180 Research Paper
9 August 2023

Neglected Dimension of the Inventive Step as Applied to Pharmaceutical and Biotechnological Products: The case of Sri Lanka's Patent Law

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SOUTH CENTRE

RESEARCH PAPER

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NEGLECTED DIMENSION OF THE INVENTIVE STEP AS APPLIED TO PHARMACEUTICAL AND BIOTECHNOLOGICAL PRODUCTS: THE CASE OF SRI LANKA'S PATENT LAW

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ABSTRACT

Apart from the basic statutory definition in section 65 of the Intellectual Property Act of Sri Lanka, there do not appear to be any detailed statutory guidelines or judicial decisions to provide any framework for the assessment of inventive step in Sri Lanka. The current statutory definition is highly insufficient to evaluate the standard of obviousness in relation to biotechnological and pharmaceutical claims based on a combination or modification of a prior art reference.

The Courts in both developed and developing countries have adopted a variety of tests to evaluate the obviousness standard of a claimed invention based on a combination or modification of a prior art reference. Sri Lanka, as a developing country, should look at the development that has taken place in other jurisdictions and adapt the patent law to local conditions when developing tests or guidelines in a manner that is compatible with the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and its biotechnology/pharmaceutical policy guidelines.

This approach that is appropriate to Sri Lanka is twofold. First, it is most likely to prevent the issuance of patents on trivial or incremental inventions that do not provide any technical advance to the existing prior art and are a mere extension of what is already known in the prior art. Second, it is most likely to protect genuine technical advances to the existing prior art while at the same time enhancing competition and promoting local innovations so that the local researchers will be able to draw on the existing knowledge for the purpose of follow-on innovations.

Si l'on exclut la définition énoncée dans l'article 65 de la loi sri-lankaise relative à la propriété intellectuelle, il n'existe pas à proprement parler de directive légale précise ou de décision judiciaire susceptibles d'encadrer l'examen de l'activité inventive au Sri Lanka. La définition légale actuelle est très insuffisante en ce qui concerne les règles applicables au critère de la non-évidence dans le domaine des brevets biotechnologiques et pharmaceutiques portant sur une combinaison spécifique ou une modification de l'état de l'art.

Les tribunaux, tant dans les pays développés que dans les pays en développement, ont adopté une variété de tests leur permettant d'apprécier le caractère évident ou non d'une invention portant sur une combinaison spécifique ou une modification de l'état de l'art. Le Sri Lanka, en tant que pays en développement, devrait s'inspirer des lignes directrices et des règles mises en place dans ce domaine dans d'autres pays et les adapter au contexte local, en se conformant aux dispositions de l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC) de l'Organisation mondiale du commerce et ses lignes directrices pour l'évaluation et l'examen des brevets pharmaceutiques et biotechnologiques.

Cette approche, qui ne peut être que bénéfique pour le Sri Lanka, a le double avantage d'empêcher que des brevets ne soient délivrés pour des inventions triviales ou incrémentales qui ne comportent aucune avancée par rapport à l'état de l'art et ne font que reprendre des éléments connus, et de favoriser le progrès technique tout en renforçant la concurrence et en encourageant la recherche à l'échelle locale de sorte que les chercheurs puissent s'appuyer sur les connaissances existantes et ainsi contribuer à la poursuite de l'innovation.

Aparte de la definición legal básica que figura en la sección 65 de la Ley de Propiedad Intelectual de Sri Lanka, no parece haber ninguna directriz legal detallada o decisión judicial que proporcione algún marco para la evaluación de la actividad inventiva en Sri Lanka. La actual definición legal resulta sumamente insuficiente para evaluar la norma de evidencia en relación con las reivindicaciones biotecnológicas y farmacéuticas sobre la base de una combinación o modificación de una referencia artística anterior.

Los tribunales tanto de los países desarrollados como de los países en desarrollo han adoptado diversas pruebas para evaluar la norma de evidencia de una invención reivindicada sobre la base de una combinación o modificación de una referencia artística anterior. Sri Lanka, como país en desarrollo, debería examinar la evolución que ha tenido lugar en otras jurisdicciones y adaptar el derecho de patentes a las condiciones locales cuando elabore pruebas o directrices, de manera que sea compatible con el Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC) de la Organización Mundial del Comercio y sus directrices de política en el ámbito biotecnológico y farmacéutico.

Este enfoque apropiado para Sri Lanka es doble. Por un lado, es muy probable que evite la emisión de patentes sobre invenciones triviales o graduales que no aporten avances técnicos algunos al estado de la técnica existente y sean una mera ampliación de lo que ya se conoce en el estado de la técnica. Por otro lado, es muy probable que proteja los verdaderos avances técnicos en el estado de la técnica existente al tiempo que mejora la competencia y promueve la innovación local para que el personal investigador local pueda recurrir al conocimiento existente con el propósito de llevar el seguimiento de las innovaciones.

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PART I

INTRODUCTION

The obviousness or inventive step inquiry in the patent law in relation to biotechnological and pharmaceutical inventions usually involves a combination of multiple related prior art references or modification of a single prior art reference of various genetic or chemical materials to suggest an inventive step or non-obviousness.

The assessment of the inventive step or non-obviousness regarding biotechnological and pharmaceutical inventions is a complicated patentability requirement for a number of reasons. First of all, the assessment of inventive step or non-obviousness is generally shown to exist either by combining the teachings of multiple related prior art references or by modifying a single prior art reference so as to suggest an inventive step or non-obviousness.[1] Secondly, in the biotechnology field, in particular, the inventions involve genetic material such as DNA, RNA, proteins, and amino acid sequences, which is isolated from its natural environment or produced by a technical process, although the existence of biological material is previously known. Thirdly, in the biotechnology and pharmaceutical industries, inventions involve unpredictable interactions of various genetic/chemical materials producing unpredictable final results. This makes it more difficult for the person with the skill in the relevant art to determine whether a combination of multiple prior art references or modification of a single prior art reference is obvious or non-obvious.

The patent protection has been afforded to biotechnology and pharmaceutical inventions like any other field of technology under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which provides that an invention should be new, involve an inventive step, and be capable of industrial application.[2] The basic statutory definition for the assessment of inventive step is contained in section 65 of the Intellectual Property (IP) Act of Sri Lanka. The Act provides that an invention shall be considered as involving an inventive step if, having regard to the prior art, it would have been obvious to a "person having ordinary skill in the art." Only the general statutory terms remain in the definition. Therefore, the critical question posed in the section is to be answered by the person having ordinary skill in the art ("PHOSITA").

The PHOSITA standard in patent law is a central concept throughout the lifetime of a patent. It not only helps to determine whether a patent can be issued in respect of an invention but also defines the scope of claims during the patent term and impacts the infringement analysis.[3] Thus, under the Sri Lankan patent law, the judgment of inventive step should be made from the perspective of a "PHOSITA," who has to determine whether a given combination of multiple prior art references or modification of a single prior art reference are obvious.

Apart from the basic statutory definition in section 65 of the IP Act of Sri Lanka, there are no other statutory provisions or case law guidelines in Sri Lanka concerning the biotechnology or pharmaceutical field to enable the judge or the patent examiner to approach the test of inventive step in a structured way.

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1 Zachary Quinlan, "Hindsight Bias in Patent Law: Comparing the USPTO and the EPO", *Fordham International Law Journal*, Volume 37, Issue 6 (2014), Article 3, p. 1787, p. 1790.

2 TRIPS Agreement, Article 27 (1).

3 Jonathan J. Darrow, "The Neglected Dimension of Patent Law's PHOSITA Standard"*, Harvard Journal of Law & Technology*, Vol. 23, No.1 (Fall 2009), p. 227.

The standard for assessing the inventive step in relation to biotechnological and pharmaceutical inventions capable of protecting local technical advances and preventing obvious extensions or mere workshop variations already existing in the prior art is not settled in Sri Lanka.

The courts in certain developed countries such as the United States and European Union seem to apply the inventive step approach in the patent law to the assessment of inventive step with certain modifications to suit the biotechnology and pharmaceutical inventions. It seems, however, that those countries have also grappled with several difficulties in creating appropriate judicial guidelines for the assessment of the inventive step.

Developing countries such as India and Brazil seem to have developed suitable tests to assess the inventive step by adapting the patent law to local conditions using the TRIPS flexibilities that are more consistent with their biotechnology/pharmaceutical patent law/policy objectives and the TRIPS Agreement.

PURPOSE OF THE RESEARCH PAPER

This research paper seeks to examine the appropriate inventive tests that are likely to be adopted in Sri Lanka for the assessment of inventive step or non-obviousness in a manner more consistent with its patent law/policy and public policy objectives as a developing economy. The appropriate inventive tests are extremely important to Sri Lanka particularly due to its low level of technological development in the area of biotechnology patent law, in order to protect local inventors, promote competition and the development of incremental and large-scale local innovations, and safeguard the rights of stakeholders by taking the space left by the TRIPS flexibilities.

This paper proceeds as follows: First, it sets forth the basic patentability requirements under the TRIPS Agreement and the definition of inventive step in Sri Lanka. Secondly, it examines the policy approaches suitable for determining the inventive step in Sri Lanka as a developing country. Thirdly, it compares and contrasts the different approaches adopted in the USA in developing a proper non-obviousness standard. Finally, it describes an appropriate inventive step analysis to be adopted in Sri Lanka in the light of the US and United Kingdom/ Indian approach in a manner consistent with the patent/public policy objectives of Sri Lanka within the statutory language in section 65 of the IP Act.

This paper argues that while the criterion in deciding whether or not the claimed invention involved an inventive step is a wholly objective question and while the current statutory definition remains the starting point as defined in section 65 of the IP Act, Sri Lanka should also develop judicial tests or guidelines that enable the Patent Office and Patent Court to approach the statutory question(s) in a more structured way.

REQUIREMENTS OF PATENTABILITY UNDER THE TRIPS AGREEMENT

Article 27.1 of the TRIPS Agreement provides that, subject to the provisions of paragraphs 2 (exclusions from patentability to protect public order or morality) and 3 (general exclusions from patentability), patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new (novelty), involve an inventive step (or are non-obvious), and are capable of industrial application (or are useful).

WTO members, under Article 1:1 of the TRIPS Agreement, are obliged to implement the TRIPS provisions on minimum standards by incorporating them into their domestic law.

However, they shall not be obliged to implement in their domestic law more extensive protection than is required by the Agreement, provided that such protection does not contravene the provisions of the TRIPS Agreement. WTO members are thus, free to determine the appropriate method of implementation in their domestic law as long as such protection in the domestic law does not contravene the provisions of the Agreement.

The TRIPS Agreement does not, however, define "novelty," "inventive step," or "industrial applicability." Therefore, Sri Lanka as a WTO Member is free to adopt the standard of novelty or inventive step that suits its local conditions in a manner consistent with the provisions of the TRIPS Agreement. The appropriate novelty or inventive step standard has to be adopted, however, within a framework of policy coherence between the domestic patent law/policy and public policy objectives, which is vital for the protection of biotechnology/pharmaceutical inventions and the promotion and development of local innovations in these fields.

PURPOSE AND DEFINITION OF "INVENTIVE STEP"

The importance of the inventive step/non-obviousness inquiry is that it seeks to measure technical accomplishment—a quality more abstract than novelty or utility.[4] The purpose of the inventive step or non-obviousness requirement is to avoid granting patents for inventions that only follow from "normal product design and development"[5], namely minor or incremental improvements to the existing state of the art.

The inventive step/non-obviousness inquiry asks whether a development is a significant enough technical advancement to merit the award of a patent. Thus, the theory is that even if a development is new and useful, it does not rise to the level of a true invention deserving of a patent if it merely represents a trivial change to the prior art.[6] In short, the inventive step/non-obviousness standard can be accurately described as a "nontriviality" requirement in patent law, an inquiry designed to winnow the trivial from the nontrivial, mainly because the non-obviousness tries to measure technical, not economic triviality.[7]

The importance of the inventive step/non-obviousness inquiry is that it attempts to measure technical accomplishment—a quality more abstract than novelty or industrial applicability/utility.[8] If rigorously applied, the inventive step requirement implies incentives for genuine innovations rather than for "minor or incremental improvements" thereby minimizing or avoiding the "proliferation of economically insignificant patents that are expensive to research and license".[9]

Thus, the inventive step/non-obviousness inquiry seeks to achieve a proper balance between the incentives provided by the patent system by encouraging innovation and the social cost of the patent system by conferring temporary monopolies.[10] The statutory the inventive step/non-obviousness test thus serves a gatekeeping function of the patent: it seeks to prevent obvious developments that may compromise the incentives that the patent system provides to develop.[11] Therefore, the non-obviousness standard encourages researchers to pursue

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4 Robert Merges and John Duffy, *Patent Law and Policy: Case and Materials* (7th ed., Carolina Academic Press, 2017), p. 513.

5 John H. Barton, "Non-obviousness", *IDEA*, vol. 43, No. 3 (2003), pp. 475-506. (Thus, only research beyond that done as part of normal product design and development should be rewarded with a patent and thus, a routine redesign of minor or incremental nature should not be enough to provide incentives for such research to have a monopoly right.)

6 Merges & Duffy, *Patent Law and Policy (7th ed.),* above note 4.

7 Ibid.

8 Ibid.

9 Ibid., p. 516.

10 Barton, "Non-obviousness", above note 5.

11 Merges & Duffy, above note 4, pp. 513, 516.

projects whose success appears highly uncertain at the outset and insists that only the results from uncertain research should be rewarded with a patent.[12]

The non-obviousness or inventive step requirement as the ultimate condition for patentability demands a significant technical advance to merit the award of patent, that represents the "nontriviality" requirement in patent law.[13]Thus, the invention must be of a "significant enough technical advance to merit the award of a patent."[14] The inventive step/non-obviousness test postulates that "protection should not be given to what is already known as part of the prior art and to anything that the person with ordinary skill would deduce as an obvious consequence thereof".[15]

The philosophy behind the obviousness analysis was succinctly conceptualized by Justice Oliver L.J. in the Court of Appeal case of *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.*,[16] which is sometimes called "workshop variation". In this case, Oliver L.J. held that the philosophy behind the doctrine of obviousness is that the public should not be prevented from doing anything which was merely an obvious extension or a worship variation of what was already known in the art at the priority date.[17]

Thus, if it is found that the patentee has come up with a solution to his problem, which according to the "PHOSITA", is no more than an obvious extension or a workshop variation of what was already in the prior art, he cannot have a monopoly for his solution whether or not the skilled person would be likely to have known in the prior art in question.[18]

A mere workshop improvement of a well-known apparatus or product or process or a well-known character or something made in a well-known way is not an invention[19] unless the presence of the characteristics and quality of the invention can be distinguished from a workshop improvement. It follows that the lack in inventive step/non-obviousness may be demonstrated if the solution presented by the patentee to his problem was not an obvious extension or a workshop variation of what was already known in the prior art, but it involves a degree of invention of significant technical advancement to the existing prior art to merit a monopoly for his solution.

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12 Ibid., p. 559.
13 Ibid., p. 513.
14 Robert Patrick Merges & John Fitzgerald Duffy*, Patent Law and Policy: Cases and Materials* (5th ed., 2011), p. 619.
15 Intellectual Property Reading Material, WIPO Publication N0.476 (E), p. 16.
16 *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.,* (1985) R.P.C. 59.
17 Ibid., 61.
18 Observations of Millett L.J. in *PLG Research Ltd. and Another v. Ardon International Ltd. and Others* (1995) R.P.C. 287, 291.
19 *H.E. Curtis & Son Ld. v. R.H. Heward* & Co. (1923) 40 R.P.C. 53 at 60 & *Shaw v. Burnet* (1924) 41 R.P.C. 432, 439.

PART II

DEFINITION OF INVENTIVE STEP AND STATUTORY QUESTION IN SRI LANKA

The Sri Lankan IP Act defines "inventive step" in section 65 and states that an invention shall be considered as involving an inventive step if, having regard to the prior art relevant to the patent application claiming the invention, such inventive step would not have been obvious to an ordinary person having skill in the art (PHOSITA). Thus, the inventive step inquiry gives rise to the following three main statutory questions in section 65 of the Intellectual Property Act:

1. Who is the person having ordinary skill in the art (PHOSITA)?
2. What is the prior art relevant to the inventive step?
3. What is the test to determine whether something is obvious or non-obvious?

PERSON HAVING ORDINARY SKILL IN THE ART (PHOSITA)

The statutory definition in section 65 of the IP Act suggests that there is no inventive step when the claimed invention is obvious to a person with ordinary skills in the relevant art (PHOSITA). Thus, in analyzing the inventive step requirement in Sri Lanka, the obviousness must be evaluated from the perspective of a person having ordinary skill in the art (PHOSITA) at the time of filing a patent application.

One critical question that the Courts of Sri Lanka are invited to determine is the patent law's fundamental inquiry of the assessment of the inventive step standard in the context of the PHOSITA's skill in the art and what the PHOSITA does within the relevant field. Until recently, there are no statutory or judicial guidelines as to the nature, qualifications, and characteristics of the PHOSITA and the extent of the common knowledge in the relevant art attributed to the PHOSITA.

To the knowledge of the author, the solitary patent decision in Sri Lanka that sought to develop an inventive step analysis in a structured way to assist the PHOSITA in approaching the statutory question posed by section 65 of the IP Act[20] appears to be the case decided by the Commercial High Court of Sri Lanka in *Ravindra v. Riyad Ismail and Director General of Intellectual Property*.[21] Although this decision relates to a mechanical and an electronic invention, it discusses the appropriate standard of inventive step to be developed concerning claims based on a combination or modification of prior art references.

PRIOR ART RELEVANT TO INVENTIVE STEP

"Prior art" is the document that can be used against a patent application to show that it is not novel or is obvious; any particular piece of the prior art is called a reference, whether it is a patent, a technical publication, or a public use of an invention.[22] The prior art is defined for the purpose of novelty in section 64 of the IP Act of Sri Lanka as follows:

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[20] Intellectual Property Act of Sri Lanka No. 36 of 2003.

[21] *Ramawickrema Gamachchige Ravindra v. Riyad Ismail and Director General of Intellectual Property*, Commercial High Court of Sri Lanka, Case No. HC (Civil) 01/2010/IP, unreported, decided on 07.02.2018.

[22] 1 Donald S. Chisum, Chisum on Patents GI-18 (Matthew Bender, Release No. 144 2014); Black's Law Dictionary 126-27, 1393 (9th ed. 2009) (defining "prior art" and "reference" as terms of art in patent law referring to the knowledge available to reject a patent application), cited in Zachary Quinlan, "Hindsight Bias

(2) Prior art shall consist of -

(a) everything disclosed to the public, anywhere in the world, by written publication, oral disclosure, use or in any other way, prior to the filing or, where appropriate, the priority date of the patent application claiming the invention;

(b) the contents of a patent application filed in Sri Lanka, having an earlier filing or, where appropriate, priority, date than the patent application referred to in paragraph (a), to extent that such contents are included in the patent granted on the basis of the said patent application made in Sri Lanka.

(3) A disclosure of the invention shall not be taken into consideration for the application of prior art under the following two different situations:

(a) If such disclosure occurred within one year preceding the date of the patent application and if such disclosure or in consequence of acts committed by the applicant or his predecessor in title;

(b) If such disclosure occurred within 6 months preceding the date of the patent application and if such disclosure was by reason or in consequence of any abuse of the rights of the applicant or his predecessor in title.

However, the "prior art" for the purpose of determining novelty and the "prior art" for the sake of assessing obviousness are not identical and there are some differences that exist regarding its application.[23] As observed by the US Federal Circuit in *Hodosh v. Block Drug Co.*,[24] the question of whether a prior art reference is available in the claimed element is determined by the application of the inventive test while the question of whether a prior art reference anticipates the claim (i.e. contains every claimed element) is determined by the application of the novelty test.

The difference between the novelty examination and inventive step examination is mainly twofold. The first difference is that in many jurisdictions patent applications that have priority over the application in suit are not included in the state of the art for the purpose of assessing inventive step/non-obviousness.[25] The second difference is that, unlike in the assessment of novelty, it is possible to combine together information from different sources (different prior art references) to demonstrate the obviousness, provided however that they are related to the invention.[26]

In addition, there are two more differences. First, a novelty may be destroyed when the invention is disclosed anywhere in the world, either in explicit or implicit terms. In such cases, the invention may be anticipated by the prior art, whereas an invention can be obvious even if it is not identically disclosed anywhere in the world. Second, the novelty is destroyed when the claimed invention was part of the prior art, which consists of everything disclosed to the public anywhere in the world before the filing or, where appropriate, the priority date of the application claiming the invention. Similarly, as the time when the invention was made is not known nor investigated by the patent office or the court, the relevant date for testing the inventive step is the filing or priority date of the application claiming the invention.

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in Patent Law: Comparing the USPTO and the EPO", *Fordham International Law Journal*, Vol. 37, Issue 6 (2014), p. 1790.

[23] Iver P. Cooper, *Biotechnology and the Law* (2000 revision, West Group, Vol. 1), paras. 4.1, 4-3.

[24] *Hodosh v. Block Drug Co., Inc.,* 786 F.2d 1136.

[25] Lionel Bently and Brad Sherman, *Intellectual Property Law*, 2nd ed. (Oxford, 2004), p. 475.

[26] Ibid.

In determining whether the invention is obvious, the PHOSITA will be required first to identify the prior art relevant to the invention and its subject matter (claim). Secondly, the PHOSITA has to consider whether the differences between the prior art elements and the claimed subject matter would have been obvious to one having ordinary skill in the art (PHOSITA).

PART III

POSSIBLE POLICY APPROACHES IN SRI LANKA FOR THE DETERMINATION OF INVENTIVE STEP

The statutory question defined in section 65 of the IP Act is to determine whether an invention is obvious to the "PHOSITA", having regard to the prior art relevant to the patent application claiming the invention. The determination of this question is wholly an objective test that remains the starting point in the inventive step inquiry in Sri Lanka.

The most important policy question is: what sort of an inventive standard does Sri Lanka need as a country with a low level of technological development in the area of biotechnology/pharmaceuticals? There are two possible approaches available to Sri Lanka in determining the standard of inventive step, either low standard or strict standard of the inventive step.

Determining the requirement of the inventive step within a policy framework in Sri Lanka is extremely necessary to protect and enhance the incentives created by the patent system, spur innovations, and promote incremental innovations of a commercial nature. This policy framework is crucial for Sri Lanka as a developing country to ensure that the patents are granted to inventions that involve technical advancement compared to the existing prior art that makes the invention not obvious to the PHOSITA. This strikes a balance between exclusive rights and access to the public domain. If Sri Lanka adopts a low requirement of the inventive step, it will lead to the granting of patents on minor or trivial variants of existing products or processes, as it would naturally be easy for the patent applicants to obtain exclusive patent rights. This approach, however, is likely to block or restrict access to substances needed by local researchers and competitors, thereby restricting further research and development and free competition.

Correa notes that the low standard often applied to assess the level of inventive step (or non-obviousness) of patent applications relating to plants may have serious implications for further research and breeding and for the availability of multiple sources of supply of genetic resources – and, hence, for food security.[27] According to Jaffe, A. and Lerner, J., the lax standards of patentability is a more general problem, as it also affects inventions in other fields of technology[28] such as pharmaceuticals.

Given that Sri Lanka is a country with a low level of technological development in this area, it is most likely that such a low-level standard approach would make it more difficult for local researchers and industry to draw on the existing technical knowledge to make follow-on innovations.

Correa further notes that technologically advanced countries that invest a substantial portion of their Gross National Product (GNP) in research and development may understandably favour permissive or flexible novelty standards and low inventive step standards.[29] Referring to less technologically advanced countries, he argues that they may prefer to set higher

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[27] Carlos M. Correa, *TRIPS-Related Patent Flexibilities and Food Security: Options for Developing Countries, Policy Guide* (Geneva, QUNO-ICTSD, 2012), p. 10.

[28] A. Jaffe and J. Lerner, *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It* (Princeton University Press, 2004); and Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003). Available from www.ftc.gov/os/2003/10/innovationrpt.pdf.

[29] Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (Geneva, South Centre, 2000), p. 38.

standards for novelty and the inventive step in order to preserve and enhance competition without violating minimum international standards.[30] In doing so, they would simply follow in the footsteps of many of today's advanced countries, which adopted similar policies when they were themselves developing countries.[31]

One of the advantages of adopting a higher inventive step standard is that it would increase the value of patents because patents issued under this rule are stronger and less vulnerable to challenges from competitors.[32] If the higher standard of the inventive step is followed, it would render more difficult the patenting of trivial variations that do not represent significant gains in efficacy and, thus, make it more difficult to obtain exclusive rights in any given product or process.[33]

On the other hand, Correa notes that high standards of the inventive step in developing countries can also work against local innovators who cannot themselves meet these standards.[34] This may discourage local producers capable of making incremental innovations at the expense of foreign research-based pharmaceutical companies.[35] This, however, would not be a sound argument to lower the standard as exclusive rights (which amount to a legal monopoly) should only be granted when the applicant has made a genuine contribution to a particular technological field and not a mere minor or trivial change or improvement.

The adoption of standards which are likely to limit the exclusive rights to the minimum required under the TRIPS Agreement would mean that inventions inconsistent with the domestic patent law/policy would be disallowed, while local researchers and industry will be encouraged to draw on existing technological capacities and experience to make follow-on innovations. This approach is necessary to protect public health and nutrition, and promote access to scientific research and education data, free competition, technology transfer, and access to information and materials required for local innovations.

The other approach is to adopt *sui generis* laws—laws outside the patent system—to protect unpatentable local incremental innovations that fail to meet the patentability standard but promote follow-on innovations of local researchers and industries.[36] This approach will provide non-exclusive rights to local incremental innovations by stimulating follow-on innovations in exchange for compensation without any strong exclusionary rights.[37]

This approach is also crucial to prevent the granting of patents for inventions that only follow the trivial or incremental developments of the technology. The patenting of such trivial inventions is most likely to block access to substances researchers and competitors need for their research and development.

METHODOLOGY FOR THE ASSESSMENT OF INVENTIVE STEP TO APPROACH THE STATUTORY QUESTION DEFINED IN SECTION 65 OF IP ACT

Developing countries such as India and Brazil have adopted their own tests to assess the inventive step that will suit their local conditions while taking into account certain statutory interpretations and judicial guidelines adopted mainly by the US and the EU. For example, the

30 Ibid., p. 39.
31 Ibid.
32 Ibid.
33 United Nations Conference on Trade and Development (UNCTAD), *A Reference Guide* (New York and Geneva, United Nations, 2011), pp. 56 & 66.
34 Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries,* p. 40.
35 UNCTAD, *A Reference Guide*, p. 56.
36 Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries,* p. 40.
37 Ibid.

semblance of statutory tests adopted by the US and the UK is also found in the Indian approach while rejecting the tests that do not suit its domestic patent policy objectives in the assessment of inventive standards.[38]

Under such circumstances, this paper examines in detail the US approach for the assessment of the inventive step and then consider how Sri Lanka should address this issue in its domestic patent law, having taken into consideration approaches taken by the US and developing countries such as India and Brazil.

[38] See infra, the tests adopted by *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.,* [1985] R.P.C. 59 and Indian Patent Examination Guidelines 2015.

PART IV
US APPROACH TO INVENTIVE STEP

OBVIOUS TO TRY AND HINDSIGHT BIAS (PRIOR ART SUGGESTED KNOWN OPTIONS)

The test of "obvious to try" was commonly applied prior to the enactment of the 1952 US Patent Act. The "obvious to try" test is applied in situations involving "a finite number of identified, predictable solutions.[39] This means that the invention is obvious for a person having ordinary skill in the art (PHOSITA) to try with known prior art references when the prior art references suggest the claimed invention.

The "obvious to try" test was thus, founded on three elements, namely (i) there is a problem to be solved; (ii) there are a finite number of identified, predictable solutions; and (iii) a person having ordinary skill in the art (PHOSITA) has good reason to pursue the known options within his or her technical grasp.[40] Thus, in early patent applications, hindsight bias (the actual outcome is predictable or foreseeable or inevitable, or obvious) was an important issue when determining if an invention had an inventive step because it is a subjective judgment that can be influenced by the evaluator's perspective of the past. Also, it is very often the crux of patent examination and litigation.[41]

The "obvious to try" doctrine has, however, suffered from certain inherently flawed issues, such as the fact that it is a mere restatement of the obviousness standard rather than a test. Thus, it does not help with its interpretation.[42] Secondly, the test could be applied with hindsight bias[43] because it uses the inventor's reasoning to solve the problem against him/her.[44]

COMMON PITFALLS - PROPER AND IMPROPER APPLICATION OF "OBVIOUS TO TRY" TEST

Prior to the enactment of the 1952 US Patent Act, the US Courts decided that the "obvious to try" test would not be accepted as a test for the determination of obviousness in the absence of a reasonable expectation of success.[45] For example, in *O' Farrell*,[46] the Federal Circuit

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[39] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007).

[40] Ibid., p. 402.

[41] Stephen G. Kunin & Philippe J.C. Signore, *A Comparative Analysis of the Inventive Step Standard in the European and Japanese Patent Offices from US Perspective*, IP LITIGATOR, Jan./Feb. (2008), at 16 (describing obviousness as a subjective determination) cited in Zachary Quinlan, "Hindsight Bias in Patent Law; Comparing the USPTO and the EPO", *Fordham International Law Journal*, Vol. 37, Issue 6 (2014), p. 1795.

[42] Mariam Divya Williams and Dr. T.K. Bandyopadhyay, "An Analysis of Obviousness Standard in Patent Law - US and Indian Perspective", p. 6. Available from https://www.uspto.gov/sites/default/files/documents/2015quality_f_williams_15jun2015.pdf.

[43] Hindsight bias is a mental bias present in the evaluation of past decisions or events where the evaluator knows the outcome of those decisions or events, particularly when judging the likelihood, foreseeability, or predictability of a past event from an ex-ante perspective (Neal J. Rose & Kathleen D. Vohs, Hindsight Bias, 7 PERSPECTIVES ON PSYCHOLOGICAL SCI. 411, 411–12 (2012), cited in Zachary Quinlan, "Hindsight Bias in Patent Law; Comparing the USPTO and the EPO", *Fordham International Law Journal*, Vol. 37, Issue 6 (2014), p.1789).

[44] Ibid.

[45] In *re Merck & Co., 800 F. 2d 1091*, 1100 (Fed. Cir. 1986).

[46] In *re Patrick H. O' Farrell,* 853 F. 2 d 894, 902. (This is an appeal from the United States Patent and Trademark Office (USPTO) Board of Patent Appeals and Interference (board) affirming the patent examiner's

questioned the validity of the "obvious to try" test and outlined the following two situations (pitfalls) in which "obvious to try" is not the standard under section 103:

1. In some cases, what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.[47] The skilled person in this situation merely pursues only "known options from a finite number of identified, predictable solutions"[48] to decide that the invention is obvious. In such circumstances, if the Court assesses the obviousness based on combinatorial prior art possibilities, it would only succumb to hindsight claims of obviousness;[49]

2. In others, what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, whereas the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.[50]

Rich J. in *O' Farrell* agreed with the findings of the United States Patent and Trademark Office Board of Patent Appeals and Interferences (Board) that the appellants' claimed invention would have been obvious within the meaning of section 103, where the prior art "contained detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful."[51] Rich J. thus, observed that the prior art reference should contain not only "a suggestion to modify the prior art to practice the claimed invention, but also evidence suggesting that it would be successful."[52]

The Court also considered the parameters of success—whether it requires a high degree of success or not. In *O' Farrell*, the Court held that the obviousness does not require absolute predictability of success, but only a reasonable expectation that the beneficial result will be achieved, to show obviousness.[53] Rich J. observed as follows:

> "Obviousness does not require absolute predictability of success. Indeed, for many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. There is always at least a possibility of unexpected results, that would then provide an objective basis for showing that the invention, although apparently obvious, was in law nonobvious."[54]

In *O' Farrell*, the Court found that the "obvious to try" is inappropriate where the prior art contained only general guidance as to the form of the claimed invention and a method suggesting how to practice/achieve it. The "obvious to try" thus contradicts section 103, which prohibits patentability of inventions unless "the improvement is more than the predictable use of prior art elements according to their established functions."[55]

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final rejection of patent application entitled "Method and Hybrid Vector for Regulating Translation of Heterologous DNA in Bacteria." The application was rejected undersection 103 on the ground that the claimed invention would have been obvious at the time the invention was made in view of a published paper by two of the three co-inventors and a prior publication.)

47 Ibid., at 902.

48 *KSR International Co. v. Teleflex, Inc.*

49 In *re Marek Z. Kubin and Raymond G. Goodwin 561 F. 3d 1351 (Fed. Cir. 2009).*

50 In *re Patrick H. O' Farrell* 853, F 2nd 894 (Fed. Cir. 1988) at 903.

51 Ibid., at 902.

52 Ibid.

53 Ibid.

54 Ibid., at 903.

55 *KSR International Co. v. Teleflex, Inc.*

Thus, the evidence of a reasonable expectation of success has long been held to be an important component of obviousness determination in the chemical and pharmaceutical arts.[56] The limits to the "obvious to try" analysis adopted by *O' Farrell* seem to have accurately expressed the limits of the "obvious to try" analysis. It described two situations in which "obvious to try" should not be erroneously equated with obviousness under section 103. [57]

Seven years after the *O' Farrell* decision, the Federal Circuit took the view in *re Deuel*[58] that "obvious to try" is an inappropriate test for the assessment of obviousness as follows:

> "[T]he existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question of whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNAs. 'Obvious to try' has long been held not to constitute obviousness. A general incentive does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out".[59]

The Court in *Deuel* reversed the U.S. Patent and Trademark Office Board of Patent Appeals and Interference's conclusion and held that a prior art reference teaching a gene cloning method, together with a reference disclosing a partial amino acid sequence of a protein, rendered DNA molecules encoding the protein obvious.[60] The court in *Deuel* held that "knowledge of a protein does not give one a conception of a particular DNA encoding it."[61]

Although the "obvious to try" standard existed even before the statutory non-obviousness requirement in the US, the enactment of 35 U.S.C. Section 103 slowly but effectively signalled the end of "obvious to try" as a proper patentability standard [62] in the absence of a reasonable expectation of success.

HOTCHKISS V. GREENWOOD STANDARDS PRIOR TO 1952 PATENT ACT

Prior to the 1952 Patent Act, the US Circuit Court for the District of Ohio in *Hotchkiss v. Greenwood* [63] held that where a claimed invention combines old elements, the invention is not patentable in the eyes of the law where the combination requires no more "ingenuity and skill" than that was "possessed by an ordinary mechanic acquainted with the business."[64] The Court was of the view that the improvement was the work of the skillful mechanic but not that of the inventor, and the evidence of more ingenuity and skill, which constitute essential elements of every invention, should be satisfied as the condition for patentability.[65]

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[56] Ibid., at 2634.

[57] Matthew I. Kreeger, "Federal Circuit Changes Course, Finds Claims to Novel Gene Obvious", Morrison Foerster, August 2009.

[58] In re *Deuel*, 51 F.3d 1552 (Fed. Cir. 1995).

[59] Ibid., at 1559.

[60] Ibid.

[61] Ibid.

[62] Andrew V. Trask, "'Obvious to Try': A Proper Patentability Standard in the Pharmaceutical Arts?" *Fordham University Law Review*, Vol. 76, Issue 5 (2008), p. 2629.

[63] *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1851). The patent in question was a mere substitution of materials - porcelain or clay for wood or metal in doorknobs. The only thing new was the substitution of a door knob made out of clay in that peculiar form for a knob of metal or wood. This might have been a better or cheaper article but is not the subject of a patent. The test was that if no more ingenuity and skill was necessary to construct the new knob than was possessed by an ordinary mechanic acquainted with the business, the patent was void and this was a proper question for the jury.

[64] Ibid., at 265-266.

[65] Ibid., at 267.

The recognition of the *Hotchkiss* judicial test of "no more than the ordinary mechanic's ingenuity and skill" necessarily meant that to be patentable, you need an inventor's "ingenuity and skill" to make the invention rather than a mere incremental change from the one that is found in the public domain. Thus, the *Hotchkiss* test, which laid the foundation for the statutory definition of the non-obviousness standard in section 103, required a comparison between the patent application's subject matter and the innovator's background skill, and this comparison led to the determination of patentability.[66]

US STATUTORY GUIDELINES FOR OBVIOUSNESS STANDARD

The 1952 US Patent Act was intended to codify the judicial precedents embracing the principle long ago announced in *Hotchkiss v. Greenwood,* which laid down the general level of innovation necessary to sustain the non-obviousness requirement.[67] Subsection (a) of section 103 of the US Patent Act 1952 makes "non-obviousness" one of the conditions of patent protection. It states that a patent for a claimed invention can be obtained, notwithstanding that the claimed invention is not identically disclosed or described as outlined in section 102:

> "If the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made".

The essence of section 103 statutory test seems to provide a framework of comparison since it tells the judge what to look at, and from what perspective, in order to determine if the invention is obvious.[68] Thus, it supplies both (i) a yardstick to compare the invention with the whole of the prior art and (ii) a fictional artisan (PHOSITA) to apply that prior art to the problem addressed in the patent.[69]

GENERAL TEST - GRAHAM TEST OR GRAHAM FACTORS

Graham v. John Deere Co. of Kansas City[70] was the first case that applied conditions set out in section 103 and addressed the effect of section 103 upon the traditional statutory and judicial tests of patentability. It was undoubtedly the lead case that developed certain factors to avoid or combat hindsight bias in assessing the inventive step.

The US Supreme Court held that in determining the obviousness or non-obviousness of subject matter (claimed invention) under section 103, the Courts should make the following three-part basic factual inquiries, better known as the 3-step Graham test:

1. Determine the scope and content of the prior art (previous work) to which the invention pertains. Thus, similar to novelty, the court should determine the scope of the prior art and the claimed invention;

2. Ascertain the differences between the prior art (previous work) and the claims (gap) and how the invention differs from the prior art. Thus, the fundamental question is whether such differences or gaps between the prior art and the claimed invention would

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66 Merges & Duffy*, Patent Law and Policy* (5th ed.), p. 538.
67 Merges & Duffy, *Patent Law and Policy (7th ed.),* p. 532.
68 Merges & Duffy, *Patent Law and Policy (7th ed.),* p. 531.
69 Ibid.
70 *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 148 USPQ 459 (1966).

have been obvious to the PHOSITA. If the differences are so obvious to the PHOSITA, it may establish a *prima facie* case of obviousness;

3. Determine the level of ordinary skill in the pertinent art when the invention was made.[71] The court must determine what the PHOSITA would have been able to infer from the prior art at the time the patent application was filed.[72] For example, the United States Courts of Appeals consider factors such as the educational qualifications of the inventors, the type of problems encountered in the art, the prior art solutions to these problems, the sophistication of the technology, the rapidity with which the invention was made;[73]

The US Supreme Court further stated that secondary considerations such as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances.[74]

FINAL GRAHAM ANALYSIS - THE ROLE OF PHOSITA

After following the three-step Graham test, the Court should consider whether the claimed invention's subject matter is obvious to the PHOSITA. It is the person having ordinary skill in the art (PHOSITA) who has to evaluate the invention and determine whether an invention is obvious to him under the Graham test.

OTHER NON-OBVIOUSNESS GUIDELINES

Thus, the question is how, in combination or modification of prior art references, PHOSITA should read and use prior art references to determine whether the invention is obvious or non-obvious. While *Graham v. John Deere Co.* decision established a basic framework and conditions that must be satisfied for judging non-obviousness or obviousness, Merges & Duffy[75] observe that it merely restates the language of section 103. In other words, it did not provide clear guidance on the details of the analysis.[76] They argue that section 103 does not offer a proper analysis of these factors and how precisely the Court should make the ultimate determination.[77]

Whilst the three Graham factors are regarded as the basic conditions that must be satisfied to determine the obviousness or non-obviousness standard, the US courts have identified several other guidelines to determine the "level of ordinary skill in the art" in cases of a combination or modification of prior art references.

(i) TSM Test (Teaching, Suggestion and Motivation Test)

Prior to the US Supreme Court decision in *KSR International Co. v. Teleflex Inc.*,[78] the Federal Circuit Courts consistently applied the "teaching-suggestion-motivation" (TSM) test adopted by the Federal Circuit in *ACS Hospital Systems, Inc. v. Montefiore Hospital Systems*[79] to

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[71] Ibid., at 17.
[72] J.R. Thomas, *Pharmaceutical Patent Law* (Washington, D.C., BNA Books, 2005), pp. 156-157.
[73] Ibid.
[74] *Graham v. John Deere Co. of Kansas City*, Part V.
[75] Merges & Duffy, *Patent Law and Policy (7th ed.),* p. 567.
[76] *Graham v. John Deere*, 11.
[77] Ibid.
[78] *KSR International Co. v. Teleflex Inc.*
[79] *ACS Hosp. Sys., Inc. v. Montefiore Hosp.* 732 F.2d 1572 1577 (Fed. Cir. 1984).

determine the obviousness standard in combination inventions. This analysis required a TSM in the prior art that would give the PHOSITA a reason to perform a combination or modification to reach the invention and render it obvious and not patentable.

The Federal Court held that "obviousness" cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there are some suggestions or incentives to do so and the prior art fails to provide any such suggestion or incentive. [80] The TSM test was intended to curtail hindsight bias based on the reasoning that "combining prior art references without evidence of such a suggestion, teaching or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability - the essence of hindsight."[81]

Under this analysis, if the existing prior art would have suggested the claimed invention, the claimed invention is obvious. If not, the claimed invention is not obvious. The "suggestion test" thus asks a helpful question: to what extent would the prior art "have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success"?[82]

The TSM test is used to determine that the invention is obvious when it is shown that some evidence of explicit TSM exists to combine known prior art elements to create or form a claimed invention.[83] In the *ACS Hospital Systems* case, it was held that "obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teaching of references can be combined only if there are some suggestion or incentive to do so. The prior art of record fails to provide any such suggestion or incentive and accordingly, claimed invention would not have been obvious to one of ordinary skill in the art under section 103".[84]

This test allows the combination or modification of prior art and references and requires consideration of whether or not the prior art would have suggested the claimed invention. If so, the claimed invention is obvious; if not, the claimed invention is not obvious. Thus, the inquiry under the TSM test is whether there is any element in the prior art that would suggest to the PHOSITA that the invention is a combination of previously known elements. The invention is obvious if the patent examiner can show that some suggestion, teaching, or motivation exists to combine known elements in the prior art to form a claimed invention so that the invention was a combination of previously known elements.

Under this formula, when the prior art reference or references combined suggest or teach that the claimed invention would have a reasonable expectation of success, as found by those skilled in the art, the claimed invention is obvious. Thus, the TSM test captures a helpful insight because an invention composed of several known elements is not proved obvious merely by demonstrating that each element was independently known in the prior art to form a claimed invention.[85]

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[80] Ibid., paragraph 2 under obviousness.

[81] D. Benjamin Borson, "KSR v. Teleflex, Inc.: The Supreme Court Reviews Obviousness", *Journal of the Patent and Trademark Office Society,* Vol. 89 (2007), p. 525.

[82] *Brown and Williamson Tobacco Corp. v. Philip Morris*, 229 F.3d 1120, 1124 (Fed. Cir. 2000).

[83] Donald S. Chisum, Tyler T. Ochoa, Shubha Ghosh, Mary Lafrance, eds., *Understanding Intellectual Property Law*, 3rd Ed. (Lexis Nexis, 2015).

[84] *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, paragraph 2 under obviousness.

[85] *KSR International Co. v. Teleflex Inc.*, 415.

(ii) *KSR* Test

In the case of *KSR International Co. v. Teleflex Inc*.[86], the question arose whether the claimed invention could be held "obvious" and thus, unpatentable under section 103 in the absence of evidence of "teaching, suggestion or motivation" that would have led the PHOSITA by combining previously-existing prior art teachings in the manner claimed.

The Supreme Court held in *KSR* that the TSM test was still valid. It captured a helpful insight and was consistent with the Graham analysis formula for the determination of inventiveness. However, the TSM test was not to be applied mandatorily/rigidly and as an exclusive test for determining non-obviousness.[87]

The Court reasoned that the obviousness could also be established despite the absence of clear TSM to combine various prior art references.[88] The Supreme Court held that instead of a rigid application, a more flexible approach based on common sense and full consideration of the prior art and the invention was the most appropriate method for applying the TSM test for the determination of non-obviousness.

Changes Made by KSR in Combination of Patents & "Obvious to Try" Approach

The *KSR v. Teleflex* analysis, which was decided after the enactment of the 1952 Patent Act, seems to revive some form of the "obvious to try" approach as one of the factors to address the standard of obviousness, as follows:[89]

> "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. In that instance, the fact that a combination was "obvious to try", might show that it was obvious."

Some scholars argue that with this language, the Supreme Court conceivably advocated some version of an "obvious to try" standard of patentability,[90] which increases additional hindsight bias to inventiveness. Importantly, however, the Supreme Court has limited this standard to scenarios accompanied by "predictable solutions" and "anticipated success".[91]

In fact, the changes introduced by *KSR* seem to suggest that "obvious to try" is decided from a finite number of identified, predictable solutions, with a reasonable expectation of success.[92] It is more likely that the *KSR* Court may have resurrected the "obvious to try" doctrine in a qualified form, although it was rejected earlier by Federal Courts as an improper obviousness standard in the absence of reasonable expectation of success.

The *KSR* does not, however, appear to have adopted the same version of the "obvious to try" test originally applied in the Federal Courts prior to the enactment of the 1952 Act. Its application of predictable solutions is rather linked with the reasonable expectation of success, as clearly adopted by *O' Farrell*.

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86 Ibid.
87 Ibid.
88 Ibid.
89 See paragraph 8 for KSR guidelines and for application of obvious to try under KSR analysis.
90 Harold C. Wegner, "Making Sense of KSR and other Recent Patent Cases", *Michigan Law Review First Impressions*, Vol. 106 (2007), p. 39, p. 41.
91 Trask, "'Obvious to Try'"., p. 2648.
92 USPTO Guidelines, 2143 (R-08.2012).

The version of the "obvious to try" test applied by *KSR* thus suggests that it applies only in situations where a finite number of identified, predictable solutions, with a reasonable expectation of success exists. The *KSR* analysis appears to be linking the obviousness test to the predictability standard with a reasonable expectation of success. It is, thus, necessary to consider whether the changes made by the statutory non-obviousness regime in the 1952 Patent Act is consistent with the approach adopted by the *KSR* for the assessment of inventive step.

Hence, it would be important to examine the changes that have been made by the US Patent Act and factors developed by case law to avoid or combat hindsight bias on the obviousness standard before examining whether the *KSR* is an appropriate approach.

KSR Predictability Analysis - Predictability is the Deciding Factor

In *KSR,* the Supreme Court introduced a variety of factors applied in *Winner International Royalty Corp v. Wang* [93] to determine whether the invention is non-obvious, such as predictability of use (Type 1 predictability) and predictability of results (Type 2 predictability).[94] The *KSR* has, thus, expanded the inventive test standard by introducing two distinct types of flexible predictability standards for determining non-obviousness in combination inventions: predictability as to the use (predictability 1) and predictability as to the results (predictability 2).

Accordingly, when considering the obviousness of a combination of known elements, the relevant question is whether the improvement is more than the predictable use of prior art elements according to their established functions (predictability as to the use - predictability 1 and predictability as to the results - predictability 2).[95] This seems to suggest that the doctrine of *prima facie* obviousness is no longer the standard test for obviousness under *KSR* guidelines, but the predictability of use and predictability of results doctrines applies.

Predictable Use (Type 1 Predictability)

The predictability as to use requires the PHOSITA to combine the two prior art and conclude whether the technological gap between the prior art and the claimed invention is large enough to warrant patent protection.[96] The Court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. [97] If the gap between the prior art and the claimed invention is too small, then the invention is obvious, and if the gap is too large, the invention is non-obvious. [98]

Predictable Result (Type 2 Predictability)

On the other hand, predictability test 2 focuses not on whether the combination or change is predictable (type 1 predictability) but on whether the behaviour of the resulting combination or change is predictable, viz, the result is predictable (predictability as to the results).[99] However, Type 2 predictability as to results focuses on the invention itself instead of the gap between the prior art and the invention.[100]

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93 *Winner International Royalty Corp v. Wang*, 202 F.3d 1340, 1348.
94 Christopher A. Cotropia, "Predictability and Non-obviousness in Patent Law After KSR", *Michigan Telecommunications and Technology Law Review*, Vol. 20, Issue 2 (2014), p. 402.
95 *KSR International Co. v. Teleflex Inc.*, at 420-21.
96 Cotropia, "Predictability and Non-obviousness in Patent Law After KSR", pp. 404-405.
97 *KSR International Co. v. Teleflex Inc.*, at 417.
98 Ibid.
99 Ibid., at 404.
100 Ibid., at 405.

Therefore, the inquiry is whether the invention, once created, acts in a predictable manner - namely, does it operate how a skilled artisan would believe it to when the prior art elements are changed or combined?[101] Cotropia observes that the technological gap between the combined prior art and the claimed invention under predictability test 2 is irrelevant because it focuses on the invention itself instead of the gap between the prior art and the invention.[102] He further argues that predictability test 2 presents a different approach to determine non-obviousness, which moves the inquiry away from the technical gap between the prior art and the claimed invention which the person having the ordinary skill is required to conclude.[103]

Accordingly, the difference between the prior art and the invention—the gap—is irrelevant in a Type 2 predictability analysis[104] . The important aspect is the predictability of results. The gap between the prior art and the claimed invention is not relevant in the non-obviousness analysis.

It is submitted that predictability test 2 of *KSR* is the modified version of the TSM test since both TSM and predictability test 2 seek to conclude first that (i) the result of the invention which is based on the combination of elements found in the prior art performs the same function and (ii) the combination is regarded in both tests as obvious unless the combined elements would create or yield more than predictable results. The difference seems to be that teaching, suggestion or motivation factors are applied in TSM analysis, whereas in *KSR*, predictability factors are applied to test obviousness.

Since the decision in *KSR*, the United States Patent and Trademark Office (USPTO) issued new guidelines known as KSR Guidelines, under which the law of obviousness was refined.[105] The Manual of Patent Examining Procedure (MPEP) provides grounds for rejecting applications for obviousness.[106] Those refined Guidelines state that the Patent Office, based on the *KSR* judgment, should apply the aforesaid factual inquiries announced in *Graham v. John Deere Co.* as the foundation of any determination of obviousness and then apply the KSR principles.[107] The new guidelines [108] provide that the following rationales should be considered when assessing the inventive step:

1. Combining prior art elements according to known methods to yield predictable results.

2. Simple substitution of one known element for another to obtain predictable results.

3. Use of known techniques to improve similar devices, methods, or products in the same way.

4. Applying a known technique to a known device, method, or product ready for improvement to yield predictable results.

5. "Obvious to try"- choosing from a finite number of identified, predictable solutions with a reasonable expectation of success.

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[101] Ibid.
[102] Cotropia, "Predictability and Non-obviousness in Patent Law After KSR".
[103] Ibid.
[104] Ibid.
[105] KSR Guidelines, Federal Register/Vol. 75, No. 169/ 01.09.2010, 53644-53660 & MPEP section 2143. Available from https://www.govinfo.gov/content/pkg/FR-2010-09-01/pdf/2010-21646.pdf.
[106] Ibid.
[107] KSR Guidelines & Training Materials of USPTO, 2143. Available from https://www.uspto.gov/patents/laws/examination-policy/examination-guidelines-training-materials-view-ksr.
[108] MPEP 2144.08.

6. Known work in one field of endeavour may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to the person skilled in the art.

7. Some teaching, suggestion, or motivation (TSM test) in the prior art that would have led a person skilled in the art to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

The USPTO, the Federal Circuits, and the lower Courts used Type 2 predictability extensively after *KSR*.[109] Merges and Duffy, however, argue that Type 2 predictability contradicts the statutory language of section 103 of the Patents Act.[110] Further, it introduces hindsight bias, discriminates against certain technologies, and conflicts with basic patent theory. Hence, the use of Type 2 predictability and its interpretation require serious review.[111]

(iii) Obviousness After *KSR* & Re-emergence of the Standard of "Reasonable Expectation of Success" in Biotechnology Inventions

The Federal Circuit employed both types of predictability in its non-obviousness opinions after KSR, and most notably, the court has used Type 2 predictability to invalidate a patent.[112] Cotropia argues that Type 2 predictability as a non-obviousness test not only substantively changes the law and creates a non-obvious standard that is contrary to patent theory but also introduces a number of disadvantages to the patent system.[113]

First, he argues that the change violates the plain language of Section 103 and the statutorily-mandated focus on the difference between the prior art and the invention instead of the result itself.[114] Second, he argues that the change also increases the likelihood of hindsight bias because the perspective of the skilled artisan is changed from being prospective to retrospective.[115]This fact, in turn, increases the likelihood of errors in non-obviousness determinations.[116] Third, he argues that Type 2 predictability also biases patent protection against simple and predictable technologies and can result in unwarranted protection of unpredictable technologies.[117] His argument is that by definition, the operation and interaction of these technologies such as mechanical, electrical, and computer software technologies is easy to predict.[118] Cotropia further criticizes the Type 2 predictability arguing that if the test for non-obviousness is whether an invention has predictable results, then uncomplicated technologies are unlikely to be deemed nonobvious, and therefore unlikely to receive patent protection.[119] Referring to a simpler the technology, he argues that it is easy for a skilled artisan to predict how it will behave and therefore, under the Type II predictability, patent applications and issued patents covering these technologies will fare poorly both at the USPTO and courts and are more likely to be found obvious.[120]

The situation has become more complicated in biotechnology inventions that involve isolating and naturally occurring DNA sequences, which has been held by the US Supreme Court not

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[109] Merges & Duffy, *Patent Law and Policy (7th ed.)*, pp. 594-595.
[110] Ibid.
[111] Ibid.
[112] Cotropia, "Predictability and Non-obviousness in Patent Law After KSR", p. 415.
[113] Ibid., p. 424.
[114] Ibid.
[115] Ibid.
[116] Ibid.
[117] Ibid.
[118] Ibid., p. 430.
[119] Ibid.
[120] Ibid.

to constitute a patentable subject matter in the case of the *Association for Molecular Pathology v. Myriad Genetics*.[121]

In re Kubin

Merges and Duffy observe that the decision of the Federal Circuit Court in *re Kubin*, a biotechnology case, remains good law in its teaching on the obviousness doctrine.[122] In *re Kubin,*[123] there was a claim to a classic biotechnology invention—the isolation and sequencing of a human gene that encodes a particular domain of a protein. The appellants claimed DNA molecules ("polynucleotides") encoding a protein ("polypeptides") known as the Natural Killer Cell Activation Inducing Ligand ("NAIL").

The Board of Appeals and Interferences rejected the appellants' claims as invalid, *inter alia*, under section 103 over the combined teachings of U.S. Patent No. 5,688,690 ("Valiante") and 2 Joseph Sambrook et al., Molecular Cloning: A Laboratory Manual 43-84 (2d Ed. 1989) ("Sambrook") on the basis that the appellants' methodology of isolating NAIL DNA was essentially the same as the methodologies and teachings of Valiante and Sambrook.[124]

The Board concluded that appellants' claim was "the product not of innovation but of ordinary skill and common sense," leading us to conclude NAIL cDNA is not patentable as it would have been obvious to isolate it.[125] The Federal Circuit considered the assessment of obviousness in the context of classical biotechnological cases, especially in *re Deuel*[126] and *O' Farrell*.[127] It observed that those cases directly implicate the *Kubin* case.

In Kubin, the Federal Circuit declined to 'cabin KSR to the "predictable arts" (as opposed to the "unpredictable art" of biotechnology)' holding that a claimed 'genus of isolated nucleic acid molecules coding the NAIL protein' was reasonably expected in the light of the prior art and "obvious to try". [128] The Court held that the record shows that one of skill in the advanced biotechnology art would find these claimed "results" profoundly "predictable" and the well-known, and reliable nature of the cloning and sequencing techniques in the prior art, not to mention the readily knowable and obtainable structure of an identified protein.[129] The Federal Court, in declining to apply formalistic rules for obviousness in specific fields of technology such as biotechnology, observed:

> "This Court cannot, in the face of *KSR,* cling to formalistic rules for obviousness, customize its legal tests for specific scientific fields in ways that deem entire classes of prior art teachings irrelevant, or discount the significant abilities of artisans of ordinary skill in an advanced area of art... 'Our function is to apply, in each case, section 103 as written to the facts of disputed issues, not to generalize or make rules for other cases which are unforeseeable.'…'[t]he problem of obviousness under section 103 in determining the patentability of new and useful chemical compounds... is not really a problem in chemistry or pharmacology or in any other related field of science, such as biology, biochemistry, pharmacodynamics, ecology or others yet to be conceived. It is a problem of patent law.'"[130]

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[121] *Association for Molecular Pathology v. Myriad Genetics,* 133 S. Ct. 2107 (2013).
[122] Merges and Duffy, *Patent Law and Policy (7th ed.)*, pp. 584-585.
[123] In *re Marek Z. Kubin and Raymond G. Goodwin* 561 F3d 1351 (2009).
[124] Ibid., Part II & III.
[125] Ibid.
[126] In *re Deuel*, it was held that a prior art reference teaching a method of gene cloning, together with a reference disclosing a partial amino acid sequence of a protein, rendered DNA molecules encoding the protein obvious.
[127] *O' Farrell* emphasized that 'obvious to try' is not the standard under section 103.
[128] In *re Marek Z. Kubin and Raymond G. Goodwin*, p. 1360-1.
[129] Ibid., at 1360.
[130] Ibid., at1360-1361.

It seems that in *Kubin,* the Court declined to adopt the *KSR* "predictable arts" test as opposed to the "unpredictable art" of biotechnology, where the combined biotechnology prior art references generally produce unpredictable results.[131] The Federal Circuit in *Kubin* considered the degree of success recognized in *In re O'Farrell* to determine whether the parameter of success requires a high degree of success or a low degree of success and held that "obviousness does not require absolute predictability of success… all that is required is a reasonable expectation of success".[132]

The Federal Circuit affirmed the Board's finding that there was a reasonable expectation of success in obtaining the claimed invention, and the relevant standard is still a "reasonable expectation of success." This means that when the prior art does not provide a reasonable expectation of success, the invention is non-obvious; when the art provides it, the invention is obvious, as held in *O'Farrell*.[133]

Thus, the evidence of a reasonable expectation of success remains an important component of obviousness determination in the chemical, pharmaceutical, and biotechnological arts. The limits to the "obvious to try" analysis adopted by *O' Farrell* seem to have accurately expressed the limits of the "obvious to try" analysis, which described two situations in which "obvious to try" should not be erroneously equated with obviousness under section 103.[134]

It is unlikely that applying "obvious to try" as a stand-alone test would be the appropriate test to assess the inventive step in biotechnology cases where the combination of prior art references is generally producing unpredictable results unless there is evidence of a reasonable expectation of success.

It seems that a number of post-*KSR* decisions followed *Kubin* in that the standard of obviousness is the "reasonable expectation of success" as held by the Federal Circuit in *O'Farrell*. Although, for example, in *PAR Pharm., Inc. v. TWI Pharm., Inc.*[135] it was held that the reasonable expectation of success requirement for obviousness does not necessitate an absolute certainty of success.

It seems that post-KSR decisions have declined to apply "obvious to try" as a proper test for the determination of obviousness in the absence of a reasonable expectation of success. *Kubin,* a classical biotechnology case, has recognized this principle.

Flexible TSM Approach

In contrast to *Kubin*, some Federal Circuit decisions seem to adopt the flexible TSM test because the TSM test is not at all dead, and all that the Supreme Court in *KSR* rejected was the rigid application of the TSM test.[136] For example, in *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc.*,[137] the Federal Court held that "a flexible TSM test remains the primary guarantor against a non-statutory hindsight analysis."[138] Again, in *Takeda Che. Indus. v. Alphapharm Pty. Ltd.,*[139] the Federal Circuit acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" in an obviousness determination.[140] It

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131 Merges and Duffy, *Patent Law and Policy (7th ed.)*, p. 589.
132 In *re Kubin,* Part III, B.
133 Ibid., Part III, B.
134 Mattew I. Kreeger, "Federal Circuit Changes Course, Finds Claims to Novel Gene Obvious", Morrison & Foerster LLP, August 2009.
135 *PAR Pharm., Inc. v. TWI Pharm., Inc.,*773 F.3d 1186, 1198 (Fed. Cir. 2014).
136 Merges and Duffy, *Patent Law and Policy (7th ed.)*, p. 590.
137 *Ortho-McNeil Pharm.*, *Inc. v. Mylan Labs., Inc*., 520 F.3d 1358 (Fed. Cir. 2008).
138 Ibid., 1365.
139 *Takeda Chemical Industries v. Alphapharm Pty. Ltd.,* 492 F.3d 1350, 1357 (Fed. Cir. 2007).
140 Ibid., Part B, paragraph 8.

also observed that there is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis. As long as the test is not applied as a "rigid and mandatory" formula, that test can provide "helpful insight" to an obviousness inquiry.[141]

While the basic test for the determination of non-obviousness is the Graham analysis, there is no dispute that the TSM test, which is not inconsistent with the Graham analysis, is also a helping test for the determination of the inventive step. Its application to cases involving an advanced technology such as biotechnology, where the final result is generally expected to be unpredictable, has also been questioned. The problem seems to be that in *KSR*, the Supreme Court said that obviousness could also be established despite the absence of clear TSM to combine various prior art references; therefore, any testimony concerning motivation (reason) to combine may be unnecessary.

An attempt was made in *Ortho-McNeil Pharmaceutical* to convince that the reformed TSM test need not always be written references, as they may be found within the knowledge and creativity of ordinary, skilled artisans. Thus, no rigid application of the evidentiary requirements for obviousness can be detected in the facts of the case.[142] Merges and Duffy [143] questions the appropriateness of this approach as there is no certainty as to when a Court or patent examiner can hold that the unwritten creativity of the ordinary artisan provides the necessary motivation to make the claimed invention and when it would be obvious to PHOSITA within his knowledge and creativity.

It appears, however, in the test followed in *Kubin,* that the standard of obviousness is the "reasonable expectation of success" as held at the Federal Circuit in *O'Farrell* together with a common sense approach of objective considerations such as recourse to logic, judgment and common sense, and public and commercial response to an invention as suggested by KSR.

(iv) More Flexible "Common Sense" Approach & Objective Considerations in Obviousness - Secondary Indicia as Additional Factors

As described, the emphasis has been placed now on the fourth Graham factor in the obviousness analysis after the *KSR*, which almost recognized a flexible common sense approach of objective considerations in lieu of a flexible TSM approach for the determination of obviousness.

The *Graham* Court also observed that secondary considerations might be utilized in case of doubt to serve as evidence of non-obviousness. Those secondary considerations include:

1. Commercial success resulting from the device's inventive aspect.

2. Long felt but unsolved needs.

3. Failure of others—the claimed invention solves a specific problem that unsuccessful attempts by skilled persons failed to solve.

4. Unexpected results, praise for the invention, etc., to give light to the circumstances surrounding the origin of the subject matter sought to be patented.[144]

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[141] Ibid.
[142] *Ortho-McNeil*, at 1365.
[143] Merges and Duffy, *Patent Law and Policy (7th ed.)*, p. 591.
[144] Ibid., pp. 17-18.

Public and Commercial Responses to an Invention

The Courts have held in relation to objective evidence of non-obviousness that secondary considerations may often be the most probative and cogent evidence of non-obviousness and provide evidence of how the patented device is viewed by the interested public, not the inventor, but persons concerned with the product in the objective arena of the marketplace.[145] Objective indicia are essential safe-guards that protect against hindsight bias.[146] The objective indicia analysis is, therefore, a fundamental part of the overall section 103 obviousness inquiry. [147] As a result, the Board must consider all such evidence of objective indicia and determine the weight to give it "*en route* to a determination of obviousness."[148]

In *Arkie Lures, Inc. v. Gene Larew Tackle, Inc*,[149] the Federal Circuit recognized that the Objective Indicia such as public and commercial response to an invention is a factor (*Graham,* fourth factor) to be considered in determining obviousness, and is entitled to fair weight. In this case, considerations of commercial success, licensing activity and copying were markedly prevalent, and were not disputed. It was further held that secondary considerations are just that—secondary, and they cannot make a clearly unpatentable product patentable.[150]

Commercial Success of an Invention

If a product that embodies the invention supplants prior art products and is a great commercial success due to the claimed features of the invention, then it can be inferred that the invention was not obvious.[151] However, in *Hybritech Inc.*,[152] it was held that there must be a casual "nexus" between the evidence of commercial success and the claimed invention to prove non-obviousness. Further, the product success must flow from the functions (developed by the patentee) and advantages disclosed or inherent in the patent specification.[153] On the other hand, external factors such as extensive advertising or dominant market position cannot be regarded as evidence of commercial success.[154]

Undue reliance on the invention's commercial success as a secondary factor to show non-obviousness, identified in the *Graham* case, has been criticized by the US Federal Trade Commission (FTC) in its Report to Promote Innovation.[155] The FTC observed that in applying the "commercial success" test, it is required first to evaluate on a case-by-case basis whether commercial success is a valid indicator that the claimed invention is not obvious. Second, the burden is placed on the patent holder to prove the claimed invention caused the commercial success. Then, it is presumed that the invention caused commercial success.[156] It is, therefore, necessary to place the burden on the patent holder, who is the best source of

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[145] *Advanced Display Sys., Inc. v. Kent State Univ.* , 212 F.3d 1272, 1285 (Fed. Cir. 2000) (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983).

[146] *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig. ,* 676 F.3d 1063, 1079 (Fed. Cir. 2012).

[147] *W.L. Gore & Assocs., Inc. v. Garlock, Inc.,* 721 F.2d 1540, 1555 (*Fed. Cir. 1983).*

[148] Stratoflex, Inc. 713 F.2d at 1538.

[149] *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.,* 119 F. 3d 953 (Fed. Cir. 1997).

[150] Ibid., Part V, paragraph (e).

[151] Chisum, Ochoa, Ghosh, Lafrance, eds., *Understanding Intellectual Property Law*, 3rd Ed., p. 79.

[152] *Hybritech Inc. v. Monoclonal Antibodies Inc*. 802 F.2d 1367 (Fed. Cir. 1986).

[153] *In re Vamco Machine & Tool, Inc.,* 752 F.2d 1564 (Fed. Cir. 1985).

[154] *Pentec, Inc. v. Graphic Controls Corp*. 776 F.2d 309 (Fed. Cir. 1985).

[155] US Federal Trade Commission (FTC), *Report to Promote Innovation: The Proper Balance of Competition and Patent law and Policy* (October 2003). Available from https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf.

[156] Ibid., p. 11.

information on what has caused commercial success on its product, to prove the claimed invention caused the commercial success.[157] The FTC, however, observed that:

> "Commercial success can result from many factors, however, some of which have nothing to do with the claimed invention. For example, marketing, advertising, or an incumbent's unique advantages may cause commercial success. An undue reliance on commercial success to show non-obviousness can raise a number of competitive concerns. Commercially successful inventions may be more likely than others to occur even without the prospect of a patent. Patents on commercially successful products are more likely to confer market power than those on less successful products."[158]

The FTC further observed that, "This test fails to ask, first, whether factors other than the invention may have caused the commercial success. By contrast, the USPTO properly requires that commercial success is "directly derived from the invention claimed" and not the result of "business events extraneous to the merits of the claimed invention."[159] Secondly, the FTC observed that the "judicial standard too easily shifts the burden to the challenger. The patent holder is the best source of information on what has caused the commercial success of its product and should be required to show that, in fact, the claimed invention caused the commercial success".[160] For this reason, the FTC observed that the USPTO's approach that the commercial success is required to be "directly derived from the invention claimed" and not the result of "business events extraneous to the merits of the claimed invention" is justified.[161]

Long Felt the Need/Failure of Others to Find a Technical Solution to a Technical Problem

Merges argues that commercial success is a poor indicator of patentability because it is indirect as it depends for its effectiveness on a long chain of inferences, and the links in the chain are often subject to doubt.[162] Merges & Duffy argue that, unlike commercial success, the failure of others to make an invention proves directly that parallel research efforts were underway at a number of firms and that one firm (patentee) won the race with a common goal.[163] Merges, however, argues that for failure of the other to be persuasive, a patentee must establish two preliminary facts. First, there must be parallel research, research aimed at the same goal. Second, the patented invention must result from more than minimal research efforts.[164]

Unexpected Results

The most important objective consideration is the unexpected results because, for the average expert in the field, they are treated as evidence in support of the patentee and a finding of non-obviousness of the claimed invention.[165] By contrast, the absence of secondary consideration, like unexpected results, is not treated as evidence of obviousness.[166]

In the *United States v. Adams*,[167] Adams invented a water-activated battery that could be fabricated and stored indefinitely without any fluid in its cells. Once it is activated by adding

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157 Ibid.
158 Ibid.
159 Ibid. & USPTO, MPEP, s. 716.03(b).
160 Ibid.
161 USPTO, MPEP § 716.03(b).
162 Robert Patrick Merges, "Commercial Success and Patent Standards: Economic Perspectives on Innovation", *California Law Review, Vol. 76* (1988), p. 805.
163 Merges and Duffy, *Patent Law and Policy (7th ed.)*, p. 616.
164 Ibid.
165 Mark A. Lemley, "Expecting the Unexpected", *Notre Dame Law Review*, Vol. 92, Issue 3 (2017), p. 1373.
166 Ibid.
167 *United States v. Adams* 383 U.S. 39, 148 U.S.P.Q. (BNA) 479 (1966).

water, the battery continues to deliver electricity. Though each of the battery's elements was well known in the prior art, to combine them as Adams did requires that a person reasonably skilled in that art to ignore that open-circuit batteries which heated during normal use were not practical and that water-activated batteries were successful only when combined with electrolytes harmful to the use of magnesium.

While holding that the secondary consideration cannot overcome a strong case of obviousness, the Supreme Court observed that although the claim elements were known in the prior art, the repeated failure of others, coupled with the combination of known prior art elements, can do more than yield a predictable result. Here, the Supreme Court held that though each of the elements of Adams' battery was well-known in the prior art, Adams combined the pre-existing water-activated batteries with electrolytes harmful to the use of magnesium which made it have wholly unexpectedly valuable advantages over other existing wet batteries. The Supreme Court, however, observed that:

> "This is not to say that one who merely finds new uses for old inventions by shutting his eyes to their prior art disadvantages thereby discovers a patentable innovation. We do say, however, that known disadvantage in old devices which would naturally discourage the search for new inventions may be taken into account in determining obviousness."[168]

[168] Ibid., part IV, page 383 U.S. 52.

PART V

PROPOSED SRI LANKAN APPROACH TO DETERMINE THE INVENTIVE STEP IN SRI LANKA

(A) STATUTORY DEFINITION

The basic statutory definition of the "inventive step" and the fundamental test for assessing the inventive step are contained in section 63 of the IP Act. Under that Act, an invention shall be considered as involving an inventive step if, having regard to the prior art relevant to the patent application claiming the invention, such inventive step would not have been obvious to the PHOSITA.

The current Indian statutory definition to the term "inventive step" is broader than the Sri Lankan definition as India has defined the term "inventive step" in both technical and economic terms based on technical advancement and or economic significance of the claimed invention over the existing knowledge that make the invention not obvious to a person skilled in the relevant art. [169]

As per the Indian Patent Act of 2005, an invention means a new product or process involving an inventive step and capable of industrial application.[170] Inventive step is defined in section 2 (1) (ja) of the Indian Patent Act as follows:

> "Inventive step" means "a feature of an invention that involves a technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art".[171]

Inventive step, thus can refer to the feature of the invention that satisfies the following three criteria:

1. The feature of the invention having technical advance over the existing knowledge (prior art) and that makes the invention not obvious to a person skilled in the art (non-obvious technical advancement); or

2. The feature of the invention having economic significance and that makes the invention not obvious to the person in the art (non-obvious feature of economic significance); or

3. The feature of the invention having technical advancement and economic significance and that makes the invention not obvious to the person in the art (non-obvious technical advancement or non-obvious feature of economic significance).

The Supreme Court of India referring to the combined reading of section 2 (1) (j) in the *Novartis* decision[172] held that in order to qualify as "invention", a product must, therefore satisfy the following tests:

1. It must be new;

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[169] Indian Patents Act, s. 2 (1) (ja).
[170] Indian Patents Act, s. 2 (1) (j).
[171] Indian Patents Act, s. 2 (1) (ja) & Indian Manual of Patent Office Practice and Procedure Chapter 8, section 8.3.3.1.
[172] *Novartis Ag v. Union of India & Ors*, Decided on 01.04.2013, paragraph 90.

2. It must be capable of being made or used in an industry;

3. It must come into being as a result of an invention which has a feature that -

   (a) entails technical advance over existing knowledge; or

   (b) has an economic significance; and

   (c) makes the invention not obvious to a person skilled in the art.

Although the distinction between the term "economic significance" and the concept of "industrial application" has not so far been clarified, it can be argued that the term "economic significance" is indicative of a "profitable use" of the invention in the industry as it is described in the European Patent Office (EPO) Case Law relating to Article 57.[173]

The inventive step could be defined in Sri Lanka on the basis of technical advancement over the existing knowledge or prior art that make the invention not obvious to a person skilled in the art as the primary statutory consideration. The economic significance, however, can only be considered as a secondary consideration and it is unlikely that the assessment of inventive step which is only a technical inquiry can be coupled with economic considerations.

It is submitted that an invention shall be considered in Sri Lanka as having involved an inventive step, if the features of the invention having technical advancement over the existing knowledge (prior art) would make the invention not obvious or self-evident from the state of the art to the PHOSITA.

One option for Sri Lanka is to clarify the existing statutory provision in section 65 of the IP Act through wording without changing the existing statutory provisions thereof as follows:

Option 1

"An invention which manifests a feature involving technical advancement as compared to the existing knowledge shall be considered an inventive step in Sri Lanka if, having regard to the prior art relevant to the patent application claiming the invention, such inventive step would not have been obvious to a person having ordinary skill in the art".

The other option is to clarify the inventive test in section 65 of the IP Act more broadly so as to incorporate suggestions or combined elements by further limiting the scope of the invention to render it obvious to the person skilled in the art, as follows:

Option 2

"An invention shall not be considered as involving an inventive step if the prior art provides suggestion, teaching or motivation to try the invention or when the combined elements of prior art with a reasonable expectation of success would render the invention obvious to a person skilled in the relevant art".

The statutory inventive step criteria in the existing IP Act can be either amended or clarified by incorporating the two suggested statutory definitions so as to prevent patenting of inventions obtained through obvious methods or trivial variations of existing prior art.

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[173] EPO Case Law of the Boards of Appeal, Patentability, section relating to Article 57, heading 1.2. Available from https://www.epo.org/law-practice/legal-texts/html/caselaw/2022/e/clr_i_e_1_2.htm.

(B) OBJECTIVE, SUBJECTIVE AND QUALITATIVE TESTS FOR THE DETERMINATION OF INVENTIVE STEP

In line with the strict inventive step criteria, the inventive step in Sri Lanka can be strict, subjectively and objectively judged having considered the technological advancement over the existing knowledge by the PHOSITA so as to determine the invention as either obvious or non-obvious.

As described, in determining the obviousness or non-obviousness of the subject matter under section 103, the Courts should make three-part basic factual inquiries adopted by the *Graham* decision and decide whether the invention is obvious or not. It will be seen that the current approaches adopted by countries including the EU and a developing country like India are consistent with the guidelines set out by the Graham Court to determine the question of obviousness.

For example, in the EU, the assessment of inventive step is based on the problem and solution approach (PSA) as objective elements and secondary considerations, which were developed by the Supreme Court in the Graham analysis. In order to assess inventive step in an objective and predictable manner, the examining division, the opposition division and the boards of appeal of the EPO apply the "problem-and-solution approach" (technical contribution to the art to be solved) in order to decide whether the invention involves an inventive step.[174]

Objective Factors - this approach consists of the following objective elements:

(i) identifying the "closest prior art" - the most relevant prior art or at least a realistic starting point;

(ii) establishing the "objective technical problem" to be solved. This is determined in view of the closest prior art. The technical problem which the claimed invention addresses would be successfully solved; and

(iii) considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person[175] (claimed solution to the objective technical problem would have been obvious to the skilled person in view of the state of the art).

This approach was primarily developed by the Technical Board to objectively assess the inventive step and under this approach, the assessment of the inventive step (i.e. a chemical invention) has to be preceded by a determination of the technical problem based on objective criteria and not on subjective criteria achieved by the inventor.[176] Under this approach, the application has to teach the ordinary person skilled in the art how to solve a technical problem and the technical problem is to be determined on the basis of such objective criteria.

It seems that the test of obviousness in India is also based on the technological advancement as compared to the existing knowledge or having economic significance or both, that makes the invention not obvious to the PHOSITA.[177]

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[174] EPO Examination Guidelines, Part G, Chapter VII, section 4, the assessment of Inventive Step. Available from https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g.htm.

[175] Ibid., Chapter VII, Part 5 - Problem-Solution Approach.

[176] *T 0001/80 (Carbonless copying paper) of 06.04.1981.* Available from https://www.epo.org/law-practice/case-law-appeals/recent/t800001ep1.html.

[177] Indian Patents Act, s. 2 (1) (ja).

For example, in *Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries Ltd.,*[178] the Supreme Court held that the inventive step in India is strictly, subjectively and objectively judged,[179] having considered the technological advancement as compared to the existing knowledge that makes the invention not obvious to a person skilled in the art. The Supreme Court further identified the following two questions for the determination of inventive step:

1. *Biswanath Prasad* Test 1- Prior art explicitly suggested the invention to a person skilled in the art - "Obvious to try". The question to be determined is whether the alleged discovery lies so much out of track of what was known before so as not to naturally suggest itself to a person thinking on the subject; it must not be obvious or a natural suggestion of what was previously known.[180]

2. *Biswanath Prasad* Test 2 - Problem-solution approach – the question to be determined is this: Had the document been placed in the hands of a competent craftsman (or engineer as distinguished from a mere artisan), endowed with the common general knowledge at the "priority date", who was faced with the problem solved by a patentee but without knowledge of the patented invention, would he have said, "this gives me what I want".

It seems to suggest that the semblance of the *Graham* factors as well as the EU problem-solution approach has been recognized in Indian cases for the determination of inventive standard. It is to be observed, however, that the "obvious to try" test has been recognized and modified in India by the application of strict, subjective and objective factors having considered the technological advancement as compared to the existing knowledge that makes the invention not obvious to a person skilled in the art.

(C) *WINDSURFING* TEST AS AN APPROPRIATE APPROACH IN SRI LANKA

In the UK, an overall structured test for the assessment of inventive step has been adopted in the Windsurfing/Pozzoli Test for obviousness. The Courts of the UK currently follow the 4 elements of the *Windsurfing International Inc. v. Tabur Manne (Great Britain) Ltd.*,[181] which were slightly reformulated in the Court of Appeal case of *Pozzoli SpA v. BDMO SA*[182] for the determination of inventive step in the UK, as follows:

1. (a) Identify the notional person skilled in the art; and (b) identify the relevant common general knowledge of the person;

2. Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;

3. Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;

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[178] *Biswanath Prasad Radhey Shyam v Hindustan Metal Industries,* AIR 1982 SC 1444.

[179] Ibid.

[180] The test suggested by Salmon, L.J. in *Rado v. John Tye & Son Ltd.* (1967) RPC 297, 305 - "Whether the alleged discovery lies so much out of the track of what was known before as not naturally to suggest itself to a person thinking on the subject; it must not be the obvious or natural suggestion of what was previously known".

[181] *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.,* (1985) R.P.C. 59.

[182] *Pozzoli Spa v. BDMO SA* (2007) EWCA Civ. 588 (22.06.2007).

4. Viewed without any knowledge of the alleged invention as claimed, do these differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

The Indian Guidelines for Examination and Search of Patent Publication[183] suggests that India has adopted the current UK Windsurfing/Pozzoli Test for obviousness. The Indian Guidelines for examination and search of patent application provide that the following factors should be considered objectively by the Indian Patent Office[184] for the determination of inventive step:

1. Identify the inventive concept of the claim in question;

2. Identify the "person skilled in the art" - i.e. competent craftsman or engineer as distinguished from a mere artisan;

3. Identify the relevant common general knowledge of that person at the priority date;

4. Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;

5. Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of inventive ingenuity?[185]

This seems to suggest that *Graham* factors have been incorporated into the 2nd, 3rd and the 4th elements of "*Windsurfing* approach" which has also been adopted by the Indian Manual of Patent Office Practice and Procedure, as described. It is most likely that the elements of the *Graham* test are an expansive and flexible approach to the obviousness question for the determination of inventiveness. This suggests that the Indian examination guidelines follow the *Windsurfing or Pozzoli* test adopted by the UK for the assessment of the inventive step rather than the 3 steps-problem and solution approach (PSA) of the European Union.

Thus, the resemblance of *Graham* factors can be seen in the Indian approach; for example, step 3 of the *Graham* test is more or less equivalent to the first step of the Indian approach and step 2 of the *Graham* test is more or less equivalent to the third step of the Indian approach (or *Windsurfing or Pozzoli*). On the other hand, the third step of the EU problem solution approach (PSA) is more or less equivalent to the fourth step of the Indian (*Windsurfing or Pozzoli)* approach.

In line with the strict inventive step criteria and having regard to the low level of technological development in the fields of biotechnological and pharmaceutical inventions, the inventive step in Sri Lanka can be strict, subjectively and objectively judged having considered the technological advancement over the existing knowledge.

It is submitted that *Graham* factors have been incorporated in the "*Windsurfing /Pozzoli* approach", which have also been adopted by developing countries such as India as the basic objective standard of inventive step. It is suggested that Sri Lanka should adopt the modified principles of the "*Windsurfing/Pozzoli"* objective approach consisting of the following 5 steps to reduce the risk of hindsight in the context of statutory reforms and respond to the statutory question posed by section 65 of the IP Act as follows:

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[183] Indian Guidelines for search and examination of patent applications 2015, p. 35 & Guidelines for examination of patent applications in the field of pharmaceuticals 2014, p. 20.

[184] Ibid.

[185] Ibid.

1. Identify the inventive concept embodied in the claim and if that cannot readily be done, construe it;

2. Identify the person skilled in the art and the common general knowledge of the person;

3. Identify the closest prior art relevant to the claimed invention;

4. Identify what, if any, differences exist between the prior art and the claimed invention;

5. Decide, without any knowledge of the claimed invention, whether these differences constitute steps which would have been obvious to the person skilled in the art or whether they require any degree of invention.

(a) What is the Inventive Concept Embodied in the Claim? - Step 1

It is important to have a clear understanding of the meaning of the inventive concept, skilled person in the art, common general knowledge, closest prior art and differences identified in the proposed objective factors for the determination of inventive standard in Sri Lanka.

“Inventive concept” is concerned with the identification of the core (or kernel, or essence) of the invention - the idea or principle, of more or less general application which entitles the inventor’s achievement to be called inventive.[186] However, there is a difference between the “inventive concept” of a claimed invention and its “technical contribution to the art”.[187]

The invention’s technical contribution to the art is concerned with the evaluation of its inventive concept—how far forward has it carried the state of the art? The inventive concept and the technical contribution may command equal respect, but that will not always be the case.[188]

It is the inventive concept of the claim in question that must be considered, not some generalized concept to be derived from the specification as a whole.[189] However, different claims can, and generally will, have different inventive concepts. The first stage in identifying the inventive concept of a claim is likely to involve a purposive construction of the claim – what does it mean to the skilled person?[190] The inventive concept is concerned with the identification of essential elements of the invention with the assistance of the person skilled in the art.[191]

In *Generics (UK) Limited and others v H Lundbeck A/S,* [192] Lord Walker explained however, that there is a difference between the “inventive concept” of a claimed invention and its “technical contribution to the art” and that the novel and non-obvious product claimed formed the technical contribution to the art, whilst the process of how it had been made formed the inventive concept. He stated at paragraph 30:

> *"Inventive concept" is concerned with the identification of the core (or kernel, or essence) of the invention—the idea or principle, of more or less general application (see Kirin-Amgen [2005] RPC 169 paras 112-113) which entitles the inventor's achievement to be called inventive. The invention's technical contribution to the art is concerned with the evaluation of its inventive concept—how far forward has it carried*

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186 *Kirin-Amgen Inc v. Hoechst Marion Roussel Ltd.* [2005] RPC 169, paras. 112-113.
187 *Generics (UK) Limited and others v. H Lundbeck A/S* [2009] UKHL 12.
188 Ibid.
189 *Unilever PLC v Chefaro Proprietaries Ltd* [1994] RPC 567 at 580.
190 Ibid.
191 *JK Smit & Sons Inc v. McClintock* (1940) SCR 279.
192 *Generics (UK) Limited and others v H Lundbeck A/S,* 2009] UKHL 12, [2009] RPC 13.

the state of the art? The inventive concept and the technical contribution may command equal respect but that will not always be the case".

The identification of the essence will thus involve constructing something akin to a précis (essential points), stripping out unnecessary verbiage from the purposefully construed claim.[193]

(b) A Person Having Ordinary Skill in the Art (PHOSITA)

The PHOSITA is a hypothetical person with common sense, who has to evaluate the differences between the invention and the prior art and determine whether modifications or combinations of prior art references are obvious, having considered the type of problem to be solved. His/her background, experience, skills, education and practical qualifications and the relevant technology come into play when deciding whether a PHOSITA could have performed a given combination or modification of prior art, rendering the invention obvious.[194]

This will also play a role when deciding whether the combination or modification would have been beyond the PHOSITA's creativity, and therefore not obvious.[195] In the EPO, the person skilled in the relevant field art is a skilled practitioner in the relevant field of technology, who possesses an average knowledge and ability in the art at the relevant date and general knowledge in the relevant field.[196] Thus, he/she must be prepared to display a reasonable degree of skill and common knowledge of the art in making trials and to correct obvious errors in the specification.

In Brazil, however, the person skilled in the art must not only be a college educated professional with regular academic knowledge in that field, but he must also have practical experience in the specific area connected to the invention. [197]

The inventive step of an invention should be assessed against the expertise of a person skilled in the art, whose required skills and knowledge should be above a person having ordinary skill in the art to ensure that patents are granted to inventions that have made a genuine technical contribution to the prior art. The PHOSITA should thus, be able to (i) identify the scope of the claimed invention and understand the elements of the prior art; (ii) compare the elements of the prior art and claimed invention and (iii) ascertain whether or not the invention satisfies the inventive step requirement.

The person having ordinary skill in the art in Sri Lanka cannot be a person of "ordinary" level, such as a mere artisan, but must be an expert such as a competent craftsman or engineer who is academically or professionally competent and possesses average general knowledge in the specific technical area. It is submitted that the Sri Lankan IP Act should also require the knowledge of an expert in the relevant field to assess the inventive step, thereby leading to a more rigorous analysis of the inventive step, which is consistent with the policy suggested in this paper.

Sri Lanka is also free to determine for specific factors to be taken into account for the determination of the level of ordinary skill in the relevant art of the person. In some jurisdictions, such as the US, factors that may be considered in determining the level of ordinary skill in the art include: (i) educational levels of both the inventor and active workers in the field; (ii) type

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[193] UK Manual of Patent Practice, 2016, Identifying the Inventive Concept, 3.34.

[194] Zachary Quinlan, "Hindsight Bias in Patent Law; Comparing the USPTO and the EPO", *Fordham International Law Journal*, Vol. 37, Issue 6 (2014), p. 1800.

[195] Ibid.

[196] EPO Technical Board decisions, T/4/98, T 143/94 and T 426/88.

[197] Gabriel F. Leonardos, "The Inventive step Requirement in Brazil", AIPPI Forum Buenos Aires 2009, 11 October 2009, p. 10. Available from https://silo.tips/download/the-inventive-step-requirement-in-brazil.

of problems encountered in the art; (iii) prior art solutions to those problems; (iv) sophistication of the technology; and (v) rapidity with which the invention was made.[198] It is submitted that the above factors could also be adopted in Sri Lanka to determine the level of ordinary skill in the pertinent art of the person.

(c) Common General Knowledge in the Art

The inventive step is, thus, measured against what will be obvious to a person skilled in the art, who is deemed to have the common general knowledge in the field to which the invention relates.[199] To a large degree, the capacities of the skilled person will be determined by the nature of the common general knowledge identified as being "relevant".[200] The UK courts, for example, explained the common general knowledge in *Raychem Corp's Patents* [201] as follows:

> "The common general knowledge is the technical background of the notional man in the art against which the prior art must be considered. This is not limited to material he has memorized and has at the front of his mind. It includes all that material in the field he is working in which he knows exists, which he would refer to as a matter of course if he cannot remember it and which he understands is generally regarded as sufficiently reliable to use as a foundation for further work or to help understand the pleaded prior art. This does not mean that everything on the shelf which is capable of being referred to without difficulty is common general knowledge nor does it mean that every word in a common textbook is either.
>
> In the case of standard textbooks, it is likely that all or most of the main text will be common general knowledge. In many cases, common general knowledge will include or be reflected in readily available trade literature which a man in the art would be expected to have at his elbow and regard as basic reliable information".

It has been further held that the reference to "public general knowledge" should be read as "common general knowledge".[202] However, even individual patent specifications and their contents do not normally form part of the relevant common general knowledge.[203] It is not sufficient to prove that a particular disclosure is common general knowledge if it is made in an article, or series of articles, in a scientific journal unless it is accepted generally by those engaged in the art to which it relates.[204]

Based on common elements across jurisdictions, the following are the sources from which the skilled person can acquire his/her information which can be characterized as the level of skill of the person in the relevant art: [205]

1. A person skilled in the art (PHOSITA) is presumed to have access to all publicly available state of the art;

2. PHOSITA is able to comprehend all technical matters in the relevant art;

3. PHOSITA possesses academic or professional knowledge of the technology in question;

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[198] UNCTAD, *A Reference Guide*, p. 69.
[199] Jennifer Davis, *Intellectual Property Law* (4th ed., Oxford, 2012), p. 297.
[200] Ibid.
[201] *Raychem Corp's Patents* [1998] RPC 31.
[202] *British Ore Concentration Syndicate Ltd v Minerals Separation Ltd* (1909) 26 RPC 124.
[203] *General Tire & Rubber Co v. Firestone Tyre & Rubber Co Ltd* [1972] RPC 457.
[204] Ibid.
[205] World Intellectual Property Organization (WIPO), Standing Committee on the Law of Patents, Study on Inventive Step, SCP/22/3, 6 July 2015, pp. 7-9.

4. PHOSITA possesses practical skill in the technical field in question;

5. PHOSITA is aware of or possessing common general knowledge in the relevant art at the relevant date;

6. PHOSITA has the average skill and the capacity to use prior art as is usual for the technical field in question;

7. PHOSITA is availed of the normal means and capacity for routine experimentation in order to clarify ambiguities on known technology;

8. If the problem prompts a search in another technical field, a PHOSITA in that field is the person qualified to solve the problem;

9. PHOSITA may be a team of persons working in various relevant fields.

(D) COMBINATION OF PRIOR ART REFERENCES & REASONABLE EXPECTATION OF SUCCESS IN BIOTECHNOLOGY INVENTIONS

As it is followed in the US, it is unlikely that the application of "obvious to try" as a stand-alone test would be the appropriate test to assess the inventive step in biotechnology cases in Sri Lanka where, the combination of prior art references is generally producing unpredictable results, unless there is evidence of a reasonable expectation of success.

The TSM is also a helping test for the determination of inventive step in cases involving a combination of known elements according to known methods which is likely to be obvious when it does no more than yield predictable results. The TSM however, may not be appropriate in cases involving biotechnology where the research involves unpredictable results. As described, *Kubin* suggested that the reasonable expectation of success is the appropriate test to decide the obviousness in biotechnology cases as opposed to predictability tests suggested by *KSR,* which is not appropriate in biotechnology cases. *Kubin* appears to be the appropriate test for biotechnology inventions as described in Part IV; the standard of obviousness is the "reasonable expectation of success" as held by the Federal Circuit in *O'Farrell* although the reasonable expectation of success requirement for obviousness does not necessitate an absolute certainty of success.

The same approach appears to have been applied in the EU. The test of reasonable expectation of success was developed by the EPO to assess inventive step in the field of genetic engineering and biotechnology. An invention under this test is considered to be obvious within the meaning of the European Patent Convention's Article 56,[206] when there is a suggestion in the prior art for the invention with a reasonable expectation of success.[207]

An invention in the EPO would, thus, be considered obvious when the skilled person would have carried out the invention in expectation of some improvement or advantage and if the answer is in the affirmative, the invention lacks inventive step.[208] In other words, obviousness

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[206] European Patent Convention, Article 56.

[207] EPO Case Law of the Boards of Appeal, Patentability, Inventive Step, 9.3.1. Existence of a combination invention.

[208] *T 0002/83 (Simethicone Tablet)* of 15.03.1984. Available from https://www.epo.org/law-practice/case-law-appeals/recent/t830002ep1.html (accessed on 13.10.2011).

is not determined purely on the predictability of the invention, but having regard to the question of whether there was a reasonable expectation of success.[209]

As regards biotechnological inventions, the making of rational predictions about the possibilities of success and the evaluation of the reasonable expectation of success are regarded as meaningful and reliable tools in the assessment of inventive step.[210] In assessing inventive step in genetic engineering cases, inventive step is not denied on the sole basis that a project is obvious to try. But in cases where there is a reasonable expectation of success, the said project can be put into practice, and the try and see approach may apply.[211] However, what constitutes a reasonable expectation of success must be considered on a case by case basis and based on the several different documents, it could be decided whether success is plausible.[212]

In spite of uncertainties which always characterize experiments using biological compounds like proteins and antibodies, in assessing inventive step, the pertinent question to be asked is: whether the PHOSITA at the relevant date of the patent, had a reason to adopt a skeptical attitude or if he would have had either some expectations of success or at worst, no particular expectations of any sort, but only a "try and see" attitude.[213]

On the other hand, the test of reasonable expectation of success which has been recognized both in the US and EU has also been adopted in the Indian Examination Guidelines.[214] The Indian Guidelines provide that "'the mere existence in the prior arts of each of the elements in the invention will not *ipso facto* mean obviousness'".[215] As "'most of the inventions are built with prior known puzzle-pieces'", there must be a reasonable expectation of success or in other words, "'coherent thread leading from the prior arts to the obviousness, the tracing of the thread must be an act which follows obviously'".[216] This means that when the skilled person would have carried out the invention in reasonable expectation of the success, an invention would have been obvious to such person of ordinary skill in the art at the time the invention was made. [217] The Indian guidelines regard the presence of reasonable expectation of success embedded in the prior art which motivates the skilled person to reach to the invention as a crucial determining factor in ascertaining inventive step.[218]

The Indian guidelines also provide that obviousness cannot be avoided by showing some degree of unpredictability in the art so long as there was a reasonable probability of success. Similarly, the obviousness does not require absolute predictability of success, but only a reasonable expectation of success as opposed to absolute predictability would be sufficient.[219] It is submitted that *Kubin* appears to be the appropriate approach that is suitable for Sri Lanka for the assessment of obviousness as the test of reasonable expectation of success in combination of prior art references in biotechnology and pharmaceutical inventions.

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[209] *T 0149/93 (RETINOIDS/Kligman II)*, 23.03.1995. Available from https://www.epo.org/law-practice/case-law-appeals/recent/t930149eu1.html (accessed on 11.10.2011).
[210] *T 0737/96 (Astaxanthin/DSM)* of 09.03.2000. Available from https://www.epo.org/law-practice/case-law-appeals/recent/t960737eu1.html (accessed on 12.08.2011).
[211] *T 0091/98 (Antiviral nucleosides/WELLCOME)* of 29.05.2001, para. 8. Available from https://www.epo.org/law-practice/case-law-appeals/recent/t980091eu1.html (accessed on 23.08.2011).
[212] *T 0918/01 (Inflammatory Bowel Disease/ BIOGEN)* of 06.10.2004, para. 9. Available from https://www.epo.org/law-practice/case-law-appeals/recent/t010918eu1.html (accessed on 12.10.2011).
[213] T 0759/03 (FIV/ST. VINCENT'S INSTITUTE, et al) of 17.08.2006, para. 36. Available from https://www.epo.org/law-practice/case-law-appeals/recent/t030759eu1.html (accessed on 10.10.2011).
[214] Indian Guidelines for examination of patent applications in the field of pharmaceuticals, October 2014, p. 20.
[215] Ibid.
[216] Ibid.
[217] Ibid.
[218] Ibid.
[219] Ibid.

(E) STATUTORY GUIDELINES FOR COMBINATION OF PRIOR ART ELEMENTS (NEW FORM OF KNOWN SUBSTANCES)

It is significant to note that section 3 (d) exception under the Indian Patents Act will play an important role in restricting patenting of a trivial combination or modifications of known prior art elements or new use of known substances unless it results in the enhancement of the efficacy of that substance. Section 3 (d) reads as follows:

> "The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use of a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
>
> Explanation: For purposes of this clause, salts, esters, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."

This section has the following three limbs:

1. A new form of a known substance which does not result in the enhancement of the known efficacy of that substance;
2. The mere discovery of any new property or
3. New use of a known substance or process, machine or apparatus.

This seems to suggest that mere combinations of known substances and new forms of known substances will not be patentable and is not treated as a new substance unless such existing substance can demonstrate increased efficacy or significant enhancement of the known efficacy in properties. The term "efficacy" in the case of a pharmaceutical substance has been defined by the Madras High Court[220] as "therapeutic effect" in healing a disease or "having a good effect on the body". However, in the case of non-pharmaceutical substances, the Supreme Court in *Novartis AG v. Union of India* [221] stated that the "significant enhancement of efficacy" in section 3(d) of the 2005 patent amendment Act can be demonstrated by significantly "improved power of producing an effect". This means that the test of "efficacy" would vary from case to case as per the situation and it would depend upon the function, utility or the purpose of the product under consideration. [222] The Supreme Court further held that in the case of a medicine that claims to cure a disease, the test of efficacy can only be "therapeutic efficacy" and a "therapeutic efficiency" of a medicine must be judged strictly and narrowly. [223]

The Supreme Court held in *Novartis AG v. Union of India* [224] that the invention in question was only a new form of a known substance called Imatinib Mesylate also known as "Gleevee" or "Glivec" (a combination of Imatinib and methane sulfuric acid addition salt) without having any significant improvement of efficacy and therefore not patentable under section 3 (d) of the Act.

Section 3 (d) exception is significant to determine the obviousness in pharmaceutical inventions, in particular, as it restricts patenting of trivial modifications of patented inventions

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[220] *Novartis AG v. Union of India* (2007) 4 Madras L.J. 1153.
[221] *Novartis Ag vs Union of India & Ors* (SC) CIVIL APPEAL Nos. 2706-2716 of 2013, decided on 01.04.2013.
[222] Ibid., paragraph 180.
[223] Ibid.
[224] *Novartis Ag vs Union of India & Ors* (SC), paragraphs 193-195.

by disallowing patenting of new use of known substances unless it results in the enhancement of the efficacy of that substance.

It is submitted that a clarification similar to Indian 3 (d) exception under section 65 of the IP Act is more likely to restrict the patenting of new use of known pharmaceutical substances unless it results in the enhancement of the efficacy of that substance. This approach can equally be applied to bio-pharmaceutical inventions in Sri Lanka, which usually produce unpredictable results so that the patenting of new forms of known trivial substances without passing the test of "efficacy" would be ineligible for patent protection. This is likely to promote local innovations by having access to the genetic material in the public domain to make innovations without infringing the exclusive patent rights.

(F) SECONDARY CONSIDERATIONS

Like in the US, secondary considerations were developed in cases of doubt, where the objective evaluation of the prior art teachings fails to assess the inventive step.[225] Secondary factors such as commercial success, long felt, but unsolved needs, failure of others and unexpected results may be a fundamental part of the overall section 65 obviousness inquiry in Sri Lanka[226] to determine the obviousness, and the weight to give it in Sri Lanka, such considerations are just that—secondary, and they cannot make a clearly unpatentable product patentable.

[225] *T 0645/94 (Treibladungspulver//WNC-NITROCHEMIE)* of 22.10.1997. Available from https://www.epo.org/law-practice/case-law-appeals/recent/t940645du1.html (accessed 10.10.2011).
[226] Section 65 of the Intellectual Property Act which defines the inventive step.

PART VI

RAMAWICKREMA GAMACHCHIGE RAVINDRA V. RIYAD ISMAIL AND DIRECTOR GENERAL OF INTELLECTUAL PROPERTY

To the knowledge of the author, the Commercial High Court patent infringement case of *Ramawickrema Gamachchige Ravindra v. Riyad Ismail and Director General of Intellectual Property*,[227] appears to be the only case that has applied the *Windsurfing* test for the assessment of inventive step. The case involves however, a mechanical/electronic invention. The 1st Defendant's invention concerned a cooking stove titled "EZ Turbo Charcoal Stove" that could use charcoal efficiently and safely while also providing a cost effective and convenient cooking solution to specific problems in the field of technology. It was a thermostatically controlled automated fan with built in manual override function that helps to regulate and maintain the optimum cooking temperature, thus, avoiding overcooking/undercooking of food and also helps increase the efficacy of the stove by saving of fuel.

One of the issues was whether the invention involved an inventive step within the meaning of section 65 of the IP Act. The High Court applied the Windsurfing tests and held that the 1st Defendant's invention entails a high degree of technical uncertainty at its outset and involves a technical advance as compared to the existing knowledge that makes the invention not obvious to the PHOSITA. The High Court held that the 1st Defendant had applied ingenuity and skill rather than a mere incremental change from the one that is found in the public domain, which makes the invention not obvious to the PHOSITA.

In holding that the 1st defendant's "EZ Turbo Charcoal Stove" is novel, involves an inventive step and industrial applicability with unique and novel features, the High Court applied the 5 steps, including the identification of common general knowledge and inventive concept adopted in *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd*.

[227] *Ramawickrema Gamachchige Ravindra v. Riyad Ismail and Director General of Intellectual Property,* HC/Civil/01/2010/IP decided on 07.02.2018.

CONCLUSION

This paper argued that the current Sri Lankan approach for the determination of inventive step/non-obviousness is not settled in the area of biotechnology and pharmaceutical fields in comparison with countries such as the US, EU, UK and India. The solitary case decided by the Commercial High Court, however, is limited to an invention in the area of mechanical/electronic technology.

It was further argued that any approach to grant new patents for trivial improvements to existing knowledge, such as combined elements of living biological materials without the evidence of significant technological advancement to the existing prior art would go against the national patent law/policies of Sri Lanka.

This article examined an appropriate test/s for the assessment of inventive step in Sri Lanka, including the justification of various tests adopted by the US, EU, UK and India, including the evolution of inventive test standards and justification of different statutory and judicial approaches. It was highlighted that the semblance of *Graham* factors and certain judicial approaches adopted by the US, EU and UK are applied in developing countries such as India, which has further adopted their own legal approaches to restrict the exclusive rights to the minimum recognized by the TRIPS Agreement to suit its local patent law and local innovation landscape.

It argued that the *Windsurfing* approach that was adopted by the UK is more consistent with the US statutory definition and the *Graham* factors and therefore, it is an appropriate approach for Sri Lanka for the determination of the inventive step in a structured way. As for the inventions in the field of biotechnology in particular, it argued that the approach adopted in *re Kubin* that the evidence of a reasonable expectation of success remains an important component of obviousness determination in the biotechnological arts as followed by *O' Farrell* is appropriate for Sri Lanka.

It was pointed out that given the low level of technological development, Sri Lanka should adopt a strict inventive step standard so that the patenting of incremental and trivial inventions would be restricted to the minimum required by the TRIPS Agreement while the local innovations would be able to utilize the existing technologies for follow-on local innovations.
In this context, it remains to be seen whether the application of the *Windsurfing* approach in the Commercial High Court of *Ramawickrema Gamachchige Ravindra v. Riyad Ismail and Director General of Intellectual Property* also remains an appropriate approach with necessary modifications, for the determination of the inventive step in Sri Lanka in biotechnology and pharmaceutical fields.

The correct approach for the assessment of inventive step is extremely important to a less technologically advanced country such as Sri Lanka to determine the extent to which the exclusive patent rights should be provided to patent owners. This approach is extremely useful for local innovators and researchers' access to the public domain and free competition to prevail in a manner consistent with its policy objectives and the provisions of the TRIPS Agreement.

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ISSN 1819-6926