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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

1st-To-File System Isn't New To Drug Companies

Law360, New York (March 04, 2013, 1:00 PM ET) -- On March 16, 2013, the first-to-file provisions of the America Invents Act take effect. This is one of the biggest changes ever made to U.S. patent law, and completely rewrites what is prior art. Since the AIA was passed, many legal experts have recommended that applicants avoid filing applications under the new law where possible — or file under both the old and new law to keep options open — for fear of being subject to prior art that would not be available under the old law. While avoiding the unknown first-to-file realm has tactical merit, every applicant should carefully consider the pros and cons of filing under each of the regimes before expending time and money to accelerate patent filings to make the March 15 cutoff.

There are no black and white answers, and certain applicants, such as pharmaceutical companies involved in drug discovery, may find that many of the perceived negative aspects of the first-to-file provisions do not present significant new risk in their quest for patent protection. Some applicants may even come to realize that there may be distinct advantages in the new regime.

One of the reasons drug companies may not be overly concerned with the new first-to-file provisions is that they are already operating in a first-to-file world and have already assumed the associated risks in their patent filing strategies. Securing global patent protection of new drug molecules is typical for these companies, and the majority of foreign countries already operate under first-to-file laws.

For example, Europe is one of the most common regions for pursuing patent protection of drug molecules, but it is also a strict first-to-file jurisdiction. Thus, the first-to-file provisions of the AIA do not constitute a new concept to drug discovery companies. Since these companies value patent protection in Europe and other first-to-file regions, their filing strategies may not need to be significantly changed, if at all, since their filing strategies already take into account the risk of being “scooped” by an earlier third-party filer who may not be known for up to 18 months when the prior art patent application publishes.

Since many drug companies already operate under a first-to-file strategy, they may not view elimination of the ability to swear behind a reference as a substantial drawback under the new law. Drug companies rarely take advantage of the antedating provisions to overcome third party prior art under Sections 102(a) and 102(e) because, if they find themselves in a position where antedating is the only means of overcoming the prior art, it means that their invention is unpatentable in most foreign jurisdictions. So much value and importance is placed in foreign rights in the pharmaceutical industry that companies will consider dropping a promising drug candidate (particularly when early enough in the product development timeline) if they cannot obtain patent protection abroad. Thus, elimination of the ability to antedate a prior art reference under the old laws will not be greatly missed for those who already practice in a first-to-file world.

Disadvantage or Advantage?

Additionally, some applicants may not find much disadvantage in either the elimination of the Hilmer doctrine or the inclusion of ex-U.S. activities related to the sale or public use of an invention. While these first-to-file provisions theoretically expand the world of prior art, practically speaking, the impact on some applicants, including drug companies, may be minimal. In the pharmaceutical industry, the development timeline of a new drug product is so long, and the process so secret, that sales and public uses are rarely a prior art issue, particularly with respect to new drug compound applications. It should also be considered just how often the Hilmer doctrine was actually effective in excluding prior art. A closer look might reveal that the types of prior art documents excluded under this doctrine came up fairly infrequently.

Many proponents of filing applications under the old law cite exposure to post-grant review (PGR) under the AIA as a distinct disadvantage of the new law. In a PGR proceeding, the patent can be challenged on any basis relating to invalidity of a claim. However, applicants are already exposed to inter partes review (IPR), a similar but slightly more limited proceeding based on validity issues arising from patents and printed publications. So, the possibility of becoming involved in a PGR proceeding may be viewed by some as not a significant amount of additional risk over IPR.

Additionally, some applicants may foresee little risk that their AIA patents will ever be opposed under PGR because of certain drawbacks associated with the proceeding. One major drawback is the broad scope of estoppel associated with PGR that prevents the PGR-filer from rechallenging the patent on any grounds that were raised during PGR or those that reasonably could have been raised. Thus, industries that are typically involved in patent litigation and have deep pockets or large litigation budgets, such as in the pharmaceutical industry, may decide to skip PGR (and IPR) altogether and take their patent disputes into the more familiar and expensive federal court system where they are able to take advantage of the legal process of that forum, including full discovery. Accordingly, exposure to possible PGR may not be a significant first-to-file deterrent.

Additionally, some first-to-file provisions of the AIA could be considered quite attractive to certain patent-filers. For example, expansion of the Section 103(c) carve out for common ownership or activities within the scope of a joint research agreement offer applicants additional protection from some prior art. Under the old law, a 102(e) reference could not be used in a 103(a) obviousness rejection if “the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.”

Under the AIA, this exception is expanded such that the 102(e) reference also cannot be used for an anticipation rejection. The exception is even further expanded with respect to the time period of common ownership. Under the old law, common ownership (or activities within the scope of a joint research agreement) must have existed "at the time the claimed invention was made." Under the AIA, the critical date for common ownership is later in time — "not later than the effective filing date of the claimed invention."

These expansions may be particularly attractive for prolific patent filers who are at increased risk for inadvertently creating prior art against themselves, and for applicants that routinely engage in joint research agreements. With a propensity for research alliances coupled with the pressure to secure an early priority date, drug discovery companies may find the expanded carve out a welcoming change in the law.

Consider Risks and Benefits

As the first-to-file deadline nears, applicants should carefully consider the risks and benefits of pursuing their applications under each of the regimes in view of the nature of their technology and practices within their industry, and should not presume that one regime is significantly better than the other simply based on public opinion. From the perspective of an international patent filer like a pharmaceutical company involved in drug discovery, some of the perceived drawbacks of the new law may be regarded simply as inconsequential or low risk, while some positive aspects, like the expanded prior art carve out, may be regarded as particularly attractive.

--By Christine A. Goddard, Fish & Richardson PC

Christine Goddard, Ph.D., is a principal in the patent group at Fish & Richardson in Boston.