

Are method patents still valuable?

Broad claims are failing, but sharper ones need not

by Vern Norviel and Anie K. Roche

Intellectual property issues are looming larger for most companies, but nowhere do they matter more than in the biotechnology industry. That is why a couple of recent decisions on so-called method patents in biotech have attracted such wide interest—and raised so many questions.

The first case involved the University of Rochester and its claim against the hugely valuable anti-inflammatory drugs known as COX-2 inhibitors, Pfizer Inc.'s Celebrex and Merck & Co.'s (recently withdrawn) Vioxx. The second involved a patent holder suing Bayer AG for importing into the U.S. data generated by a screening process that it had patented. Since the former is a "method of treatment" patent and the latter a "research tool" patent—two major categories of method patents—and since the courts ruled against the patent holders in each case, many people have wondered whether method patents have lost much of their utility. But as a review of the facts shows, what the courts have really done is to tighten the standards. Well-written method patents remain competitive tools for many biotech companies.

The University of Rochester patent covered the treatment of a human using any selective inhibitor of the COX-2 gene but did not identify any drug as a potential inhibitor. This patent appeared to give the university broad rights to exclude others from selectively inhibiting the COX-2 gene to treat a human disease—regardless of the small-molecule or gene therapy approach employed.

While the university's patent application was still pending, Pfizer developed a specific COX-2 inhibitor and brought it to market under the name Celebrex. Once the patent was issued, the university sued

Pfizer for infringing on it. But in February the court ruled against the university on the grounds that the patent lacked an adequate written description. With respect to method claims for treating a disease, the court said, a patent application must describe at least one compound by "a precise definition, such as by structure, formula,

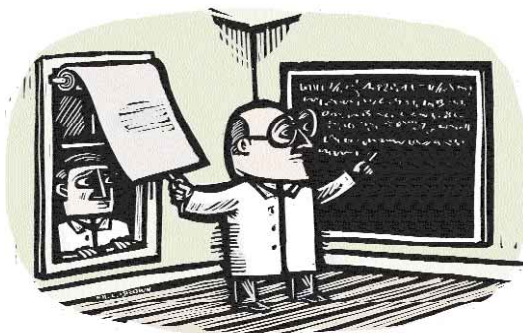


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chemical name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

In the Bayer case, the patents at issue described methods of screening for activators and inhibitors of proteins by monitoring cells that express the protein. This assay would be useful to identify drugs targeting the protein of interest. The patent holder sued Bayer because it conducted the patented assay in Germany and imported the data from that assay into the U.S., going on to develop a drug using the data.

At issue in this case was whether the importation of data, rather than a physical product, obtained via the patented method was an act of infringement. Bayer argued that the plain language of the infringement statute only covered the importation of physical products—and in a ruling in August 2003, the court

agreed. Further, a drug product whose characteristics were studied using the patented research processes was held to not be a product "made by" the patented processes. This ruling significantly limited the acts that would infringe some research tool patents.

Taken together, these rulings seem to threaten the many biotechnology companies whose business models involve the identification of novel targets for treatment of diseases and new research tools to be used to identify such targets. But careful patent writing can, in fact, keep those business models viable.

In situations where a new target has been identified, such as in the Rochester case, the company should include at least some of the following in the patent application: possible compounds that can be used to practice the claimed method; knowledge of macromolecular structure of the target; and sequences of possible gene therapy agents.

Problems with importation of data can be avoided as well, by including the appropriate claims, such as method claims (including computer-implemented and software claims); and business method claims directed to methods of employing this knowledge to develop and market therapeutics.

The current trend in patent case law is running against unreasonably broad claims—as, indeed, is public opinion. But better-crafted method-patent claims can still succeed. **CD**

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