On the Brink of Change—Congress Passes Patent Reform

The need to reform U.S. patent law has been perceived for almost a decade. Reports from government agencies (*e.g.*, the Federal Trade Commission in 2003) and the National Academies of Science (in 2004), and advice from academics, pundits, and others identified purported inefficiencies and inequities in patent law as interpreted by the Court of Appeals for the Federal Circuit and the U.S. Patent and Trademark Office, and proposed solutions. Congress responded by introducing and passing (in one chamber or another) three different patent reform bills in the last three Congresses. But until now, there was insufficient consensus for Congress to pass a patent reform measure.

That has changed: on September 8th, the Senate passed a bill, the "Leahy-Smith America Invents Act," previously passed in the House of Representatives (that itself is a modification of a bill already passed by the Senate), and it has been sent to President Obama for signature (which is virtually assured, since the President is on record as supporting patent reform as a way to stimulate the economy). The final Senate vote was 89-9, reflecting broad support for patent reform legislation in this Congress—the Senate passed its version of the bill (S. 23[1]) by a vote of 95-5, and the House bill (H.R. 1249[2]) passed by a 304-117 margin. Accordingly, it is time to consider the changes, some extensive, that will soon be law. While the bill contains 37 sections, this article discusses only the most significant of these, including several sections that are particularly relevant to those in the biotechnology and pharmaceutical industries and those involved with university-derived inventions.

Changes to 35 U.S.C. §§ 102 and 103

The amendments to 35 U.S.C. §§ 102 and 103 will change the U.S. patent system from a "first to invent" to a "first inventor to file" system.[3] This is perhaps the most significant change in the legislation, because it increases the pressure to file an application as quickly as possible after conception and, if time permits, actual reduction to practice. In addition to providing that priority is awarded to the first inventor to file a patent application containing a disclosure that satisfies 35 U.S.C. § 112, the amendments to § 102 change the nature of activities that fall within the new one-year "grace" period. These activities would now be personal to the inventors, and would be limited to publications or public disclosures; thus, public use and "on-sale" activity would no longer be included as protected activities under the grace period. In addition, public disclosure by a third party any time before an applicant's filing date would constitute prior art. The changes in the law will enable inventors to publish (an important consideration for universities) within one year prior to filing an application for inventions to be protected solely in the U.S.

Interferences, which are used to determine priority of invention under the current first-to-invent regime, will be replaced by derivation proceedings, whereby any inventor who is not the first to file can claim that another applicant derived the invention from him (rather than invented the claimed invention herself).[4]

These provisions will not go into effect until 18 months after enactment of the legislation,[5] raising the

likelihood that applicants will be incentivized to file any possible divisional or continuation applications prior to that date. This will probably result in a "bubble" of new patent filings at that time, further exacerbating the backlog of unexamined patent applications.

Assignee Filing

The "Leahy-Smith America Invents Act" will permit an assignee to file in the name of an unavailable or unwilling inventor,[6] and removes the requirement that naming (or changing) inventors be done without deceptive intent.[7] While there are many potential applications of this change, one in particular might be useful for universities in solving the problem created by the Supreme Court's recent decision in *Stanford v. Roche*[8]: requiring a blanket assignment agreement from university personnel could permit university officials more latitude in exerting control over patent filings for publicly supported inventions. These changes will go into effect one year after the date of enactment, and will apply to applications filed on or after that date.[9]

Prior User Rights

The concept of prior user rights as a defense against patent infringement was first introduced into U.S. patent law under the American Inventor Protection Act of 1999 ("AIPA"). Prior user rights permit an accused infringer to establish the use of a claimed invention prior to the patentee's earliest priority date. The AIPA limited these rights to business methods, under the rationale that prior to *State Street Bank*,[10] business methods were not believed to be patent-eligible, and thus the "true" inventor might have justifiably eschewed pursuit of patent protection. The prior user rights defense is expanded under the patent reform bill to be available to any accused infringer of any patented technology, but is limited to commercial use of the claimed invention.[11] As such, it can be expected that method claims (particularly manufacturing methods) will be most impacted by the expansion of the defense. University patentees are protected from this change in the law, since the defense is not available against accusations of infringement of university-owned patents.[12] It can further be expected that this will increase the value of university-licensed technology directed to such methods. Prior user rights will be available as an affirmative defense against an infringement allegation for all patents that are issued on or after the enactment of the legislation.[13]

Post-grant Review and Changes to Re-examination Provisions

The bill also creates a post-grant review ("PGR") similar to European oppositions, and like those proceedings, can be requested within nine months of the issuance of a patent.[14] Grounds for review will include any substantive requirement of patentability except best mode, and the standard for granting review will be that it is "more likely than not" that at least one claim in the granted patent will be found to be invalid.[15] Review will be limited to applications filed under the revised "first inventor to file" provisions of the bill (and thus will be delayed until the first patents grant from applications filed 18 months after enactment of the legislation),[16] and participation in a PGR that results in a final written decision will raise an estoppel against the requestor for any issues that were raised or

reasonably could have been raised in the PGR proceedings.[17]

Inter partes re-examination practice is also revised in the bill, to change the current "substantial new question of patentability" standard to a "reasonable likelihood that the requestor will prevail" with regard to at least one claim.[18] As with PGR, engaging in an *inter partes* re-examination that results in a final written decision will raise an estoppel against the petitioner for any issues that were raised or reasonably could have been raised in the *inter partes* reexamination proceedings.[19] These changes will go into effect one year after the date of enactment, and will apply to all patents."

Patent Office Fee-setting Authority

In addition to granting the Office fee-setting authority,[21] the new law provides for the creation of "micro-entity" status for universities, resulting in a 75% reduction in fees.[22] The Office is authorized to institute a 15% across-the-board increase in fees 10 days after enactment of the bill,[23] and further provides for a surcharge for prioritized examination ($4,800, reduced by half for small entities).[24]

Supplemental Examination

Under the Senate bill, *ex parte* re-examination was modified to permit a patentee to submit prior art not considered during patent prosecution, under circumstances where a patentee might fear an inequitable conduct allegation from an accused infringer.[25] A finding of patentability over such art was intended to absolve the patentee from such an allegation.[26] The House bill removed the provisions for absolution,[27] and these provisions are not part of the bill as enacted by the Senate.

Patent Term Extension

The final relevant substantive provision of the bill changes the deadline for filing a patent term extension ("PTE") application under 35 U.S.C. § 156(d)(1).[28] If an approval letter from the regulatory agency ("FDA") is sent after 4:30 p.m. Eastern Time, the 60-day clock for filing the PTE application does not begin until the next business day. This change will specifically benefit The Medicines Company's application for Orange Book listed patents for Angiomax®, as well as a handful of other applicants.[29] The change "shall apply to any application for extension of a patent term under section 156 of title 35, United States Code, that is pending on, that is filed after, or as to which a decision regarding the application is subject to judicial review on, the date of enactment of this Act."[30]

Patent Studies

The bill also contains a number of sections authorizing the Patent Office to perform studies on certain patent-related issues. These include Sections 27 and 34 of the bill.

Prior to passage of H.R. 1249 in the House, Section 27 of the bill permitted individuals with the opportunity to obtain a "second opinion" for any genetic diagnostic test. Introduced by Rep. Debbie

Wasserman-Schulz, this section originally provided that "[w]ith respect to a genetic diagnostic test provider's performance of, or offering to perform, a confirming genetic diagnostic test activity that constitutes infringement of a patent under section 271(a) or (b) of this title, the provisions of section 281, 283, 284 and 285 of this title shall not apply against the genetic diagnostic test provider with respect to such confirming genetic diagnostic test activity."

Although this section was ultimately stricken from the House bill, current Section 27 requires the Director of the U.S. Patent and Trademark Office to conduct a study directed to identifying "effective ways to provide independent, confirmatory genetic diagnostic testing" when a patented test has been exclusively licensed.

Section 34 of the House bill directs the Comptroller General of the U.S. to conduct a study on what effects non-practicing entities ("NPEs"), which includes universities, have on patent litigation (presumably, the conclusion is foregone that NPEs increase the number of patent infringement complaints).

Limitation on Issuance of Patents

Finally, Section 33 of the bill codifies a provision that has been part of appropriations bills since 2003 (often referred to as the Weldon Amendment) that prohibits the U.S. Patent and Trademark Office from granting patents "directed to or encompassing a human organism." As was the case with similar provisions of prior appropriations bills, supporters of this section provide reassurances that this provision is not intended to impact patents on either human genetic material or stem cells.

Senate Passage

Prior to passage of H.R. 1249 in the Senate on September 8, three amendments to the legislation were considered. The first amendment to be considered, which would have struck Section 37 concerning the calculation of the 60-day period for application of patent term extension, was rejected by a narrow 51-47 vote. The second amendment, which offered a replacement for Section 18 providing a transitional program for covered business-method patents, was rejected by an 8513 vote. The third and final amendment to be considered, which would have replaced Section 22 of the House bill concerning USPTO funding with the USPTO funding provisions of S. 23 (preventing fee diversion), was tabled by a close 50-48 vote (equivalent to defeating the amendment). Passage of these sweeping changes in U.S. patent law will require thorough review of almost all aspects of patent practice; further explication of the significance and impact of these changes can be expected to be found in these pages in the coming months. Visit Patent Docs, authored by MBHB attorneys, at http://www.patentdocs.org/ for additional information on this topic.

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Endnotes

1. *See* http://www.gpo.gov/fdsys/pkg/BILLS112s23es/pdf/BILLS-112s23es.pdf.
2. *See* http://www.gpo.gov/fdsys/pkg/BILLS112hr1249pcs/pdf/BILLS-112hr1249pcs. pdf.
3. *See* H.R. 1249, Sections 3(b) and (c).
4. *Id*. at Sections 3(h) and (i). 5
5. *Id*. at Section 3(e).
6. *Id.* at Section 4(b).
7. *Id.* at Section 4(a).
8. *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc*., 563 U.S. ____, 131 S. Ct. 2188 (2011).
9. *See* H.R. 1249, Section 4(e).
10. *State St. Bank & Trust Co. v. Signature Fin. Group*, 149 F.3d 1368 (Fed. Cir. 1998).
11. *Id.* at Section 5(a).
12. *Id.*
13. *Id.* at Section 5(c).
14. *Id.* at Section 6(d).
15. *Id.*
16. *Id.* at Section 6(f).
17. *Id.* at Section 6(d).
18. *Id.* at Section 6(a).
19. *Id.*
20. *Id.* at Section 6(c).
21. *Id.* at Section 10(a).
22. *Id.* at Sections 10(b) and (g).
23. *Id.* at Section 11(i).
24. *Id.* at Section 11(h).
25. S. 23, Section 10.
26. The Senate bill states: “The making of a request under subsection (a), or the absence thereof, shall not be relevant to enforceability of the patent under section 282.”
27. *See* H.R. 1249, Section 12.
28. *Id.* at Section 37.
29. *See, e.g., Medicines Co. v. Kappos*, 731 F. Supp. 2d 470 (E.D. Va. 2010).
30. *Id.*