



## PATENT LAW 2005: The Year in Review

By Anna Carr

In 2005, the Federal Circuit and the Supreme Court rendered decisions in several cases that will have a significant effect on the field of patent law. In addition, Congress has proposed new legislation that, if enacted, would substantially alter the practice of patent law. A brief discussion of some of these cases and the proposed legislation is given below.

### INFRINGEMENT

Both the Federal Circuit and the Supreme Court decided several cases relating to infringement and exceptions to infringement.

The Supreme Court examined the scope of the **experimental use** exemption in *Merck v. Integra*. The Court held that the exemption "necessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process." Further, the Court went on to interpret the exemption broadly, finding that there was no indication that the exemption "excludes either (1) experimentation on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA" and noting that, under certain conditions, they would find "that the exemption is sufficiently broad to protect the use of patented compounds in both situations."

The Federal Circuit also examined **infringement through exportation of component parts** under §271(f) in a series of cases throughout 2005. Infringement under §271(f) occurs when a party in the United States supplies component parts of a patented invention outside the United States with the knowledge that the components "will be combined outside the United States in a manner that would infringe the patent if such combination occurred within the United States."

In *Eolas v. Microsoft*, the Federal Circuit affirmed a district court's holding that "components" under §271(f) includes software code on master disks, and that sending the disks out of the country for duplication onto hard drives by foreign computer producers constituted infringement. The Court then applied the *Eolas* holding in *AT&T v. Microsoft*, where they held Microsoft liable for infringement where Microsoft replicated software abroad from a master version that it exported from the United States with intent to be replicated. Finally, in *Union Carbide v. Shell Oil*, the Court found that

shipping a catalyst for a reaction for use outside the United States would similarly constitute infringement under §271(f).

The Court however, did determine that the application of §271(f) to **method claims** was not as inclusive. In *NTP v. Research in Motion (RIM)*, the Court examined whether Blackberry devices infringed the patents-in-suit. After finding infringement of NTP's product claims, the Federal Circuit noted that it was "difficult to conceive of how one might supply or cause to be supplied all or a substantial portion of the steps of a patented method in the sense contemplated by the phrase "components of a patented invention" in section 271(f)." The Court then explicitly found the method claims were not infringed under §271(f) because the sale of the device was "not the statutory supply of any component steps for combination" into the patented methods.

### UTILITY

In *In re Fisher*, the Federal Circuit looked at whether an EST (Expressed Sequence Tag) was patentable. The Court examined the **utility of an EST** standing alone, and held that ESTs were unpatentable for lack of utility under 35 U.S.C. § 101 unless there is a known use for the genes from which each EST is transcribed. The Court further explained, "[a]bsent such identification, we hold that the claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent."

### ANTICIPATION AND STATUTORY BAR

In *SmithKline Beecham v. Apotex*, the Federal Circuit explored a type of anticipation referred to by Judge Newman as "**inherent anticipation.**" In *Smithkline*, the patented compound at issue was formed as a by-product when manufacturing a product under a prior art patent. The prior art patent did not disclose the compound at issue, nor was the compound at issue discovered until years after the prior art patent was filed. However, the Court held that the patent-in-suit was invalid as anticipated because the claimed compound was created as a by-product to the prior art patent and therefore was inherently disclosed in the prior art patent.

The Federal Circuit has repeatedly held that a sale of the invention more than a year before filing a patent application will invalidate the patent. The Court

previously distinguished this rule in *In re Kollar*, finding no invalidating sale where the patentee had, more than a year before filing its patent application, signed a **research and development agreement** that would provide the right to commercialize the invention. The Court distinguished this holding in *Enzo-Biochem v. Gen-Probe*. In *Enzo*, the Court held that entering a research and development agreement that specifically provided for the sale of products from the agreement was an invalidating sale. In so holding, the Court distinguished *Kollar*, noting that "[u]nlike the invention in *Kollar*, Enzo's claimed invention...is a tangible item or product that can be sold or offered for sale."

The Federal Circuit also decided several cases relating to whether a use was an **invalidating public use** or merely a **permissible experimental use**. In *Lisle v. A.J. Manufacturing*, the Federal Circuit affirmed a jury finding of experimental use where the patentee's use of the patented product for more than 30 months prior to filing its patent application was documented by "substantial evidence" that the use was "experimental." The patentee was able to show that, although there were no confidentiality agreements signed, the parties to whom the product was distributed were aware of its experimental nature, provided continuous feedback on the product, and repeatedly altered the product based on advice received from the field.

The Court did not, however, find an experimental use in *General Motors v. General Electric*, where the customer did not appear to be aware that the goods it purchased were to be involved in any "testing." The Court explicitly stated that customer awareness and control exerted over the testing were the two most critical elements in determining if the use is "experimental use."

### CLAIM CONSTRUCTION

After several years of inconsistent rulings as to whether **dictionary definitions** or definitions contained in a patent specification control in claim construction, the Federal Circuit rendered an *en banc* decision in *Phillips v. AWH*. The Court ultimately reaffirmed the importance of intrinsic evidence in interpreting claims and put further emphasis on reviewing both the context of the claims themselves as well as the context of the claim terms within the specification. Further, the Court determined that the use of dictionaries was not to usurp **intrinsic evidence** within the patent. "While extrinsic evidence can shed useful light on the relevant art...it is less significant than the intrinsic record in determining the legally operative meaning of claim language."

### INEQUITABLE CONDUCT

The Federal Circuit decided several major cases relating to inequitable conduct in 2005.

In *Bruno Independent Living Aids v. Acorn Mobility Services*, the Court held that a failure to disclose to the USPTO information **contemporaneously disclosed to the FDA** in an application for permission to sell a product covered by the patent warranted a finding of inequitable conduct.

In *Purdue Pharma v. Endo Pharmaceuticals*, the Court upheld a finding of inequitable conduct where Purdue made "repeated and convincing representations to the PTO" regarding the novel properties of its **oxycodone** formulation. In fact, Purdue had no clinical support for these statements at any point during the prosecution of the patents in suit. The court noted that the representations made by Purdue evidenced a "clear pattern of intentional misrepresentation."

The Court similarly found inequitable conduct in the face of misrepresentations about the functionality of a patented product in *Novo Nordisk, v. Bio-Technology General*. The Court found that presenting the PTO with an **example that had never been shown to work and was written in the past tense** was inequitable conduct, particularly because the patentee was given numerous opportunities to disclose that the example was not functional.

### PATENT MISUSE

In *US Philips v. ITC*, the Court examined whether it was patent misuse for Philips to require licensees to license patents exclusively through **package licenses** when some patents in the package might not be essential to perform the functions sought by the purchaser. The Court held that such package licenses were not *per se* illegal.

On a related note, the United States Supreme Court will be rendering a decision in 2006 in *Independent Ink v. Illinois Tool Works* which will further examine the issue of **tying arrangements** between a patent and an unpatented product.

### PROPOSED LEGISLATION

In 2005, Congress proposed (but did not enact) some dramatic changes to U.S. patent law. The most dramatic change would be a shift from the United States' **first-to-invent** system to a **first-to-file** system similar to that found in most other jurisdictions. The legislation would also institute **post-grant opposition procedures**.