

Patent Reform Legislation: Good News For Drug Discovery?

BY HERB HART

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Much has been said and written about the United States patent system over the past few years, most of it quite critical. The system, so it is said, is broken and needs fixing. And so we've seen a move to "reform" the patent system, i.e., "[t]o improve by alteration, correction of error, or removal of defects; put into a better form or condition."¹

If the patent system is broken and needs fixing, what's it supposed to be doing for us? The constitutional basis for the system is Article I, Section 8: "The Congress shall have power to . . . promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries; . . ." So, if the destination is to "promote the progress of science and useful arts", will patent "reform" move us in the right direction?

Very briefly, the term "patent reform" encompasses an amalgam of wide-ranging proposed changes to the patent laws. Though a number of bills have been put before Congress, the two pending versions that have been the subject of hearings and debate are S.1145 and H.R.1908. Another more recent proposal has been put forward by Senator Kyl of Arizona, but no significant action has been taken on it at the time of this writing. Both S.1145 and H.R.1908 would work comprehensive changes on the system, and they have many provisions in common, including, (1) adopting a first-inventor-to-file system; (2) mandating "applicant quality submissions", and (3) creating a post-grant review proceeding.

There's been great debate about the wisdom of various provisions of the bill,

particularly those that seem aimed at weakening patent rights. As to these, the IT sector tends to favor them, while the life science sector opposes them. The prospect of weakened patents is of particular concern in the pharmaceutical sector, where, as has been widely reported, the cost of bringing a new product to market exceeds one billion dollars. Without secure patent rights, future market exclusivity is in doubt, and the return on investment in drug discovery can be far less favorable than it is even today. Indeed, certain of the proposed reform provisions could be more likely to discourage than encourage investment in pharmaceutical research because they tend to create more uncertainty as to the strength of patents. So let's have a look at a few of the more significant proposals to see why that might be the case.

FIRST-INVENTOR-TO-FILE

The primary effect of adopting a first-inventor-to-file system is to eliminate prior invention by another as prior art. The result would be that patent interferences would be eliminated, as there would be no need to determine who "invented" first. There would be no need to understand or apply the technical rules for determining whether or not "interfering subject matter" exists, nor any need to understand or apply the technical rules for proving who's first, such as the rules concerning proof of conception, diligence, and reduction to practice.

What are the motivations for adopting such a system? The most commonly-given reason is to "harmonize" US law with that of the rest of the world. Nearly every other jurisdiction operates under a first-inventor-to-file system. Other practical reasons that have been identified are (1) eliminating "secret prior art" – i.e., unpublished research work of others; (2) eliminating expensive and complex interference proceedings; (3) reducing a patent applicant's cost and delay; and, (4) eliminating a patent owner's uncertainty about its patent rights. It's been said, as well, that moving to the first-inventor-to-file system would reduce the recordkeeping burden on researchers, because they'd no longer be

concerned about having to document actual dates of invention.

But are there reasons why we shouldn't adopt such a scheme? It's been argued – though not widely so – that the plain meaning of the term "inventors" in Article I, Section 8 is "first inventors." It's also been observed that "harmonization" is really a misnomer for a first-inventor-to-file provision, since there's little evidence that European, Japanese, or other patent laws are proposed to be changed to "harmonize" them with their US counterparts. Interestingly, H.R. 1908 proposes to adopt the first-inventor-to-file system only on a reciprocity basis, i.e., it "shall take effect 90 days after the date on which the President issues an Executive order containing the President's finding that major patenting authorities have adopted a grace period having substantially the same effect as that contained under the amendments made by this section."

If there is uncertainty created by adopting the proposed first-inventor-to-file system, it lies in leaving for other decision-makers the issues other than priority that are currently litigated in interference proceedings. For example, derivation disputes – if arising more than one year after grant of an affected patent – would presumably be resolved in court rather than by the Board. Inventorship disputes not involving derivation² appear not to be addressed in either S.1145 or HR.1908.

Though the need to resolve which inventor actually invented first will be eliminated by a first-inventor-to-file system, there will remain a need to determine the relative priority dates of individual claims. In other words, there will be a need to resolve – instead of priority of invention – priority of disclosure. A still further issue not addressed by the first-inventor-to-file provisions is how to resolve the issues created by the issuance of a patent wrongly granted to the later of two applicants.

APPLICANT QUALITY SUBMISSIONS

A rather controversial provision of the proposed bills is a requirement that patent applicants submit what's called – in S.1145 – an "Applicant Quality Submission" (or "AQS"). The submission must include "a search report and analysis relevant to patentability" (S.1145) or a "search report and other information and analysis relevant to patentability" (HR.1908). As its name

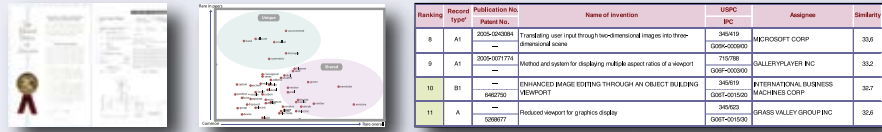
implies, the stated purpose is to improve the quality of examination of patent applications by requiring the applicant to identify and comment on the most pertinent prior art. Another benefit is said to be that having an AQS in the file will promote “efficiency” in patent examination. And, of course, the rationale is given that patent applicants, who usually are those who work in the field daily, are in the best position to know the prior art. The intended result is “higher quality” patents.

But what’s the cost of these “higher quality” patents? First, there’s the burden and the monetary cost of obtaining a search and preparing the “analysis relevant to patentability.” And what will be the benefit to the examination of the application if the Examiner must then do an independent search and analysis? Will that benefit – in the form of a “higher quality” patent, or a more efficient examination – be significant enough to outweigh the burden on the applicant? At least one major intellectual property law association has opposed the measure on the ground that the benefit simply won’t be a meaningful one. Instead, the AQS requirement is seen as a vehicle for shifting from the Examiner to the applicant the burden of conducting the examination.

Other implications of the proposal are more troubling. One is an exception to the requirement for filing an AQS for so-called “micro-entities.” Given the stated reasons for the proposal, one is left to believe that a patent granted to a “micro-entity” will be the product of a less efficient and less rigorous examination – in other words, a lower quality patent. And that can’t be good news for those micro-entities that seek to leverage their intellectual property assets into capital investment so that they can grow and be more economically competitive. Another is the high likelihood that the AQS itself will be the source of a flood of inequitable conduct claims based on the “analysis relevant to patentability.” That is particularly true under S.1145, which maintains the current standard of materiality: “a reasonable patent examiner would consider such information important in deciding whether to allow the patent application.” Even under the standard of HR.1908 – “a reasonable examiner would have made a prima facie finding of unpatentability, or maintained a finding of unpatentability” – it seems likely that the AQS would nonetheless be a breeding ground for inequitable

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conduct defenses. That, in turn, would lead to more uncertainty about a patent owner’s rights – in other words, weaker rather than stronger patents.

POST-GRANT REVIEW

There is general agreement that some sort of post-grant review proceeding would be a desirable addition to US patent practice. Indeed the limitations of the present reexamination scheme – including both ex parte and inter partes proceedings – have been widely discussed. Yet there’s sharp disagreement about how a post-grant review system should be implemented.

Both S.1145 and HR.1908 propose to provide a new vehicle for post-grant review and to address the perceived limitations of reexamination, but they differ in significant respects.

Opposition

Both H.R.1908 and S.1145 provide that any person may initiate an opposition proceeding by filing a petition within one year of grant of the patent. This is the so-called

“first window,” and, in HR.1908, it’s the only window for initiating an opposition proceeding. In a proceeding initiated during the “first window”, the presumption of validity does not apply, and invalidity can be proven by a preponderance of the evidence.

S.1145, however, provides a “second window” under certain circumstances; namely, (a) “the petitioner files a petition not later than 12 months after receiving notice, explicitly or implicitly, that the patent holder alleges infringement” or (b) “the patent owner consents in writing to the proceeding.” In a proceeding initiated during the “second window”, the presumption of validity *does* apply, and “the existence, authentication, availability, and scope of any evidence offered to establish invalidity shall be established by clear and convincing evidence.” Yet the proposal also provides that “invalidity shall be proven only if the persuasive force of such facts demonstrates invalidity by a preponderance of the evidence.”

Why create a vehicle for a post-grant challenge? Again, the refrain of improving “patent quality” is heard. An interested private party can bring to bear far greater resources and has a far greater incentive to challenge the patent than does an Examiner. As a result, the challenger will likely do a far better job finding prior art and explaining its significance than an Examiner is able to do during the limited time allotted to an ordinary examination. Thus, a patent that survives a post-grant opposition proceeding will be a stronger, “higher quality”, patent.

Another reason given for creating a post-grant review proceeding is to remove existing barriers to challenging patents. Under current law, only owners of patent applications or patents claiming “interfering subject matter” can challenge a patent by provoking an interference. Initiating a post-grant opposition, however, doesn’t require the petitioner to own a “ticket”, i.e., a patent application or patent claiming “interfering subject matter.” And under current law, one wanting to challenge a patent in court must (with one significant exception for pharmaceutical patents) make and sell a product, or practice a method, covered by the patent in order to provoke either a lawsuit or the threat of one. Resolving issues of patent validity in a post-grant opposition can be less costly, because administrative proceedings are ordinarily far less expensive than District Court litigation. The principal reason for the cost difference is that discovery is – in both proposed bills – quite limited in the same way that discovery in interferences is limited under current law; i.e., “upon order of the Director, as required in the interests of justice.” As any interference practitioner will tell you, interference discovery is narrowly limited and bears little resemblance to discovery available as of right in ordinary civil litigation.

So what’s not to like about having a post-grant review proceeding? The most obvious complaint is that there’s no presumption of validity to protect the patent owner, and it could be said that adopting a lower standard of proof (preponderance of the evidence rather than clear and convincing evidence) undermines patent integrity. Moreover, nothing in either S.1145 or H.R.1908 precludes multiple challenges by the same party, provided that each is based on a ground not asserted in a prior petition.

In a “single window” scheme, each patent will be subject to a new limited – and well-defined – period of vulnerability for one year after grant. In a “second window” scheme, each patent will be subject to a further period of vulnerability – a contingent one – the term of which is commenced by any effort of the owner to enforce the patent.

Inter Partes Reexamination

Once woefully underused, *inter partes* reexamination is gaining popularity. Under current law, it’s the most robust way – other than an interference – to challenge a patent without commencing litigation. And the trend is that many courts stay litigation involving patents which are the subjects of *inter partes* reexamination.

H.R.1908 would expand *inter partes* reexamination; offering an enhanced version in lieu of providing a “second window” for the commencement of a post-grant review proceeding. S.1145 takes the opposite approach, eliminating it altogether in favor of the “second window.”


No matter which approach is adopted, there’s an important question to be answered: Is the post-grant scheme practical? As proposed, both post-grant oppositions and *inter partes* reexamination proceedings (under H.R.1908) would be decided by Administrative Patent Judges sitting as the tribunal renamed as the Patent Trial and Appeal Board. This is the same group of individuals who are currently handling patent interferences and *ex parte* appeals. From the standpoint of an experienced interference practitioner, this seems an easy transition, since much of the post-grant procedure bears strong resemblance to current interference procedure. But does the Patent and Trademark Office have sufficient resources to handle the expanded workload? The Board’s case load of *ex parte* appeals is experiencing rapid growth, and that growth has been planned for. Yet there will quite likely be far more oppositions than there have been interferences (as noted, there’s no “ticket” required), and the resulting *inter partes* case load is sure to strain the Board – at its current strength – to the breaking point. Coping with a far greater *inter partes* docket will require the Office to hire and train dozens more APJs, and no ready source of qualified candidates in the needed numbers has been identified.

BALANCING THE EQUATION

Considering just these few major proposals, what can be said about the likely effect of proposed patent reform on drug development investment? Are the risk (a billion-dollar drug development investment) and the reward (market exclusivity based on patent rights) in balance? Would one conclude that patent rights will be more or less secure?

Without secure patent rights, there’s less incentive to invest heavily in drug development, since there’s less likelihood that market exclusivity can allow an innovator to recover and profit from that investment. On the other hand, increasing the quality of patents increases the respect and value they can command, which in turn increases the likelihood that the investment risk will be rewarded.

Much of what appears in the reform proposals suggests that the measures designed to raise patent quality will necessarily result in greater uncertainty for the patent owner. Certainly the provision in S.1145 of a “second window” extends period of vulnerability, just as the H.R.1908 scheme – including “enhanced” *inter partes* reexamination – makes mounting a challenge more attractive. And the requirement of an AQS – with no inequitable conduct reform – is sure to create yet another litigation issue and yet another source of vulnerability. The likely result, it seems, is a still further hurdle – in addition to the existing “open season” on drug patents created by Hatch-Waxman – to overcome before an innovator can reap a reward from a very large investment in drug discovery research and development.

So, as the proposals now stand, they offer both good news and bad for the pharmaceutical innovator. 

ENDNOTE

1. “reform”. Dictionary.com. The American Heritage® Dictionary of the English Language, Fourth Edition. Houghton Mifflin Company, 2004. <http://dictionary.reference.com/browse/reform> (accessed: October 15, 2008).
2. See Gholz, “Interference Issues That Wouldn’t Be Handled by the Proposed Legislation,” 15 Intellectual Property Today No. 2 (Feb. 2008).