

Life Sciences Law Blog

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Patent Reform

By [Don J. Pelto](#) and [Andrew Keith](#)

The Senate passed their version of a Patent Reform Bill (Senate Bill No. S. 23), on March 8, 2011 by a wide 95-5 margin. The bill makes significant changes, most notably including a first-inventor-to-file system, and an enhanced post-grant review procedures that will be conducted within the USPTO. There are 26 sections to the Senate bill. Some key features of the Senate Bill include:

1. A first-inventor-to-file system and limitation of the one year grace period (Sec. 2);
2. A Post-grant review proceeding (Sec. 5);
3. New *inter partes* review proceeding (Sec. 5a);
4. Preissuance submission by third parties (Sec. 7);
5. USPTO fee-setting authority and USPTO funding (Secs. 9 and 10);
6. A supplemental examination proceeding (Sec. 11);
7. Elimination of the best mode defense (Sec. 15.);
8. A transitional post-grant review of covered business method patents (Sec. 18); and
9. A change to the False marking Statute (Sec. 2).

The House of Representatives introduced their own version of the Patent Reform Bill (House of Representatives Bill No. H.R. 1249) on March 30, 2011. The House bill is very similar to the Senate bill, but includes some notable differences. The first-inventor-to-file system and limitation of the one year grace period is the same in the passed Senate bill and recently introduced House bill. Regarding the post-grant review and *inter partes* review proceedings, however, the House bill changes some of the standards of review and time limits in the Senate bill.

Below is a summary of some of the key features of the Senate bill, followed by a short analysis describing some important differences in the House bill.

1) First-inventor-to-file-system

The Senate bill moves to a first-inventor-to-file system, which would become effective 18 months after its enactment. The Senate bill eliminates current 35 U.S.C. § 102(g) and interferences, and questions of conception, diligence, reduction to practice, abandonment,

suppression, and concealment.

Moving to a first-to-file system fundamentally changes other aspects of 35 U.S.C. §§ 102 and 103 (new 35 U.S.C. §§ 102 and 103 language provided on page 7). The Senate bill significantly reduces the present one-year grace period, which applies to prior art or disclosures from any source, be it derived from the inventor or from another. Under the Senate bill, that one-year grace period is limited to scenarios where the disclosure was (1) derived from the inventor or (2) made public after the inventor publicized his invention. In practical terms to a patent practitioner, the Senate bill severely limits the ability to antedate or use § 1.131 declarations to swear behind prior-filed references (when the applicant was prior inventor). The Senate bill would remove any possibility to swear behind prior art references or disclosures in, for example, the following cases:

1. References (not derived from the inventor) that are published by another less than one year before the effective filing of the patent application.
2. Some Section 102(e) secret prior art references.

For example, there would be no possibility to swear behind patent applications filed more than one year before the effective date of the patent application at issue, but published less than one year before that effective date.

The Senate bill appears to limit public uses or sales of the invention before the effective filing date. Under the current law, sales and offers-to-sell do not constitute a loss of right of a patent if those sales or offers-to-sell occurred less than one year before the effective filing date of the application. Any such grace period appears to be removed. This, however, may depend on the definition of "disclosure" made by the inventor. The Senate bill allows for "disclosures" made by the inventor if "1 year or less before the effective filing date" of the patent application. If sales or offers-to-sell constitute "disclosure," then the rules regarding sales and offers-to sell of the invention (at least in the United States) would remain the same.

The Senate bill also removes geographic limitations for public uses or sales of the invention. Under the current law, an invention is not patentable if it was in public use or on sale in the United States more than one year prior to the effective filing date of the application (§ 102(b)); or it was known or used by others in the United States prior to the date of invention (§ 102(a)). The Senate bill removes these geographical limitations. 35 U.S.C. § 102 of the Senate bill states that an invention is not patentable if it was "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." No limit to the United States is stated. Thus, public use, sales, and knowledge by others, anywhere in the world could result in the loss of right to a patent.

House bill Provides the exact same language regarding 35 U.S.C. §§ 102 and 103.

2) Post-grant review

The Senate bill provides another way for a third party to challenge a patent. The post-grant review has some interplay with the new *inter partes* review, which is summarized next. The post-grant review procedure includes the following features:

- Allows third parties to file a petition within nine months from when the patent issues.
- Third party may challenge any claim of the patent based on any provision of the statute (i.e., §§ 101, 102, 103 and 112). In other words, it is not limited to just prior art references as in present *inter partes* and *ex parte* Reexamination.
- The standard for whether a post-grant review will be conducted by the "Director" is:

if "information presented in the petition, if not rebutted would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." The determination for conducting a post-grant review "may also be satisfied by showing that the petition raises a novel or unsettled legal question that is important to other patents or patent applications." § 324.

- The patent owner may file a statement to challenge the petition.
- The determination to proceed with a post-grant review is not appealable.
- Post-grant reviews will be handled by a Patent Judge (Patent Trial and Appeal Board).
- Post-grant reviews may not be instituted if the petitioner has filed a civil action challenging the validity of the patent. § 325.
- If an infringement claim is filed within three months of the issuance of a patent, the court cannot stay the consideration of the patent owner's motion for preliminary injunction against infringement due to the filing of a petition for a Post-grant review or if a Post-grant review was granted. § 325.
- The Director is given broad discretion on how to regulate the post-grant review process, including for example procedures for submitting supplemental information, procedures for

discovery, and providing either party with the right to an oral hearing. § 326.

- The proceeding can be terminated by settlement of the parties or by a final decision of the board. § 327.
- Final decisions are appealable to the Federal Circuit.

3) New *inter partes* Reexamination(now called *inter partes* review)

As stated above, the timing for *inter partes* review interplays with the post-grant review system. A request for *inter partes* review can be filed only on the later of nine months after the issuance of a patent or after a post-grant review is terminated. (§ 311(c)). Other features include:

- The standard for granting a request for *inter partes* review has changed in the Senate bill to "a reasonable likelihood that the petitioner will prevail with regard to at least one claim," thereby raising the standard from a "substantial new question of patentability" under current *inter partes* reexamination. § 314(a).
- The scope of review is still patents and printed publications, i.e., only challenging the patentability of one or more claims under §§ 102 or 103. § 311(b).
- Unlike the current *inter partes* reexamination, the Senate bill's *inter partes* review proceeding will be held before a Patent Judge (Patent Trial and Appeal Board).
- The *inter partes* review may be terminated by settlement or by a final decision of the board. § 317.
- The Director is given broad authority to establish regulations and how the proceedings will be carried out. For example, giving each party the right to an oral hearing, establishing procedures for submitting supplemental information, setting standards for discovery. § 316.
- The decision to proceed with *inter partes* review is not appealable § 314(d).
- Allows a preliminary response to be filed by the patent owner to explain why no *inter partes* review should be instituted. § 313.
- The Senate bill prohibits an *inter partes* review from being initiated or maintained if the petitioner has filed a civil action challenging the validity of a claim of the patent or if more than six months have passed since the petitioner was served with a complaint alleging infringement. § 315(a and b).
- The Senate bill includes estoppel provisions as provided in *inter partes* reexamination and does not allow for broadening of the claims. § 315(e).

- The final decision by the board may be appealed to the Federal Circuit. § 319.

4) Preissuance submission by third parties

This provision of the Senate bill allows for third parties to file publications or patents for consideration to the USPTO if the submission is made in writing before the notice of allowance or the a later of: 1) 6 months after the application for patent is first published; or 2) the date of the first rejection of any claim by the USPTO. The brief language is provided below.

GENERAL. Any third party may submit for consideration and inclusion in the record of a patent application, any patent, published patent application, or other printed publication of potential relevance to the examination of the application, if such submission is made in writing before the earlier of

- A. the date a notice of allowance under section 151 is given or mailed in the application for patent; or
- B. the later of
 - i. 6 months after the date on which the application for patent is first published under section 122 by the Office, or
 - ii. the date of the first rejection under section 132 of any claim by the examiner during the examination of the application for patent.

5) USPTO fee-setting authority and USPTO funding

Currently, Congress diverts some fees collected by the PTO for government operations. It has been estimated that about \$800 million in collected patent fees have been diverted over the past two decades. The Senate bill eliminates fee diversion by amending 35 U.S.C. § 42(c).

6) Supplemental Examination Proceeding

The Senate bill provides an additional, streamlined supplemental examination similar to an *ex parte* reexamination. The proceeding permits a patent owner to request "supplemental examination" for the USPTO to "consider, reconsider or correct information believed [by the patent owner] to be relevant to the patent." The standard for granting such a request is that the information raises a "substantial new question of patentability," which is the same as the current *ex parte* reexamination standard. In this proceeding, the patent owner does not have the right to file a patent owners statement. The proceeding appears to also be a means to correct any "inequitable" conduct during the prior examination. "A patent will not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of

the patent. The making of a request under subsection (a), or the absence thereof, shall not be relevant to enforceability of the patent under section 282."

7) Elimination of the best mode defense

The best mode under section 112 is still a condition for patentability. Best mode, however, can not be used as a defense for which a patent may be invalid or unenforceable. The Senate bill language is as follows:

(3) Invalidity of the patent or any claim in suit for failure to comply with:

- A. any requirement of section 112, except that the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable; or
- B. any requirement of section 251.

8) Transitional post-grant review of covered business method patents

The Senate bill provides a post-granted review proceeding to determine the validity of business method patents. The proceeding is limited to petitioners who have been sued or charged with patent infringement of the particular business method patent.

9) False-Marking Statute

The Senate bill limits false-marking suits to the United States or any person who suffered a competitive injury as a result of a false-marking violation.

Key Differences in the House Bill

Again, the first-inventor-to-file system and limitation of the one year grace period is the same in the House bill. The big differences in the House bill relate to the post-grant review and *inter partes* review proceedings. The House bill changes some of the standards for determining whether to proceed and the House bill includes some important language regarding stay of other proceedings, such as patent infringement litigation. In general, the House bill's changes are not favorable to the patentee. The House bill makes it easier to proceed with an *inter partes* review by lowering the standard and the House bill appears to make it easier to stay patent infringement actions in civil courts until these proceedings are terminated.

1) Post-Grant Review

The House bill expands the window of the post-grant review to twelve months after the issuance of a patent (rather than nine month window in the Senate bill). The House bill also permits review on the standard of "a novel legal question that is important to other patents or

patent applications."

The House bill also includes a new section providing guidance regarding requests for stays in other proceedings. The House bill includes considerations the courts should make regarding whether to grant a stay in a "civil action" (including patent infringement litigation as well as actions before the International Trade Commission); the court "shall decide" whether to grant the stay based on "whether the stay, or denial thereof, will simplify the issues . . . and streamline the trial." (§ 330).

2) *Inter partes* review

The House bill differs from the Senate bill by keeping the old standard for proceeding with a reexamination -- a substantial new question of patentability (rather than showing a "reasonable likelihood that the petition would prevail with respect to at least one of the claims challenged in the petition" in the Senate Bill).

The *inter partes* review timing period is changed due to the expansion of the post-grant review window. A petition can be filed for an *Inter partes* review from the later of twelve months after the issuance of a patent or after a post-grant review is terminated.

The House bill also includes a new section not in the Senate version regarding requests for stays similar to the post-grant review. The House bill provides guidance when a party seeks a stay in a "civil action" (including patent infringement litigation as well as actions before the International Trade Commission); the court "shall decide" whether to grant the stay based on "whether the stay, or denial thereof, will simplify the issues . . . and streamline the trial" (§ 320).

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§ 102. Conditions for patentability; novelty

(a) NOVELTY; PRIOR ART. A person shall be entitled to a patent unless:

1. the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
2. the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

(b) EXCEPTIONS.

1. DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION.

- A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if:
 - A. the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
 - B. the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

2. DISCLOSURES APPEARING IN APPLICATIONS AND PATENTS.

- A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if:
 - A. the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor;
 - B. the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
 - C. the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.

(c) COMMON OWNERSHIP UNDER JOINT RESEARCH AGREEMENTS Subject matter disclosed and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of subsection(b)(2)(C) if:

1. the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;

2. the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and
3. the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

(d) PATENTS AND PUBLISHED APPLICATIONS EFFECTIVE AS PRIOR ART. For purposes of determining whether a patent or application for patent is prior art to a claimed invention under subsection (a)(2), such patent or application shall be considered to have been effectively filed, with respect to any subject matter described in the patent or application

1. if paragraph (2) does not apply, as of the actual filing date of the patent or the application for patent; or
2. if the patent or application for patent is entitled to claim a right of priority under section 119, 365(a), or 365(b), or to claim the benefit of an earlier filing date under section 120, 121, or 365(c), based upon 1 or more prior filed applications for patent, as of the filing date of the earliest such application that describes the subject matter.

§103. Conditions for patentability; nonobvious subject matter

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Authored by:

[Don J. Pelto](#)
(202) 772-5362
dpelto@sheppardmullin.com

and

[Andrew Keith](#)
(202) 772-5367
akeith@sheppardmullin.com