

## *Bayer v. Housey*: Patent Prosecution for Research and Discovery Methods

On August 22, 2003, the Court of Appeals for the Federal Circuit (CAFC) rendered a decision that should receive careful consideration by owners of patents on research and discovery methods. The case, *Bayer AG and Bayer Corporation v. Housey Pharmaceuticals, Inc.*, No. 02-1598 (Fed. Cir., Aug. 22, 2003;), was an appeal of a 2002 Delaware district court decision dismissing Housey's claims that Bayer infringed US patents on a drug discovery method. The CAFC upheld the dismissal, finding that a patent on a method that generates information does not entitle the patentee to exclude a competitor from importing into the United States information obtained by carrying out the patented method overseas. The court also ruled that the patentee cannot exclude the making, using, or selling of a drug discovered through use outside of the United States of information derived from a patented method.

Housey sought to rely on the provisions of 35 U.S.C. 271(g), which makes it an act of infringement to import into the United States a product manufactured by a process that is covered by a U.S. patent. In particular, that statute provides:

Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent.

The court rejected Housey's argument that information obtained using its patented process was a "product" within the meaning of the statute. The court found that infringement under 35 U.S.C. 271(g) is limited to physical manufactured goods, and declined to extend the protection of the statute to information generated by a patented process. Similarly, the court rejected Housey's assertion that a drug discovered by the use of information derived from the patented process was a "product" of that process under the statute.

This decision should be considered carefully by owners of US patents on research and discovery methods and by companies that use those techniques. If the result of the patented process is information, and not a physical product, under current U.S. law neither importation of the information obtained by the patented method, nor importation of a drug discovered through use of the patented discovery method, are infringing acts. The patentee therefore cannot exclude importation of either the information or the resulting products, and may be vulnerable to ineffective patent protection from drug developers having access to overseas research facilities.

The imported information in this case was the biological activity of a drug molecule, which was obtained by practicing Housey's patented drug screening method overseas. The decision would seem to apply equally to the importation of other types of information, such as DNA sequence information and information about the chemical, biochemical, physical, or pharmacological properties of materials and devices in general. Many U.S. discovery and research method patents have only basic process claims, and the decision in *Bayer v. Housey*, along with other recent decisions, suggests that for certain types of assay claims, the U.S.

patent system does not prevent competitors from practicing the patented assays abroad and using the resulting information (or products obtained from using the resulting information) in the United States.

The holding in this case might significantly affect business plans that are predicated upon commercial exploitation of process patents on research and discovery methods. We have evaluated the drug discovery strategy and intellectual property issues raised by *Bayer v. Housey*. Please contact us if you would like us to assist you in assessing how this case may affect your drug discovery strategies or your business plans that revolve around proprietary research or discovery methods.

For assistance on this and other market protection matters, please contact your Ropes & Gray attorney