The patenting challenges of gene discovery

Bioentrepreneurs need to be careful not to claim too much when it comes to genes.

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For many bioentrepreneurs, the application of genomics to therapeutic development represents an enormous opportunity as well as a challenge. The race to patent genes is therefore of the utmost importance in laying the foundation for commercialization of this enterprise. As part of this foundation, the inventor wants to capture the broadest intellectual property protection possible for his or her invention in order to maximize those commercial possibilities.

In most instances, under US patent law, the practice of using prophetic examples is a perfectly acceptable device to accomplish this. For example, an inventor who has discovered a broad class of chemical compounds, normally need only prepare one or two as the basis for claiming a broad class of compounds. The basis for this is that all the compounds in the class will possess the same basic properties as the compounds made and tested.

But bioentrepreneurs and inventors alike should be aware that recently the US Federal Circuit Court has taken a narrow view of what is necessary and sufficient to adequately fulfill this requirement when it comes to gene sequences. Whereas many inventors of nonhuman genes have in the past used prophetic examples in their patent applications to describe how one would obtain the human gene using the same basic method used for obtaining the nonhuman gene, this is no longer a viable strategy, even when the entire sequence of the encoded human protein is known, according to the court.

The written description requirement

The logic behind this was revealed by the US Court of Appeals for the Federal Circuit when it recently invalidated claims to a "mammalian" insulin gene sequence and a "human" insulin gene sequence in *University of California v. Eli Lilly*[1]. According to the court, the University of California failed to meet the so-called written description requirement as to these claims when it included only the rat insulin gene sequence in the specification section of its patent[1]. Under US patent law, the written description requires that, "the applicant must [ ] convey to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*."[2,3] The reason that this is so critical to the patent's interpretation is that, "The invention is, for the purposes of the written description inquiry, *whatever is now claimed*."[4]

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In reaching its decision in favor of Lilly, the court held that the University of California's claim was invalid because no written description of the human gene sequence was provided in the specification. The court required that "'a precise definition such as structure, formula, chemical name, or physical properties' [be provided], not a mere wish or plan for obtaining the claimed chemical invention."[5]

The court went on to say that, "The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity."[6] In other words, the University of California had to have the human cDNA sequence for insulin in order to meet the court's threshold of the written description requirement of 35 USC 112.

Chemistry versus biology

How, then, can chemists claim broad classes of compounds based on one or two examples? In cases relating to chemical materials, the court stated that a generic structure is usually adequate written description because "[o]ne skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass."[7] However, with genetic material claims, terms such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without further description, is not an adequate written description of the *genus* because it does not distinguish the claimed genus from others, except by function[8]. Such a genus, according to the court "does not define any structural features commonly possessed by members of the genus that distinguish them from others."[9] Accordingly, the claiming of a single species—the rat insulin gene—was insufficient to support a larger genus claim such as "mammalian," which would cover many insulin genes not directly described in the University of California patent application.

Interestingly, the *Lilly* court did not suggest that to support a generic gene claim, one had to isolate and sequence each and every species claimed in order to meet the description requirement. Under this standard one may theoretically be able to meet the written description requirement for a generic gene claim without having to isolate each and every sequence. However, the court did not elaborate on what would be a representative number or an ample recitation of structural features sufficient to meet the description requirement. This left open the possibility that it might be possible to successfully claim a generic gene based upon the identification of homologous regions within a gene among the various species.

Conclusions

The lesson for bioentrepreneurs is that at present it may be wiser to limit one's disclosure to what is actually isolated and sequenced when it involves gene claims. Rather than risk invalidating your patent at some future date, for now the prudent path is to pursue only genes that have actually been isolated and identified. Otherwise, one may find oneself in the situation that befell the University of California in *Lilly*. Part of the enormous opportunity of genomics will be to successfully meet just these sorts of intellectual property challenges.

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1. *University of California v. Eli Lilly and Co.*, 43 USPQ 2d 1398 (Fed. Cir. 1997).
2. 35 U.S.C. §112, first paragraph.
3. *Vas-Cath Inc. v. Mahurkar*, 935 F2d 1555, 1563-4 (Fed. Cir. 1991) (emphasis in original.)
4. *Id.*
5. *Id.* at 1404, (quoting *Fiers v. Revel*, 984 F2d 1164, 1171 (Fed. Cir. 1993)).
6. *Id.* at 1405.
7. *Lilly*, 43 USPQ 2d at 1406.
8. Id.
9. Id.