Physician proposals could cost biotechs thousands

Physician organizations are lobbying US legislature with proposals that could mean the loss of millions of dollars of royalties and license fees from gene-based diagnostics for the biotech industry. The American Society of Clinical Pathologists (ASCP; Chicago, IL) formally asked the US Secretary's Advisory committee on Genetic Testing (SACGT; Washington DC) in June to review the current patent law governing on laboratory test methods. The society is proposing that the law be changed so as to exempt pathologists and other medical practitioners from infringement lawsuits when using patented laboratory tests. The Biotechnology Industry Organization (BIO; Washington, DC) is working in a determined manner to avert congressional support for the proposal, which seems ill considered and could reek havoc in a public market already oversensitive to the topic of gene-based patents.

In a two-page position paper, the ASCP charges that patent licensing fees have increased the cost of lab tests, such as for human chorionic gonadotrophin screening, thus reducing patient access to necessary diagnostics. The 75,000 member physicians organization asked SACGT to review the issue, proposing several options. One is to create an alternative mechanism to oversee the patent process so that gene-based lab tests won't be patented in the first place. Another is selective enforcement so that only specific individuals or entities may infringe on patents for specific activities. "For example, patents hindering the process for clinical researchers trying to cure cancer, or laboratory tests used to identify cancer might be excluded".

The ASCP also suggests changing current language in patent law to the same effect. This would mean altering the 1996 Ganske-Frist amendment to the infringement statue of US patent law (35 USC §287). The amendment exempts from infringement lawsuits medical practitioners who perform patented medical or surgical procedures that do not employ a patented device or process, so long as the procedure is carried out in association with a health-care entity such as a medical clinic, university, or hospital. Thanks to intensive lobbying by the biotechnology community at the time, the amendment currently specifically excludes biotechnology patents or any patent tied to molecular biological methods and life science. "I suspect the intention [of the ASCP] is to expand the Ganske amendment to include all diagnostic products, methods, kits, and gene sequences," says Stephen Bent, a partner in the law firm Foley and Lardner (Washington, DC).

In addition to the ASCP's paper, both the American College of Medical Genetics and the American College of Pathologists have released similar position statements on gene patents and accessibility of gene testing, which were discussed as part of the agenda at a meeting of the House of Delegates—the policy making arm of the American Medical Association—during its annual meeting in June.

This is "a very sensitive, very complicated, and very political subject," says Chuck Ludlam, vice president for government relations at BIO. Indeed, he insists that no actual proposal exists. "There is no legislation now and, as far as we know, no drafts," he told *Nature Biotechnology*.

Yet BIO has distributed a "talking point" document detailing arguments against the "pending immunity proposal", and is proactively educating legislatures on the negative commercial impact of removing a patent holders right to enforce their patent. BIO has had discussions with several legislators including Senator Orin Hatch (Utah), congressman Jerry Costello (D-IL) and other House Science Committee Democratic Staff, and Iowa's congressman Greg Ganske, co-author of the Ganske-Frist amendment.

According to BIO's document, entitled *Apples and Oranges: Medical Procedure Patents and Genetic Test Patents*, the immunity proposal is a direct attack on biotechnology companies and academic institutions that file and license gene-based patents because it would mean that any patent claiming a method for carrying out a diagnostic test or the gene-sequence or antibody needed to perform the test would not be enforceable. BIO argues that it will cost the biotech industry royalty and licensing revenue streams from the 1800 patents already awarded on human, animal, and plant genes, as well as from the 7000 pending applications. Granting any type of immunity legislation, says BIO, diminishes the incentives provided by the patent laws to conduct genomic research and develop genetic tests.

Patricia Granados, a patent litigation attorney at Foley and Lardner, agrees, warning that, without patent protection, emerging industries will suffer. If such legislation were to be passed, "It is questionable whether [genomics-based] industries will be able to obtain the investment money needed for research and development", she says.

BIO is concerned that this type of legislation could provide a "massive loophole" providing companies without patent protection a powerful incentive to partner with immune medical entities, allowing the companies to expand the marketing and sales of their genetic tests in direct competition with the patent holder. BIO is further concerned that the legislation, if drafted broadly enough to include patented gene sequences, could also extend to drug screening, gene therapy and other uses outside the scope of delivering genetic tests.

BIO's reluctance to admit to *Nature Biotechnology* that a proposal actually exists may reflect concern that the topic, if discussed by Congress, could set off a rerun of the $55 billion loss the industry suffered following the Clinton-Blair remarks on gene-based patents (*Nature Biotechnology*, **18**, 365). That Ludlam has targeted a few key congressman who understand gene patents suggests BIO is trying to impede passage of the proposal early on by blocking any possible congressional or committee support. "We are making our arguments to a more targeted [legislative] group now," concedes Ludlam, still claiming no knowledge of a written proposal. "This is very, very sensitive stuff," he reiterates, adding, "we do not want to mischaracterize the position of the medical specialty societies."

Certainly, that could be easy to do as the ASCP's position paper seems somewhat impolitic. For instance, Bent points out that the margin on diagnostics is actually limited by the government, which controls the market through government reimbursement of Medicaid. In addition, current patent law *already* has a research exemption immunizing academic researchers who engage in purely academic research from infringement litigation. Not only that, but Bent adds that the ASCP "may be barking up the wrong tree due to the fact that Ganske-Frist seems to only cover method patent claims, not composition of matter claims like gene sequences."

Moreover, such a proposal could actually be damaging to physicians themselves as it would cut off license fees and royalty payments to those academic institutions and hospitals that are major patent holders. In 1998, for example, licensing income for technology patents paid to universities worldwide reached $110 billion with $725 million paid to US universities. Similarly, US government agencies collected over $250 million.

As *Nature Biotechnology* was going to press, BIO, together with a "gene patent working group" made up of representatives from many of the major genomics companies including Incyte, Millenium, Celera, Human Genome Sciences and Myriad, was due to discuss the issues with several pathologist groups including the College of American Pathologists, Association of Molecular Pathology and the American Association of Clinical Chemistry.

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