

The Impact of Patent Reform on Nanotechnology: File Early and File Often

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ABSTRACT

Legislation introduced in 2005 was touted as a tsunami of patent reform. But disparate positions taken by big pharma and the electronics industries slowed the tide. In 2006, similar legislation combined with new patent examination rules proposed by the United States Patent and Trademark Office (“USPTO”) may form the perfect storm that finally changes the U.S. patent system landscape. If this occurs, companies trying to protect nanotechnology inventions will not be spared.

Keywords: patent, reform, examination, legislation.

1 INTRODUCTION

Proposed changes to the U.S. patent system include harmonization of U.S. practices to more closely track those of other countries, radical examination changes, and patent litigation reform. Harmonization proposals impact three unique aspects of the U.S. patent system: first to invent, interference practice, and the best mode requirement.[1] The main proposed changes to the USPTO’s examination practice include severely limiting the number of claims to be examined per application, shifting the burden of novelty searching to applicants when additional claims are sought, and sharply curtailing continuation application practice. Patent litigation reform initiatives include, but are not limited to, changing the standards for inequitable conduct, willful infringement, and injunctive relief.

2 HARMONIZATION PROPOSALS

A cornerstone of the U.S. patent system is the first to invent concept. The USPTO awards patents to inventors who are first to invent, in contrast to the rest of the world that awards patents to the first to file. Determining the first to invent can be very complicated, thus necessitating the U.S. interference practice.[2]

Historically, the argument has been that a first to file system disadvantages individual inventors and small businesses. However, the expense and uncertainty of determining the first to invent during a U.S. interference proceeding may cause the first and true inventor to be better off with a first to file system in which simply filing first determines priority.[3] As a result, the adoption of a first to file system in the U.S. -- once thought impossible--

would likely occur if no other patent reforms were pending. But since so much reform is being inserted into the legislation, passing of any reform is more complicated. Nonetheless, more predictability early in the patent process will help nanotechnology applicants to attract investors.

Once the first to file concept is eliminated in the U.S., it logically follows that the U.S. interference practice would be converted into an opposition system. Patent offices around the world, including the European Patent Office, allow for third parties to file oppositions following the grant of a patent. The U.S. opposition system being proposed includes two opportunities to oppose an issued patent. The first opportunity would occur within nine months of the grant of a patent, and the second would occur no later than six months after an infringement allegation. Proposed grandfathering of currently pending applications that grant and harsh estoppel provisions – preventing opposition arguments from being repeated in court – may limit wide use of a U.S. opposition system. While the cost associated with an interference may effectively only be postponed until after grant by the adoption of an opposition system, small companies, nanotech or otherwise, may benefit.

Legislators have also proposed elimination of the best mode requirement.[4] The best mode rule requires an inventor to disclose the best way to carry out the claimed invention (i.e., any tricks related to the claimed invention must be disclosed as part of the quid pro quo for the granted right to exclude). No other country has a best mode requirement, but applications filed in the U.S. based on foreign priority applications must still disclose the best mode. While it has been argued that the best mode requirement increases litigation costs, little data exists to support elimination of the best mode rule.[5] Contrastingly, elimination of this requirement may permit nanotechnology applicants to maintain best mode manufacturing techniques, for example, as trade secrets.

3 RADICAL EXAMINATION CHANGES

At a USPTO Town Hall meeting held February 1, 2006 in Chicago, John Doll, Commissioner for Patents, and James Toupin, General Counsel for USPTO, provided extensive remarks and explanations on a series of USPTO examination initiatives aimed to address extraordinary challenges facing the USPTO to improve patent quality and reduce patent application pendency. The USPTO seeks

more “focused” examination and “burden sharing” with applicants. Specific rule changes to limit continuation practice and initiate representative claim examination were described, along with changes to double patenting rules. [6] These rule changes were formally proposed by the USPTO on January 3rd and are in a 120-day comment period. The meeting also touched on other reform efforts, including some not yet released to the public, in areas of electronic web-based filing, accelerated examination, and the duty of disclosure/inequitable conduct.

3.1 Continuation Practice

A key proposal is to limit continuations and requests for continued examination (“RCEs”) to only one filing as a matter of right. Additional continuations or RCEs will only be permitted if a special showing is made. This showing is expected to be fairly strict. Applicants must show that amendment, argument or evidence “could not have been” presented earlier. Special rules are also proposed for divisionals and continuation-in-part (“CIP”) applications. CIPs introduce “new matter”, which is material beyond the scope of the original or “parent” application. The proposed rules include that no voluntary divisional applications will be permitted[8]; divisionals can only be filed in reply to a restriction requirement; divisionals may only claim benefit of a single prior-filed non-provisional application; and CIPs have an identification requirement requiring applicants to identify what claims are supported by a parent disclosure. Accordingly, claims not identified are only given the filing date of the CIP. Any continuation of the CIP will only be entitled to the benefit of the CIP’s filing date. As a practical result, only claims drawn to “new matter” of CIP will be pursued in any continuation of a CIP. Assuming application filing costs are not reduced, the overall cost for developing a portfolio will rise if more discrete applications must be filed to compensate for a limited continuation practice.

Several substantive changes to double patenting practice have also been proposed. Applicants must identify other applications or patents having a common inventor, common assignee, and filed within two months of each other (taking into account priority/benefit claims). A rebuttable presumption of double patenting will be created if identified applications/patents have the same effective filing date and substantially overlapping disclosures. An applicant can overcome the presumption by showing claims are patentably distinct, or by filing a terminal disclaimer and explaining why patentably indistinct claims in different applications should be maintained.[9]

The USPTO has also proposed required merger or cancellation of patentably indistinct claims in one application or across multiple applications where at least one common inventor exists and the applications are

commonly-owned, unless the applicant can provide a good and sufficient reason for not doing so.

3.2 Representative Claim Examination

Key proposed revisions to claim examination include representative claim designation and requiring an applicant to provide examination support documentation. Under the proposed changes, an applicant must designate up to ten claims for initial examination. Full initial examination would be conducted for designated representative claims only. Only when representative claims are allowed would the remaining dependent claims be examined.

Designation of more than ten claims would only be possible if an applicant provides an examination support document. The examination support document must identify the scope of search conducted by an applicant (including U.S., International patents, and non-patent literature); identify all limitations of representative claims that are disclosed by the cited references; explain how all representative claims are patentable over the cited references; show support in the specification for each representative claim; and identify utility for each independent claim.

The USPTO has proposed that these examination changes apply to pending applications that have not yet received first action on merits.[10] This is in stark contrast to the manner in which the USPTO typically implements changes. Usually, new rules only apply to applications filed on or after the date of enactment of the new rules.

While the USPTO has not formally proposed rule changes to the duty of disclosure, the USPTO has indicated that proposed changes to the duty of disclosure may also be presented this year.[11] The USPTO has indicated that it wants to shift the burden to applicants to identify the most relevant portions of larger references and to identify the most relevant documents in larger prior art listings.

4 LITIGATION REFORM

Legislative patent reform proposals seek to decrease the cost and increase the predictability of patent infringement litigation by modifying the laws related to willful infringement, best mode, and inequitable conduct.[12] All three normally require significant discovery to prove or disprove an allegation. Thus, some of the proposals eliminate the best mode requirement, substantially limit allegations of willful infringement, and remove determinations of violations of the duty of disclosure. There is a general consensus among interested parties that modifications in these three areas would be beneficial and these changes will likely find their way into the final legislation.

The reform deal breaker, however, relates to attempts to change the law as it pertains to permanent injunctions and damages. The patent owner's right to exclude is grounded in the U.S. Constitution. Congress has the power "to promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." [13] This exclusivity has been historically enforced using permanent injunctions. Some in the electronics industry have proposed drastically changing the current law by creating a system where permanent injunctions would be denied unless the patentee demonstrates a reason to grant one. Later this year, the United States Supreme Court will consider whether a patentee who does not practice the invention should be able to enjoin an infringer. [14] However, patent holders, such as nanotech start-ups, rely on excluding others from practicing their inventions to gain market access or to dominate in a new field. The proposed changes would be a major blow to these classical incentives for innovation.

The second hotly debated topic is codification of a definition for "reasonable royalties." Again, big pharma and a sector the electronics companies are at odds on this topic. The proposal is to codify factors to be considered when determining a reasonable royalty, such as the amount of realizable profit or value to be credited to contributions arising from the claimed invention (as distinguished from contributions arising from manufacturing processes or improvements added by the infringer or from the business risks the infringer undertook in commercialization). This is an attempt by some to severely limit the amount of damages available to a party holding rights to an improvement used in an electronic device. [15]

5 IMPLICATIONS

The emphasis on focused examination will make portfolio strategy at the time of filing more critical. Quality claim drafting in the initial filing and throughout examination will be more important. Applicants will not have as much flexibility to introduce new thinking or take claims in different directions later. Making the most of the initial Office Action response will also be much more important. Patentability searches prior to filing may be more important to avoid unnecessary rejections on overly broad claim sets.

One strategy to consider when nanotech invention is ongoing is to file on incremental improvements using plural provisional applications. The concept is to file a first provisional application shortly after the basic concept is fully conceived, followed by one or more short provisional applications on discrete improvements before the one year anniversary of a first-filed provisional. This provides the applicant more time to fully consider the merits of the earlier filed provisional concepts and strategize a final non-

provisional filing just before the anniversary of the first-filed provisional.

If international protection is sought, a Patent Cooperation Treaty ("PCT") application can be filed in lieu of, or in addition to the non-provisional filing. [16] A PCT search report and early examination by the EPO, for example, can help applicants gain an early understanding of the relevant prior art to better strategize the U.S. case before compressed reform examination begins.

Examination will be more contentious as applicants have less flexibility and options. Interviews and negotiations with the examiners will take on a larger role – prior to or after an initial office action. This puts a premium on counsel with a working knowledge of the USPTO. Doll and Toupin acknowledged this and highlighted proposed changes in USPTO rules to allow for interviews before an initial office action. Appeals will also be more important. Doll especially emphasized the pre-appeal brief conference procedure and the recent drop in cases pending at the Board of Patent Appeals and Interferences. The USPTO expects applicants to be more vigorous in traversing improper final rejections and filing appeals.

Collectively, proposals on continuation and representative claim designation would make it very hard for companies to file a series of continuations. The strategy of keeping a continuing application pending to allow maximum claim drafting flexibility later would no longer be practical. Patent families would generally be nuclear families – limited to parent and child non-provisional applications. Divisional applications would only be permitted in cases of restrictions. Patent families would be more likely to be targeted to one invention – more like a strategic bullet than the shotgun approach of a complex patent family tree. Strategies where an omnibus case is filed covering a range of inventions would have to be examined carefully. A limit to only one RCE or continuation may make it difficult to mine and claim all available subject matter. At minimum, the omnibus case would likely have to include a very large, well-drafted claim set covering all expected inventions to trigger a restriction by examiner and allow for divisionals to be filed.

The focused examination approach would favor applicants with a clear strategy executed and negotiated well with the Examiner. The flexibility of having applications pending and introducing new claim sets in follow on cases would be curtailed. Broadening reissue practice may also be important to accommodate claim strategies for future developments (such as coverage of an emergent infringing product) in lieu of an available pending continuation application.

It is said that a rising tide lifts all boats. If U.S. patent reform and/or the proposed examination changes take effect, nanotechnology applicants will need to row hard to stay ahead of this tide, along with everyone else. It will be most interesting, however, to see if the USPTO can survive the flood of new applications filed by applicants to accommodate these changes.

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REFERENCES

- [1] S. Ludwig *et al.* "U.S. Patent Reform And The Future Of Nanotechnology" Washington Law Foundation, Vol. 20 No. 37 August 12, 2005.
- [2] An interference is an inter parties administrative trial conducted by the USPTO, with limited discovery as compared to district court litigation.
- [3] Ludwig *et al.*, *supra*.
- [4] In addition to disclosing best mode, 35 USC § 112, first paragraph, requires that the application describe the invention so as to enable those skilled in the art to make and use the invention.
- [5] M. Dowd, "Elimination of the Best Mode Requirement, Throwing the Baby Out with the Bathwater?" ABA IPL Newsletter, Vol. 24, No. 1, Fall 2005.
- [6] "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications containing Patentably Indistinct Claims," 71 Fed. Reg. 48 (January 3, 2006); "Changes to Practice for the Examination of Claims in Patent Applications," 71 Fed. Reg. 61 (January 3, 2006).
- [8] Because the USPTO works on a production system, examiners are encouraged to only examine one invention at a time. If more than one invention is claimed in an application, the examiner can require that the inventions be divided, which is commonly referred to as a restriction requirement.
- [9] A terminal disclaimer links two patents such that they expire together to prevent the time-wise extension of the first.
- [10] Almost 600,000 applications are in a backlog awaiting examination on the merits at the USPTO.
- [11] Also referred to as the duty of candor and good faith, the duty to disclose (37 C.F.R. § 1.56 or "Rule 56") requires applicants to submit to the USPTO information that is material to patentability. Information is material if it:

establishes, by itself or in combination with other information, a *prima facie* case of unpatentability; or refutes, or is inconsistent with a position that the applicant takes in opposing a USPTO argument of unpatentability or asserting an argument for patentability.

- [12] Ludwig *et al.*, *supra*.
- [13] Article I, Section 8, Clause 8
- [14] *MercExchange, LLC v. eBay, Inc.*, 401 F.3d 1323 (Fed. Cir. 2005), cert. granted, (U.S. Nov. 28, 2005) (No. 05-130).
- [15] Coalition Print, H.R. 2795, 109th Cong. (September 1, 2005).
- [16] The PCT process facilitates protecting inventions internationally. The process permits a single patent application to be filed, which results in a single search, later accompanied by a written opinion (and optionally a preliminary examination). Since the PCT does not lead to the grant a patent (no "international patent" exists), national filing and examination (if provided by national law) is required. Thus, separate applications must then be filed in the countries where protection is sought. Prosecution and grant procedures are then handled by the relevant national or regional authorities.