ideas on intellectual property law

year end 2005

in this issue

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All shook up

The Supremes rock copyright with Grokster

The U.S. Supreme Court's much-awaited decision in *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, created waves on the Internet by introducing patent law's inducement theory of secondary liability into copyright law. While it may be too late for the *Grokster* defendants to avoid such secondary liability, if you distribute products capable of both lawful and unlawful uses — and almost everything is — you may need to assess your own potential liability for copyright infringement by third parties using your products.

HARD HABIT TO BREAK

The defendants, Grokster and StreamCast Networks, distribute free computer software products that allow users to share electronic files directly through peer-to-peer networks. Generally speaking, a user can send a request for a certain file and, if the file is found residing on another user's computer, it can be downloaded directly. The downloaded file is placed in the first user's designated sharing file, from where other users can subsequently download the file to their computers.

Most significantly, users' computers communicate with each other directly, not through central servers. Because the communications don't pass through a central server, the defendants have no way of knowing when users copy particular files.

Music lovers and movie fans have used the defendants' networks to share copyrighted music and video files without the copyright owner's authorization. The defendants generate income by selling advertising space, with ads delivered to users while they use the software. Thus, the greater the number of files shared, the higher the price the defendants can charge advertisers and the greater their revenue.

A group of copyright holders sued Grokster and StreamCast, alleging the companies knowingly and intentionally distributed their software to enable users to reproduce and distribute works in violation of the Copyright Act.

THE LONG AND WINDING ROAD

The Supreme Court's decision extensively referenced its earlier decision in *Sony Corp. v. Universal City Studios*, which established the "substantial noninfringing uses" test. Sony was accused of being contributorily liable for infringement that occurred when VCR owners taped copyrighted programs because it supplied the means to infringe and had constructive knowledge that infringement would occur.

Trial evidence showed consumers used the taping capability primarily to time-shift televised programs for more convenient watching. The Court found this to constitute noninfringing fair use and noted

the absence of evidence indicating Sony intended to promote infringing uses of its technology. Ultimately, the Court ruled Sony couldn't be held liable solely on the basis of distributing the VCR because it was "capable of commercially significant noninfringing uses."

Following this logic, the *Grokster* defendants argued that copyright owners can authorize free copying of copyrighted works and that their software had significant potential noninfringing uses. The Ninth Circuit Court of Appeals found the software was capable of substantial lawful use, precluding liability for copyright infringement under *Sony*, and granted the defendants summary judgment.

But the Supreme Court declared that the *Sony* rule doesn't limit liability where evidence demonstrates an *intent* to induce infringement. It noted that evidence of a defendant actively encouraging use of its product for infringement by third parties outweighs the law's reluctance to impose liability when a defendant merely sells a product capable of a lawful use.

In reaching this conclusion, the Supreme Court expressly adopted the inducement rule from patent law for copyright. Under this adopted rule, if you distribute a device and promote its use to infringe a copyright, as shown by clear expression or other affirmative steps taken to foster infringement, you're liable for the resulting acts of infringement by third parties.

YOU CAN'T ALWAYS GET WHAT YOU WANT

The Court found that the evidence in *Grokster* indicated that the vast majority of downloads

With a rebel yell

While the entire Court believed the Ninth Circuit was incorrect in its granting of summary judgment for MGM, they didn't agree on everything. In two concurrences to the majority opinion in *Grokster*, Justices Ginsburg and Breyer clashed over how parties can satisfy the "substantial noninfringing uses" test first articulated in *Sony*.

Justice Ginsburg believes the Ninth Circuit misapplied the *Sony* test. The court had concluded that the defendants met *Sony's* requirement, holding that "a product need only be *capable* of substantial noninfringing uses." According to Ginsburg, the court reached its conclusion largely on the basis of declarations submitted by the defendants; she found this insufficient.

Ginsburg would have required the defendants to demonstrate, "beyond genuine debate, a reasonable prospect that substantial or commercially significant noninfringing uses were likely to develop over time." In other words, Justice Ginsburg didn't think the defendants presented enough evidence to meet the *Sony* test.

Justice Breyer strongly opposed such an approach. He argued that Ginsburg's theory would require the production of considerably more concrete evidence to earn *Sony's* protection, undercutting that protection in the process.

Instead, Breyer found that the record revealed a significant future market for noninfringing uses of Grokster-type peer-to-peer software. For example, such software permits the exchange of *any* sort of digital file — whether that file does or doesn't contain copyrighted material. As more and more uncopyrighted information is stored in swappable form, Breyer found a likely inference that lawful peer-to-peer sharing will become increasingly prevalent.

Breyer wrote that Ginsburg's more stringent reading of *Sony* would make life easier for copyright holders but also increase the legal uncertainty surrounding the creation or development of a new technology that could be put to infringing uses. Breyer warned that the additional risk and uncertainty would mean a consequent additional chill of technological development.

made with the defendants' software constitute infringement. In fact, the Court observed that the probable scope of copyright infringement was staggering. In contrast to *Sony*, the record overwhelmingly showed that both Grokster and StreamCast *intended* to promote the use of their services to download copyrighted works and actively encouraged infringement.

In light of the evidence of intent, the Supreme Court concluded that Grokster and StreamCast could be found liable for third-party infringement accomplished using their software. It vacated the Ninth Circuit's judgment and remanded the case for further proceedings.

MESSAGE IN A BOTTLE

Although the Supreme Court narrowed the scope of the "substantial noninfringing use" defense, mere knowledge of potential or actual infringing uses is insufficient to subject a device's distributor to liability. Nor is a distributor liable for failing to take affirmative steps to prevent infringement if the device is otherwise capable of substantial noninfringing uses. Rather, liability for copyright infringement under the inducement rule is premised on purposeful, culpable expression and conduct.

Supreme Court expands patent safe harbor for drug research

The U.S. Supreme Court has issued a decision with dramatic implications for pharmaceutical research. In *Merck KGaA v. Integra LifeSciences*, the Court reversed the Federal Circuit and expanded the safe harbor from patent infringement liability for biomedical research activities. The ruling gives drug companies wide berth to use rivals' patented products in preclinical research. As a result, the companies may now find it easier to develop new drugs.

FIGHTING THE DRUG WAR

Merck entered an agreement with Scripps Research Institute to fund research to find potential drug candidates. After Scripps discovered a promising peptide, the organizations formed another agreement, whereby Merck funded the necessary experiments to satisfy the biological and regulatory requirements for clinical trials of the peptide. Scripps' research included the use of the RGD peptide patented by Integra.

Integra brought suit for patent infringement, and Merck asserted as a defense the 1984 safe harbor

statutory amendment that protects activities "reasonably related" to the development and submission of information to the Food and Drug Administration (FDA). It states: "[I]t shall not be an act of infringement to … use … or import into the United States a patented invention … solely for uses reasonably related to the development and submission of information under a Federal law which regulates the … use … of drugs."

The Federal Circuit held that the safe harbor covered only the research stage that involves human trials. In its view, the exemption didn't extend down the chain of experimentation to

preclinical trials or general biomedical research to identify new drug compounds. Specifically, the court found that the exemption didn't apply to 1) experimentation on drugs that aren't ultimately the subject of an FDA submission, or 2) the use of patented compounds in experiments that aren't ultimately submitted to the FDA. It affirmed the jury's award of $15 million.

HEADING FOR HARBOR

The Supreme Court disagreed with the Federal Circuit's finding that the exemption categorically excluded such types of experimentation. Scientific testing is a process of trial and error. In most cases, drug makers have no way of knowing whether an initially promising candidate will prove successful over a series of experiments — that's why they conduct the experiments.

The Court held that Congress didn't limit the safe harbor solely to the development of information to be included in a submission to the FDA. Rather, it exempted all uses of patented compounds reasonably related to the process of developing information for submission under any federal law that regulates the manufacture, use or distribution of drugs, including uses in preclinical studies.

According to the Court, use of a patented compound is "reasonably related" to the development and submission of information under federal law if a drug maker:

- Has a reasonable basis for believing that compound may produce a particular physiological effect through a particular biological process, and
- Uses the compound in research that, should it be successful, would be appropriate to include in an FDA submission.

Similarly, the safe harbor protects the use of patented compounds in preclinical studies if a reasonable basis exists for believing the experiments will produce the type of information that is relevant to an FDA submission.

COMPARING RISKS AND BENEFITS

Integra had argued that at the investigational new drug submission stage the FDA is interested only in information related to human safety. The Court agreed that safety is one of the FDA's primary objectives but declined to accept that the FDA was therefore uninterested in reviewing information related to other characteristics of a drug.

The FDA's evaluation of the safety of proposed clinical experiments cannot be conducted in a vacuum: It requires the comparison of the associated risks and benefits, which necessarily includes the review of preclinical studies of a drug's efficacy in accomplishing particular results.

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The Court further rejected Integra's argument that the exemption shouldn't have applied because the experiments in question failed to conform with the FDA's "good laboratory practices" regulations. The Court found the regulations apply only to experiments to test a drug's safety, not to preclinical studies on efficacy, mechanism of action, pharmacology or pharmacokinetics.

The Court did recognize some limits on the safe harbor from patent infringement. It explained that the exemption didn't apply to research performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce.

EXTENDING THE SAFE HARBOR

Under the *Merck* decision, the statutory safe harbor now extends to preclinical data related to the safety of drugs in humans, as well as preclinical studies related to a drug's efficacy, mechanism of action, pharmacology or pharmacokinetics. The Court declined to address whether it would allow the use of patented research tools in the development of information for a regulatory process. Nonetheless, the decision certainly allows drug companies to experiment using patented compounds without fear of infringement.

Patent prosecution insight: Honesty is the best policy

A pharmaceutical company learned the hard way that securing a patent isn't enough to ensure infringement protection. Although it found infringement, the U.S. Court of Appeals for the Federal Circuit denied the plaintiff protection because it engaged in inequitable conduct by consistently and repeatedly misrepresenting the origin of its discovery during the patent application process.

THE TRUTH HURTS

Purdue Pharma L.P. v. Endo Pharmaceuticals Inc. arose from three patents related to controlled release oxycodone medication (marketed as OxyContin) for the treatment of moderate to severe pain. Purdue sued Endo for infringement of those patents based on Endo's production of a generic form of OxyContin.

During the patent application process (known as patent prosecution), Purdue pointed to its dosage range in an attempt to distinguish the product from prior art. Each patent's written description opened with a statement declaring "it has now been surprisingly discovered that the presently claimed controlled release oxycodone formulations acceptably control pain over a substantially narrower [range] … in approximately 90% of patients."

The company also made repeated statements to the Patent and Trademark Office (PTO) that it had discovered a formulation for controlling pain over a smaller range of dosages for 90% of patients, compared to a higher range for similar drugs. The product's inventor testified at trial that it was insight that led to discovery of the reduced range.

The Federal Circuit began its review by reiterating patent applicants' duty to prosecute patents with candor and good faith, including the duty to disclose information known to be material to patentability. A patent applicant can breach this duty through misrepresentation, failure to disclose, or submission of false material information, paired with intent to deceive or mislead the PTO. To establish inequitable conduct that would render a patent unenforceable, the court said, a party must prove materiality and intent.

INSIGHT IS MATERIAL

The district court had found that Purdue failed to disclose material information by withholding the fact that discovery was based on insight, not scientific proof. Purdue contended the lack of scientific proof was irrelevant and thus didn't expressly represent a material fact because it never stated that discovery had been clinically tested.

The Federal Circuit ruled that, although Purdue may never have expressly stated the discovery was based on clinical studies, Purdue's language clearly implied such a conclusion. The company's patent application referred to the smaller range as a "result," cited the "clinical significance" of the discovery, and compared the dosage range to that of other analgesics in concise, quantitative terms. The information that the dosage range was based only on insight — not experimental results — was material because it was inconsistent with Purdue's statements suggesting otherwise.

The court acknowledged that discoveries may be made by insight or experiment, and that alone wouldn't affect patentability. Here, though, Purdue repeatedly asserted to the PTO that its dosage range distinguished the invention from prior art and Purdue failed to inform the PTO that its discovery was based only on insight.

WORDS BETRAY INTENT

The court next considered whether Purdue intentionally withheld material information about the source of its "surprising discovery." It found that Purdue's carefully chosen language suggested it had obtained clinical results, a suggestion that was left unclarified.

The court then concluded that the consistent, repeated nature of the company's communications with the PTO showed that it intended to withhold and misrepresent the discovery's true origin to the PTO.

FULL DISCLOSURE

The Federal Circuit's decision in *Purdue* demonstrates that the way a company conducts its patent prosecutions may come back to haunt it. To avoid painful results down the road, disclose all relevant information at the outset, particularly if it could be viewed as material. As the court pointed out, the showing of intent to establish inequitable conduct requires proportionately less when balanced against high materiality.

Pop-ups elude trademark infringement

What constitutes trademark use when software programs use "key words" on the Internet? A recent decision — *1-800 Contacts, Inc. v. WhenU.com, Inc.* — sheds some light on the future of targeted online advertising, particularly when directed at consumers searching for information about competitors.

WhenU is an Internet marketing company that operates proprietary software. The software is typically downloaded by computer users as part of a bundle of programs. The program responds to computer users' recent activities by generating pop-up advertisement windows. WhenU listed 1-800 Contacts' Web site address (or URL) among the 32,000 Web sites in its directory, causing competitors' pop-up ads to appear on users' screens above, below and along the edge of 1-800 Contacts' Web site.

1-800 Contacts sued WhenU for trademark infringement. The district court found that causing the pop-ups to appear constituted trademark "use" within the meaning of the Lanham Act and granted a preliminary injunction. WhenU appealed.

On appeal, the Second Circuit observed that WhenU didn't use the plaintiff's trademark in the manner ordinarily at issue in an infringement claim — it didn't "place" the trademark on goods or services to pass them off. In fact, WhenU didn't use the trademark (1-800 Contacts) at all; rather, it used the company's URL (www.1800contacts.com). The court found the differences between the URL and trademark significant — they transformed the protectable trademark into a word combination that essentially acted as a "public key" to the company's Web site.

The court also pointed out that the directory wasn't accessible by users or the public, precluding any chance of visual confusion with the trademark. Further, WhenU didn't allow advertising customers to purchase specific keywords, like "1-800Contacts" — only categories, such as "eye care." A company's internal use of a trademark in a way that doesn't communicate it to the public is similar to an individual's private thoughts about a trademark. This simply doesn't violate the Lanham Act. So the trademark claims failed as a matter of law.

The Second Circuit specifically noted that, unlike other Internet advertising companies, WhenU didn't sell trademarked keywords or allow customers to pay so their ads would appear on a particular Web site or in connection with a particular trademark. This holding offers guidance on how online advertisers can avoid trademark infringement liability.

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