio in the *Graham* and *Stratoflex* and “**American Innotek Inc. v. United States**”⁶⁰ cases state otherwise. In the US SI is an integral and compulsory part of deciding the non-obviousness of an invention.

By introducing terms such as ‘commonsense’ as a ground for invalidation of a patent the *KSR Case* has demonstrated need for considering SI. The ratio in *KSR Case* has directed the FCC to follow a more elastic application of the Teaching Suggestion Motivation Test (“**TSMT**”) by applying common sense. This has diluted the threshold to be satisfied to prove obviousness and defeats the purpose of patent law, which is to incentivise inventors to constantly strive for innovation. The *KSR test* has also increased the possibility of HB. To keep the possibility of HB at minimum mandatory consideration SI are of paramount importance.

It is clear that there is substantial differences in the European and US approaches towards

⁵⁷*Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983).

⁵⁸John Paul Putney, *Are Secondary Considerations Still ‘Secondary’?: An Examination of Objective Indicia of Non-obviousness Five Years After KSR*, 4 AMERICAN UNIVERSITY INTELLECTUAL PROPERTY BRIEF 45 (2013). Also See: *Apple Inc. International Trade Commission* 725F.3d1356(Fed.Cir.2013) and *Leo Pharmaceutical Products Ltd. v. Rea* 726F.3d1346(Fed.Cir.2013)

⁵⁹*Ibid*

⁶⁰*American Innotek, Inc. V. United States*, No. 17-1178 (Fed. Cir. 2017)

consideration of SI, but there are certain similarities as well. For SI to have bearing on the facts of a case there needs to be reasonable nexus with the invention. This is a requirement in both the US and the European States.⁶¹ For example, commercial success is one of the most relied upon SI; however, commercial success can also result from a unique advertisement campaign.⁶² In such a situation, there is no nexus between the originality and the utility of an invention, and the cause of its commercial success. Hence, the establishment of a nexus is a prerequisite for establishing commercial success.

Another similarity is that a singular SI is often insufficient to prove non-obviousness. This is a constant principle laid down by courts in both the US and European States. For commercial success to be insufficient to prove non-obviousness, it has to be coupled with the failure of others and satisfaction of a long-felt need.⁶³ A presence of those factors and a clustered interpretation makes a strong case for non-obviousness.

The last similarity is providing industry-specific emphasis on the mandatory consideration of SI. Both the jurisdictions have noted that the patents involving an invention related to pharmaceutical or medical (i.e. DNA modification) need a higher degree of consideration with regards to SI. The Courts have appreciated the fact that pharmaceutical drugs are frequently a combination of already existing elements. Similarly, modification of DNA will also involve elements of prior art in the form of already existing DNA structures. Both the jurisdictions have consistently held that efficacy of the drug, commercial success, failure of others, and ability to solve a long-felt need are few of the necessary SI to be considered.⁶⁴ For example, the *Smith Case* dealt with improved artificial teeth sets that used vulcanized rubber to form individual teeth. This invention was obvious considering the prior art; however, the court took notice of the fact that the invention provided an economical method and revolutionised the field of dental practice. The court also took notice that no one in the field of dental medical science had discovered such a method to solve that long-felt need; therefore, it was apparent in this case that the court gave more importance to SI than the primary considerations for determining the non-obviousness of the invention.

Another interesting case is that of “***Eli Lilly and Co. v. Sicor Pharmaceuticals, Inc.***”⁶⁵ “Eli Lilly was the initial patent holder for a drug containing Gemcitabine that is used to treat ovarian

⁶¹Jolie D. Lechner, *Rebutting Obviousness in the Pharmaceutical Industry: Secondary Consideration of Analogs*, 11 CHICAGO-KENT JOURNAL OF INTELLECTUAL PROPERTY 146 (2012)

⁶²*Supra* note 22

⁶³*Supra* note 27

⁶⁴*Ibid*

⁶⁵*Eli Lilly and Co. v. Sicor Pharmaceuticals, Inc.*, 705 F. Supp. 2d 971 (S.D. Ind. 2010)

cancer, breast cancer, non-small cell lung cancer, and pancreatic cancer”.⁶⁶ Sicor Pharma (“SP”) was found to be marketing a similar drug and Eli Lilly sued for patent infringement. SP argued that the patent held by Eli Lilly is invalid as it is obvious and the District Court decided in favour of SP, finding the patent for the drug Gemcitabine was structurally obvious considering the prior art existing at the time of the invention.⁶⁷ Upon appeal the FCC reversed the decision passed by the district court to find that the Eli Lilly patent was non-obvious and that Eli Lilly spent several years formulating the drug. The Court stated that merely because the drug is visually similar to others does not mean that it is easier to conjure such a drug easily in the laboratory. The Court also considered that several other companies tried to formulate the drug before Eli Lilly; however, those companies failed to succeed. Further, the Court also found that the patent drug Gemcitabine resulted in an enhanced year of survival chance in cases of pancreatic cancer. We find that the Court considered 3 main SI. *Firstly* the Court identified considerable research and development efforts undertaken by Eli Lilly. *Secondly*, the Court noticed the failure of others to conjure the same compound before Eli Lilly. *Lastly*, the Court considered the efficacy of the drug and found that it was more effective in the treatment of cancer than its counterparts. Thus, the Court utilized the SI to declare the patent as non-obvious regardless of a *prima facie* finding of obviousness based on the primary considerations.

Based on the facts presented, consideration of SI should be a mandatory requirement based on the 4 points. *Firstly*, SI is a part of the 4-pronged test laid down by the *Graham Case* in the US. *Secondly*, it provides for a balanced approach in addressing the HB. *Thirdly*, it is necessary in a post-KSR regime because the Court diluted the threshold to prove obviousness. *Lastly*, SI are objective considerations and there is no scope of conducting a subjective, technical analysis. This will assist the Courts that may not possess the technical knowledge to ascertain obviousness or inventive step of an invention. Furthermore, it adds the possibility of an evolving standard i.e. a standard which evolves as the industry progresses. There is an element of social transformation involved in SI, as is apparent from the industry-specific approach considered above. SI is just of the most essential piece to the jigsaw puzzle i.e. the test for the determination of non-obviousness as it can be trusted and substantial reliance can be placed on them to prevent inventions falling into the abyss of HB.

V. ROAD TO THE FUTURE

The road to the future is mandatory consideration of the SI in the determination of non-

⁶⁶*Supra* note 60

⁶⁷*Ibid*

obviousness of an invention. To achieve this current ambiguity in the US surrounding this issue that arises from the absence of precedent clarity needs to be addressed. The SCA has refused to consider this issue to be of importance and in my opinion; they are waiting for an appropriate case to consider the issue extensively. The paper intends to propose certain stepping stones on the road to mandatory consideration of the SI in the US.

The US legislature should provide statutory force to the mandatory use of the SI.⁶⁸ To accomplish this, legislature should enshrine SI into section 103 of the Patent Act; thus, establishing its legitimacy and provoking the court to consider the same in every case.⁶⁹ The SCA should consider providing rules in the form of precedents. By rules, it is suggested that standards of proof and the burden to be discharged should be stated in succinct terms. The court must equate them with the primary considerations and clarify the evidentiary value associated with the SI. On a case to case basis the elements that are required to be proved for each SI must be clarified by the court. This will inform the litigants about the essential thresholds that are needed to prove a commercial success, licensing and copying.

The court must reconsider judgements such as *KSR*, *Leapfrog and Apple*, which set dangerous precedents. This may sound extreme but terms like “common sense” cannot be quantified by law. The subjective nature of these terms lead to two possible scenarios. It may lead to the opening of a Pandora’s Box of litigation based on the commonsense notion, causing the court to be overburdened by a plethora of cases. The other scenario concerns excessive discretion being exercised due to the subjective nature of the term “common sense”. This will act as a disincentive for inventors to develop and research further, while also leading to a further dilution of the threshold to prove obviousness.

Additionally, the courts could interpret SI in consonance with the prior art in question.⁷⁰ The SI may assist the courts in evaluating industry-related events that took place at the time of the invention. The assessment of prior art and industry condition can flow from an analysis of SI. Lastly, the courts should cease using terms such as common sense to determine obviousness and consider using a probability of success determination instead.⁷¹ This would entail the court considering the probability for a combination of the prior art and the result of such a success.⁷² In other words, if there is a lesser probability of combining the prior art and the result achieved

⁶⁸TOSHIKO TAKENAKA, *PATENT LAW AND THEORY : A HANDBOOK OF CONTEMPORARY RESEARCH* 436 (2008)

⁶⁹*Ibid*

⁷⁰*Supra* note 9

⁷¹Gregory Mandel, *The Non-Obvious Problem: How the Indeterminate Non-obviousness Standard Produces Excessive Patent Grants*, 42 UC DAVIS LAW REVIEW 57 (2008)

⁷²*Ibid*

are highly beneficial the court may consider this to be non-obvious. If there is a higher probability of combination and similarity of results the courts will consider such an invention to be obvious.

VI. CONCLUSION

The paper strongly recommends granting a mandatory consideration status to SI. This is an essential improvement that is needed in the US considering judgements of the *KSR*, *Leapfrog* and *Apple Cases*. Consideration of SI will prevent the courts to from falling prey to the HB. The author has also found that there is substantial ambiguity surrounding this issue in the US rather than in the EU. The approach to determination in the US and EU is similar; however, the EU has a designated role for SI. Furthermore, the balance scale approach followed in the EU needs to change over time. The EU has already realized the need to adopt a SI based approach in the pharmaceutical industry and it is time to adopt a similar approach for other industries too. It will help in preserving the crux of patent law in general i.e. to provide scientists and inventors with incentives to continuously innovate.
