

## Re-examination systems

# United States of America

The patent law of the United States of America, currently in force, provides two types of re-examination mechanisms: the *ex parte* re-examination under 35 U.S.C. § 302 to § 307 and the *inter partes* review under 35 U.S.C. § 311 to § 319.

### (i) *Ex parte* re-examination

The re-examination procedure is codified in 35 U.S.C. §§ 302-307 (often called “*ex parte* re-examination”). These provisions were enacted in 1980 in order to resolve patent validity disputes more quickly and less expensively than litigation, permitting courts to defer issues of patent validity to the expertise of the United States Patent and Trademark Office (USPTO).<sup>1</sup> The re-examination proceedings allows anyone, including the patent owner, to file a request for re-examination of any claim of a patent by providing the USPTO with a written request for re-examination accompanied by the fee, the pertinent prior art, and the manner of applying the prior art to the claim(s) at issue. The identity of the real party in interest may be kept confidential, as an attorney representing the real party in interest may file the request.<sup>2</sup> The prior art cited to the USPTO by the requester must consist of patents or printed publications.<sup>3</sup> Unless the person requesting re-examination is the patent owner, he will then be notified by the USPTO of the request for re-examination.

The USPTO will determine within three months whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, and if so, a re-examination proceeding will be initiated. The USPTO, in making its determination, is not limited to the prior art submitted by the requester, but may also consider other patents and printed publications.<sup>4</sup> For example, any relevant prior art patents or printed publications submitted by a third party that have been included in the official file under 35 U.S.C. § 301 (see Chapter VI(2)) may be considered in the re-examination process. The determination that no substantial new question of patentability has been raised is final and non-appealable by both parties.<sup>5</sup>

Where the USPTO issues an order for re-examination of the patent, the patent owner will be given a period not less than two months from the date the copy of the determination is given to him, within which he may file a statement including any amendments he may wish to propose. Where a patent owner files such a statement, its copy is communicated to the requester. The requester may submit a response to the statement made by the patent owner.<sup>6</sup> If the patent owner decides not to file a statement, the requester may not file any further communications in the proceeding.

After the time limits for filing the statement by the patent owner and reply by the third party requester have expired, the re-examination procedure will be conducted in a manner similar to that of the initial examination process. In any re-examination proceeding, the patent owner is permitted to propose any amendment to his patent and a new claim to distinguish his patent from the prior art cited, although the scope of the claims may not be enlarged.<sup>7</sup>

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<sup>1</sup> See 145 Cong. Rec. H6929, H6944 (daily ed. Aug. 3, 1999).

<sup>2</sup> *Syntex Inc. v. United States Patent and Trademark Office*, 882 F.2d 1570, 1573 (Fed. Cir. 1989).

<sup>3</sup> 35 U.S.C. § 302.

<sup>4</sup> 35 U.S.C. § 303(a).

<sup>5</sup> 35 U.S.C. § 303(c).

<sup>6</sup> 35 U.S.C. § 304.

<sup>7</sup> 35 U.S.C. § 305.

Once the USPTO renders a decision, the patent owner may appeal an adverse determination to the Board of Patent Appeals and Interferences (BPAI). A further appeal can be made to the Court of Appeals for the Federal Circuit or to the District Court.<sup>8</sup> The *ex-parte* re-examination requester, other than the patent owner, has no right to participate in either appeal.

#### *A Substantial New Question of Patentability*

The *ex parte* re-examination procedure is ordered only when there is “a substantial new question of patentability” in at least one claim of the patent. If there is no such “question”, no re-examination can be initiated. The meaning and scope of the “substantial new question of patentability” is developed through case law.

A prior art patent or printed publication raises a substantial question of patentability where there is a substantial likelihood that a reasonable examiner would consider the prior art patent or printed publication important in deciding whether or not the claim is patentable. If the prior art patents and/or publications are considered important, then the examiner should find that “a substantial new question of patentability” exists.

However, if the same substantial question of patentability has already been decided previously, re-examination will not be proper. For example, if the examiner finds that the additional prior art patents or printed publications are merely cumulative to similar prior art already fully considered in a previous examination of the claim, there is no “substantial new question of patentability”.

Accordingly, for “a substantial new question of patentability” to exist, it is necessary that:

- (i) the prior art patents and/or printed publications raise a substantial question of patentability regarding at least one claim. This means that the teaching of the prior art is such that a reasonable examiner would consider the teaching to be important in deciding whether or not the claim is patentable; and
- (ii) the same question of patentability as to the claim has not been decided by the Office in a previous examination or pending re-examination of the patent or in a final holding of invalidity by the Federal Courts in a decision on the merits involving the claim.

It is not necessary for the submitted prior art to form a “prima facie” case of unpatentability. A “substantial new question of patentability” as to a patent claim may exist even if the examiner would not necessarily reject the claim as either anticipated by, or obvious in view of, those prior art patents or printed publications.

#### (ii) *Inter partes* review

*Inter partes* review is a new trial proceeding introduced by the Leahy-Smith America Invents Act (AIA) of September 16, 2011, which took effect on September 16, 2012. The *inter partes* review is conducted by the Patent Trial and Appeal Board to review the patentability of one or more claims in a patent only on a ground that could be raised under 35 U.S.C. §§ 102 or 103, i.e., novelty and non-obviousness, and only on the basis of prior art consisting of patents or printed publications.<sup>9</sup> The *inter partes* review process begins with a third party filing a petition after the later of either: (1) nine months after the grant of the patent or issuance of a reissue patent; or, (2) if a post-grant review is instituted, the termination of the post-grant

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<sup>8</sup> 35 U.S.C. § 306.

<sup>9</sup> 35 U.S.C. § 311.

review. However, there are certain circumstances where an *inter partes* review may not be instituted. They include the cases where a petitioner filed a civil action challenging the validity of a claim before filing a petition for *inter partes* review. Similarly, an *inter partes* review may not be instituted if the petition is filed more than one year after the date on which the petitioner is served with a complaint alleging infringement of the patent.

The petition has to be based on copies of patents and printed publications, affidavits or declarations of supporting evidence or any other document. It will be made available to the public. For the institution of an *inter partes* review, it will be necessary to show that there is a reasonable likelihood that the petitioner would prevail with respect to at least one claim.<sup>10</sup> Similar to the post-grant review, there is no possibility to appeal to the determination of the threshold by the Director.

If the proceeding is instituted and not dismissed, a final determination by the Board will be issued within one year, extendable up to six months. The rules for estoppel and the stay of civil litigation are similar to those of the post-grant review.<sup>11</sup> The conduct of the *inter partes* review is similar to that of the post-grant review and may include oral hearings.<sup>12</sup> It is possible to appeal against the final decision of the Board to the Court of Appeals for the Federal Circuit.

As of 2019, *inter partes* review are the most common form of those proceedings at the USPTO.<sup>13</sup> In 2018, the Supreme Court issued an opinion confirming the constitutionality of *inter partes* review as a viable administrative procedure for challenging the validity of a patent.<sup>14</sup> In a separate decision, the Supreme Court also found that instituted *inter partes* reviews should address all challenged claims of a patent (rather than a subset of challenged claims).<sup>15</sup>

In June 2021, the USPTO implemented an [interim process](#) that allows a party to request review by the Director of the USPTO of a Patent Trial and Appeal Board (PTAB) final written decision in *inter partes* review (IPR) or post-grant review proceedings, and also provides the Director the option to *sua sponte* initiate the review of any PTAB decisions (at the Director's discretion). Until the process is formalized, the existing, interim Director review process will remain in place. The interim process has allowed the USPTO to quickly and efficiently implement [United States v. Arthrex, Inc.](#), a 2022 U.S. Supreme Court case holding that the PTAB's final decisions must be subject to review by the Director. *See United States v. Arthrex, Inc.*, 141 S. Ct. 1970, 1986 (2021).

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<sup>10</sup> 35 U.S.C. § 314 (a).

<sup>11</sup> 35 U.S.C. § 314

<sup>12</sup> 35 U.S.C. § 316.

<sup>13</sup> PTAB, Trial Statistics (June 2019), <https://www.uspto.gov/patents-application-process/patent-trial-and-appealboard/statistics>.

<sup>14</sup> *Oil States Energy Servs. v. Greene's Energy Grp.*, 138 S. Ct. 1365, 1370 (2018).

<sup>15</sup> *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1356-57 (2018).