



## In Search of a Simple Test to Determine Non-obviousness of Inventions: A Short Communication

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**Abstract:** To have a high bench mark for inventions so as to qualify for patent protection, non-obviousness was introduced as a criterion for patentability. But there does not seem a uniform test or methodology for the determination of non-obviousness.

Each case law, from *Graham V John Deere* nearly 50 years ago to the recent *KSR V Teleflex* has raised more questions than answers. It appears to a researcher that Patent Laws are unable to keep abreast with the advancements in technology especially in areas such as Information Technology and Biotechnology. Further, keeping a low level of inventiveness as a criterion for patentability has not resulted in the encouragement of innovation. Also a bench level innovator or inventor, still does not have a simple "to use and implement" test that provides him with an opinion on patentability of an idea or results obtained.

In this review, the authors have studied the literature to assess whether there is a requirement to design a simple test to determine the ultimate condition of patentability. The authors conclude that there definitely exists a need for such a test to aid the bench level innovator to protect his inventions.

**Key words:** Invention, non-obviousness, patent laws, simple test

### I. Introduction

Life sciences have made a rapid progress in the last few decades and this trend is expected to continue at a much faster pace in future. Work in the field of life sciences is making a profound impact on the life of a common man through its applications in the fields of health care, pharmaceuticals, biotechnology biosimilars, diagnostics, nutraceuticals, agriculture, aquaculture, animal husbandry and others [35]. The rapid strides made in this field have therefore resulted in the generation of a number of inventions for which patent protection is sought. According to the Organization for Economic Co-operation and Development (OECD), the number of overall patents rose by 5% annually from 1990-2000. However, the same study indicated that the number of patents granted in biotechnology rose annually by 15 percent at the United States Patent and Trademark Office (USPTO), and by 10.5 percent at the European Patent Office (EPO). The rise in the number of patents explicitly implies the pivotal role of patents to the life science industry. Today the mantra of successful life science companies is to be able to distinguish themselves from their competitors through their intellectual property portfolios [33].

Non-obviousness is one of the three basic criteria for judging an invention's patentability. This requirement is uniformly coded in the statutes of all IP honouring states [1], [2], [3], [4], [5], [6]. It is synonymously referred to as 'an inventive step' in some domains. The other two basic criteria for patentability are novelty and utility or capability of industrial application [1], [2], [3], [4], [5], [6]. Although the earliest requirements for patentability were novelty and utility, non-obviousness is now the most critical element to patentability. In order to determine whether an invention is obvious or not, one must determine the scope and content of prior art; ascertain the differences between the claimed invention and the prior art; resolve the level of ordinary skill in the pertinent art and consider the objective indicator of non-obviousness [27] [34]. In order to ensure that monopolistic rights, even if granted for a limited period of time, did not go towards trivial inventions or incremental inventions that may be obvious, inventiveness or non-obviousness was introduced in the late 1800s to satisfy patentability criteria [7], [8], [27]. According to several researchers in this field, it is considered the ultimate "gate keeper" for patentability of inventions [7], [27].

The procedural aspects of determination of novelty and utility are well laid down in the country wise manuals for examination of patent applications [9], [10]. The opinion provided by the patent examiners with respect to these two criteria is usually accepted readily by the inventors. Also, their determination *per se* has not much been the subject matter of debates or litigations across various technological or geographical domains. This affords the inventor a fair degree of assurance of passing the tests for these criteria. However, the simplicity of

the concept and definition, and ease of determination is not the same for non-obviousness as for novelty and utility.

## II. The criterion and the test

Non-obviousness or inventive step is defined as “an advance with respect to the state of art that is not obvious to a person possessing ordinary skill in the art” [1], [2], [3], [4], [5] [6]. Non-obviousness is that feature of the invention that is unanticipated, unexpected, surprising, unforeseen and sometimes serendipitous. It may also be judged on the basis of fulfilling a long felt need or gap in the art, or the resolution of an unresolved need in the art. The 35 US Code Section 103 states as follows: A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made [3]. The Chinese government in its laws pertaining to the grant of patent rights opines that the invention should possess prominent substantive features and should represent notable progress [6]. The Japanese Patent Office has stated in Article 29 (2) that for an invention to be eligible for patent right it should not be obvious to make [5].

The determination of non-obviousness involves determination of state of art or “relevant” prior art or arts. The next query to be addressed then is ‘whether the invention is obvious to a person having ordinary skill in the art?’ The concept of ‘person having ordinary skill in the art’ is mythical and not very well defined. A factor that is left unconsidered is that most inventions are the results of a team of scientists or technologists who may belong to different disciplines. In such instances, ‘Who is the person having skill in the art?’, ‘Which is the art that is being referred to?’ and ‘To whom is the invention obvious?’ are the essential queries to be answered. A claim by claim analysis may be a possible remedy, but the claims of invention are not stand alone entities. In an invention, especially where the subject matter seeking patent protection is inter disciplinary or cross disciplinary, the claims cannot be considered to be unrelated. Thus the process of determination of inventive step is highly subjective, and that makes it decidedly vulnerable to debates, interpretation and litigation.

The continuously evolving areas such as life sciences and information technology, and their applications in various fields where patenting is prolific, has gained substantial attention with respect to patentability criteria, especially non-obviousness. This is evident from the domain specific guidelines issued by national patent offices such as the Indian Patent Office [11], [12]. A review of literature as listed herein brings out the vast differences in the methodologies and opinions pertaining to the determination of non-obviousness.

## III. Study of literature and case laws

In the year 2007, John Thomas *et al* [7] provided an overview of a variety of tests applicable in the statutes of various countries for the determination of non-obviousness. However, the authors did not comment as to whether any of the tests were best suited for the determination or whether better approaches were required to be followed to ascertain non-obviousness. Thomas *et al* [7] proceeded to trace the history of non-obviousness in the 35 USC and Patent Act of 1952, where it was first introduced that, if an invention as a whole is obvious to a person having ordinary skill in the art, then it is not patentable. Almost 100 years later the Graham construct was proposed in the landmark case of Graham V Deere in 1966 [13] and the Court elaborated on secondary considerations.

In 1982 the Federal Circuit conceptualized the “Teaching, Suggestion, Motivation (TSM) test” with the objective to avoid the “hindsight” issue. But Thomas *et al* [7] opined that the TSM test could rather be a beginning to determine non-obviousness than the end. The primary reason for this argument was that the TSM test did not account for skills of the inventor. The point that the authors desired to convey was that even in scientific fields, skill of the inventor was an aspect that should be considered while assessing an invention. This parameter seemed to be completely overlooked in the TSM test. It only considered publications that were read, which on combination made an invention obvious to try. The authors further stated that the TSM test was not well established in the statutes, and could be subject matters of a tough challenge any time. They concluded that KSR V Teleflex [14] could affect in more number of ways than the judgment deciding the fate of the case. It would probably impact every patent application in the USPTO classified in any field and would also affect the cases that were subjudice at the time of the judgment [17].

To briefly explain the KSR V Teleflex case, Teleflex held the exclusive license to the patent entitled "Adjustable Pedal Assembly with Electronic Throttle Control." One claim of the patent involved adding an electronic sensor to the pedal which then transmitted information to the computer controlling the engine's throttle. KSR added an electronic sensor to its existing pedal design. Teleflex (Plaintiff) sued KSR (Defendant) for patent infringement. Defendant argued the claim by Plaintiff was invalid under 35 U.S.C. Sec 103 because the addition of the electronic sensor was obvious. The district court granted summary judgment to Defendant and Plaintiff appealed. The court of appeals applied the "teaching, suggestion, motivation" [TMS] test and reversed the district court's verdict. But the Supreme Court judged in favour of the defendant and opined that the claims were obvious.

Gregory Mandel commented in 2006 [15] that non-obviousness had no defined standards and no set methodology for its determination. The consequences for lack of standards and methodology were that, while on one hand the Patent and Trademark Office (PTO) granted excessive patents, on the other hand too many patent applications disclose obvious inventions. The author opined that an invention with a high level of technological innovation would be considered to be non-obvious and would pass the test for the same. This may benefit patentees across various industries including the various branches of Life Sciences such as Pharmaceuticals, Biotech companies etc as well as the field of Information Technology.

In 2008, Fromer [16] stated that an invention that possessed an element of technological or scientific breakthrough over the state of art would be designated as non-obvious. But the debate is over the subject matter that is judged obvious or non-obvious: What particular aspect of the invention should be non-obvious? Is it the claims of the invention which seeks to protect the concept or the idea, or the practical aspect of performing the invention that is termed as 'reducing the invention to practice'? The author persuades the stakeholders to view non-obviousness in the light of the judgment in *KSR V Teleflex*, where the Court had highlighted the need for flexibility in the assessment of obviousness. The author finally concludes that the matter has not been resolved, the debate is continuing, leaving these issues unresolved. Furthermore, in the same article in 2008, Fromer [16] emerges with an interesting observation that laws pertaining to IP have not been able to keep up with the progress in science and technology, especially in life sciences and information technology. But, he urges to use this as an opportunity to understand the IP statutes better, than treating it as a problem.

In a study in 2004 titled "Obvious to whom? Evaluating inventions from the perspective of PHOSITA" Rebecca Eisenberg [18] laments the lack of understanding and utilization of the concept of 'person having ordinary skill in the art' (PHOSITA) by both the Patent Office as well as the judiciary in the determination of non-obviousness, with special reference to the Graham construct and the Court's decision in the case. She states that an invention that may appear non-obvious at the time it was made may appear to be obvious by the time it is being examined (due to "hindsight" of patent examiner). The level of skill of inventor, PHOSITA, examiner and judge affects the opinion and judgment arrived at. She also extensively studies the conflicts in the opinions of the Federal Circuit and the Supreme Court on the effects that primary and secondary considerations have on non-obviousness.

Rebecca Eisenberg has a valuable suggestion to overcome the conflicts referred to. While cost and confidentiality have to be critically considered, an approach suggested by her is to "outside-review" patent applications - that is examination of patents by peers or experts in the field, than by patent examiners. This is with an aim to provide inputs from technology practitioners. She also suggests that the Courts seem to be willing to move away from only documented record of prior arts towards also considering the tacit knowledge base of the technologists, specific to the technological field of the invention.

In a detailed case study published in 2007, Duffy [27] vividly traces the history of incremental changes that occurred in the patenting system. The system had felt the need for improvement from only satisfying the novelty and utility criteria in order to obtain patent rights to a higher standard to prevent patenting of trivial inventions. The French proposed early that 'mere changes' were not patentable. William Phillips, who according to the author, Duffy can lay the best claim for inventing non-obviousness proposed it in 1837, while the US Supreme Court judges are credited for having popularized the concept in the decision delivered in the case, *Hotchkiss V Greenwood* [8] in 1851. The judgement delivered was that an invention is obvious if the material of construction of a product is the only novelty and the process of preparation is described in publicly available documents. Along with the study of the history of evolution of non-obviousness in the US, the Venetian concept of hard work and ingenuity and the English contributions to the concept have also been studied. Duffy elaborates on the rights conferred by copyright and patents; the former protects expression of ideas, while the latter protects so much more. Therefore, there is a need for a stringent criterion such as non-obviousness for granting patent rights. Duffy also comments on the economic effects of trivial patenting, the progress from novelty being the criterion for obtaining patent rights to 'sweat of brow' to 'flash of genius' and compares the US and English laws. He laments that while the countries are certainly borrowing from each other to progress, the pace of such activities remains quite slow.

Correa conducted a study in 2006[24] and opined that non-obviousness or inventive step determines the extent of contribution an invention makes to a subject matter technically. But 'inventive step' is not defined in the Trade Related Intellectual Property Rights (TRIPS) Agreement, and is left to the member countries to decide the levels or standards they want to employ to have to determine the same. The author encourages the developing countries to instill a high standard for evaluating inventiveness in order to encourage innovation, avoid evergreening and disrupt the policy of multinational organizations, especially with context to pharmaceutical companies who file patents to prevent or discourage competition. Correa is of the opinion that developing countries should not set the level of inventiveness of an invention very low, in the hope that this will encourage the local industry to file patents prolifically. He augmented these arguments by stating that local industries do

not file profusely, especially when compared to multinational organizations, due to several other factors, including the costs involved in obtaining patent protection.

In another article in 2011, Correa [25] states that contrary to the general belief that patenting system encourages innovation, it actually seems to be stifling the very concept it seeks to encourage and protect. The author draws this conclusion based on the opinion of several stake holders of the patenting system, namely the industry, the academia and the government. One of the primary reasons attributed to this observed fact is the low levels of standards that were applied by the United States Patent and Trademark Office towards non-obviousness. Correa further adds that this low level of standard was one of the factors causing increasing criticism to the functioning of the patent system.

An in depth analysis of the KSR V Teleflex [14] decision was conducted by Cotropia in 2014 [17] with respect to the Type I and Type II predictabilities outlined by the Court in its decision. He states that the USPTO was widely using the Type II predictability after KSR V Teleflex, leading to a host of issues, such as it did not find support in the statutes, introduced hindsight bias, discriminated technologies and was conflicting with the patent theory itself.

One of the most recent articles on the Indian context is penned by Nair et al [28] where the authors review the current state of patent related case laws in the field of pharmaceuticals in India. Even though the amendments to patent laws in India are as young as ten years, this short period has seen an enormous evolution in the field of pharma- patent related judgments.

Praveen Raj [22] discusses the issue of non-obviousness with a specific reference to the definition of a person of ordinary skill in the art and whether an invention would be obvious to such a person. The Erlotinib case between Roche and Cipla of India [23] was the subject matter of a study by Zakir Thomas [21], where the defendant Cipla was sued by Roche for infringing its patent on Erlotinib, a drug to treat cancer. Cipla counter sued Roche alleging that the patent in question was invalid, since the invention was obvious. Cipla contended that Erlotinib is a quinazoline derivative and that such compounds are known to possess anti-cancer activity. The author further discusses the effect of the KSR V Teleflex case [14] and the inadequacies of the TSM test and its over emphasis on only scientific literature.

Ohly [20] conducted an in-depth study and analysis of the definitions of invention, new invention and pharmaceutical substance, and moved to specific sub sections of Sec 3 of the Indian Patent Act 1970[1] and amendments thereafter that pertain to the pharmaceutical substances that is 3d, 3e, 3f and 3i. He studied sec 3 (d) of the Act [1] and commented on how a US court would have interpreted Section 3 (d) in light of the definitions in Sec 2 and other provisions of the Act. Ohly contended that a US court would first evaluate an invention in light of the definitions for an invention and new invention as specified in Sec 2 of the Act [1]. The process of determining whether the invention is patentable or not eligible for patent protection under Sec 3 of the Indian Patent Act [1] will follow the above mentioned determination, and not the other way around. So, in essence, patentable inventions will be evaluated to determine whether they fall under the purview of Sec 3.

#### IV. Conclusion

From the above discussion it is quite clear that while there has been a process of evolution in the determination of non-obviousness, there is a clear need for a simple test for the determination of non-obviousness. It will be advantageous for such a test to have further features such as “easy to comprehend and easy to implement” in order to enable scientists to exercise the test on their own, to determine whether their invention will pass the test for non-obviousness or not.

One valuable suggestion that can come to the aid of an individual inventor comes from Kenneth Chuah in his book “The 5 second inventor” [26], stating that the inventor may run his invention through a few experts from the relevant field and their reaction may give him an inkling of the reaction of the examiner to the invention. If they opine the invention is obvious, then the inventor may receive queries from patent office. This may overcome the subjectiveness associated with the evaluation of non-obviousness. This seems almost akin to Eisenberg’s [18] suggestion enlisted above.

The fulfillment of the test of non-obviousness does not mean one is against patenting. This is actually the only critical test that an invention needs to clear before being patented; novelty, subject matter and utility being relatively easy to define, determine, defend and comprehend. Therefore it becomes even more critical to provide a simple diagnosis tool to decide non-obviousness.

There is also an urgent need to move away from the mythical concept of ‘A person of ordinary skill in the art’, to make the test for non-obviousness more meaningful.

As against the current system, one test across all scientific and technological domains where innovations are carried out may not be meaningful. The design of the test should consider aspects such as practical issues, enablement criteria, undue experimentation and avoid the reliance on “what the prior arts state, teach, suggest or motivate”. The expertise, experience and skill of the inventor should also be taken into account while conducting the determination of the inventiveness of an invention.

The test applied too stringently or too leniently, either ways may lead to a plethora of issues such as patents being granted to obvious inventions, or rejecting applications that are indeed non-obvious. The grant of patent rights to obvious inventions defeats three objectives:

- inhibits the progress of the relevant field
- demotivates a genuine researcher and
- defeats the purpose of disclosing the invention such that it may be practiced, but after patent term expiry.

While the judgments in the various case laws such as *KSR V Teleflex* [14], the *Alice* case [29], the *Myriad* case [30] and the *Prometheus* case [31] have provided new insights to the understanding of patentability of inventions as well as determining obviousness; nevertheless non-obviousness still remains conceptually elusive and inadequately defined, with no crystal clear approach for its determination and no assurance that the subjectivity of the determination will change soon, such that an inventor is confident his invention will be opined patentable.

Thus a study of the various relevant literature, case laws and national statutes should be undertaken to evolve a “simple kit” for determining non-obviousness of inventions in the field of sciences. This will be a valuable tool for the researchers and technologists in order to gain legal protection for their work. The kit will serve to not only aid the researcher, but will also encourage the researcher to disclose the inventions while seeking patent protection, thereby aiding in the progress of science as a whole.

Literature till date has suggested various tests, but none of them are either complete or serve the purpose of determination of this criterion in a fool proof manner. Evolution of a simple kit will be a challenging task and inputs from inventors, attorneys, patent office officials and judiciary will have to be vigorously considered to avoid the pitfalls of known methodologies. To evolve this test as on date, the researcher may need to adopt a path hitherto hidden, unexplored or untrodden. This may eventually lead us to a test for determining non-obviousness without undue issues or debates or litigations.

## V. Conflict-of-interest Disclosure

The authors declare no competing financial interests

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