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Patent Considerations in Drug Development Agreements: 2012 and Beyond

Intellectual properties and issues relating to their ownership and transfer have been pointed to as significant impediments to the collaborative development of drugs. With new laws changing the definition of what may be patented and what will be considered prior art, it is now more important than ever that those involved with collaborative research agreements have a clear understanding of the patent considerations. In addition, although new model agreements, such as the "express license," are noble attempts to simplify the process, they may produce non-optimal results with respect to how collaboratively developed patents are owned and prosecuted, and how developers are compensated.

Patent Ownership and Control of Patent Prosecution

Collaborative research agreements commonly direct that resulting patents are owned by the party, who makes the invention. In other words, if the employee of a party to the agreement is listed as an inventor on a patent, that party is an owner of that patent. This arrangement may be complicates by the fact that inventorship is a legal determination, which is made on a claim by claim basis. For certain claims, there may be more than one inventors. And for certain patents, there may be different inventors for different claims. As each patent owner may make, use, offer to sell or sell the patented invention within the United States, or import the patented invention into the United States without the consent of and without accounting to the other owners, ownership by inventorship can produce uncertain results.

Accordingly, it typically also makes sense to provide that the party, who will ultimately commercialize the product have exclusive rights under all relevant patents. This exclusivity may be accomplished by requiring that all non-commercializing patent owners exclusively license their patent rights to the commercializing party.

It typical also makes sense for drug development agreements to provide a mechanism for determining who is an inventor (whose patent attorney is going to make that call), as well as, who determines how various claims will be filed.

Typically the party who pays the patent costs will want to control the patent filing and prosecution. In other words, the party who pays will want to determine when patent applications are filed, in which countries and what claim scope will be pursued. However, many institutions require control of prosecution for patents in which they have an ownership interest. In which case, a licensee should at least have an opportunity to advise and comment and only pay for what it agrees to.

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Patent Royalties

Agreements transferring patent rights from a patent owner/licensor to a licensee typically require the licensee to pay a running royalty on net sales of licensed products. "Licensed products" have traditionally been defined as products, which are covered in whole or in part by a "valid claim" of the patent rights. "Valid claim" has traditionally been defined as an issued or granted patent claim that has not been held invalid or unenforceable. In other words, traditionally, a royalty has only been paid to the patent owner/licensor to compensate for the beneficial patent protection that has been developed. Or if there is a royalty paid for just the "technology" transferred, it is at a lower rate.

Certain university express licenses define "valid claim" to include not only issued patent claims, but also those contained in pending patent applications. In other words, these agreements provide the licensor with a royalty even if no patent claim ever issues. And since many of these agreements also give the licensor control of patent filing and prosecution at the licensee's expense, the licensor may be incentivized to keep unpatentable claims pending in order to receive a royalty. Although royalty compensation schemes offer the potential to delay repayment until products are actually sold, the royalty base needs to be carefully considered.

The America Invents Act and Collaborator Generated Prior Art

Since 2004, U.S. law has excluded from consideration for obviousness purposes, prior art made by a non-inventor collaborator, if the prior art and the claimed invention were, at the time the claimed invention was made, commonly owned or subject to an obligation of assignment to the same entity. A claimed invention and subject matter developed by a collaborator, which qualifies as prior art are deemed to be owned by the same entity or subject to an obligation of assignment to the same entity, if:

1. The claimed invention is made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;

2. The claimed invention is the result of activities undertaken within the scope of the joint research agreement; and

3. The application for patent on the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement. (35 USC §103(c))

For patent applications filed on or after March 16, 2013, this prior art exclusion also applies to the assessment of novelty. In particular, new section 102 of the America Invents Act provides that a disclosure shall not be considered prior art to a claimed invention 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 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 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.

The AIA also expands the type of prior art that may be considered for novelty and obviousness purposes. Patents, printed publications, public uses and sales are specifically mentioned as well as any other form of disclosure that was "otherwise available to the public" before the effective filing date of a claimed invention (e.g. experimental uses and oral presentations).

Further, where a patent is issued over prior art generated by a collaborator, the AIA now requires patent applications to be amended to disclose the names of all parties involved in the collaborative research.

As it may be difficult to prove whether prior art generated by a collaborator was actually obtained from an inventor, it is now more important than ever that drug development agreements be drafted and research conducted in a manner which avoids unintended bars to patentability.

In particular, to preserve patentability, research agreements must be in writing and signed by all relevant parties before the relevant research begins. These agreements should broadly describe the scope of work being pursued, so that resulting inventions are clearly covered. Also research collaborators should maintain good written records- not only of laboratory research, but also of public and confidential disclosures to, from and by collaborators for use as evidence, if prior art generated by a collaborator ever becomes an issue.

Also, the names of all parties involved with the research should be documented, so that relevant prior art generated by a non-inventor collaborator may be identified and if appropriate resulting patent applications amended to disclose the names of all parties involved in the collaborative research.

Patent applications to new compositions of matter (NCEs and biologics) and formulations of the same should continue to be filed as soon as adequately supported by sufficient written description and enablement.

Patentable Subject Matter: Higher Bars for Patent Eligibility and Written Description

The Supreme Court recently held that a correlation between metabolite level and drug efficacy was an un-patentable law of nature and that the steps of administering the drug and determining the level of metabolite of that drug failed to transform the correlation into patent-eligible subject matter. (Mayo Collaborative Services v. Prometheus Laboratories, Inc. S. Ct. 2012). There is now a heightened scrutiny on patent eligibility, particularly of method claims (e.g. research methods or diagnostic or therapeutic methods of use). In order to be considered patentable, the method must include at least one novel step or accomplish some type of a transformation.

In addition to restrictions on what will be considered patent eligible subject matter, the courts have also raised the bar on what needs to be disclosed in a patent application to adequately support the claims. Broad generic claims must be supported by a detailed written description of multiple exemplary species. In addition, reach-through claims to activators or inhibitors of a particular protein in a disease pathway based only on the description of a novel biomarker or discovery that a known biomarker is associated with a particular disease will not comply with the written description requirement. The disclosure of actual chemical structure is needed.