Challenging the Validity of Patents: Stepping in Line with EPO and US Jurisprudence

Abstract

As a matter of law patents are granted with a presumption of validity. However, with the public interest considered as an essential basis for the granting of exclusive rights, subject only to procedural fairness, a competent national or regional authority may revoke or invalidate any patent that fails to comply with formal patentability requirements as grounded in law. Remarkably, at the heart of most successful patent regimes lies a sensible framework that allows any interested third-party to challenge the validity of questionable patents except that these instruments are not found within the least developed patent regimes. Importantly, given the conceptual reasoning that invalidly granted patents stand to prejudice the overriding public interest, a principle centrally established in the patent system, this article examines the extent to which states can implement legislative instruments on patent opposition to mitigate the potential consequences of granting questionable patents. Therefore, drawing on the jurisprudence containing substantive law and procedural requirements of patent opposition proceedings within the EPO and USPTO, the author argues that citizens in whose interests’ patents are granted have the right to participate in the patent system and to check that only inventions that deserve exclusive rights are granted patents. The conclusion is that, if WTO members without patent opposition mechanisms were to explore and strengthen their regimes, citizens, competitors and other interest groups would be able to detect and invoke key provisions to challenge the granting of invalid patents, while maintaining that the patent system is untainted and free from questionable patent claims.

Keywords: Patents, Opposition Proceedings, Public Interests, Questionable Patents.

I. Introduction

The patent system was designed with the intention of promoting innovation, and the exclusive rights granted to patentees are subject to limitations. Monopoly rights confer on their owners the right to prevent others from carrying out certain acts, such as using, selling or importing patented products or processes without the patent owner’s consent. Mainly, the patent landscape is governed by the World Trade Organisation’s (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement), which provides adequate standards concerning the availability, scope and use and appropriate means for the enforcement of patent rights. As a matter of empirical logic, just as the patent system has its positives, there also exist social cost implications. The social cost aspect of the patent system is related to the notion of static efficiency losses resulting from monopoly and other market distortions, which can undermine the public interest.

1 Reichman and Hasenzahl 2004, p. 13.
2 § 271(d)(4) of 35 U.S.C. 1952. Dawson Chem. Co. v Rohm & Haas Co., 448 US 176, 215 (1980) in which the judgment recognised the long-settled view that the essence of a patent grant is the right to exclude others from profiting by the patented invention. See, Drahos and Braithwaite 2002, p. 151, explaining that the patent monopoly by its nature gave its owner strong rights over the making of the invention including the terms on which it could be licensed.
3 The WTO Agreement 1994.
4 The TRIPS Agreement 1994.
5 Part II, Section 5, Article 27(1) of TRIPS. See, UNCTAD/ITE 1 1996, paras. 111–114.
7 Cotter 2013, p. 47.
Importantly, Article 8 establishes principles that underpin the entire TRIPS Agreement, and this provision captures well the need to protect the public interest. However, this is not automatic, and it does not exist in a vacuum. The central thrust is that while patent law provides the legal framework for the patent system, it does not define the scope of public interest in terms of a specific outcome. Keeping in perspective this understanding, several other features should support the patent system so that it works in the way that it is intended to work to promote this. To meet this objective, patent law should lay down some rigorous requirements, both procedural and substantive, for obtaining patents, in satisfaction of the public interest. Those requirements are fundamental to a well-functioning patent system, as they were created to ensure that only those inventions that are worth protecting for the purposes of facilitating innovation and meeting the broad public interest obtain patent protection.

Despite Article 29 of TRIPS setting out certain conditions that the applicant must satisfy a requirement to disclose the invention in a manner sufficiently clear and complete, in reality, it may happen that a substantive examiner in the absence of lax patentability standards, as an instrument of government policy, may overlook a piece of prior art and advertently reach a positive decision regarding the patentability of the claimed invention. In other words, regardless of patent law normally having a general set of legal rules to govern the validity of a patent, even with the most rigorous examination system, the state cannot guarantee that the rights that it grants are valid, as there is always the possibility that a prior art may be overlooked or a specification misunderstood. That is, the increase in demand for patent rights places additional pressures on Patent Offices to examine and grant patent applications, and examiners may make mistakes in judging novelty or inventive step in the light of the state of the art that the patent search revealed.

Added to this fact is the argument that some applicants, with a view to obtaining exclusive rights, may submit questionable patent applications. The general meaning of a “questionable patent” relates to “poor quality” or any patent that has been granted improperly. Where this is the case, it will provide a workable basis for invalidating such patents given its presumed inconsistency with the general statutory requirements. These include novelty, non-obviousness, usefulness, and the requirement of disclosure as grounded in the law against which patent applications are evaluated. Moreover, several grounds are often covered, which

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8 Yu 2009, p. 1009, stating that Article 8(1) lays out the public interest principle in the TRIPS Agreement. Reichman 1995, p. 352, stating that TRIPS rules reflect compromise efforts to balance private and public interests.
9 WIPO, SCP/12/3 Rev.2 2008, p. 70.
10 ibid. p. 68, para. 255.
12 WIPO, SCP/14/5 2009, p. 5, para. 18.
13 WIPO, SCP/12/3 Rev.2 2008, p. 63, para. 266. See also, Beier 1990, pp. 255-256.
15 WIPO, SCP/12/3 Rev.2 2008, p. 56, para. 198.
18 Burk and Lemley 2009, p. 25.
19 Drahos 2010, p. 72. See also, “WIPO, SCP/12/3 Rev.2 2008, p. 56, para. 201.
20 Manu 2015, p. 403.
21 Note that there is no universally accepted term for patents that are issued by the Patent Office but do not meet the statutory standards for patents, and different sources refer to them with different terms. For instance, the Federal Trade Commission (FTC) Report 2003, ch. 5, p. 1 refers to such patents as ‘improvidently granted patents or patents of improper breadth’. See also, Shapiro 2004, p. 1018.
commonly include: suppression of information about foreign filing, and anticipation having regard to traditional knowledge.24 Traditionally, opposition proceedings have been limited to competitors and governments.25 The government can challenge issued patents and even revoke them.26 However, such government-led actions are currently rare.27 Notably, several countries have broadened this to include interested persons, such as civil society organisations.28

Consequently, where the patent system allows too many questionable patents to prevail, without offering an inexpensive and timely mechanism for invalidation, such a regime will not be fit for purpose, as it ignores the social benefit gained by granting patents, and overlooks the fundamental fact that patents are for the benefit of the public.29 It is on this foundation that several countries continue to take policy decisions that allow opposition proceedings to restrain the granting of questionable patents and claim a right over the same.30 The problems associated with the existence of questionable patents, and the need for an effective, inexpensive legislative vehicle for challenging them is not an entirely new norm to the patent system.31 Importantly, the patent validity challenge is not an accident or a mistake; rather, it is an inherent part of our patent system.32 No international treaty sets standards on the general framework of patent opposition mechanisms as such.

Importantly, some general procedural requirements prescribed in the TRIPS Agreement, and the Patent Law Treaty (PLT)33 may also be applicable to opposition procedures. The attitude of these two treaties is, via the international accepted standards, to remind states of the guiding principles of fundamental fairness that must be the hallmark of opposition proceedings rather than to strictly prescribe a constitutive approach to the same. To take an illustration of this, Articles 32 and 62 of TRIPS and the PLT Article 10(2) leave open cases in which signatory states can exercise wider discretion on this subject matter.34 Under the framework of TRIPS, the Agreement does not state specifically the grounds upon which members should provide opposition mechanisms.35 Therefore, members are free to provide, or not to provide, an opposition mechanism in their national laws,36 except that the most successful patent regimes, such as the European Union (EU),37 the United States (US),38 Japan39 and India,40 which uphold the notion of public interest protection, allow for some form of opposition mechanism.

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25 WIPO, SCP/12/3 Rev.2 2008, para. 51.
27 Lemley and Shapiro 2005, p. 90.
29 Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 5-6 (1966).
30 Puasiri 2013, p. 223.
31 Lemley and Shapiro 2005, p. 95.
34 Taubman, Wager and Watal (eds.) 2012, p. 115.
36 WIPO, SCP/14/5 2008, p. 7, para. 27.
Nevertheless, these instruments of contestation are not common in some countries,\textsuperscript{41} or may be highly ineffective in countries where they exist,\textsuperscript{42} whereas a conceivable reality is that a high number of questionable patents may be being issued by Patent Offices and, at the same time, many of them are not being invalidated.\textsuperscript{43} Importantly, given the conceptual reasoning that invalidly granted patents stand to prejudice the overriding public interest, a principle centrally established in the patent system, this article examines the extent to which states can implement legislative instruments on patent opposition to mitigate the potential consequences of granting questionable patents. Therefore, drawing on the jurisprudence containing substantive law and procedural requirements of patent opposition proceedings within the EPO and USPTO, the author argues that citizens in whose interests’ patents are granted have the right to participate in the patent system and to check that only inventions that deserve exclusive rights are granted patents. The conclusion is that, if WTO members without patent opposition mechanisms were to explore and strengthen their regimes, citizens, competitors and other interest groups would be able to detect and invoke key provisions to challenge the granting of invalid patents, while maintaining that the patent system is untainted and free from questionable patent claims.

\section*{II. Deficient Prosecution and the Grant of Questionable Patents}

A common normative belief in the patent system is that patents are normally granted to protect genuinely new and inventive products and processes.\textsuperscript{44} Notwithstanding this, patents are not awarded automatically but rather, they must be applied for and will only be granted if the examiner in the Patent Office, via the prosecution process, considers that the application meets all of the necessary legal requirements; the key requirements, as already mentioned, are that the invention is novel and not obvious.\textsuperscript{45} Some countries have adopted strict patentability criteria regarding what does and does not deserve a patent, via the prosecution process.\textsuperscript{46} The common theme of this stringent system is based on the notion that the lower the quality of patents, the greater the fraction of rights that have been improperly issued, and the less efficient the patent system is at stimulating innovation and promoting the public interest.\textsuperscript{47}

However, it is important to keep in mind that even when a Patent Office has strict standards for patentability during patent prosecution, there is no guarantee that they will be adequately applied; put differently, such mechanisms are far from perfect.\textsuperscript{48} In a general legal sense, prosecution has a different context in IP law; it is the process of writing and filing a patent application and pursuing protection for the patent application with the Patent Office.\textsuperscript{49} Put differently, it is the stage between the filing of a patent application and its final disposition. This involves the entire administrative procedure through which a patent application becomes

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\textsuperscript{41} Williams 2006, parts II.C, I.E.
\textsuperscript{42} For example, the national legislation of Uganda and Tanzania-Zanzibar provides for pre- and post-grant administrative opposition procedures. \textit{See}, Section 28(7)-(12) Section 32(5) & (6) of the Uganda Industrial Property Act, 2013 & Sections 10(7)(a) and 16 of the Zanzibar Industrial Property Act of 2008. Burundi only provides for pre-grant administrative opposition procedures. \textit{See also}, Article 47 and 48 of Law No. 1/13 of July 28, 2009 relating to Industrial Property in Burundi. Article 16 of the Egyptian Law on the Protection of Intellectual Property Rights 82 of 2002 provides for only pre-grant opposition. The other African countries have neither pre-grant nor post-grant opposition mechanisms.
\textsuperscript{43} Shapiro 2004, p. 1028, citing costs as one of the limitations.
\textsuperscript{44} Correa 2007a, p. viii.
\textsuperscript{45} Murray 2016, p. 227.
\textsuperscript{46} Correa 2007a, p. 3.
\textsuperscript{47} Lemley and Shapiro 2005, p. 77.
\textsuperscript{48} Carrier 2011, p. 105.
\textsuperscript{49} FTC Report 2003, p. 27.
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a patent. However, patent examination is an *ex parte* proceeding between the Patent Office examiner and the applicant.\textsuperscript{50} It does not therefore seem sensible, following this one-sided procedure, to treat every granted patent as though it has always met some higher standards of patentability.\textsuperscript{51} Central to this debate is the pervasive and growing concern that the Patent Office grants far too many questionable patents, which, were they to be subjected to a thorough review, would be likely to be found invalid.\textsuperscript{52}

The causes of poor quality examination at the Patent Office are manifold and well documented in the literature.\textsuperscript{53} Frequently cited reasons include: inadequate Patent Office resources to thoroughly review each application, biased procedures that favour the patent applicant or skewed incentives that make it easier for an examiner to allow an application rather than reject it.\textsuperscript{54} These general insights shift the conventional view in a subtle but, importantly, understandable way and it becomes clear that the quality of a patent depends on the underlying examination at the Patent Office.\textsuperscript{55} The patent rules of practice and administrative regulations are the genesis of the problem, and driving this are evidentiary mechanisms that include presumptions and shifting burdens of proof.\textsuperscript{56} Put differently, this problem often flows directly from key administrative practices and operating procedures, whereby there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed.\textsuperscript{57}

This presumption obliges the Patent Office examiner to treat as true the patent applicant’s assertions, or documentary evidence that is filed regarding certain facts in relation to the asserted usefulness of the invention; unless countervailing evidence can be provided to dismiss the accuracy or reliability of such information then there is no legitimate basis to doubt the credibility of such an application.\textsuperscript{58} Under these constricted substantive and procedural environments, a patent applicant enjoys a presumption of patentability.\textsuperscript{59} That is, at the time of filing, the application is rebuttably presumed to comply with the utility, novelty, non-obviousness, and disclosure requirements of the patent law.\textsuperscript{60} This presumption allocates the burden of proof to the contrary, and it commonly tends to favour the issuance of a patent unless the Patent Office can establish a *prima facie* case for rejection of the patent application.\textsuperscript{61} Thus, the burden of proving unpatentability rests with the Patent Office.\textsuperscript{62} Under this conceptual logic, the Patent Office must issue a patent unless it can affirmatively prove that the invention is unpatentable.\textsuperscript{63}

\textsuperscript{50} ibid. p. 9.
\textsuperscript{51} ibid. p. 10.
\textsuperscript{52} Lemley and Shapiro 2005, p. 83. Lemley and Sampat 2008, p. 192, estimating that over 70 per cent of applications eventually issue as patents.
\textsuperscript{53} Kesan 2002, pp. 765-766.
\textsuperscript{55} FTC Report 2003, p. 19.
\textsuperscript{56} Durham 2009, § 5.1.
\textsuperscript{57} 35 U.S.C. § 112 para. 1.
\textsuperscript{59} A presumption is an assumption that must be drawn by the decision-maker in the absence of rebuttal evidence. See, Wigmore 1981, § 2491 (ed) Chadbourne, p. 305.
\textsuperscript{60} Seymour 2013, p. 995 & 997.
\textsuperscript{62} In re Rijckaert, 9 F.3d 1531, 1532 (Fed. Cir. 1993), finding that an examiner must affirmatively prove unpatentability.
\textsuperscript{63} In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992), if examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to the granting of the patent.
This presumption is seen by many as preserving the strength of patent applications given that this presumption is not to be overthrown, except by clear and cogent evidence that tilts the presumption. The scales are therefore tipped even further towards issuance if the examiner lacks the time, materials or incentives to conduct a high-quality examination. The bottom line is that anyone who files a patent application for anything starts off in a very good position.

Added to the foregoing assumption is the norm that an issued patent is presumed valid, and the courts require a party that challenges a patent to prove its invalidity with clear and convincing evidence to overturn that presumption. Perhaps the most important threshold requirement to invalidate a questionable patent is to establish that the claimed invention does not meet one or more of the patentability criteria. Still, the risk that a patent will surely be declared invalid is unpredictable.

Even though the patent applicant owes a duty of candor to the Patent Office, no-one believes that everything that the applicant knows about the invention ends up before the examiner despite a legal obligation on the patent applicant to disclose information material to patentability. Moreover, that duty does not require an applicant to search for prior art beyond that about which he already knows. We learn immediately that if the examiner does not produce a prima facie case (of obviousness), then the applicant is under no obligation to submit evidence of non-obviousness. Of course, the information deficit inevitably allows questionable patents to be granted. This difficult position is compounded by the fact that while the examiner may be aware of potential abuse, they often cannot lawfully reject an application on the grounds of poor disclosure, except in extreme cases. Several cases in which “patent trolls” and clear abuses of the system have occurred over the years, especially in the US, have shown that applicants in bad faith can take advantage of the mild enforcement of the duty of disclosure, and scholars have extensively discussed this problem.

Likewise, the US Manual of Patent Examining Procedure states that the USTPO “does not investigate” duty of disclosure issues and “does not . . . reject” applications on that basis. Within this notion, even if sound patent policy calls for targeted legislative intervention to sanitise the patent system, then this may not be a fruitful exercise at times. Moreover, patent examiners’ tasks are particularly challenging if the technological or scientific frontier is moving fast, and if relevant information has not yet been included fully in the written material.

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64 Miller 2004, 689, stating that the Patent Office appears to grant many patents that, when carefully scrutinised, fail to meet basic patentability standards.
65 Long 2002, pp. 667-668, observing that the constraints of time, information, and evidentiary standards create a situation where the Patent Office’s evaluation of a patent application may be so poor or hurried as to be near meaningless. Leslie 2006, p. 109. Shapiro 2004, p. 1019.
66 FTC Report 2003, ch. 5, p. 9, finding that Patent applicants are in a great position because by filing an application they are presumptively entitled to receive the grant.
67 ibid. p. 8.
68 ibid. p. 9.
69 37 C.F.R. § 1.56(a) (2012).
70 ibid. § 1.56. A duty of candor and good faith in dealing with the Patent Office include a duty to disclose to the Office all information known to that individual to be material to patentability. See, Seymour 2013, p. 1011, footnote 131.
72 In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992),
74 See, USPTO (2001) Manual of Patent Examining Procedure, § 2010, explaining that such PTO determinations “would significantly add to the expense and time involved in obtaining a patent with little or no benefit to the patent owner or any other parties with an interest”.
that they are using to understand the state of the art. Another challenging aspect is the mounting number of patent applications that the Patent Office must examine, and this could lead to the granting of questionable patents. Professor Wagner flags this quite clearly: as ‘the amount of patenting activity has grown rapidly worldwide, the administrative apparatus of the patent system has been strained to its limits’, thereby emphasising the claim that the reason why we have questionable patents is because ‘the incentives to file low-quality patents are too high, and the incentives to file high-quality patents are too low’.

This is relevant, as hundreds of thousands of applications filed each year end up having no commercial significance. Where the Patent Office’s resources to evaluate patent applications seem inadequate, such as an underfunded Patent Office, then there may not be sufficient time to evaluate patent applications fully or to allow efficient and accurate screening of all patent applications. This has contributed to an extensive debate in which experts have mapped out policy reforms to nurture the quality of patents. Scholarly debates have categorised reforms into five broadly defined themes: administrative changes, patent law changes, better patent information to patent applicants and examiners, better incentives to improve patent quality and more technical advancement for patent examiners. However, as Professor Miller has argued; ‘even if the Patent Office were to invest far more in reviewing applications, its review would still suffer from a basic knowledge deficit compared to that which well-informed inventors and their competitors possess’.

Importantly, Professor Lemley balances accuracy and operational overheads, and argues persuasively in support of the viewpoint that strengthening the examination process is not cost effective, and society is better off spending its resources on a more searching judicial inquiry into validity in those few cases in which it matters, rather than paying for a more protracted examination of all patents ex ante. In the narrative, he states that while maintaining a check on the quality of patents is the most vital consideration for any Patent Office, an opposition system seems to be an efficient way of providing an additional layer for checking any errors and abuse in the patent system to ensure the quality of patents.

III. Challenging the Validity of Patents: Jurisprudence of the EPO and US

Most of the successful patent regimes have statutory mechanisms whereby an interested third-party can express his opposition against the granting of a patent or against a granted patent. In general, opposition proceedings are conducted before the Patent Office, and not a court per
An opponent must allege at least one of the grounds for opposition among those that are prescribed in the applicable law. Opposition procedures are closely related to the patent granting procedure. An opposition may be requested soon before the granting of a patent (pre-grant opposition) or after the granting of a patent (post-grant opposition). In some countries, an opposition may be filed within a certain time immediately after the publication of the application for a patent and before the examination phase, in which case the procedure resembles, to a certain extent, the so-called third party observation system. It is possible to combine pre-grant and post-grant opposition systems.

The advantage of having a pre-grant opposition system is that it precludes questionable patents from being granted at an early stage and may also be beneficial for a patentee, since the patentee and the public can have more trust in the validity of the patent. However, a common drawback of a pre-grant opposition system is that it may cause a substantial delay in the whole process of finalising the granting of a patent, in the end, stifling technological progress and causing economic harm. Similarly, the major shortcoming of a post-grant opposition system is that it leads to the wrongful monopoly of a patent holder until the time at which an opposition is filed for the patent. While such laws differ in terms of their substantive construction and the general procedural requirements, their legal logic is similar. The common objective is to provide a simple, quick and inexpensive means to increase patent quality by providing additional input to the process to ensure that undeserving patents are not granted exclusive rights.

These mechanisms also provide an alternative to potentially lengthy and costly judicial proceedings, since the current patent system has a de facto reliance on litigation as the primary vehicle for invalidating patents - a reliance that has adverse public consequences. It is worth noting that no international treaty regulates post-grant patent opposition mechanisms as such, and there are operative provisions in the current patent regime, specifically dealing with the regulation of opposition procedures, which consider what was set forth on procedural matters.

89 WIPO, SCP/14/5 2009, para. 12.
90 In the EPO, where the subject-matter of the European patent is not patentable under Articles 52 to 57 because it is not new (Articles 52(1), 54, 55); does not involve an inventive step (Article 52(1), 56); is not susceptible to industrial application (Articles 52(1), 57); is not regarded as an invention under (Article 52(1)(3) or is not patentable under Article 53. Additional grounds are that the European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art or is not patentable under Article 53. If the patent was granted on a divisional application or on a new application filed under Article 61 (new application in respect of the invention by the person adjudged in a final decision to be entitled to the grant of a European patent), beyond the content of the earlier application as filed (see, Article 76(1)).
91 WIPO, SCP/17/9 2011, p. 5, para. 15.
93 India, for example, provides both a pre-grant and a post-grant opposition system. Section 25 of the Indian Patent Act 1970.
94 Manu 2015, p. 409, observing that pre-grant opposition is cheaper, simpler and faster and can therefore be an effective means to help ensure that only high-quality patents are granted.
95 Drahos 2010, p. 163.
96 WIPO, SCP/17/9 2011, p. 10, para. 29, observing that since anyone can file an opposition, a great number of oppositions could be filed in complex cases. Footnote 13, finding that, for example, the Oncomouse case (EP 0169672) received 17 oppositions, and the Edinburgh/stem cells case (EP 0695351) received 14 oppositions. See, Harhoff and Reitzig 2004, p. 444.
97 Chien and Lemley 2012, p. 28. See also, WIPO, SCP/14/5 2009, p. 5, para. 18.
98 Hall and Harhoff 2004, p. 1014.
in general under TRIPS,\textsuperscript{100} and within the PLT.\textsuperscript{101} This paucity thereby leaves WTO members free to decide on the matter. Under this logic, and consistent with WTO Dispute Settlement Understanding findings, each state creates its own regime, and these laws emphasise the overriding character of national patent policies, which are essentially the result of the legal vacuum created by the international treaty,\textsuperscript{102} leaving members free to determine the appropriate method of implementing opposition mechanisms within their own legal system and practice.\textsuperscript{103} Both the European and US patent regimes support patent opposition instruments.

Under US patent law, an opposition proceeding is called a reexamination.\textsuperscript{104} Originally, there were two types of reexamination procedure in the US and these requests fall into one of two categories: \textit{inter partes} reexaminations, which allow the requesting party to participate in the proceedings; and \textit{ex parte} reexaminations, which are conducted substantially exclusively between the patent owner and the United States Patents and Trademarks Office (USPTO).\textsuperscript{105} However, the Leahy-Smith America Invents Act introduced post-grant review proceedings into US patent law, by adding a new Chapter 32 to Title 35 of the United States Code.\textsuperscript{106} Although prior to this the US patent law permitted a form of post-grant review of issued patents through reexamination proceedings,\textsuperscript{107} the reexamination proceedings were limited to issues of patentability relating to prior art patents or printed publications that establish “a substantial new question of patentability”.\textsuperscript{108}

The America Invents Act significantly expands these options, by providing a new post-grant review proceeding, which is, in many respects, similar to foreign opposition mechanisms.\textsuperscript{109} In other words, the America Invents Act reformed \textit{inter partes} reexamination proceedings with two different types of administrative post-grant proceedings: post-grant review and \textit{inter partes} review.\textsuperscript{110} Under the new America Invents Act, any third party “who is not the owner of a patent” can challenge the validity of an issued patent using either post-grant review,\textsuperscript{111} or \textit{inter partes} review by filing a petition with the USPTO.\textsuperscript{112} The primary objective of the \textit{inter partes} reexamination procedure is to reduce costly patent litigation in US District Courts by providing an expanded means for third parties to challenge the validity of a patent.\textsuperscript{113}

\textsuperscript{100} Article 32 of TRIPS reads: ‘An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available’.

\textsuperscript{101} Article 10 of the Patent Law Treaty, June 1, 2000, 39 I.L.M. 1047. Note that the aim of the Patent Law Treaty (PLT) is to harmonise and streamline formal procedures in respect of national and regional patent applications and patents and, thus, to make such procedures more user friendly. With the significant exception of filing date requirements (Article 5), the PLT provides the maximum sets of requirements that the office of a contracting party may apply (Article 2). This means that a contracting party is free to provide for requirements that are more generous from the viewpoint of applicants and owners, but the requirements under the PLT are mandatory in regard to the maximum an office can require from applicants or owners.


\textsuperscript{103} Article 1 of TRIPS in part provides that ‘members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice’.

\textsuperscript{104} Okediji and Margo 2014, p. 167.

\textsuperscript{105} Merges and Duffy 2013, p. 1039, observing that reexamination proceedings provide an opportunity for the USPTO to reconsider the validity of patent claims.

\textsuperscript{106} Leahy-Smith America Invents Act 2011.

\textsuperscript{107} 35 USC. §§ 302 and 311.

\textsuperscript{108} 35 USC. §§ 303 and 312.

\textsuperscript{109} § 6(d) of H.R. 1249, 2011.


\textsuperscript{111} 35 USC. § 321.

\textsuperscript{112} 35 USC. § 311.

\textsuperscript{113} 145 Cong. Rec. E1788, at E1789-90.
Nevertheless, post-grant review must be initiated within nine (9) months of the issuance of a patent, and permits any patentability issue to be raised, which can be based on any evidence, and at least one claim of the patent. That is, the petition for post-grant review must provide evidence that supports the grounds for the challenge to each claim, except that an inter partes review cannot be initiated until the later of nine (9) months after a patent issue or after post-grant review is complete. Furthermore, inter partes review is limited to the grounds of novelty or non-obviousness, and non-patentable subject matter. The person challenging the validity of the granted patent does not need to show an interest in it, and requests may be filed any time during the enforceability of a patent after the foregoing period has expired. In this case the burden of proof is on the challenger due to the jurisdictive notion of the “presumption of validity”.

However, while this legal logic follows the US patent law principle, which says that “patents shall be presumed valid”, what deviates from the US legal scope is the trial procedure created under the American Invents Act. In litigation, under 35 U.S.C. § 282, an issued patent is “presumed valid”. Accordingly, an invalidity defence in court must be proved by clear and convincing evidence. In contrast, in each of the new post-issuance validity proceedings, there will be no presumption of validity for patents that are reviewed; thus, invalidity need only be established by a preponderance of the evidence. Likewise, the new Trial Practice and Procedure Rules confirm that “the default evidentiary standard is a preponderance of the evidence”, which is a lower threshold than the clear and convincing evidence standard applied to invalidity determinations in litigation.

Under the EU jurisprudence, a notice of opposition may be filed at the European Patent Office. The post-grant opposition in the EU is more of a post-contentious, inter partes, administrative procedure intended to allow any European patent to be centrally opposed. Opposition proceedings are available to the public. More importantly, as per the European Patent Convention (EPC), any person, natural person or legal entity who is not the patent owner can file an opposition to a European patent within nine (9) months of the publication of details in the European Patent Bulletin. The opposition applies to any European patent in all

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114 35 USC. §321(b).
115 35 USC. § 322(a)(3).
116 35 USC. § 321(b). See also, 35 USC. § 324(b).
118 Chapter 1901 – Protest under 37 CFR § 1.291 reads: [A] protest is literally a protest against the application for a patent. It is designed to bring information to the attention of the USPTO that is relevant to avoiding the issue of invalid patents.
120 35 U.S.C. § 282
122 See, e.g., Microsoft Corp. v. i4i Limited Partnership, 131 S.Ct. 2238 (2011).
123 35 U.S.C. § 316(e) (inter partes review), 326(e) (post-grant review, and by extension covered business methods).
124 37 CFR § 42.1(d).
128 Article 99(1) EPC.
129 Subject to some exceptions in Rule 144 EPC. See, Article 128(4) EPC.
131 Article 99(1) EPC.
contracting states in which the said patent has effect. 132 Significantly, an opposition may be filed by a straw man to hide the identity of the party actually interested in having the patent revoked. 133 A straw man is ‘a party acting on behalf of another person’. 134

In 1999, the Enlarged Board of Appeal held that the use of a straw man did not render the opposition inadmissible unless ‘the involvement of the opponent is to be regarded as circumventing the law by abuse of process’. 135 As provided by Article 100 of the EPC, the opposition must at least be based on one ground for opposition, 136 accompanied by evidence that supports the grounds for opposition. 137 The following grounds are available for interested parties to trigger: the subject-matter of the patent is not patentable; 138 the invention is not sufficiently disclosed to allow a person skilled in the art to carry it out; and the content of the patent extends beyond the content of the application as filed or, the patent was granted on a divisional application or on a new application filed under Article 61, beyond the content of the earlier application as filed. 139

According to Article 101 of the EPC, if the opposition is admissible, 140 the Opposition Division shall examine whether at least one ground for opposition under Article 100 prejudices the maintenance of the European patent. 141 Decisions of the Opposition Divisions are subject to appeal to the EPO Board of Appeal. 142 Moreover, decisions to reject an opposition as inadmissible are also subject to appeal to the EPO Board of Appeal. 143 The opposition rate before the EPO is consistently higher in the closest available proxy for the pharmaceutical sector than it is in organic chemistry and all other sectors (overall EPO average). In 2015, overall, 2417 new opposition cases were filed in the EPO, with 1202 (inter partes) representing 52.6 per cent of patents opposed. 144

IV. Justifying the Patent Opposition Mechanisms

The theory that justifies the granting of a patent is based on the “incentive to create”. 145 The principal basis of this incentive is to provide adequate compensation for the patentee. 146 This occurs by rewarding inventors with the right to try and exclude others from commercially exploiting their patented invention for a specific period 147 by taking two steps that they

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132 id.
134 Stauder and Singer 2003, p. 95.
135 Enlarged Board of Appeal. Decisions G 0003/97 and G 0004/97 (OJ 21 January 1999, 245, 270. Headnote 1(a), 1(b)) that the opponent is the person who fulfils the requirements of Article 99(1) in conjunction with Article 100, Rules 76 and 77(1) EPC (former Rules 55 and 56(1)) EPC 1973.
136 See also, Rule 76(2)(c) EPC.
137 Rule 76 EPC.
138 Articles 52 to 57, patentable inventions, exceptions to patentability, novelty, non-prejudicial disclosures, inventive step, industrial application.
139 WIPO, SCP/14/5 2009, para. 67.
140 Rule 77 of the Implementing Regulation to the EPC provides grounds for a rejection of the opposition as inadmissible.
141 Fox 2007, p. 104. See also, Dowie-Whybrow 2013, p. 344.
142 Article 106 EPC and Rule 99 EPC.
143 Article 106 EPC. See, Rules 77 and 99 EPC.
146 Hall and Harhoff 2004, p. 1014.
probably would not otherwise take: to invent in the first instance, and to reveal information to the public about these inventions.\textsuperscript{148} This ensures that socially important products that, but for a patent, never would have been developed or would have been developed at a markedly slower pace, actually materialise or emerge at an accelerated speed.\textsuperscript{149} While patents have been found to be significant in themselves as a component of the market value for economic growth, it is also true that the same can sometimes undermine public interests if there are not adequate safeguards. Therefore, even the firmest advocates of the patent system must sometimes acknowledge that the legitimacy of the same relies upon two principal conditions.

First, it requires that valid patents be granted. Second, it necessitates that questionable patents be revoked or reduced to their proper scope. This is because the value that patent law provides society lies in stimulating original invention and rewarding the same with exclusive rights. As a matter of public policy, a patent must contain a non-obvious technical contribution to the state of the art, whereby a technical problem is solved by technical means,\textsuperscript{150} and innovation and technological advancement are best served when an inventor is issued a patent with the scope of protection that is deserved. Therefore, resolving the issue of what is questionable should be a desirable feature of every serious patent system.\textsuperscript{151} The opposition mechanism offers the opportunity to reduce the risk of patents being granted without sufficient scrutiny or to ensure that only innovations with valuable technology are worthy of receiving exclusive protection under patent law.\textsuperscript{152} That is, the general patent policy in this direction seeks to ensure that the Patent Office does not grant, and the courts do not uphold, invalid patents. As stated already, opposition proceedings are conducted before the Patent Office,\textsuperscript{153} and the purpose of this is to give opponents, such as competitors, the opportunity to challenge the validity of patents.\textsuperscript{154}

This mechanism provides an additional, administrative layer of review, which is simpler than a court procedure or a quasi-judicial procedure.\textsuperscript{155} To add to that, opposition proceedings have a shorter timeline and the involvement of technical experts who are well-suited to navigate the complex scientific concepts embodied in patents.\textsuperscript{156} It is also noted for being cost-effective, as the procedure is a departure from the strictly formal set up of a court of law.\textsuperscript{157} Uncertainty about the validity of a patent has several potential socio-economic costs. First, low quality patents can create considerable uncertainty among inventors or would-be commercialisers of inventions, which in turn can slow either the pace of innovation or investment in the commercialisation of new technologies.\textsuperscript{158} Aside from being technically invalid,\textsuperscript{159}

\begin{thebibliography}{99}
\bibitem{149} Adelman et al. 2003, pp. 28-29.
\bibitem{150} Cook 2002, p. 179.
\bibitem{151} Hall and Harhoff 2004, p. 992.
\bibitem{153} WIPO, SCP/14/5 2009, para. 12.
\bibitem{154} Enlarged Board of Appeal. Decision G 0009/93, 6 July 1994, Reasons, point 3.
\bibitem{155} WIPO, SCP/12/3 Rev.2 2008, p. 57, para. 198.
\bibitem{156} Turchyn 2016, p. 1499.
\bibitem{158} Hall and Harhoff 2004, p. 992.
\bibitem{159} FTC Report 2003, p. 5, a poor quality or questionable patent is one that is likely invalid or contains claims that are overly broad.
\end{thebibliography}
commentators have argued that such patents are worthless\(^{160}\) and burdensome on the patent system,\(^{161}\) particularly in regard to the issue of unnecessary litigation.\(^{162}\) It has been proposed in one sense that litigation as a socially optimal instrument for nullifying questionable patents is insufficient.\(^{163}\)

One empirical study has suggested that roughly half of all litigated patents are found to be invalid, including some of great commercial significance.\(^{164}\) The core insight along this premise is that very few patents are litigated, and even when litigation is initiated, most cases settle without hearing.\(^{165}\) Reasoning in ideal terms, the risk that a patent will be declared invalid is substantial because the amount a party is willing to spend on litigation closely correlates with that party’s probability of winning an invalidity contest.\(^{166}\) For opponents in financially weaker positions, the effects of such a system are even more acute because of the ever-increasing costs of litigation.\(^{167}\) Therefore, the party with the deepest pocket is the one most likely to receive a favourable validity ruling.\(^{168}\) This contention is relevant given the empirical evidence suggesting that litigation by individuals and the government on patent validity is rare.\(^{169}\)

Added to the foregoing is the practical viewpoint that fear of litigation may cause smaller entrant firms to avoid areas where incumbents hold large numbers of patents.\(^{170}\) Such entry-avoidance may be rational and even welfare-enhancing if the incumbents’ patents are known for certain to be valid, but low quality patents held by incumbents may also deter entry into a technological area if the cost of invalidating the patents is too high. In these circumstances, technological alternatives may not be commercialised and consumer welfare suffers.\(^{171}\) This may also slow the pace of innovation in fields characterised by cumulative invention, in which one inventor’s efforts rely on previous technical advances or advances in complementary technologies.\(^{172}\) The key problem is “evergreening”.\(^{173}\) If these previous technical advances are covered by patents of questionable validity, the costs to inventors of pursuing inventions that rely on them may be so high as to discourage such cumulative invention.\(^{174}\)

This will eventually increase uncertainty among inventors concerning the level of protection enjoyed by these related inventions, which in turn will make it more costly and difficult for inventors to build on these related inventions in their own technical advances.\(^{175}\) Following the foregoing logic, it is safe to argue for a self-checking mechanism in the market, where patents

\(^{160}\) Kitch 1990, pp.122-123, stating that most issued patents are worthless, or very nearly worthless. Merges 1999, p. 603, observing that most patented technologies will not be economically successful.


\(^{162}\) Lanjouw and Schankerman 2001, p. 140.

\(^{163}\) Williams 2006, Parts IV. B.1.

\(^{164}\) Lemley and Shapiro 2005, p. 76.

\(^{165}\) id.

\(^{166}\) Farrell and Merges 2004, p. 949.

\(^{167}\) id. p. 948, stating that an infringement case now costs roughly $2 million for each party when there is $1 million to $25 million at risk.

\(^{168}\) Williams 2006, Parts IV. B.1.a.

\(^{169}\) Farrell and Shapiro 2008, p. 1348.

\(^{170}\) Lerner 1995, pp. 486-487.

\(^{171}\) Hall and Harhoff 2004, p. 992.

\(^{172}\) FTC Report 2003, ch. 2, discussing the effects of patents on “stand-alone” and “follow-on” innovations.

\(^{173}\) Granstrand 2015, p. 1, defining evergreening as the strategic extension of the duration of a temporary monopolistic or market dominant position by means of patent strategies.


\(^{175}\) ibid. p. 3 & 28.
that have actual market power are legally challenged by competitors, who are often aware of the most relevant prior art and can probe beneath the surface of an applicant’s affidavits and declarations.\textsuperscript{176} More specifically, making firms more vigilant about their competitors’ inventions would also encourage the dissemination of information contained in patent applications.\textsuperscript{177} In this vein, parties with superior knowledge could challenge the validity of patents.\textsuperscript{178} Thus, through the participation of third-parties who may be well informed about the technology concerned, the opposition procedure would complement the examination procedure and increase the credibility of granted patents.\textsuperscript{179}

This is particularly important when individuals may not have the technical ability to supply evidence in challenging the validity of a pending or granted patent.\textsuperscript{180} In this case, the burden of searching prior art would shift from the Patent Office to the inventor’s competitors, who are likely to have better information.\textsuperscript{181} Relatedly, the system could help educate examiners in issues presented by emerging technologies.\textsuperscript{182} Because third parties are likely to have more knowledge of prior art in new fields, opposition proceedings could uncover areas unknown to examiners.\textsuperscript{183} This mechanism could be used to target the most valuable patents; that is, patented inventions that are most likely to have an effect in the market are most likely to be opposed.\textsuperscript{184} Moreover, the granting of questionable patents is also likely to spur significant increases in patent applications, further straining the already overburdened examination processes of the Patent Office.\textsuperscript{185}

A vicious circle may result, in which cursory examinations of patent applications result in the issue of questionable patents, which triggers a rapid swelling in applications, further exhausting the limited resources of the Patent Office, and eventually limiting the examination of individual applications, and further degrading the quality of patents.\textsuperscript{186} Thus, the benefits of avoiding highly uncertain patents are sufficiently great that every patent regime must consider them.\textsuperscript{187} In other words, since invalidating a patent provides a public good, typically to the benefit of competitors and consumers, one can naturally consider policies to enhance this regime.\textsuperscript{188} This point reflects the theoretical view that at the heart of every successful IP system lies an elementary legal foundation that the patent system operates to promote the fundamental interest of the public.\textsuperscript{189} Importantly, while the current patent regime marked a new era of obligations regarding the protection and enforcement of patent rights, WTO members retained important policy options, including the right to protect their public interests.

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\textsuperscript{176} Hall and Harhoff 2004, pp.1014-1015.
\textsuperscript{177} Gallini 2002, p. 148.
\textsuperscript{178} Graham and Harhoff 2006, p. 1.
\textsuperscript{179} WIPO, SCP/12/3 Rev.2 2008, 57, para. 198.
\textsuperscript{180} Enlarged Board of Appeal. Decision G 0009/93, 6 July 1994, Reasons, point 3.
\textsuperscript{181} Graham and Harhoff 2006, p. 6.
\textsuperscript{182} Levin and Levin 2003, p. 140.
\textsuperscript{183} ibid.
\textsuperscript{185} Hall and Harhoff 2004, p. 993.
\textsuperscript{186} ibid. p. 994.
\textsuperscript{188} Lemley and Shapiro 2005, p. 90.
\textsuperscript{189} Mercurio and Tyagi, 2010, p. 281.
\end{flushright}
Therefore, the public interest norm, a principle on which the granting of patents rests, is captured by several provisions under TRIPS.\textsuperscript{190} For example, the TRIPS Agreement unreservedly expresses the intent that the scope and patent form should be defined in a way that promotes the public interest.\textsuperscript{191} Thus, the overriding objective of the public interest norm under TRIPS suggests that the meaning of the rule of law therein should conform to the underlying socio-economic welfare of the people, and that the Agreement was designed to serve, particularly, what is best for the national interest.\textsuperscript{192} Within this spirit, Article 8 of TRIPS allows member states to use their discretion when formulating or amending their laws and regulations, and to adopt measures necessary to protect the public interest.\textsuperscript{193} This primarily follows Article 8(2) of TRIPS, which envisages that such private rights stand to be abused by the right-holders, and this will be detrimental to the legitimate public interest.\textsuperscript{194}

In fact, the wider discretion afforded to members to protect the public interest is established on the territorial foundation of patent law; that is, an internationally recognised norm that is qualified by several clauses under TRIPS.\textsuperscript{195} Despite the common standards agreed upon by WTO members to protect patents the territorial foundation of patent law is intact, and TRIPS did not destroy this norm. This principle is grounded in the notion that every government has sovereignty within its borders or territories on patent law matters.\textsuperscript{196} Thus, in relation to the principle of territoriality, and also subject to national treatment and the most favoured nation clause,\textsuperscript{197} the scope of protection of a patent right is limited to the territory of the state where the right is granted, and justifies, for example, exclusive jurisdiction of the authorities of the granting state with respect to questions related to the validity of rights conferred and their limitations.\textsuperscript{198}

Without any recourse for effective mechanisms to challenge the validity of patents, the public interest, a principle centrally established in the patent system, may be undermined. The opposition mechanism supports the conceptual viewpoint that granting patents without an effective quality control mechanism could potentially lead to negative spill-over effects on competition and innovation, not to mention adverse effects on economic growth.\textsuperscript{199} That is, to say, a reasonable principle along this line would certainly have several merits including preventing a patent holder from enjoying a wrongful monopoly over a questionable patent to the detriment of the public.\textsuperscript{200} The conclusion drawn from the failure of WTO members to explicitly include any operative provisions in relation to the patent opposition mechanism is firstly, an indication that individual members can exercise a certain amount of appropriate discretion on the subject, and secondly, such a national action will be consistent and legitimate under WTO jurisprudence, and nothing in the light of TRIPS will, in fact, preclude the possibility of any country cleaning the patent system.

\textsuperscript{190} Reichman 1995, p. 352, stating that TRIPS rules reflect compromise efforts to balance private and public interests.
\textsuperscript{191} Article 8.
\textsuperscript{192} UNCTAD Reports: TD/B/COM.2/CLP/10, 1999, para. 28.
\textsuperscript{194} Section 8 of TRIPS, dubbed “control of anti-competitive practices in contractual licences.” Article 40(2) allows members to adopt relevant legislation to prevent abuse of patent rights. \textit{See}, Carvalho, 2010, p. 204.
\textsuperscript{195} \textit{See}, Articles 8, 31, 40.
\textsuperscript{196} Ladas 1957, p. 400.
\textsuperscript{197} Evans, 1999, p. 714.
\textsuperscript{198} Abbott, Cottier and Gurry 2011, p. 602.
\textsuperscript{199} Puasiri 2013, p. 220.
\textsuperscript{200} Manu 2015, p. 421.
V. Conclusion

This paper has examined the need for states without any legal instruments to challenge the validity of patents to implement patent opposition mechanisms to mitigate the potential consequences of granting questionable patents. This is because while a great deal of importance is placed on the act of obtaining a patent itself, sometimes the necessity of checking the validity of patents remains less appreciated in certain countries, where the patent practice has focused extensively on the granting of patents rather than anything else. The need for a post-grant opposition mechanism seeks to reverse this, and is more supportive of the viewpoint that good patents are those with social value that promote the public interest. Put differently, the patent opposition mechanism is one central instrument whose normative foundation extolls the legislative wisdom requiring that the overriding public interest in the patent system is protected, since invalidly granted patents may potentially prejudice the same. That is, as an essential hallmark of the patent system, a potentially vital principle on which the granting of patent rights sits underlines the virtues that the patent system has always been to promote rather than to impede protection of the public interest.

This view then destroys the accounts of patent advocates who have often concluded, without the benefit of evidence, that more patents are better for society even if they are weak. Therefore, under the conceptual purview that the principal basis for granting patents embodies a utilitarian character, a strong theme in this article has been premised on the argument that citizens in whose interests patents are granted have the right to participate in the patent system and to check that only inventions that fall within the fundamental interests of the public deserve exclusive rights. Consequently, drawing on the jurisprudence containing substantive law and procedural requirements within the EPO and USPTO pursuant to patent opposition proceedings, it has been shown that if WTO members without patent opposition mechanisms were to explore and strengthen their regimes, citizens, competitors and other interest groups would be able to detect and invoke key provisions to challenge invalid patents while ensuring that the patent system is untainted and free of questionable claims for patents.

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