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An Integrated Strategy for Challenging Validity in the USPTO and EPO

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I. Introduction

This article discusses the various options available to challenge the validity of patents in the United States Patent and Trademark Office (USPTO) (including Post-Grant Review (PGR) and Inter Partes Review (IPR)) and similar European Patent Office (EPO) proceedings. As practitioners adjudicate more of the recently available USPTO proceedings and, in particular, become more comfortable with the associated procedures, it will become increasingly important for them to develop an integrated strategy to achieve a client's goals in challenging patents—one that utilizes USPTO proceedings, proceedings in foreign patent offices, and U.S. federal and foreign court proceedings. Notably, the use of patent office proceedings need not be limited to post-grant proceedings, like PGR and IPR, because several pre-grant procedures also provide opportunities to challenge the scope and validity of pending claims before issuance, both in the USPTO and the EPO. This article focuses on the available options for challenging validity in the USPTO and EPO and the interplay between these patent office proceedings and proceedings in U.S. and foreign courts.

II. Choosing When and Where to Challenge Validity

Patent challengers must first consider when, where, and which type of validity challenge to use against a patent or pending application. A challenger may raise invalidity issues before or after grant, but must consider the risks of creating a statutory estoppel if certain proceedings are used and the challenge fails. And even beyond possible statutory estoppel, positions taken in an early challenge to a patent or patent application may have future ramifications for the challenger, including the potential for other legal or equitable estoppels.

A challenger may institute a proceeding in the USPTO, EPO, U.S. federal courts, or European national courts. The choice of which type of proceeding to use is largely governed by when and where the challenge will be made and the (often global) legal and business strategies developed by the challenger with respect to the technology and IP at issue. The decision of "when" to challenge validity often will depend on the issues that can be raised pre-grant and post-grant and the possible statutory estoppel that arises from the use of certain USPTO procedures. Additionally, U.S. and European counterpart patent applications and patents may be more advanced or less advanced in their prosecution relative to one another, which may also influence where, when, and which type of validity challenge is made.

If a challenge is launched pre-grant, the challenger may submit Third-Party Observations (TPOs) in the EPO, Third-Party Submissions (TPSs) in the USPTO,[2] or a Protest in the USPTO. Each proceeding allows challenges to the sufficiency of disclosure, novelty, and nonobviousness, but the statutory bases and rules governing these challenges differ. Details of these challenges are described below.

If a challenge is launched post-grant in the USPTO, a patent challenger may challenge the validity by filing, for example, a petition to institute a PGR or IPR. (A patent holder may also request a review of allowed claims via ex parte reexamination,[3] reissue,[4] or supplemental examination.[5]) Petitions to institute either a PGR or IPR are barred, however, if the petitioner has already filed a declaratory civil action in U.S. federal court in which the validity of the patent has been challenged.[6] In addition, PGR petitions are barred unless filed within nine months of the issuance of the patent,[7] and IPR petitions are barred if the petitioner was served with an infringement complaint asserting the patent more than one year prior to filing the IPR petition.[8] In the EPO, a patent challenger may challenge validity post-grant by filing an Opposition.[9] Like a PGR, an Opposition must be filed within nine months of issuance of the patent.[10]

Challenging the validity of a patent post-grant via PGR and IPR proceedings has associated risks. If the patent challenger later asserts invalidity in U.S. federal court or the International Trade Commission (ITC) against the U.S. patent that survived its instituted PGR or IPR, the challenger is estopped by statute from raising any argument that was raised or that reasonably could have been raised during the PGR or IPR.[11] The possibility of statutory estoppel could therefore influence the timing of a post-grant validity challenge in the USPTO. While an early validity challenge in the USPTO may provide certainty about some aspects of validity before the challenger institutes any U.S. federal court action, a challenger may have only one chance to use the USPTO's post-grant proceedings and thus is often best served by a USPTO challenge, if made, that is thorough and complete. In contrast, however, no statutory estoppel arises in European courts based on prior proceedings in the EPO, so a challenge to patent

validity in a European national court may rely on the same prior art and prior art combinations that have already been considered by the EPO and rejected there during Opposition proceedings.

The decision of "where" to challenge validity will often be controlled by the status of prosecution in various jurisdictions as well as the markets where the potential challenger seeks freedom to operate. In addition, the decision of where to file will be influenced by the particular grounds for invalidity that may be asserted in the USPTO and EPO. As a consequence, a patent challenger may choose to challenge some aspects of validity in the patent offices and others in court, subject to any statutory estoppel that is created by PGR and IPR proceedings in the USPTO. For example, a challenger may choose to challenge a European patent application in a patent family on enablement (i.e., sufficiency) grounds in a TPO to prevent the application's issuance. The TPO also may serve other purposes, for example, as a test case for a contemplated future enablement challenge to a pending counterpart U.S. application or as a means to better assess the probability of success in a U.S. or European litigation.

III. Choosing the Type of Validity Challenge

A. EPO Challenges

As a pre-grant challenge in the EPO, a TPO may raise validity arguments based on many grounds, including novelty[12] and inventive step.[13] Because these challenges can be filed anonymously and the identity of the challenger is, at least in theory, unknown, an argument that was raised, or that could have been raised, in a TPO does not estop the patent challenger from raising the same argument later in an Opposition proceeding or a national court.

Certain post-grant grounds to challenge the validity in the EPO may be raised exclusively in TPOs, as opposed to other EPO proceedings such as Oppositions. These include challenges directed to clarity of the claims,[14] the sufficiency of disclosure,[15] and the allowability of amendments.[16] Because certain grounds for invalidity may not be raised in later Opposition proceedings, it is imperative that a European patent challenger raise these issues in pre-grant TPOs if desired.

TPOs and Oppositions have differences and similarities. Unlike TPOs, post-grant Oppositions in the EPO may raise validity arguments based on a limited set of grounds, including novelty and inventive step, and not based on clarity, support of the claims by the description, or the allowability of amendments.[17] Moreover, certain additional EPO patentability challenges to a European patent may only be raised in Opposition proceedings (and not in TPOs), namely those directed to industrial applicability,[18] patentable subject matter,[19] and exceptions to patentable subject matter.[20] Like TPOs, Oppositions may be filed anonymously, so any arguments or grounds for invalidity raised during Opposition proceedings also do not estop the patent challenger from raising the same arguments later in invalidity proceedings in national courts.

B. USPTO Challenges

For pre-grant challenges in the USPTO, a TPS may rely upon "any patent, published patent application, or other printed publication of potential relevance."[21] Submission of a TPS is subject to somewhat complex timing restrictions. First, a TPS must be submitted before the later of six months after the date of publication or the date of a first Office Action on the merits that rejects any claim.[22] Second, it must be submitted before the date of a Notice of Allowance, if such an allowance occurs before the first Office Action that rejects any claim.[23]

Protests, by contrast, are not limited to validity challenges based on patents and printed applications, but rather may be based on "any facts or information adverse to patentability"[24] and may include allegations of inequitable conduct.[25] Protests must be filed prior to the date of publication or prior to the mailing of a Notice of Allowance, whichever occurs first.[26] In general, a challenger may file only one Protest, but the USPTO may accept one or more subsequent Protests if the challenger can explain why the issues raised in the subsequent Protests are significantly different from those raised earlier and why the significantly different issues were not presented earlier.[27]

For post-grant procedures in the USPTO, PGRs allow challenges to validity based on essentially any ground, e.g., lack of patentable subject matter, lack of novelty, obviousness, failure to comply with section 112 (written description, enablement, definiteness), or any ground for reissuance.[28] IPRs allow challenges to validity based "only on a ground that could be raised under section 102 (lack of novelty) or 103 (obviousness) and only on the basis of prior art consisting of patents or printed publications."[29] In addition, PGRs must be filed within nine months after grant of the patent,[30] and IPRs can only be filed nine or more months after a patent grant or after a PGR has been terminated.[31]

In short, challenges to validity may be raised pre-grant or post-grant, may be raised in the EPO or USPTO, and may also be raised in U.S. federal courts or European national courts. Among other factors, the decision of when and where to challenge validity will be influenced by the statutory bases for the putative challenge and the risks of creating an estoppel. The choice of the specific types of invalidity challenge to assert will, in turn, be limited by the decision of when and where to challenge validity.

IV. Differing Burdens of Proof and Claim Construction Regimes

Proceedings in the U.S. and Europe may be subject to differing burdens of proof for invalidity and differing standards for determining the scope of the claims. Unlike U.S. proceedings, where differing legal standards for the burden of proof and the scope of the claims may affect the invalidity analysis, European proceedings are typically not decided on such grounds.

To prove invalidity in the USPTO, a challenger must show that a claim is invalid by a preponderance of the evidence.[32] By contrast, in U.S. federal court, a challenger must prove invalidity by clear and convincing

evidence.[33] The differing legal standards, in part, arise because an issued patent enjoys a presumption of validity after the USPTO allows it to issue.[34] As a result, in principle, it may be easier to invalidate a patent in a USPTO proceeding than in U.S. federal court because the burden of proof is lower.

Similarly, it may be easier to invalidate a patent in a USPTO proceeding because invalidity determinations there use a potentially broader claim scope than in U.S. federal court. The USPTO uses the "broadest reasonable interpretation" (BRI) in interpreting claim terms.[35] A U.S. federal court, in contrast, uses the claim construction framework set forth in *Philips v. AWH Corp*.[36] That framework begins with the ordinary and customary meaning of a claim term to a person of ordinary skill in the art at the time of invention in the context of the patent's claims, specification, and file history.[37] The application of the BRI to a claim potentially results in a broader claim construction than construction of the same claim under a *Philips* analysis. Compared to a U.S. federal court invalidity challenge, therefore, a prior art invalidity analysis in the USPTO may encompass additional prior art or the claim may require a broader disclosure under section 112 to enable the full scope of the claims. If that is the case, a claim that may not be successfully invalidated in a U.S. federal court might be invalidated in the USPTO in a PGR or IPR, or the claim may be narrowed if the claim may be amended successfully in the USPTO proceeding, because of the differing standards for interpreting claims.

V. Comparison of Procedures for Challenging Validity

Pre-grant and post-grant proceedings in patent offices and courts may be used to challenge different patentability requirements at different times and in different fora.

A. Sufficiency of Disclosure Challenges

For example, one way to challenge enablement (i.e., sufficiency of disclosure) pre-issuance is to use a TPO in the EPO, because such a challenge is generally not available in other fora pre-issuance. In addition, when such a challenge is made pre-issuance in the EPO, it does not prohibit the challenger from raising similar arguments post-issuance and in other fora. Indeed, TPOs may be used pre-issuance in the EPO to challenge clarity (a European requirement of patentability that most closely resembles the definiteness requirement in the U.S.) and sufficiency of disclosure (a European requirement of patentability that most closely resembles the enablement requirement in the U.S.) without compromising additional challenges to sufficiency in Oppositions, European national courts, the USPTO, or U.S. federal courts. Other patent office proceedings do not allow enablement challenges or allow enablement challenges subject to possible statutory estoppel. Pre-issuance challenges based on enablement are available in the U.S. only by filing a Protest, but restrictions on the timing and number of Protests limit their usefulness. Post-issuance PGRs that allow challenges grounded in 35 U.S.C. § 112 may be subject to statutory estoppel, as discussed herein. Moreover, in contrast to TPOs and PGRs, TPSs and IPRs in the USPTO cannot be used to challenge the sufficiency requirements of 35 U.S.C. § 112 because the challenges to validity allowed in these proceedings must rely only on patents and printed publications.

B. Prior Art Challenges

In addition to sufficiency requirements, challenges asserting lack of novelty and obviousness may be lodged in both the EPO and USPTO. Novelty is governed by essentially the same legal standards in both the EPO and USPTO. Nonobviousness under U.S. law resembles the inventive step requirement in the EPO, although an obviousness analysis typically combines multiple prior art references to determine whether the U.S. claimed invention as a whole would have been obvious, while an inventive step analysis usually identifies a single piece of prior art as the closest prior art, and then determines whether a European patent claim provides an inventive step over that closest prior art.

Some USPTO procedures for challenging lack of novelty or obviousness that rely on prior art patents and printed publications may create estoppels that prohibit certain additional challenges based on prior art patents and printed publications in subsequent proceedings. The filing of a pre-issuance TPS or Protest in the U.S. does not create a statutory estoppel, but a post-grant validity challenge raised in an IPR or PGR may create a statutory estoppel that limits the prior art defenses that may be raised in a subsequent U.S. federal court case or ITC investigation.

In the EPO, by contrast, as mentioned above, there is no statutory estoppel that results from pre-issuance TPOs and post-grant Opposition proceedings. As a result, later validity challenges based on the same art as considered in a TPO or Opposition, or other allowed bases to challenge invalidity that were raised in a TPO or Opposition, may be raised again in subsequent national court proceedings in Europe.

VI. Other Considerations

Challenges to validity in the USPTO and EPO may have several other potential advantages over challenges in U.S. federal or European national courts. For example, the administrative patent judges in the USPTO may have a technical background and thus a better appreciation for invalidity arguments that require a thorough understanding of scientific principles. Similarly, the examiners in the EPO, and particularly in the Opposition Division, have technical training and may have a better appreciation for invalidity arguments based on complex science. Therefore, a patent challenger potentially may have a better chance of invalidation in the patent offices if the invalidity arguments require technical sophistication or specific technical knowledge. In

other cases, a bench or jury trial may be more attractive.

In addition, challenges in the patent offices will almost always have a lower cost than litigation in U.S. federal courts or European national courts. In the U.S. federal courts, discovery is relatively extensive and expensive, but may also allow the development of a more complete record. Moreover, in Europe, it may be necessary to file invalidity actions in national courts in multiple countries because European national patents, including those originating as a European patent, must be invalidated on a country-by-country basis under the current patent statutory regime, which similarly raises the cost of court litigation.

Patent challengers are not limited to a single forum when challenging validity. In both the U.S. and in Europe, simultaneous multiple proceedings in courts and in the patent offices are possible and common. Although beyond the scope of this article, it is important to consider the strategic reasons for and effects of such a challenge in multiple fora, such as (i) the likelihood of a stay of a U.S. federal court proceeding and its value and desirability or (ii) whether a patent office decision has the potential to be persuasive to a court and, if so, whether this is a desired result.

Finally, it is important to remember that post-issuance challenges to validity can be reviewed. Even if a validity challenge in an IPR estops the challenger from pursuing additional validity challenges in U.S. federal court, any finding on the merits by the USPTO may be appealed and reviewed by the Federal Circuit and possibly the Supreme Court. Similarly, any validity finding of the Opposition Division of the EPO may be reviewed by the Technical Board of Appeal. Moreover, rehearings and reviews by expanded panels or boards are also possible in both the U.S. and in Europe.

VII. Conclusion

In sum, this article suggests that the myriad of pre- and post-grant patent office and court invalidity proceedings in the U.S. and Europe, as well as other non-U.S. jurisdictions of interest to the challenger, should be viewed as part of an overall strategy for challenging the validity of a patent family that is unique in each case. Instead of overemphasizing the dangers of a potential estoppel in U.S. federal court based on USPTO challenges to patent validity, in many cases a patent challenger may be advised to evaluate and assert the best invalidity arguments in the most appropriate fora with due consideration for the appropriate timing of such an invalidity challenge as part of its broader strategy for challenging the patent.

(Endnotes)

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[2] Although we refer in this article to a TPS as one type of validity challenge, it is more accurately a procedure to submit a publication of "potential relevance" for possible consideration by the USPTO during examination of a patent. 35 U.S.C. § 122(e)(1).

[3] 35 U.S.C. § 301 *et seq*.

[4] 35 U.S.C. § 251.

[5] 35 U.S.C. § 257.

[6] 35 U.S.C. § 315(a)(1).

[7] 35 U.S.C. § 321(c).

[8] 35 U.S.C. § 315(b).

[9] EPC Article 100.

[10] *See* http://www.epo.org/applying/European/oppositions.html.

[11] 35 U.S.C. §§ 315(e), 325(e).

[12] EPC Article 54.

[13] EPC Article 56.

[14] EPC Article 84.

[15] EPC Article 83.

[16] EPC Articles 76(1) and 123(2).

[17] *See* Guidelines for Examination in the European Patent Office, D-III, 5.

[18] EPC Articles 52(1) and 57.

[19] EPC Article 52(1)-(3).

[20] EPC Article 53.

[21] 35 U.S.C. § 122(e)(1).

[22] 35 U.S.C. § 122(e)(1)(B).

[23] 35 U.S.C. § 122(e)(1)(A).

[24] MPEP § 1901.02.

[25] 37 C.F.R. § 1.291(e).

[26] 37 C.F.R. § 1.291(b).

[27] 37 C.F.R. § 1.291(c)(5).

[28] 35 U.S.C. § 321(b).

[29] 35 U.S.C. § 311(b).

[30] 35 U.S.C. § 321(c).

[31] 35 U.S.C. § 311(c).

[32] MPEP § 706.

[33] *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292 (Fed. Cir. 2011) (en banc).

[34] 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2245-49 (2010).

[35] MPEP § 2111.

[36] 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

[37] *Id*. at 1312-17.