



PATENT LAW 2004: The Year in Review

By Anna Carr

In 2004, the Federal Circuit rendered decisions in several cases that will have a significant effect on the field of patent law. In addition, new legislation that will further influence the practice of patent law was recently passed. A brief discussion of some of the most interesting cases and legislation of 2004 is given below.

STATE IMMUNITY

In *Xechem International v. University of Texas M.D. Anderson Cancer Center*, the Court looked at whether, by entering into various relationships and contracts with Xechem, M.D. Anderson had waived its Eleventh Amendment and state immunity from suit. The Court held that M.D. Anderson had not waived its immunity because (1) There must be a "clear declaration" by the state of its intent to submit to federal jurisdiction in order for the state to waive its immunity; and (2) a state does not waive its immunity by its entry into the patent system.

ANTICIPATION AND STATUTORY BAR

The Federal Circuit decided several cases in 2004 that further defined the types of actions that will cause a party to lose the right to a patent.

In 1998, *Pfaff v. Wells Electronics, Inc.* explained that an invention was not patentable when it was (i) the subject of a commercial offer for sale and (ii) ready for patenting more than one year before filing for patent protection. In *Elan v. Andrx Pharmaceuticals*, the Court further clarified what constitutes a "commercial offer for sale" under *Pfaff*. The Court declined to find that Elan's offer "to enter into a license under a patent for future sale of the invention covered by the patent when and if it has been developed" was an **offer for sale**, affirmatively stating that "a communication that fails to constitute a definite order to sell the produce and to include material terms is not an 'offer' in the contract sense."

In *In re Klopfenstein*, the Court further expanded the types of public disclosures that can lead to the loss of patent rights. In holding that the presentation of a printed slide presentation on poster boards for several days at a conference more than one year before filing constituted a **printed publication bar**, and thus prevented the issuance of a patent, the Court delineated a list of factors to weigh in determining whether something is a printed publication: (1) the length of time the display was exhibited; (2) the expertise of the target

audience; (3) the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied; and (4) the simplicity or ease with which the materials displayed could have been copied.

The Court further examined the anticipation bar in *Schering v. Geneva Pharmaceuticals*. In *Schering*, the Court examined whether a patentee could claim rights to metabolites of its patented matter. In finding Geneva's claimed matter was merely a metabolite of Schering's patented matter and **inherently disclosed** by Schering's patent, the Court noted that its finding did not "preclude patent protection for metabolites of known drugs." Specifically, the Court stated that patent protection may still be available for (1) the metabolite claimed in its pure and isolated form; (2) the metabolite claimed as a pharmaceutical composition; or (3) a method of administering the metabolite or the corresponding pharmaceutical composition.

OBVIOUSNESS

The Court expanded and clarified the relevant time period for secondary indicia of non-obviousness in *Knoll Pharmaceutical v. Teva Pharmaceuticals*. In *Knoll*, although the specification noted a "surprising" increase in efficacy resulting from the combination of an opioid with an NSAID, much of the evidence supporting this "surprising" effect was created and gathered after the grant of the patent. The Court noted that "[e]vidence developed after the patent grant is not excluded from consideration, for understanding of the full range of an invention is not always achieved at the time of filing the patent application."

Under the Cooperative Research and Technology Enhancement Act ("**CREATE Act**"), certain types of subject matter developed by another can be avoided as prior art where "(1) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made; (2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and (3) the application for patent for the claimed invention discloses or is amended to disclose the names to the parties to the joint research agreement." The Act has an effective date of December 10, 2004.

WRITTEN DESCRIPTION

In *In re Wallach*, the Court examined whether a patent based solely on a partial amino acid sequence, molecular weight, and biological activity met the written description requirement. Although the Court noted that disclosure of an amino acid sequence would be sufficient to claim the nucleic acid molecules that encode the protein sequence, it held that where, as here, only a partial amino acid sequence is given, and where no evidence is provided to show a correlation "between the partial structure of a protein, the protein's biological activity, and the protein's molecular weight" and the structure of the DNA encoding the protein, the written description requirement is not met.

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 has decided to rehear *Phillips v. AWH Corp.* with all the judges sitting *en banc*. Specific questions that will be addressed include: the aforementioned issue; when, if ever, claim language should be narrowly construed to preserve validity; the role of the prosecution history and expert testimony in claim construction; and whether deference should be afforded to the trial court's claim construction rulings.

DOCTRINE OF EQUIVALENTS

In *Insituform Technologies Inc. v. Cat Contracting*, the Court looked at whether "the Festo presumption that a narrowing amendment made for a reason of patentability surrenders the entire territory between the original claim limitation and the amended claim limitation." The Court held that such a presumption can be rebutted where, as in this case, the amendment bears only a "**tangential relation**" to the equivalent in question. In *Insituform*, the narrowing amendment was made to overcome prior art but was not relevant to the equivalent at issue, and therefore did not fall within the *Festo* presumption.

DAMAGES

In two separate cases, the Court reexamined the holdings of *Rite Hite v. Kelley* and clarified which parties and what products should be used in calculating **lost profits damages**.

In *Poly-America v. GSE Lining*, the Court looked at whether a corporation is entitled to lost profit damages for the infringement of a patent owned by its sister corporation. The Court held that even where the sister corporations share interests, that relationship alone is not sufficient to entitle a sister corporation to claim lost profit damages. In denying damages to the sister corporation, the Court reiterated the requirement

explained in *Rite-Hite* that only licensees with exclusive rights under the patent may sue for damages.

In *Juicy Whip v. Orange Bang*, the Court examined whether a party could allege lost profits in its unpatented syrup, where the patented dispenser used in conjunction with the syrup was the subject of the infringement suit. The Court noted that under *Rite-Hite*, "physically separate unpatented components normally sold with the patented components" may be used in lost profits calculations where the components are together considered a functional unit. Here, the Court reversed the district court's holding that the dispenser and syrup did not share a functional relationship because they had been sold separately from one another and because other syrups could be used in the dispenser because "the syrup functions together with the dispenser to produce the visual appearance that is central to Juicy Whip's '405 patent."

WILLFUL INFRINGEMENT

For years, the Court has held that an accused infringer's failure to obtain or produce an exculpatory **opinion of counsel** should result in an adverse inference that the opinion would have been or was unfavorable. In an *en banc* opinion, the Federal Circuit recognized the burden this adverse inference placed on the attorney-client relationship and, in *Knorr-Bremse Systeme Fuer Nutzfahrzeuge v. Dana*, held that "no adverse inference that an opinion of counsel would have been unfavorable flows from an alleged infringer's failure to obtain or produce an exculpatory opinion of counsel."

The Court further narrowed the instances in which willful infringement will be found in *Glaxo Group Ltd. v. Apotex Inc.* In *Glaxo*, the Federal Circuit looked at whether the filing of an **ANDA application** is sufficient to support a finding of willful infringement under the Hatch-Waxman Act. The Court held that, because the Hatch-Waxman Act "is designed to create an artificial act of infringement for purposes of establishing jurisdiction in the federal courts," the filing of an ANDA application or certification is insufficient to support a finding of willful infringement.

FEE LEGISLATION

On December 8, 2004, President Bush signed into law H.R. 4818, the Consolidated Appropriations Act (CAA), which immediately altered the patent fee structure. Under the CAA, prices for applications were generally raised, and new provisions provide financial incentives for filing shorter or fewer claims by charging higher fees for applications with more than three independent claims or more than twenty total claims, as well as for those whose specifications and drawings exceed 100 sheets of paper.