

NEWSSTAND

Federal Circuit Update: Intellectual Property Bulletin - Winter 2009

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***Cipro* Settlement Agreements Between Bayer and Generic Drug Manufacturers Did Not Violate Sherman Act**

In re Ciproflaxacin Hydrochloride Antitrust Litigation 2008 WL 4570669 (Fed. Cir. 2008)

In a case involving whether settlement agreements between a patent holder and generic drug manufacturers violate the antitrust laws, the U.S. Court of Appeals for the Federal Circuit affirmed the district court's ruling that the "reverse payment" settlement agreements at issue did not violate the Sherman Act. In *Cipro*, the original litigation involved a patent infringement suit between Bayer and several generic drug manufacturers relating to the manufacturing and marketing of generic versions of the drug Cipro®.

Just before trial, the parties entered into settlement agreements that provided for payments to be made by Bayer to the generic drug manufacturers in exchange for their agreement not to manufacture or market generic versions of Cipro. Thereafter, advocacy groups and direct and indirect buyers of brand-name drugs containing the patented compound ciproflaxacin hydrochloride, the active ingredient in Cipro, sued the parties to the settlement agreements, alleging that the "reverse payments" resulted in illegal market allocation in violation of the Sherman Act and state antitrust laws.

The Federal Circuit affirmed the district court's grant of summary judgment on the grounds that the settlement agreements did not violate section 1 of the Sherman Act because any anti-competitive effects caused by the settlement agreements were within the exclusionary zone of Bayer's patent. The Court added that it was well within Bayer's rights as a patentee to exclude the generic drug manufacturers from profiting from the patented invention. The Court further stated that settlements in patent litigations are favored by the courts and such settlements, including those in which there is exchange of consideration, are not precluded by the Sherman Act even though some settlements may have adverse effects on competition. The Federal Circuit concluded that any anti-competitive effects caused by the settlement agreements could not be redressed by the anti-trust laws.

The "Machine-or-Transformation" Test Must Be Applied to Method Patent Claims

In re Bilski 4757110 (Fed. Cir. 2008)

The Federal Circuit in *In re Bilski* recently clarified that the "machine-or-transformation" test must be applied by the Patent Office and the courts when determining whether a claimed method constitutes a patent-eligible process under 35 U.S.C § 101. In *In re Bilski*, the Patent Office had rejected the patent applicants' claim relating to a method of hedging risk in the field of commodities trading on the grounds that the claim was not patent-eligible because it was not a "new and useful process," as § 101 requires.

The Federal Circuit affirmed, stating that a claimed method is patent-eligible as a "new and useful process" if it passes the "machine-or-transformation" test, which requires either that the method: (1) is tied to a particular machine or apparatus, or (2) transforms a particular article into a different state or thing. The Court also stated that the applicant must demonstrate that "the use of a specific machine or transformation of an article must impose meaningful limits on the claims' scope to

impart patent-eligibility.” This test, according to the Court, is the “only applicable test” and must be applied when evaluating the patent-eligibility of process claims.

Biotech Patents Invalid for Failing to Meet Written Description Requirements

Carnegie Mellon Univ. v. Hoffmann-La Roche Inc. 541 F.3d 1115 (Fed. Cir. 2008)

The Federal Circuit affirmed summary judgment that patent claims for recombinant DNA polymerase were invalid because they failed to meet the § 112 written description requirement. Carnegie Mellon University brought suit against Hoffman-La Roche Inc. for the alleged infringement of three patents that relate to novel recombinant plasmids. The patent claims broadly covered activity isolated from any “bacterial source.” The written description, however, disclosed only one bacterial species.

The *Carnegie Mellon* court applied the rule of law that a “patentee can lawfully claim only what he has invented and described, and if he claims more his patent is void.” Relying on its earlier decision in *University of California v. Eli Lilly*, the Federal Circuit stated that to “satisfy the written description requirement for a claimed genus, a specification must describe the claimed invention in such a way that a person of skill in the art would understand that the genus that is being claimed has been invented, not just a species of the genus.”

Resurrecting the Importance of Opinion Letters in Induced Patent Infringement Cases

Broadcom Corp. v. Qualcomm Inc. 2008 WL 4330323 (Fed. Cir. 2008)

The Federal Circuit recently held in an induced patent infringement case that a district court did not err in instructing the jury to consider all of the circumstances, including whether Qualcomm, the alleged infringing party, sought the advice of counsel as to noninfringement, in determining whether Qualcomm had the requisite intent to support a claim for willfulness.

In order to prove an inducement to infringe claim, the plaintiff must establish, through direct or circumstantial evidence, that: (1) the alleged infringer intended to cause the infringing acts, and (2) the alleged infringer knew or should have known that its actions would cause the infringement.

The district court had instructed the jury that “the absence of a lawyer’s opinion, by itself, is insufficient to support a finding of willfulness, and you may not assume that merely because a party did not obtain an opinion of counsel, the opinion would have been unfavorable. However, you may consider whether Qualcomm sought a legal opinion as one factor in assessing whether, under the totality of the circumstances, any infringement by Qualcomm was willful.” The jury concluded that Qualcomm had infringed several of Broadcom’s patents.

The Federal Circuit held that because opinion-of-counsel evidence may reflect whether the alleged infringer “knew or should have known” that its actions would lead another to directly infringe, such evidence is relevant to the second prong of the state-of-mind analysis. The Court further held that the failure to procure such an opinion may be probative of intent in this context.