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LEADING EDGE THINKING ON INTELLECTUAL PROPERTY

McDermott Will & Emery

SPRING 04

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McDermott Will & Emery publishes *IP Review* to provide the latest news and information on intellectual property for professionals in business and law. *IP Review* may be considered advertising under the rules regulating the legal profession.

FROM THE EDITOR

Welcome to the second issue of *IP Review*.

The *IP Review* is a biannual publication of the Intellectual Property (IP) Department of McDermott Will & Emery, generally issued during the second and fourth quarters of each year.

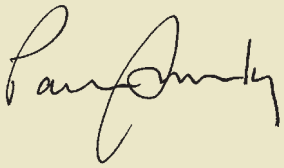
We thank the many friends of the Firm who assisted us in vetting and winnowing down topics of interest from the several dozen that were under initial consideration.

As a cursory review of the table of contents will show, the current edition includes articles covering a wide range of topics relevant to big ticket IP litigation. The articles are cross disciplinary (including antitrust and competition issues), international (addressing unfair competition from the UK, German and Italian perspectives) and provide strategic perspective on issues ranging from the use of exculpatory opinions in patent infringement litigation to the impact of the *Festo* cases on IP litigation, to the demise of the "experimental use" or FDA "safe harbor" to the focused and effective use of summary judgment motions in patent cases.

In this issue, we are fortunate to be able to present the insights of James E. Malackowski and Robert M. Hess of Ocean Tomo LLC, an integrated, intellectual capital merchant bank, on how to present a compelling, fact based economic model, consistent with Federal Circuit jurisprudence, in connection with patent damages.

In the next issue, we plan to present articles that focus on topics related to patent prosecution. While many of you know McDermott from its preeminent big ticket IP litigation capability, the Firm is also rightfully proud of its prosecution practice, which ranks among the highest of firms in the U.S. In fact, in the March 2004 issue of *IP Law & Business*, McDermott was recognized as one of the leading U.S. firms in terms of patent quality and creating value for its clients. The next edition should be of compelling interest to those readers having a stake in the process by which patent rights are born and maintained.

Heartfelt thanks for this issue of *IP Review* go to Jackie Borta and Alisha Walls of the Practice Development Group without whose hard work it could never have reached fruition. Thanks also goes to Jack Lever, IP Department Chair, whose total support and timely guidance were invaluable. Sincere thanks also go out to each of the authors for interrupting their own busy schedules to take the time to participate in this project.



Paul Devinsky

THE ANTITRUST RISKS ASSOCIATED WITH MANIPULATING THE STANDARD-SETTING PROCESS

By David S. Bloch and Scott S. Megregian

As recent cases have made clear, participants in the standard-setting process risk drawing the attention of antitrust actions regulators if they manipulate the process to ensure their patents cover the resultant standards.

In many technology-related markets, an industry standard will emerge to provide a common framework or format to ensure interoperability among related products and to foster the development of ancillary or peripheral devices. Some standards will develop as a result of open market competition. In other cases, however, standards are created from voluntary consensus or by government prescription.

Both voluntary consensus standards and government prescribed standards can be pro-competitive. They can ensure interoperability, connectivity and product safety. Indeed, many argue that industry standards are essential to the functioning of a modern economy. But they also can arouse significant antitrust concerns. A number of recent cases have considered allegations that participants have manipulated the standard-setting process in order to create a structure where they had patent coverage over certain aspects of the standard. In such cases serious anti-competitive effects, such as market foreclosure, higher prices, reduced innovation and the unlawful creation of a dominant market position, can result.

Trying to balance these pro- and anti-competitive tendencies, lawmakers have attempted to carve out a specific antitrust immunity for standard-setting organizations (SSOs). However, a number of recent court decisions also have provided important guidance on the antitrust risks arising from "strategic" participation in SSOs. Reviewing these cases should help companies to better understand the ground rules for participating in the standard-setting process.

Types of Standard

An SSO is a group composed of participants from a single market or a set of related markets, which meets in order to promulgate technical standards. There are three basic types of standards: *de facto,* government/legal and private/consensus.

A *de facto* standard arises spontaneously, either because consumers recognize the standard's superiority over competing systems or because the technology enjoys a "first mover" advantage. Because *de facto* standards do not involve affirmative collective determination, they typically are not subject to manipulation and hence are not within the scope of this article.

A government-sponsored standard may be issued directly by a government entity or may result from a government-sponsored SSO. A government-sponsored SSO is convened by a local, national, or international body to create a legally binding standard. In the United States, most government-sponsored SSOs are *ad hoc.* In Europe, most SSOs operate under the authority of the European Standards Organization Directive.[1]

Private or consensus standards are created by market participants trying to choose from among competing technologies to develop a consensus standard—private, voluntary, but essential for market participation. Because private standards are created by SSOs and typically involve coordination among competitors, they raise the greatest potential for antitrust violations.

Manipulation of Private Consensus Standards

In re Dell Computer Corporation

Until recently the United States government's approach to manipulation of the standard-setting power was best reflected by its 1996 complaint against Dell. In the early 1990s, Dell participated in the Video Electronics Standards Association, a private SSO that had begun to employ basic IP disclosure and licensing rules. Dell participated in a number of meetings at which certain VESA standards were proposed and evaluated, including a standard for the "VESA Large bus."

At the same time that the Dell representative attended the VESA meetings, Dell implemented a change in business strategy, which include building a patent portfolio. One of these early patents contained a claim, which covered certain aspects of the standard. VESA adopted the standard, and Dell threatened to initiate infringement proceedings against a variety of companies for infringing its VL bus patent.

A number of companies receiving these letters complained to the U.S. Federal Trade Commission (FTC), which initiated an investigation. The FTC claimed that (1) Dell signed a "ballot" confirming that the proposed standard did not read on any Dell intellectual property, (2) VESA may have revised the standard to design around the Dell patents, and (3) Dell misled VESA with respect to its patent holdings. The FTC argued that this conduct, taken as a whole, constituted a "method of unfair competition in or affecting commerce" under Section 5 of the FTC Act. Dell settled the matter by consent decree, so the allegations were not litigated.

The FTC's complaint was widely criticized for failing to address certain key elements of a typical violation. For example, there was scant attention to market definition, market share or competitive effects. In dissent, Commissioner Azcuenaga argued that the consent decree "introduced a new element of uncertainty into this area of the law." In the end, *Dell* left open a number of critical questions on how these cases should be analyzed.

Rambus v. Infineon and *FTC v. Rambus*

An opportunity to resolve and clarify these issues presented itself in 2000, in the form of a private lawsuit filed by Rambus Inc., a company specializing in chip design, development and licensing. Rambus participated for a short while in the Joint Electron Device Engineering Council (JEDEC), a private SSO. During its brief involvement in JEDEC, Rambus did not disclose any of its pending patent applications, nor did it advocate any particular standard. After JEDEC issued DRAM computer memory standards that read on Rambus patents, Rambus sued Infineon Technologies A.G. for patent infringement. Rambus lost at

"The Noerr-Pennington *doctrine is derived from a series of U.S. Supreme Court cases that immunize efforts to influence the legislative process—even if the outcome would be wholly anticompetitive."*

trial—a Virginia jury found actual fraud and thus declined to enforce the Rambus patent portfolio—but won on appeal to the United States Court of Appeals for the Federal Circuit. *Rambus, Inc. v. Infineon Techs. AG.,*[2, 3] The Federal Circuit concluded that JEDEC's disclosure standards were far too unclear, and that Rambus was therefore under no obligation to disclose its pending applications. In addition, the Federal Circuit threw out Infineon's fraud allegations. That case is now scheduled for retrial.

Infineon's allegations at the 2001 trial attracted the FTC's attention. The FTC's complaint, filed in June 2002, asserted that Rambus, "through deliberate and intentional means," manipulated the JEDEC standard-setting process by concealing information on pending and issued patents. The complaint also argued that Rambus modified its pending patent applications to cover technological advances discussed at JEDEC meetings, all with the goal of ensuring that the eventual JEDEC DRAM standard would read on Rambus patents. However, on February 17, 2004, the FTC Administrative Law Judge (ALJ) dismissed the case, explaining in a mammoth 348-page decision that the FTC "failed to sustain its burden of establishing liability for the violations alleged." According to the ALJ, Rambus's technology was superior to alternatives, and that when Intel adopted it, it became the *de facto* standard. Indeed, ALJ found that the FTC had failed to show *any* viable alternatives to the Rambus technology. Thus, the ALJ reasoned there was no exclusionary effect of Rambus's assertion of patent rights: "The exclusion of inferior products from the market is not exclusionary in an economic sense."

This may not be the end of the matter. The FTC may appeal the ALJ's decision, first to the Commissioner and then, perhaps, to the U.S. Court of Appeals for the District of Columbia Circuit. If the FTC manages to persuade the Court of Appeals to overturn the ALJ's decision, there would be a split between the Federal and District of Columbia Circuits, and a likely appeal to the U.S. Supreme Court.

In addition, Rambus faces serious obstacles in Europe. On February 13, 2004, the European Patent Office revoked a key Rambus patent in response to an opposition by Infineon, Micron and Hynix Semiconductor—all targets of Rambus patent-infringement suits. The EC Commission also is investigating Rambus.

Manipulation of Government-Prescribed Standards

Rambus and *Dell* both occurred within the context of a private, voluntary SSO. However, in *In re Unocal,* the FTC challenged similar conduct that occurred during government-sponsored standard-setting proceedings.

Unocal participated in the California Air Resources Board (CARB), a government-sponsored SSO convened by the State of California to formulate a new regulation/standard for low-emission gasoline. Once the CARB Phase 2 standard was promulgated, Unocal sued its competitors for patent infringement. Unocal won its patent infringement suits (*Union Oil Co. of California v. Atlantic Richfield Co.*[4]) but then was sued by the FTC for violations of §5 of the FTC Act.

The FTC alleged that Unocal provided "materially false and misleading "information concerning its internal emissions research that led the State of California to adopt a particular low-emission gasoline standard; actively participated in CARB meetings and promoted a particular standard; but concealed the fact that it owned pending patents that covered the new standard. Indeed, the FTC claimed that Unocal affirmatively stated that it did not have any "proprietary interest" in the standard it was supporting—stating that the technology in question was "nonproprietary" and "in the public domain"—even while amending pending claims in order to "resemble" CARB's emerging regulations.

In November 2003, an ALJ dismissed the FTC case because Unocal's conduct was immune from antitrust scrutiny under the *Noerr-Pennington* doctrine. The *Noerr-Pennington* doctrine is derived from a series of U.S. Supreme Court cases that immunize efforts to influence the legislative process—even if the outcome would be wholly anticompetitive. The *Noerr-Pennington* doctrine has been extended to efforts to influence executive branch agencies and into the judicial process. Indeed, this protection is almost absolute regardless of the competitive intent or effect. Adding insult to injury, the decision also held that the FTC lacked the power to adjudicate the scope of Unocal's patents.

The difference in result between *Rambus*/*Dell* and *Unocal* is largely attributable to the fact that VESA and JEDEC on one hand and CARB were different kinds of SSO, VESA and JEDEC were private SSOs—bodies created by a group of competitors to reach a consensual solution to a technical problem. By contrast, CARB was a government-created organization created to reach a *legislative* solution to a public policy problem (automobile pollution). Participation in CARB was akin to lobbying the government and therefore fell within the *Noerr-Pennington* exemption. By contrast, the Supreme Court has confirmed that participants in private SSOs "enjoy no *Noerr* immunity from antitrust liability." *Allied Tube & Conduit Corp. v. Indian Head, Inc.*[5]

As a government-sponsored SSO, CARB's disclosure policies also differed from VESA's/JEDEC's in important respects. CARB had no policy requiring disclosure or nondiscriminatory licenses. This is because, ultimately, CARB was not concerned with competitive balance. CARB's sole purpose was to identify the standard that best fit the regulatory goal set by the California legislature—the reduction of automobile pollution. If this standard placed a particular patentee in a dominant position, so be it.

Implications of the *Dell-Unocal-Rambus* Cases

Considering *Dell, Unocal* and *Rambus* together, it becomes clear that SSOs create intellectual property-antitrust problems only in a narrow range of circumstances. The issue, as explained in the *Rambus* case, is not the exercise of intellectual property rights. Instead, the fundamental antitrust problem created by standard-setting organizations is attempted monopolization that extends beyond the mere exercise of patent rights—the manipulation of the standard-setting process to create an opportunity for patent ambush.

Under §2 of the Sherman Act, attempted monopolization is illegal if the

"…[T]he fundamental antitrust problem created by standard-setting organizations is attempted monopolization that extends beyond the mere exercise of patent rights—the manipulation of the standard-setting process to create an opportunity for patent ambush."

plaintiff can show a specific intent to control prices or reduce competition predatory or anticompetitive conduct directed at this intent and coupled with a dangerous probability of success. Abuse of standard-setting bodies thus fits nicely into standard antitrust law. The FTC's defeat in *Rambus*, however, may suggest an increasing judicial and administrative hostility toward efforts to hold SSO participants liable for antitrust violations or intellectual property misuse.

Fundamentally, the judge in the *Rambus* FTC case concluded that the FTC had failed to prove its claims of monopolization, attempted monopolization, and unfair methods of competition. The decision does not foreclose antitrust liability for manipulation of SSOs *per se*. However, the decision offers SSO participants wide latitude to pursue their own competitive interests in the standard-setting process. This clearly includes the modification of pending patent applications to cover contemplated standards.

Similarly, the ALJ concluded that maintaining the secrecy of pending intellectual property applications is permissible, and does not constitute misuse or unfair competition. "These conclusions apply in the standard-setting context as in any other. A company that is the member of a standard-setting body may benefit from not disclosing information regarding its pending patent applications or its intentions to file future patent applications regardless of what standards are developed…. These benefits have to do with maximizing the ability to operate competitively, not standardization."

The *Rambus* decision also casts substantial doubt on the continuing viability of *Dell* as an accurate statement of antitrust law. Because "[c]onsent decrees provide no precedential value," the *Dell* consent decree does not provide a reasonable basis for a finding of liability under §5 of the FTC Act, which prohibits unfair methods of competition. Importantly, the ALJ in *Rambus* distinguished the JEDEC patent policy from the policy at issue in *Dell*, noting that the JEDEC patent policy merely "encouraged the voluntary disclosure of patents essential to practice JEDEC standards."

The FTC ultimately concluded that Rambus's conduct did not offend the antitrust laws but may have created private rights of action for breach of contract, fraud or equitable estoppel—issues, however, resolved in Rambus's favor by the Federal Circuit in *Rambus v. Infineon.* The decision is a clear victory for Rambus, and has positive implications for intellectual property owners participating in SSOs. It also increases the likelihood that companies implementing consensual standards will be sued for patent infringement by fellow SSO participants.

Issues on the Horizon

In addition to the "patent ambush" problem highlighted by *Dell, Unocal* and *Rambus,* other concerns may derive from participation in SSOs. This section briefly addresses three antitrust-intellectual property issues that may arise through participation in SSOs: group boycotts, misuse of the SSOs trademarks and trade secret misappropriation by an SSO.

Group Boycotts

The *Rambus* decision shifts the balance of law concerning participation in SSOs decisively in favor of patentees and other intellectual property owners. The FTC long has held that deliberate exclusion of patented products from standards is a form of group boycott. Given the *Rambus* holding that "[r] efusing to include patented technology in industry standards may subject standard setting organizations to antitrust claims and denies consumers superior products," SSOs (and individual participants) seem increasingly susceptible to group boycott claims.

SSO Trademark Misuse

A trademark protects the association of a product with its source. Logically, a trademark could never be the subject of an industry standard. But a SSO might well develop a trademark intended to designate conformity of a product with some consensual standard. The trademark to "ISO 9000," for example, is used by the International Organization for Standardization to designate an international standard for quality management. In principle, such trademarks are owned by the SSO and are used at the SSO's sufferance. But it is easy to imagine an outsider claiming the right to use the SSO's trademarks in a non-misleading fashion and accusing the SSO of trademark misuse (a recognized antitrust violation) for wrongly withholding access to the name.

Trade Secret Theft by SSOs

A trade secret is a piece of information—a technology, a process, an idea—that derives value from its secrecy. For example, the formula for Coca-Cola is a closely guarded trade secret. In theory, a standard embodying a trade secret could be blocked by the trade secret's owner, but only if the owner could prove that some SSO member misappropriated the secret. If the owner could prove misappropriation, it might well be able to recover against the entire membership of the SSO. The SSO is, in effect, a collusive enterprise; and it is not difficult to move from this simple fact to the conclusion that the SSO was a sham intended to shield an industry-wide antitrust conspiracy to misappropriate the owner's intellectual property.

Conclusion

SSOs are critical components of modern commerce. But technical standards implicate intellectual property laws, and the manipulation of intellectual property rights often leads to antitrust scrutiny. The recent *Rambus* decision offers considerable leeway to intellectual property owners participating in standard-setting efforts. SSOs are on new ground, and participating companies should tread carefully. ■

(continued on page 15)

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THE USE OF EXCULPATORY OPINIONS IN DEFENDING AGAINST A CHARGE OF WILLFUL INFRINGEMENT

By Paul Devinsky and Stephen J. Akerley

The authors address some of the key issues surrounding the use of exculpatory opinions of counsel in defending against claims of willful patent infringement.

The exercise of intellectual property rights has become a mainstay of business over the last 10 years. Indeed, business models are proliferating where obtaining patents for the purpose of licensing and enforcement are the sole activity of the enterprise. Even among those entities that routinely engage in R&D or the manufacture and sale of products, more and more are investing in the acquisition of IP rights, and many have realized that enforcement of those rights against competitors is an effective tool in protecting markets and/or generating revenue. As a consequence, corporate executives and general counsels are likely to face, at least once in their careers, a charge that their companies are infringing upon another entity's intellectual property rights.

Especially threatening is the receipt of a notice that your company's products infringe patents held by another. The threat is worrisome for a variety of reasons. First, the threat is often leveled at a company's core technology, changes to which are almost never trivial. Second, patent infringement carries with it the very real threat of devastating injunctive relief. Finally, damages in such cases, while nominally calculated in terms of a reasonable royalty or lost profits, may, at the discretion of the court, be enhanced up to three times for so-called willful infringement. In order to navigate this minefield and defend themselves against claims of willfulness, many companies engage counsel in order to obtain advice as to whether their actions violate valid patent rights of some third party and/or how to avoid such violations by design arounds. This article, addresses defenses to a charge of willfulness, and in particular, some of the issues which may arise when relying on opinions of counsel as a defense to a patent owner's claim of willful infringement.

The "Totality of the Circumstances" Test

When considering whether an infringer acted in bad faith, thereby supporting an increased damage award, courts look at a "totality of the circumstances," including (1) whether the infringer copied the invention of another; (2) whether the infringer, when it knew of the other's patent, investigated the scope of the patent and formed a good-faith belief that it was either not infringed, invalid or both; (3) whether the infringer mounted a substantial (albeit unsuccessful) challenge in the issues of validity and infringement; (4) the closeness and complexity of the legal and factual issues presented; (5) whether the infringer engaged in good faith efforts to design around the patent; and (6) the infringer's behavior in the litigation.[1] Because there are few situations where sufficient evidence of actual copying or litigation conduct egregious enough to find willfulness are present, the primary focus for courts when considering willful infringement claims is usually on whether an alleged infringer has formed a good-faith belief that its conduct was justified.

In the seminal case, *Underwater Devices, Inc. v. Morrison-Knudsen Co.,*[2] the U.S. Court of Appeals for the Federal Circuit imposed as affirmative duty on a potential infringer to exercise due care to determine whether or not its activities are infringing. This duty includes obtaining competent legal advice from counsel before initiating possibly infringing activity. The requirements for an opinion of counsel as evidence of good-faith in defense to a charge of willful infringement has led to several problems relating to waiver of the attorney-client privilege with respect to such opinions, and often to matters beyond the scope of the opinions.

Following *Underwater Devices,* in *Kloster Speedsteel AB v. Crucible Inc.,*[3] the Federal Circuit found that silence by the accused infringer on whether it obtained legal advice relating to infringement could warrant an adverse inference that the accused infringer either had not obtained an opinion (as required by *Underwater Devices*) or that the opinion was adverse. The Court followed its *Kloster Speedsteel* decision with its holding that the failure of an infringer to introduce an exculpatory opinion of counsel at trial could lead to an adverse inference instruction to the jury. *Fromson v. Western Litho Plate & Supply Co.*[4] Thus, although the test for determining willful infringement ostensibly requires a multifaceted review of the totality of circumstances, the Federal Circuit jurisprudence has, for many years, imposed an opinion requirement. In the view of many, the opinion of counsel "requirement," coupled with the adverse inference, has led to a serious erosion of attorney-client privilege.

Waiver of the Attorney-Client Privilege

Under the present state of the law, in addition to the affirmative duty to seek and obtain advice-of-counsel, if a company finds itself in a lawsuit facing a charge of willful infringement it is all but required to disclose the legal advice it received relating to infringement and/or validity. In other words, by merely raising the willful infringement claim, a patent owner presents the accused infringer with the Hobson's choice of either waiving its attorney-client communications or confronting an adverse inference instruction on the issue of willfulness. Most choose waiver.

The "choice" mandated by the Federal Circuit authority requires considerations not found in any other area of law. The most obvious is the effect and scope of the privilege waiver resulting from reliance on an opinion of counsel. There is no question that reliance on opinions of counsel as evidence of good-faith results in a waiver of privileged communications. The thorny question facing accused infringers is just how broad a waiver results. Accused infringers agonize over this question and district courts have found the task of line drawing to be a daunting one. The uncertainty on this issue is well illustrated by the following quote from a court struggling to fairly decide the issue:

"In few, if any, areas of the law has

"…[C]orporate executives and general counsels are likely to face, at least once in their careers, a charge that their companies are infringing upon another entity's intellectual property rights."

the tail taken to wagging the dog as vigorously as in the privilege waiver disputes endemic to patent infringement cases. Defendants often rely upon an advice-of-counsel defense when confronting the threat of enhanced damages for willful infringement. The consequent waiver of privileges and protections that the advice-of-counsel defense entails, however, is now the basis of innumerable disputes like the one at bar, distracting the court and the parties from addressing the fundamental questions of infringement and validity. It seems that a whole subspecialty of opinion practice has developed as part of infringement defense strategy. Litigation resources are heavily invested in delaying the moment when an accused infringer must choose between relying on advice-of-counsel or maintaining typical privileges, or in seeking bifurcation on the issue of willfulness, or in trying to control the scope of waiver, once the advice-of-counsel route is taken." *Rhodia Chimie, et al. v. PPG Industries, Inc.*[5]

Scope of Waiver

It is long settled that if an accused infringer chooses to rely on an advice-of-counsel defense, it waives privilege with respect to the communications transmitting the reliance opinion. *Thorn EMI North America, Inc. v. Micron Tech.*[6] Materials considered by reliance counsel in rendering the opinion, but not communicated to the accused infringer, are typically protected as work product and are not discoverable. ***EMI No. Am.*** See *also, Dunhall Pharm., Inc. v. Discus Dental, Inc.;*[7] and *Steelcase, Inc. v. Haworth, Inc.;*[8] Even when a work product waiver occurs it is not unlimited in time but ends once a lawsuit is filed.[9]

However, some courts have extended the waiver to include all communications between the client and counsel, in some instances including trial counsel. *Haney v. Timesavers, Inc.*[10] (Broad waiver found where "document logs show that a number of documents were sent from the [defendant's trial counsel] to the [reliance opinion counsel] and to others concerning infringement and validity…as a result, [trial counsel] has provided opinions to advise [defendants]);" *FMT Corp. v. Nissei ASB Co.;*[11] *Electro Scientific*[12] (Trial counsel implied that communications with reliance opinion counsel were substantial.); *Matsushita Elec. Corp. v. Loral Corp.*[13] (Defendant patent-owner's defense of good faith litigation was based on opinion given by trial counsel.); *Carl Zeiss Jena GmbH v. Bio-Rad Labs. Inc.*[14] (Written and oral reliance opinion were given by trial counsel.); *Fonar Corporation, et al. v. Johnson and Johnson*[15] (Various outside lawyers' authored opinion signed by in-house counsel.).

While the scope of the waiver in any given case cannot be accurately predicted, the cases provide some guidance that will help counsel limit the potential scope of the waiver.

First, where practical, opinion counsel should be separate from trial counsel. Broad waivers, including trial counsel's work product, have been found where trial counsel also rendered an opinion regarding the infringement or validity matters at issue. While the different counsel can be members of the same law firm, the risk of a broad waiver is mitigated if they are not.

Second, opinion counsel and trial counsel should not communicate on the substance of the opinions lest it be inferred that trial counsel influenced opinion counsel. Broad waivers have resulted where trial counsel and opinion counsel share information and theories. Though opinion counsel may be able to bring trial counsel "up to speed" more quickly, it must be remembered that opinion counsel was engaged to provide objective advice on issues of infringement and validity. Trial counsel's view on whether opinion counsel was articulate and appropriately analytical is only marginally relevant to trying the substantive defenses of the particular action. In preparing an opinion memo, the opinion writer typically has no more than a commercial validity search report and/or a relatively abbreviated consultation with a person knowledgeable about the accused device or method. When this is compared to the resources typically available to defense counsel, it is no wonder that different prior art and different or additional reasons for asserting non-infringement are likely to percolate up. As long as the opinion was competent as delivered and was relied upon in good faith by the client, the *Underwater Devices* criteria are met.

Third, avoid any appearance of "opinion shopping." Don't engage counsel to prepare an opinion and then stop the process in favor of a new counsel without good cause to do so.

Are the Winds of Change Blowing?

Based upon recent actions, the Federal Circuit appears to be keenly aware that these scopes of waiver issues—sequela to the duty to obtain an opinion and the negative inference imposed if the opinion is not produced to the plaintiff—need to be reviewed and addressed. Recently, the Court *sua sponte* decided to review *en banc* certain issues regarding exculpatory opinions, waiver and the adverse inferences. In *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GMBH v. Dana Corp., et al.,*[16] the Court asked for amicus submissions on the following questions: (1) Is the adverse inference appropriate when an accused infringer invokes the attorney-client privilege and/or work-product doctrine with regard to willful infringement? (2) Is it appropriate to draw an adverse inference with respect to willful infringement when the accused infringer has not obtained legal advice? (3) Should the existence of a substantial defense to infringement be sufficient to defeat liability for willful infringement even where no legal advice has been obtained?

At least 14 *amicus* briefs were submitted. With near unanimity, the amici answered the Court's questions as follows: (1) The adverse inference is inappropriate when a defendant invokes the attorney-client privilege and/or work-product doctrine with

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LITIGATING DOCTRINE OF EQUIVALENTS CASES IN THE AGE OF *FESTO*

By Brian E. Ferguson and Lucy Koh

This article describes the state of the law following the most recent *Festo* rulings and analyzes the possible effects on patent litigation.

On September 26, 2003, the U.S. Court of Appeals for the Federal Circuit issued its latest *en banc* ruling in the long-running saga of *Festo* Corporation's battle with Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd. (*a/k/a* SMC Corp.). This 15-year dispute has seen no less than nine reported rulings, including two *en banc* Federal Circuit decisions (*Festo VI*[1] and *Festo IX*[2]) and a U.S. Supreme Court decision (*Festo VIII*[3]), all directed primarily to the issue of the scope and application of "prosecution history estoppel" when determining whether patent infringement existed under the doctrine of equivalents.

Rather than repeat the long and involved *Festo* history, this article will describe the state of the law regarding prosecution history estoppel as it exists following *Festo VII, Festo VIII* and *Festo IX* and will also offer an analysis of how this precedent may affect the course of patent litigation in U.S. district courts.

The Law of Prosecution History Estoppel Following Festo

Whether prosecution history estoppel applies following *Festo* VII, VIII and IX may be summarized as follows:

(1) Has an amendment that narrows the scope of a pending claim been filed in the U.S. Patent and Trademark Office (USPTO)? If no, then the inquiry ends and prosecution history estoppel does not apply. If yes, the analysis proceeds to the second question.

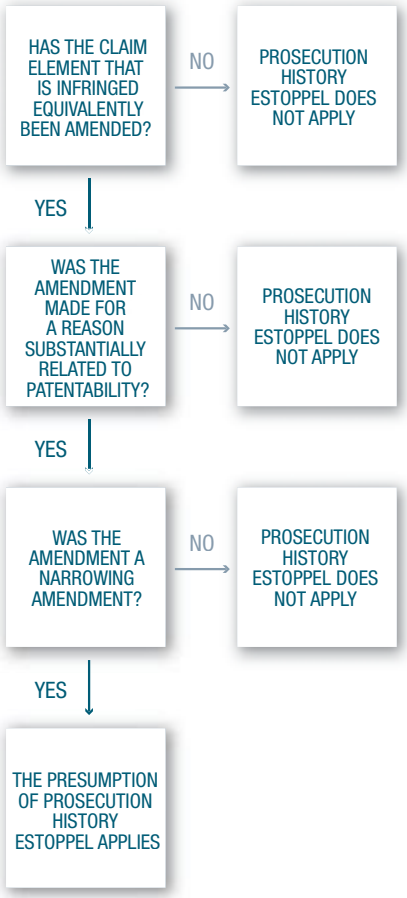
(2) Was the amendment made for a reason substantially related to patentability? An amendment is "substantially related to patentability" if it is made in order to comply with any provision of the U.S. Patent Act, including, but not limited to, 35 U.S.C. §§ 102, 103, 112. Whenever a narrowing amendment is made, there is a presumption that it was made for a reason substantially related to patentability. Thus, the patentee must overcome this presumption, and must do so by relying solely on the prosecution history record. If the patentee establishes that the amendment was not made for a reason relating to patentability (*e.g.*, merely clarifying an existing claim element without narrowing it), then prosecution history estoppel will not apply. If the patentee fails to overcome this presumption, the analysis proceeds to the third question.

(3) Has the patentee surrendered all range of equivalents between the original claim limitation and the amended limitation? Here too a presumption applies. The patentee is presumed to have surrendered all range of equivalents between the original claim limitation and the amended limitation. We will refer to this as the "*Festo* presumption." The patentee may rebut this presumption by showing, as articulated by the Supreme Court, that "at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." In *Festo IX*, the Federal Circuit confirmed that there are three ways the patentee may make this showing: (i) by demonstrating that an alleged equivalent would have been unforeseeable at the time of the amendment and thus beyond a fair interpretation of what was surrendered (the first criterion); (ii) by showing that the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent in question (the second criterion); and (iii) a patentee may establish "some other reason suggesting that the patentee could not reasonably be expected to have described the equivalent in question (the third criterion).

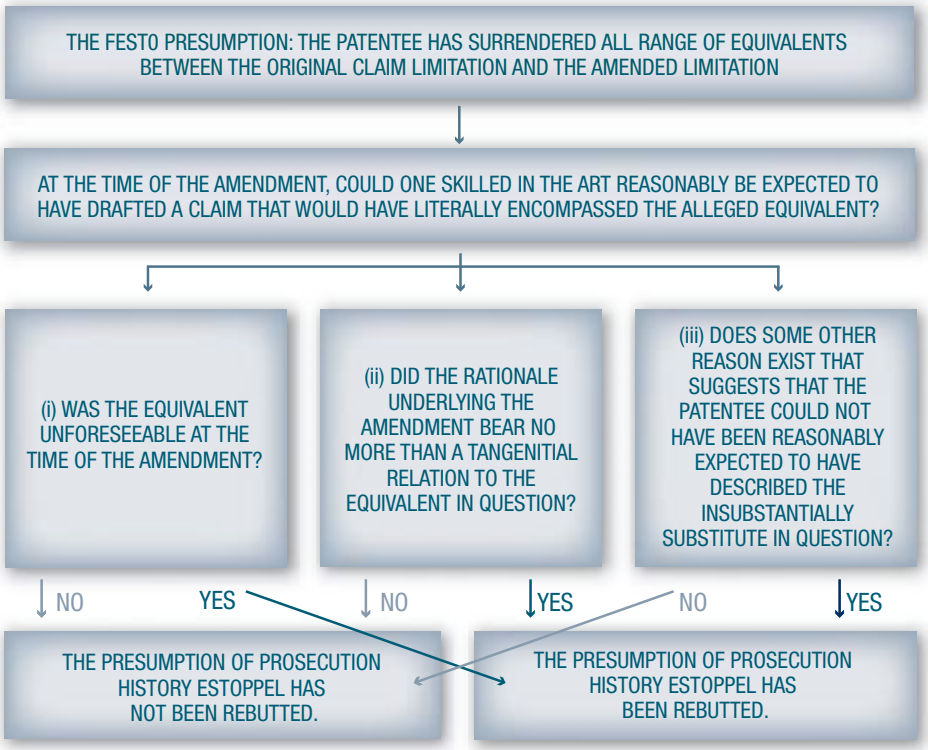
If the patentee fails to rebut the *Festo* presumption in accordance with any of the three criteria, then prosecution history estoppel bars the patentee from relying on the doctrine of equivalents for that claim limitation. But if the patentee is able to overcome the presumption, then prosecution history estoppel does not apply, and the question of whether the accused element is in fact equivalent to the claim limitation at issue is decided on the merits.

The following flow charts illustrate the *Festo* analysis for determining if prosecution history estoppel applies. (Of course, the *Festo* analysis addresses only amendment-based, not argument-based, prosecution history estoppels.)

Does Prosecution History Estoppel Apply?



Has the *Festo* Presumption of Prosecution History Estoppel Been Rebutted?



Questions Resolved

Festo IX resolved a number of questions left unanswered by the Supreme Court's decision in *Festo* VIII.

First, the Court in *Festo* IX held that determining whether prosecution history estoppel applies is a question of law.[4] In particular, the Federal Circuit held that determining whether the patentee has rebutted the presumption that prosecution history estoppel applies is a question for the court, even though there are factual matters that unquestionably will require resolution.

Second, regarding what evidence may be considered when determining whether the presumption has been rebutted, the Federal Circuit held that with respect to the first criterion (whether the equivalent was unforeseeable at the time of the amendment), expert testimony and other extrinsic evidence may be considered (to determine, for example, the state of the art and the understanding of a person of ordinary skill in the art at the time of the amendment).[4] Regarding the second criterion (whether the rationale underlying the amendment bears no more than a tangential relation to the equivalent in question), the patentee will be limited to the prosecution history record.[6] For the third criterion (whether some other reason suggesting that the patentee could not reasonably be expected to have described the equivalent in question exists), the Court cautioned that "when at all possible," the evidence should be limited to the prosecution history record.[7] The Court left open for another day the questions of when and what extrinsic evidence may be used for this criterion.

The Federal Circuit did not state what the patentee's burden of proof would be in order to overcome the *Festo* presumption. However, the lower courts interpreting *Festo* IX have applied the preponderance of evidence standard.[8]

Since the *Festo* IX decision was issued, only a few cases have applied the new *Festo* test. Those that have applied it generally held that the patentee failed to rebut the *Festo* presumption. In its own decisions applying *Festo* IX, the Federal Circuit noted that the question of "foreseeability" relates to the equivalent in question, and not to whether the patentee would have foreseen that its amendment would result in prosecution history estoppel.[9] Since then, the Court also has held that the *Festo* presumption will apply to all claims containing the limitation in question, regardless of whether a particular claim was or was not amended during prosecution. In other words, if the patentee amends a claim to include "limitation A," and it is later determined that the *Festo* presumption applies to that claim as a result of the amendment, the *Festo* presumption will also apply to all other claims containing "limitation A," regardless of whether the other claims were amended to include limitation A. In another case, the Court confirmed that if the prior art contains the alleged equivalent, and a narrowing amendment was made to avoid that equivalent, as a matter of law the subject matter could not be found to have been unforeseeable.[10]

The Effect of the *Festo* Precedent On Patent Litigation

It goes without saying that *Festo* emphasizes, more than ever before, the importance of thoughtful and strategic patent prosecution efforts. The age of measuring patent prosecution success by the volume of issued patents alone is over. It is well worth the additional effort during patent prosecution to ensure that the prosecution history record is clean of potential *Festo* issues. It requires experienced and skilled patent prosecutors who understand the technological fields at issue and are able to craft claims and amendments that maximize the patentee's chances of avoiding and/or overcoming *Festo* issues in later litigation.

Similarly, there is no doubt that patent litigation following *Festo* has entered a new era of uncertainty and thus demands skilled litigators to either navigate around, on behalf of the patentee; or plant, on behalf of the accused infringer, potential *Festo* landmines.

For example, at least one district court has already predicted that the new *Festo* decision will result in separate "*Festo* hearings"[11] in much the same way *Markman* hearings are now commonplace. This

"Festo emphasizes, more than ever before, the importance of thoughtful and strategic patent prosecution efforts."

appears likely. Following the *Markman* hearing and the almost inevitable summary judgment motions addressing infringement, a court will likely make a ruling along one of the following lines: (a) the court grants the accused infringer summary judgment of no infringement (literally or equivalently); (b) the court grants the patentee summary judgment of literal infringement; (c) the court finds no literal infringement, but leaves open the question of infringement under the doctrine of equivalents; or (d) the court denies all motions regarding literal infringement due to disputed factual issues.

If a court decides to grant either (a) or (b) above, the *Festo* issue (at least until after any appeals) is dead. If dispositive motions practice results in a decision along the lines of (c), however, and there has been an amendment in the prosecution history record that is relevant to the issue of equivalents infringement, the court is faced with the following question: Should the case proceed directly to trial and wait for the jury verdict on infringement under the doctrine of equivalents; or should the court, prior to trial, hold a "*Festo* hearing" to determine as a matter of law whether prosecution history estoppel applies, or whether the patentee has sufficiently rebutted the presumption?

We believe the better course of action is a *Festo* hearing prior to trial. The "wait and see" approach will undoubtedly lead to judicial and economic inefficiency. If the jury determines there is no infringement under the doctrine of equivalents, but the patentee is successful in overturning that verdict on appeal, the case will be remanded, and the district court will have not only to conduct a new trial but also to hear the *Festo* issue. Thus, in these circumstances, the Federal Circuit will not address the *Festo* issue until the second appeal (if there is one). If the court had considered the *Festo* matter prior to appeal, then that ruling also could be addressed by the Federal Circuit in the first appeal.

Having a *Festo* hearing prior to trial reduces the risk of multiple appeals and trials. If the court determines after the *Festo* hearing that the *Festo* presumption applies, and the patentee cannot rebut the presumption, the case ends, and the court's rulings (claim construction, literal infringement and *Festo*) may be addressed in a single appeal to the Federal Circuit. The result is the same if the court determines either that there is no *Festo* presumption, or that the patentee has rebutted the presumption. In such a case, a trial will then be held on the issue of infringement under the doctrine of equivalents, and following the jury verdict, the parties may address all contested issues in a single appeal.

Because the Federal Circuit and district courts have yet to establish clear guidelines, current parties in patent litigation will have an opportunity to influence a court's course of action with respect to prosecution history estoppel issues. We recommend that, for the foregoing reasons, parties consider requesting a "*Festo* hearing" either in conjunction with, or shortly following, the court's consideration of summary judgment motions regarding infringement. Because there remain any number of open issues regarding (1) the procedure, timing and scope of any *Festo* hearing; and (2) what evidence a court should consider for at least the first and third criteria for rebutting the *Festo* presumption, a client will best be served by experienced counsel who formulate a strategy for handling *Festo* matters that is tailored to a client's particular legal and factual circumstances.

One need only consider a recent case addressing the world of prosecution history estoppel following *Festo* IX to realize the importance of skilled and prepared counsel in handling *Festo* issues. This particular case[12] addresses the currently open-ended third criterion for rebutting the *Festo* presumption by asking the question: What "other reasons" might courts find persuasive for holding that the patentee could not have been expected to have described the equivalent in question? While the Federal Circuit cautioned that this criterion must be a "narrow one," it nonetheless clearly contemplated that there would be situations where the criterion would apply (such as language limitations at the time the amendment was filed). In the recent case in question, a court used this factor to hold that the patentee had rebutted the *Festo* presumption where the patentee put forth extrinsic evidence demonstrating that the patentee could not have been expected to draft a claim covering the equivalent in question, because those skilled in the art at the time of the amendment would have interpreted the claim as *literally* covering the equivalent.[41] This rather creative use of the open-ended third criterion demonstrates that we should all expect the unexpected when facing life after *Festo*. ■

The authors extend their thanks to Mehul Jani, Esq. for his assistance in preparing this article.

[1] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,* 234 F3d 558 (Fed. Cir. 2000).
[2] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,* 344 F3d 1359 (Fed. Cir. 2003).
[3] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,* 535 U.S. 722 (2002).
[4] *Festo IX,* 344 F.3d at 1367-1368.
[5] *Festo IX,* 344 F.3d at 1369.
[6] *Festo IX,* 344 F.3d at 1369-1370.
[7] *Festo IX,* 344 F.3d at 1370.
[8] *Amgen, Inc. v. Hoechst Marion Roussel, Inc.,* 287, F.Supp.2d 126; 2003 U.S. Dist. LEXIS 19953, 14-15 (D. Mass. 2003).
[9] *Ranbaxy Pharmaceuticals, Inc. v. Apotex, Inc.,* 350 F.3d 235; 2003 U.S. App. LEXIS 24044, 12-13 (Fed. Cir. 2003).
[10] *Talbert Fuel Systems Patents Co. v. Unocal Corp.,* 347 F.3d 1355, 1360 (Fed. Cir. 2003).
[11] *Amgen,* 2003 U.S. Dist. LEXIS 19953 at 24.
[12] *Amgen,* 2003 U.S. Dist. LEXIS 19953.
[13] *Amgen,* 2003 U.S. Dist. LEXIS 19953 at 82-83.

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DISPOSITIVE MOTIONS IN PATENT CASES — STRATEGIES AND CONSIDERATIONS

By David L. Larson and Margaret M. Duncan

A motion for summary judgment can be an effective way to favorably resolve a case without a trial. The authors examine some of the strategic considerations for bringing such motions in patent cases.

Your company has been served with a complaint alleging patent infringement against your flagship product. Your lawyers have given you the sobering news that defending the case through trial likely will cost millions of dollars, and even if you win you may never recoup that expense from the plaintiff. Even more sobering, your lawyers caution you that although your case is very strong, anything can happen at trial. "Isn't there something we can do to get rid of this thing without all that time, money and risk?" you ask.

Maybe there is. Consider an early motion for summary judgment—a motion that tells the court there is no point in presenting this case to a jury because applying the law to the clear and undisputed facts, you win. In patent cases in particular, there may be several potential grounds on which a patent may be ruled invalid, or a product may be found non-infringing, even with limited or no discovery.

A Motion for Summary Judgment Can Result in Dismissal of a Case

A motion for summary judgment, if granted, will result in a decision by the judge that resolves some or all of a case, without a trial. A successful motion may result, for example, in a finding of invalidity of a patent or of certain patent claims, in a finding of infringement (or non-infringement) as to some or all products or in the dismissal of a defense. A motion for summary judgment, or for summary adjudication of an issue,[1] is brought under Federal Rule of Civil Procedure 56. Under Rule 56, a party will prevail on such a motion if it can "show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." F.R.C.P. 56(c). Essentially, the party moving for summary judgment on a claim or defense must show that there are no genuinely disputed facts for a jury to decide at a trial, and that based on the undisputed facts, the party is entitled to judgment.

Although this standard is sometimes difficult to meet, summary judgment is especially well-suited to patent cases, where witnesses' different recollections of events are less important, and relatively objective issues – such as whether an accused product includes every element of a patent claim – are determinative.

By a successful motion for summary judgment, also known as, summary adjudication, a defendant may be able to completely eliminate from the case some or all of a patentee's claims, and a plaintiff may be able to eliminate some or all of a defendant's defenses. Similarly, certain products or classes of products accused of infringement may be found to infringe or not infringe without necessity of a trial. Disposing of the case, or at least some of the issues, early saves time and money.

Even if it is not successful, a motion for summary judgment may reveal important strategies and positions of the opposing party, which will be forced to respond to the motion by presenting the evidence that it believes precludes the entry of summary judgment.[2] Such a motion also will educate the judge in a context that allows the moving party to present its version of the case. In addition, an order denying a motion for summary judgment will usually reveal the judge's reaction to the evidence, and may provide important information in presenting the case at trial. Moreover, if a motion for summary judgment is denied because the court finds there are disputed facts that must be decided by a jury, the party who brought that unsuccessful motion generally has not lost much. (It may still present the same evidence and arguments to the jury at trial.) Finally, because motions for summary judgment often decide the most important issues, cases are more likely to settle after court order, either granting or denying such a motion.

Of course, a party moving for summary judgment is also revealing its own strategies and positions. In addition, a motion that is not well founded will irritate the court and may reduce the party's credibility. A weak motion may also encourage the court to grant a counter-motion by the opposing party—possibly resulting in disposal of the case in the opponent's favor.

In most cases, however, the potential advantages of motions for summary judgment outweigh the disadvantages, and thus, though not universally used in patent cases, such notions are very common. The decisions regarding when to bring such motions, and on what issues, are among the most important strategic choices in the case. This article examines some of the bases and important considerations for bringing certain motions for summary judgment in a patent case.

Motion for Summary Judgment – What Must Be Filed

To meet its burden of establishing that "there is no genuine issue as to any material fact," the moving party generally must file with its motion factual evidence to support its position. F.R.C.P. 56(e). For example, documents submitted to the court must be shown to be authentic and relevant, either by the declarations of witnesses or by stipulation. In some cases, the only relevant evidence will be the patent and its prosecution history. For other motions, substantial factual declarations from fact and/or expert witnesses may be necessary. Such evidence may include a declaration from an expert explaining why a patent fails to show one of ordinary skill in the art how to make or use a claimed invention, or how a prior art publication discloses each and every element of an asserted patent claim. The nature of the evidentiary showing will vary substantially depending on the grounds for the motion, several of which are discussed in more detail below.

A party opposing a motion for summary judgment may submit its own documents and declarations to show either that the material facts are disputed, and/or that the moving party's proffered

"In patent cases in particular, there may be several potential grounds on which a patent may be ruled invalid, or a product may be found non-infringing, even with limited or no discovery."

conclusions of law are incorrect. The opposing party also may object to evidence submitted by the moving party on the same grounds it could use at a trial (*e.g.*, irrelevance, hearsay, privilege, etc.). See, F.R.C.P. 56(e). In addition, the opposing party may obtain, upon an appropriate showing, an order permitting it to take discovery before filing its opposition papers (F.R.C.P. 56(f)) or an order that summary judgment is premature until the court rules on issues of disputed claim construction.

It is important to remember that patents are presumed to be valid and in order to invalidate a patent; the defending party must show invalidity by clear and convincing evidence. Motions directed at the validity of a patent must take into account this higher burden of proof.

Motions Based On the Four Corners of the Patent and Its Prosecution History

To determine what early motions for summary judgment may be effective against a claim of patent infringement, the requirements of §112 of the patent statute should be considered.

The first paragraph of §112 of the patent statute imposes three distinct (although sometimes overlapping) requirements: (1) the specification must contain a *written description* of the invention; (2) the specification must *enable* any person skilled in the art to which it pertains to make and use the invention; and (3) the specification must set forth the *best mode* contemplated by the inventor of carrying out his invention. These three requirements are commonly referred to, respectively, as the "written description requirement," the "enablement requirement" and the "best mode requirement."

The second paragraph of §112 requires that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." This requirement is known as the "definiteness" requirement.

Written Description Requirement

"The 'written description' requirement serves a teaching function, as a '*quid pro quo*' in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'" *University of Rochester v. G.D. Searle & Co.*[3] The requirement means that the patent specification must "set forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed."[4] Compliance with the written description requirement is a question of fact.[5]

The Enablement Requirement

"Enablement is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention." *BJ Services Co. v. Halliburton Energy Services, Inc.*[6] Compliance with the enablement requirement is also a question of law.[7]

The Best Mode Requirement

The best mode requirement "requires an inventor to disclose the best mode contemplated by him, as of the time he executes the application, of carrying out the invention." "…[T]he existence of a best mode is a purely subjective matter depending upon what the inventor actually believed at the time the application was filed." *Bayer AG v. Schein Pharmaceuticals, Inc.*[8] Whether or not an inventor has complied with the best mode requirement is a question of fact.[9]

The Definiteness Requirement

"The definiteness inquiry focuses on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the rest of the specification." *BJ Services Co., v. Halliburton Energy Services, Inc.*[10] Definiteness is a question of law arising out of the court's performance of its duty construing the claims. Nevertheless, "[l]ike enablement, definiteness, too, is amenable to resolution by the jury where the issues are factual in nature."[11]

Each of these statutory requirements should be carefully reviewed as a basis for a possible early attack on validity. All four concern the language and descriptions used in the patent itself. None of these theories involves whether the applicant actually invented the claimed subject matter first; whether the invention may have been on sale or disclosed in a publication more than one year prior to the applicant's patent application; whether the applicant waited too long to file his application for patent; or whether the claimed invention is obvious. Thus, a motion to invalidate a patent under any of these §112 based theories may be filed relatively early in the case, well before the close of discovery, and usually without any third party discovery at all.

Indeed, a motion arguing that a patent fails to comply with the written description requirement or the enablement requirement may be brought without any discovery whatsoever, since only the four corners of the patent are involved. A moving party, nevertheless, may wish to present evidence (via fact witnesses and/or experts) showing that the patent fails to adequately disclose or teach the invention to one of ordinary skill in the art (written description requirement) or how to make and use it (enablement requirement).

A motion for summary judgment for failure to disclose the best mode, similarly, may require no third party discovery. However, since this inquiry concerns what the inventor knew about how best to make or practice his or her invention at the time the application was filed, a motion on this ground generally will require discovery from the inventor(s).

A motion based on indefiniteness of a claim, because it is closely related to claim construction (a question of law decided by the court), often must wait until the claim construction phase of the case. Still, in many jurisdictions, claim construction generally occurs some time before the discovery cut-off or trial, and such a motion may be brought well before trial.

Motion for Summary Judgment of Invalidity Due to Prior Art

A patent is invalid if the prior art reveals the claimed invention. In particular, a patent is invalid if the invention was known or used by others prior to the applicant's invention, or if it was patented or described in a printed publication or in public use or on sale more than one year before the application was filed in the U.S. *See,* 35 U.S.C. §§102(a), (b). In patent law vernacular, §102 invalidity is called "anticipation" or "lack of novelty." In addition, a patent is invalid, even if the claimed invention is not completely disclosed in a single prior art publication,

"…[A] motion to invalidate a patent under any of these §112 based theories may be filed relatively early in the case, well before the close of discovery, and usually without any third party discovery at all."

if the differences between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art at the time of the applicant's invention. *See,* 35 U.S.C. §103. Invalidity under §103 is called "obviousness," and is usually shown by presenting more than one prior art publication along with evidence that, at the time of the invention, one of ordinary skill in the relevant would have been motivated to combine them.

Unlike the §112 based invalidity theories discussed above, anticipation and obviousness generally depend on claim construction, and therefore a motion based on such grounds is best filed only after the court has ruled on what the claims mean. In fact, some courts discourage summary judgment motions until after claim construction, or until the close of discovery.

In any event, motions based on anticipation or obviousness usually include testimony of one or more experts to explain what one having ordinary skill in the art would understand was disclosed in the prior art. Because a party often will not want its expert to be deposed until relatively late in the case, motions on these grounds generally are not filed early.

Motions based on obviousness, as a general rule, are harder to win than motions based on anticipation. Anticipation depends primarily on the meaning of the claims in the asserted patent and the disclosures made in the prior art publication. Thus, the inquiry is by its nature relatively objective. Obviousness, on the other hand, generally requires consideration of how one of ordinary skill in the art would have been motivated to combine the teachings of more than one piece of prior art—a much more subjective inquiry, and therefore one more likely to involve disputed facts (or, at a minimum, disputed expert opinions).

Motions for Summary Judgment of Infringement (or Non-infringement)

Motions for summary judgment on other bases may be brought to minimize the time and expense of litigation. In a case where the structure and operation of an accused product is not in dispute, a motion for summary judgment of infringement (or non-infringement) may help dispose of the case early. Determining infringement is a two-step process: first, the terms of the asserted patent claims are construed (*i.e.*, interpreted), and second, the accused product or process is analyzed to see if it contains every element of the construed claims. *Markman v. Westview Instruments Inc.*[12] Therefore, even though a motion directed to infringement (or non-infringement) requires claim construction by the court, such a motion may resolve the case well before trial – and before much discovery – since claim construction alone may determine the infringement issues.

Claim construction is a question of law, and therefore within the authority of the judge to decide. Most courts will hold a claim construction (or *Markman*) hearing relatively early in the case, during which the court generally will resolve disputed facts relevant to claim construction. Although the second step of the infringement analysis (whether the accused product or process includes the elements of the claims) is a question of fact; in many cases the accused product or process is not in dispute, and (assuming the opposing party has had an adequate opportunity to obtain discovery) the matter may be resolved directly following claim construction.

Motion for Summary Judgment under "Doctrine of Equivalents"

Case law has long recognized that, in some cases, even though the accused product does not literally include every element of an asserted patent claim, the differences between the product and the claim are so insubstantial that the product still infringes. In other words, the actual words used in the patent claim effectively are broadened to include a range of "equivalent" products or processes that do not literally infringe. This tenet is called the "doctrine of equivalents," which has been the recent subject of substantial appellate attention, including by the U.S. Supreme Court. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*[13] While a detailed review of this doctrine is beyond the scope of this article, a motion for summary judgment may be effective in limiting (or broadening) the scope of "equivalent" products that infringe.

In particular, the Supreme Court has made clear that any narrowing amendments an applicant makes to his or her patent claims during the course of the prosecution of the patent application, if made to overcome prior art objections or other patentability objections by the examiner, give rise to a presumption that the patent owner is precluded from later extending the reach of the claims to products having features given up by the amendments.[14] Moreover, the Federal Circuit has held that whether this doctrine, called "prosecution history estoppel," applies is a question of law. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*[15]

The patent owner may try to overcome the presumption on three specified grounds: (1) the alleged equivalent was "unforeseeable" at the time the amendment was made; (2) the narrowing amendment was merely "tangential" and not directly relevant to the alleged equivalent; or (3) some other reason why the patent applicant could not reasonably be expected to have described the insubstantial substitute in question.[16] The Federal Circuit has held that the latter two of these grounds should be confined to a review of the patent and its file history, and should not generally involve other evidence. In other words, the merit of these two grounds is a ripe topic for summary judgment determination.

The patent owner, therefore, probably will be able to raise a factual dispute only under the grounds of unforeseeability by seeking to show that the difference between the literal claim language and the accused product was "unforeseeable" at the time of the amendment.[17] Depending

(continued on page 18)

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INTEGRA V. MERCK: IS THERE A SAFE HARBOR FOR RESEARCH?

By Cathryn Campbell and Mauricio A. Flores

The Court's findings in the *Integra* case have dispelled only some of the confusion over the application of the FDA Exemption used by researchers defending themselves from claims of infringement.

Intellectual property lawyers frequently encounter scientists who believe their work cannot infringe another's patent because they only do "research." This position is contrary to the statutory definition of infringement, which specifically includes making and using a patented invention within the definition of infringing acts.[1] There are only two potential exceptions for research: the common-law "Experimental Use Exception" and the statutory "U.S. Food and Drug Administration (FDA) Exemption."[2] Both are circumscribed in their applicability, however, and recent case law has further limited their application.

The common law Experimental Use Exception derives from the 19th century case of *Wittamore v. Cutter,* which stated that "it could not have been the intention of the legislature to punish a man" who constructed a patented device "merely for philosophical experiments."[3] Recently, the U.S. Court of Appeals for the Federal Circuit, in *Madey v. Duke University,*[4] considered the applicability of the exception to potentially infringing activities undertaken in the course of student education and faculty research. The Court held that the Experimental Use Exception does not apply to work which is "undertaken in the guise of scientific inquiry but has definite, cognizable and not insubstantial commercial purposes" and furthers "the alleged infringer's legitimate business."[5] The Court emphasized that the "narrow and strictly limited experimental use exception" does not immunize activities even at a not-for-profit educational institute.[6] *Madey* dealt a severe blow to the application of the common law research exception. It is now clear that this exemption provides very little protection in today's world, where even non-profit institutions are held to have business purposes.

The FDA Exemption, codified at §271(e)(1), Title 35, United State Code, is applicable only to biomedical research activities undertaken to obtain governmental regulatory approval under the U.S. Federal Food, Drug and Cosmetic Act.[7] §271(e)(1) provides that it "shall not be an act of infringement to make, use or sell a patented invention ... solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use or sale of drugs."[8] Although the statutory FDA Exemption was enacted by Congress to rectify a specific inequity relating to generic and patented drugs, the language of the statute was not so limited.[9] Numerous defendants have invoked the FDA Exemption as a shield from claims of infringement. However, because the language of the statute is far from clear, courts have differed in their interpretations, leading to confusion and inconsistency. Generally, however, the courts have broadened the scope of the FDA Exemption beyond its original legislative purpose. Despite almost 20 years of judicial construction, questions remain as to the appropriate application and scope of the FDA Exemption.

The *Integra* Case

In its most recent consideration of the FDA Exemption, *Integra LifeSciences v. Merck KGaA,* the Federal Circuit had to determine "whether the pre-clinical research...is exempt from liability for infringement."[10] The issue before the Court was whether the FDA Exemption "reaches back down the chain of experimentation to embrace development and identification of new drugs that will, in turn, be subject to FDA approval."

The *Integra* case involved biological molecules, called peptides, containing the amino acid sequence Arg-Gly-Asp (otherwise abbreviated as RGD), which were discovered at the Burnham Institute. RGD peptides are involved in the adhesion of cells to other cells and to extracellular matrix proteins. Cell adhesion is fundamental to such varied pathologies as cardiovascular disease, where cells inappropriately adhere to form blood clots, and metastasis, where malignant cells detach from each other to seed tumors at other locations in the body. The Burnham Institute exclusively licensed to Integra LifeSciences the RGD peptides themselves along with their receptors and various methods of their use.

After their initial description in the scientific literature, RGD peptides became the subject of extensive scientific research, resulting in hundreds of publications in peer-reviewed scientific journals. A scientist working at The Scripps Research Institute discovered that RGD peptides are involved in the growth of new blood vessels, a process known as angiogenesis. Published and patented by Scripps, this discovery caught the attention of Merck KGaA, which was interested in the practical application of RGD peptides to inhibit angiogenesis and effectively starve solid tumors. Merck KGaA entered into a sponsored research agreement with The Scripps Research Institute to select the best drug candidate among several closely related RGD peptides.

Integra and the Burnham Institute sued Scripps for infringing their RGD patents and Merck for inducing Scripps' infringement. Merck and Scripps asserted the FDA Exemption as a defense. The research allegedly protected by the FDA Exemption involved in-vitro screening of certain RGD peptides for anti-angiogenesis activity as well as testing the RGD peptides on fertilized chicken eggs to determine their effect on blood vessel development.

After a 27-day trial, the jury was asked to determine whether the infringing acts were "reasonably related" to FDA approval so as to be exempt. The jury was instructed that the defendants must prove by a preponderance of the evidence "that it would be objectively reasonable for a party in Merck's and Scripps' situation to believe that there was a decent prospect that the accused activities would contribute, relatively directly, to the generation of the kinds of information that are likely to be relevant in the process by which the FDA could decide whether to

"'§271(e)(1) simply does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process.'"

approve the product in question."[11] The jury found that the defendants had not satisfied this factual standard and that the FDA Exemption did not apply to the research at issue.

On appeal to the U.S. Court of Appeals for the Federal Circuit, Merck attacked the judgment by arguing, *inter alia,* that the FDA Exemption applied as a matter of law to the research at issue and that the damage award was supported by sufficient evidence. Merck proposed that the FDA Exemption should be construed to exempt all experimentation that could serve as a "rational predicate" for subsequent experimentation leading to information directly pertinent to FDA review for safety and efficacy. Integra, on the other hand, argued that the FDA Exemption should be limited to activities bearing "relatively directly" on the generation of information relevant to the FDA.

Rejecting the broad construction proposed by Merck, the Court stated that "§271(e)(1) simply does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process."[12] The Court noted that the work sponsored by Merck "was not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds. The FDA has no interest in the hunt for drugs that may or may not later undergo clinical testing for FDA approval."[13] The Court pointed out that "the FDA does not require information about drugs other than the compound featured" in an IND.[14] Accordingly, the Court held that the Merck-sponsored research at Scripps, directed to selecting the best among several possible drug candidates, does not fall within the §271(e)(1) Exemption. "The safe harbor does not reach any exploratory research that may rationally form a predicate for future FDA clinical tests."[15]

Legislative History of the Exemption

The Federal Circuit relied heavily on the legislative history of the FDA Exemption in its decision. The FDA Exemption was enacted as part of the *Drug Price Competition and Patent Term Restoration Act of 1984*[16] (the 1984 Act), also known as the Hatch-Waxman Act. The goals of the 1984 Act as a whole were two-fold: to provide an incentive for the development of patented drugs while promoting the availability of lower-cost generic alternatives. To this end, the 1984 Act contained provisions to promote the availability of low cost generic drugs, including expedited approval for generic drugs through Abbreviated New Drug Applications (ANDA).

At the time of the 1984 Act, generic drug manufacturers could not begin the studies required for FDA market approval during the term of patent protection on the innovator drug without the risk of being sued for infringement. In *Roche v. Bolar*[17] Roche held a patent on the anti-anxiety drug flurazapam. Intending to market a generic version, Bolar imported quantities of the drug to begin the testing required for the FDA marketing approval prior to expiration of Roche's patent. The Federal Circuit declined to apply the common law Experimental Use Exception to Bolar's activities on the basis that they were being undertaken "solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry" and thus held that Bolar infringed Roche's patent.[18]

If generic drug manufacturers are prevented from performing studies necessary to obtain FDA approval until after the expiration of the patent on the innovator drug, the patent holder in effect obtains an extension of its term of exclusivity. Negating the holding of *Roche,* §202 of the 1984 Act (now codified as §271(e)(1)) obviated this patent term distortion by providing a safe harbor for otherwise infringing studies undertaken on generic drugs in order to obtain regulatory approval.

While §271(e)(1) was enacted specifically to allow generic drugs to enter the market simultaneously with the expiration of the innovator's patent, the language of the statute was not so limited. It is not, for example, limited to generic drugs but refers rather to "patented invention[s]." The uncertainties inherent in the statutory language have also led to sometimes-conflicting judicial interpretations of its scope and applicability.

Whither Tool Patents?[19]

Many of the inventions that underlie the biotechnology revolution of the late 20th century relate to basic platform technologies, new materials or methods for discovering new products. Such platform, or "tool," technology has enormously increased the types of diagnostic and therapeutic products currently available. However, patents claiming the tools themselves, rather than the products obtained through the use of the tools, present novel issues. Among these is the question of whether otherwise infringing uses of tool patents can be shielded by the §271(e) Exemption.

In *Integra*, the Federal Circuit Court considered the effect of the "rational predicate" theory urged by Merck on "tool patents." The Court noted that extending the safe harbor of the FDA Exemption to cover the experiments at issue "would effectively vitiate the exclusive rights of patentees owning biotechnology tool patents... [and] would swallow the whole benefit of the Patent Act for some categories of biotechnological inventions."[20] Under the "rationale predicate" theory, all tool patents would be worthless. While the decision may be a bellwether of the Federal Circuit's inclination to consider tool patents outside the scope of the §271(e) Exemption, the *Integra* decision should not be read to so hold.

Is the Safe Harbor Really Safe?

The *Integra* decision did not hold that all pre-clinical research necessarily is outside the scope of the FDA Exemption. In fact, the court noted that some activities that do not themselves produce FDA information might nevertheless be exempted. However, biomedical research is not exempted merely because it may lead to new drugs; the experimental work must relate *relatively directly* to the submission of data to the FDA. As the Federal Circuit noted, "[t]he focus of the entire exemption is the provision of information to the FDA. Activities that do not directly produce information for the FDA are already straining the relationship to the central purpose of the safe harbor."[21] The decision holds only that application of the §271(e) Exemption requires a specific

factual showing of relatively direct relevance to core FDA concerns of safety and efficacy. While Merck failed to make a sufficient showing that the exemption should apply, a sufficiently direct connection between infringing pre-clinical experiments and FDA review to invoke the §271(e)(1) Exemption may well be made in other cases.

The decision in *Integra* reaffirms that application of the FDA Exemption will be determined under the *Intermedics* "reasonably related" standard. The exemption is not determined as a matter of law according to either the class of infringing product or the type of patent. Instead, the analysis will focus on the nature of the otherwise infringing acts, a question of fact. For this reason, cases are more likely to go to trial, with juries deciding whether the defendant's activities satisfy the Intermedics standard and verdicts being reviewed only for substantial evidence. With biomedical technology becoming ever more complex and patent rights ever more important, doubtless many juries will grapple to determine — based on the facts of the case — when the causal chain of research events actually enters the safe harbor of the FDA Exemption. ■

[1] 35 U.S.C. 271(a) provides "whoever without authority makes, uses, offers to sell or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent."
[2] Codified at 35 U.S.C. 271(e)(1).
[3] *Wittamore v. Cutter,* 29 F. Cas. 1120, 1121 (No 17,600) (C.C.D. Mass. 1813).
[4] *John M.J. Madey v. Duke University,* 307 F.3d 1351 (Fed. Cir 2002).
[5] *Id.*
[6] *Id.*
[7] 35 U.S.C. §271(e)(1).
[8] *Id.*
[9] *See, e.g., Amgen, Inc. v. Hoechst Marion Roussel, Inc.,* 3 F. Supp.2d 104 (D. Mass 1998); *Intermedics, Inc. v. Ventirtex, Inc.,* 775 F. Supp. 1269 (N.D. Cal 1993), *aff'd,* 991 F.2d 808 (Fed. Cir. 1993); *Abtox, Inc. v. Exitron Corp.,* 888 F. Supp. 6 (D. Mass. 1995), *aff'd,* 122 F.3d 1019 (Fed. Cir 1997); *Elan Transdermal Ltd. v. Cygnus Therapeutic Sys.,* 24 U.S.P.Q 2d 1926 (N.D. Cal. 1992).
[10] *Integra LifeSciences I, Ltd. v. Merck KGaA,* 331 F.3d 860 (Fed. Cir. 2003); *Bayer AG v. Elan Phar. Research Corp.,* 212 F.3d 1241 (Fed. Cir. 2000).
[11] Jury Instructions, Integra LifeSciences I, Ltd. v. Merck (S.D. Cal. 96-CV-1307) (based on I*ntermedics, Inc. v. Ventritex, Inc.,* 775 F. Supp 1269n (N.D. Cal. 1991) *aff'd* 991 F.2d 808 (Fed. Cir. 1993)).
[12] 331 F.3d 860.
[13] *Id.* at 866.
[14] *Id.*
[15] *Id.* at 867.
[16] Pub.L. No. 84-417, 98 Stat. 1585 (1984)
[17] *Roche Products, Inc. v. Bolar Pharmaceutical Co.,* 733 F.2d 858 (Fed. Cir. 1984).
[18] *Id.* at 863.
[19] The author would like to acknowledge John B. Chasnow for the apt pun used in a different context
[20] 331 F.3d 860 at 867.
[21] 331 F.3d at 866.

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The Antitrust Risks Associated with Manipulating the Standard-Setting Process

(continued from page 4)

[1] EC Directive 98/34/EC.
[2] 164 F.Supp. 2d 743 (E.D. Va. 2001), *rev'd,* 318 F.3d 1081 (Fed. Cir. 2003).
[3] During this period, Rambus's counsel, Gray Cary Ware & Freidenrich LLP, employed Mr. Bloch. However, Mr. Bloch was not involved in the case, and all information contained herein is taken from public sources.
[4] 208 F.3d 989 (Fed. Cir. 2000), cert. den. 121 S.Ct. 1167 (2001).
[5] 486 U.S. 492, 509-510 (1988).

The Use of Exculpatory Opinions in Defending Against a Charge of Willful Infringement

(continued from page 6)

regard to willful infringement. (2) It is not appropriate to draw an adverse inference even when a defendant has not secured legal advice. (3) The existence of a substantial defense to infringement should be sufficient to defeat a willfulness claim regardless of whether legal advice was sought and obtained. Some parties went even further, asking the Court to simply abolish the *Underwater Device* rule. As of this writing, oral argument has been completed and the patent bar eagerly awaits guidance from the *en banc* Federal Circuit.

Given the Court's request and the overwhelming call for change, it appears that some Federal Circuit guidance on these issues may soon be forthcoming. However, until that happens, it is important to understand the opinion "requirement" and the attendant attorney-client privilege waiver virtually inherent in presenting a defense to a charge of willful infringement. ■

[1] See, e.g., Anjimoto Co. v. Archer-Daniels-Midland Co., 228 F.3d 1338 (Fed. Cir. 2000); SRI Int'l Inc. v. Advanced Tech. Labs. Inc., 127 F.3d 1462 (Fed. Cir. 1997); Gustafson, Inc. v. Intersystems Indus. Prods., Inc. 897 F.2d 508, 510 (Fed. Cir. 1990) ("Willfulness is determined from the totality of the circumstances...."); and Bott v. Four Star Corp., 807 F.2d 1567, 1572 (Fed. Cir. 1985).
[2] 717 F.2d 1380, 1389-90 (Fed. Cir. 1983).
[3] 793 F.2d 1565, 1580 (Fed. Cir. 1986).
[4] 853 F.2d 1568, 1572-73 (Fed. Cir. 1988).
[5] Civil Action No. 01-389-KAJ, Memorandum Opinion, October 8, 2003.
[6] 837 F. Supp. 616 (D. Del. 1993).
[7] 994 F. Supp. 1202, 1205-06 (C.D. Cal. 1998).
[8] 954 F.Supp. 1195 (W.D. Mich. 1997).
[9] Dunhall, supra.
[10] 1995 U.S. Dist. LEXIS 15222, *8-9 (D. Ore. 1995).
[11] 1992 U.S. Dist. LEXIS 21500, *7, 24 U.S.P.Q.2D (BNA) 1073 (N.D. Ga. 1992)
[12] 175 at F.R.D. 539, 540 (N.D. Cal. 1997).
[13] 1995 U.S. Dist. LEXIS 12880, *1-4 (S.D.N.Y. 1996).
[14] 2000 U.S. Dist. LEXIS 10044 *1.
[15] 227 U.S.P.Q. (BNA) 886, 887 (D. Mass. 1985).
[16] Case Nos. 01-1357, - 1376, 02-1221, - 1256 (Fed. Cir.); on appeal from the U.S. District Ct for the Eastern District of Virginia (Case No. 00-CV-803).

TRADEMARK AND UNFAIR COMPETITION IN THE UK, GERMANY AND ITALY

By Laurence Cohen, Boris Uphoff and Margherite Barié

In this article, the authors review three European systems for protecting trademarks and similar rights from unfair competition.

Europe has grown up with different systems to protect acquired unregistered rights in trademarks, signs and get up (trade dress). In common law systems this protection has taken the form of an action against passing off, while in civil law systems it has taken the form of an action against unfair competition. The common law system can be viewed as allowing everything except that which is prohibited, while the civil law system prohibits everything except that which is allowed. The UK is a common law country, while Germany and Italy are civil law countries.

For over a decade the European Union (EU) has operated two parallel protection systems for protecting get up or trade dress against unfair competition: a system of trademark registration (which has been harmonised since December 1988 in theory and since about 1994 in actuality); and an unregistered trademark system based either on the law of unfair competition or on passing off, depending upon the jurisdiction in issue.

Registered Trademark Protection

The registered trademark system is harmonised within Europe and is based on the EU Trademarks Directive 89/104/EC, which governs the harmonisation of national trademark laws, and Council Regulation 40/94/EC (the Trademark Regulation) pursuant to which the European Trademark is governed and the European Trademark Office was established in Alicante, Spain.

Registered rights are protected, once granted, from the date of the application. Grant of a Community Trademark and the marks of certain member states such as the UK may be opposed. Renewal fees must be paid, and the scope of the mark may be limited, or the mark may be expunged altogether for non-use.

The scope of protection by registration, common to the whole of the EU, is the right to prevent others from applying a mark, which is covered by the registration. This right is limited to three types of infringement:

- same mark, same goods;
- similar mark, similar goods coupled with likelihood of confusion, including association with the registered mark; or
- similar mark, dissimilar goods, but where the mark is so well known in a member state that use of the registered mark in the member state takes unfair advantage of the registered mark without due cause or is detrimental to the distinctive character or repute of the trademark.

The procedural consequences of infringement of a registered trademark anywhere in the EU are the same: namely an injunction and damages. Where the member states of the EU differ greatly is in their procedural law with regard to proving liability for infringement, time to trial, interim orders (such as seizure orders), obtaining proof (*i.e.*, discovery) and treatment of damages. In addition there is a wide gulf between the national trademark offices which examine trademark applications before grant, such as the UK, and those who do not, such as France and, as far as potential third parties' rights are concerned, Germany. However, these disparities can be avoided by opting for the unified applications procedure of the Community Trademark through the Office of Harmonization in the Internal Market (OHIM) in Alicante, Spain.

Unfair Competition, Passing Off and the Relationship with Registered Trademarks

When the EU Trademarks Directive and the Trademark Regulation were enacted, they were not formulated to be a complete code relating to trademarks. Although both adopted a "first to file" regime consistent with pre-existing civil law practice, they also permitted pre-existing accrued rights to act as a bar to registration. Such rights included those rights existing under the law of unfair competition, under the law of passing off, as well as under copyright law. Cartoon characters, packaging design and logos are examples where copyright is likely to be an earlier right in time to a trademark application; not least because of the requirement to represent the trademark graphically.

Further, the Directive and the Regulation both specifically preserved national rights in unfair competition and passing off as separate and distinct causes of action, to be decided on their merits. As a consequence, registration of a trademark does not preempt an action in passing off or unfair competition. The English Court of Appeal confirmed this in July 2003 in *Inter Lotto (UK) Ltd v Camelot Group plc.* The coexistence of such similar rights can also lead to the consequence of mutually assured destruction when one party owns the registration and another the unfair competition or passing off rights, as happened in the Australian case of *Campomar Sociedad Ltd v Nike International Ltd,* where rights in the Nike trademark were split.

The UK Perspective: The Law of Passing Off

An action in the UK based on passing off can protect rights that an action based on registered trademarks cannot. This is because passing off protects goodwill, which is the attractive force bringing in business. Under EU laws it is possible to obtain registration of a trademark, even one to which no goodwill has yet inured. Also, although use is not a requirement for registration it is required as a basis for enforcing rights under a passing off cause of action.

The classic statement of the law of passing off was made by the English House of Lords in the case of *Jif Lemon,* where the subject matter was a plastic lemon containing lemon juice. The evidence established that when the public saw

"The coexistence of such similar rights can also lead to the consequence of mutually assured destruction when one party owns the registration and another the unfair competition or passing off rights…."

a plastic lemon containing lemon juice on a supermarket shelf, it thought only of Jif Lemon. Registration of a lemon colored plastic lemon for lemon juice, as a trademark, would have been impossible, because of the evidence acquired of distinctiveness of that get up or trade dress from the *Jif* case.

The Court summarised the elements of a passing off cause of action as follows:

- the claimant must have protectable goodwill in the subject matter such as get up or trade dress;
- the defendant must be trading off that goodwill in the sense that there is a misrepresentation or confusion as to the origin of the goods or services of the defendant and those of the claimants goods or services; and
- that misrepresentation must lead to damage.

Damage is an essential element of passing off; it can be damage to goodwill, lost sales or some combination.

It is frequently the case that trademarks infringement and passing off are brought as claims in a single action. The scope of an injunction available for passing off is different than that available for trademark infringement. The latter gives rise to an absolute injunction prohibiting further infringement of the trademark. The former gives rise only to a qualified injunction prohibiting marketing of the goods or services without clearly distinguishing them from those of the claimant. Sometimes this is a difference without a distinction; other times, it is not.

A major issue in English trademark and passing off law is the claim to damages. At the moment it is not clear whether damages are restitutionary, compensatory or based on the user principle. It is an open question as to whether a small business whose rights have been infringed by a large business must be paid a reasonable royalty by the large business on all uses of the mark or trade dress, even though that far exceeds the value of the right in the hands of the small business. This issue may be resolved shortly in a number of cases that are now before the English High Court.

The German Perspective: Unfair Competition Remedies Against Counterfeiting

Germany has two different types of protection for brand names, logos and product designs: registered rights such as trademarks and unfair competition claims against counterfeiting. The rules under German trademark law are similar to those in the UK. However, the remedies under German unfair competition law are slightly different from those available under the UK passing off law.

In addition to claims under trademark law, German case law on unfair competition has developed the animal of "slavish counterfeiting." Even without a registered right, one has a cause of action if:

- the technical features of a product or service or its design are copied one-to-one;
- the counterfeiting causes a likelihood of confusion because customers think the copy was an original; and
- the counterfeiter acted in bad faith, such as by using confidential information from the manufacturer of the original.

The "slavish counterfeiting" action is a strong weapon against "me-too" products. Think of a Coke tin in the typical red and white colours and a swoosh pattern. Consumers will likely confuse such a product with the original even if the registered trademark "Coca Cola" is not on the tin. As there is a likelihood of confusion, the manufacturer of the original would have an easy case against the counterfeiter. Another good example is a company's industrial tool, which a competitor copies by using confidential drawings from a former employee of the company. In such a case, the company could sue even without having a patent or another registered right protecting its tool.

A practical advantage to consider when contemplating a counterfeiting case is that in German unfair competition litigation, the plaintiff can choose the forum. Plaintiffs tend to gravitate to the court having the strictest view on companies that attempt to exploit their competitors' goodwill, such as those sitting in Hamburg and Cologne. These courts are known to grant *ex parte* injunctions against counterfeiters within a day or two.

The downside of any sort of infringement litigation in Germany is that the plaintiff is only entitled to a modest "reasonable damages" award. Punitive damages are unknown in this jurisdiction, and the courts do not normally award more in damages than the infringer would have paid had he obtained a license at an average market price. Realizing this, some counterfeiters deliberately risk being sued, although they should not forget that trademark and patent infringement are criminal offences in Germany.

The Italian Perspective: Trade Mark Protection and Unfair Competition Remedies

Just as in the UK and Germany, Italian trademark law is subject to the EU Trademarks Directive and the EU Trademarks Regulation summarised above.

In Italy, the domestic protection of trademarks falls within the ambit of the Royal Decree No. 929 of 21 June 1942 as amended (Italian law) providing the right of the relevant owner to make exclusive use of the trademark within Italy for 10 years from filing, indefinitely renewable as long as the mark remains in use.

According to Italian law, the owner of a registered trademark has the right to prohibit third parties from using a sign identical or similar to the trademark for certain goods and services without the owner's consent.

The scope of the trademark protection under Italian law is to avoid a likelihood of confusion among consumers over the products or services of the trademark owner and those bearing an infringing mark. By this, the Italian legal system grants protection to any trademark, which serves the purpose of indicating the origin and quality (particularly for the so-called "special trademarks") of the products and goods with which they are identified. Further, trademarks are also protected in the light of their autonomous value, which is an advertising value representing the communication and investment value for enterprises and consumers. Under Italian law, trademarks possess such value, separately and aside from products or services with which they may be identified. Marks that act as certificates of geographic origin, also known

"Like its sister jurisdictions, when confronting trademark infringement allegations, Italian courts usually evaluate the likelihood of confusion arising between the defendant's goods or services and those of the owner of a trademark."

as *"application controllée,"* are particularly strong in Italy. Examples include Parma Ham, Parmesan Cheese and Chianti Wine.

The remedies provided under the Italian legal system for the protection of trademarks are divided into two different categories: *restraining remedies,* such as "description" (which in common law terms functions as "discovery" of what the defendant has been doing); seizures and pre-trial injunctions; and *ordinary remedies* such as final injunctions, recovery of damages and destruction of the materials used to commit the trademark infringement. Court decisions are published and may be required to be advertised.

Like its sister jurisdictions, when confronting trademark infringement allegations, Italian courts usually evaluate the likelihood of confusion arising between the defendant's goods or services and those of the owner of a trademark.

Recent case law provides the following guidance on the likelihood-of-confusion test under Italian law:

- Courts must take the relevant trademark's context of use (and not just the terms set out in the registration) into consideration when assessing whether it requires protection against the alleged infringement. The context to be considered will usually include associated advertising and the reputation of the mark.
- In accordance with the decisions of the Italian Supreme Court, courts will analyse the relevant trademark as a whole, rather than the separate elements making up the mark. Courts should also attempt to assess the mark from the perspective of the target consumers.
- Any assessment should take into account the fact that in addition to indicating the origin of a particular product or service, marks also have a value that is separate from the products and services to which they relate. This value stems from the fact that marks have the power to attract the interest of consumers. Under Italian law this power of attraction is now protected by the concept of risk of association, which should be included within the test for risk of confusion. This concept is similar to the goodwill associated with a mark in connection with passing off actions in the UK.
- Confusion that occurs before sale is included when assessing risk of confusion.

Under the Italian legal system, a trademark owner also can rely on the protections provided by the Italian unfair competition rules. Infringement of registered trademark and unfair competition are separate and distinct causes of action.

Also, since unfair competition is aimed at protecting consumers against confusion over the business activities of different entrepreneurs (more than against confusion regarding specific products), in order to rely on the protections provided by both Italian trademark law and unfair competition law, it is necessary to establish that the alleged infringement has been effectively used and that, as a result of such use, there exists a likelihood of confusion among consumers regarding the business activities of the registration holder and those of the competitor. ■

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Dispositive Motions in Patent Cases – Strategies and Considerations

(continued from page 12)

on the facts of the case, summary judgment may be an appropriate way to have the court determine the applicable scope of any alleged equivalent beyond the literal patent claim language.

Conclusion

A motion for summary judgment, in appropriate cases, is an effective tool for disposing of all or part of a case prior to trial, saving substantial time and money. In patent cases, there are several potential grounds for which such a motion may be filed relatively early in a case, even prior to discovery. A motion for summary judgment may also provide an opportunity to educate the court about a party's positions early in the case, and may force an opposing party to reveal its theories of the case. Such motions are especially effective in patent cases, where objectively verifiable facts often predominate over subjective recollections of witnesses. Reviewing possible grounds for summary judgment early may help create a stronger case strategy and provide a roadmap to success down the road. Whether or not and when to file a motion for summary judgment, and the grounds therefore, are among the most important strategic decisions to be made in the case. ■

[1] A motion for summary adjudication of issues refers to a motion that will resolve some issues in the case, but not the entire case. *See,* F.R.C.P. 56(d).
[2] A moving party may not bring the motion, of course, merely to learn the opposing party's case; Rule 11 requires that all motions be brought in good faith and with reasonable bases. Further, a court may deny a motion for summary judgment due to a moving party's failure, or a non-moving party's lack of opportunity, to complete adequate discovery, or as premature until the court has ruled on claim construction.
[3] 2004 U.S. App. LEXIS 2458 (Fed. Cir. 2004).
[4] *Id.*
[5] *Id.*
[6] 338 F.3d 1368 (Fed Cir. 2003).
[7] *Id.*
[8] 301 F.3d 1306, 1314 (Fed. Cir. 2002).
[9] *Id.* at 1312.
[10] 338 F.3d 1368 (Fed Cir. 2003).
[11] *Id.*
[12] 52 F.3d 967, 976, (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996).
[13] 535 U.S. 722 (2002).
[14] *Id.*
[15] 344 F.3d 1359, 1367 (Fed. Cir. 2003).
[16] *Id.* at 1369-70.
[17] *Id.* at 1369.

FEDERAL CIRCUIT DAMAGES DECISION EMPHASIZES THE IMPORTANCE OF SOUND ECONOMIC MODELS

By James E. Malackowski and Robert M. Hess

In reviewing the initial damages award in a major case and analyzing its reversal by the Federal Circuit, the authors open a window on how damage awards are determined and provide insights on creating sound damages models are created.

Introduction

On July 31, 2002 the United States Court of Appeals for the Federal Court issued its opinion in the case of *William G. Riles v. Shell Exploration and Production Company*. In making its ruling, the Federal Circuit described the damage award as being "excessive and unsupported by evidence" and therefore vacated the district court's award and remanded the case for a re-determination of damages.

While such a situation obviously creates consternation for the client, it also may cause severe hardship for outside counsel and damages experts alike in the form of strained relationships and tarnished reputations. Through a review and analysis of the initial damages award and its subsequent reversal, this article provides additional insight into the determination and calculation of sound damages awards, and highlights the importance of thoroughly supported opinions.

Background

Riles filed suit against Shell for infringement of U.S. Pat. No. 4,669,918 (the `918 patent). With respect to the construction of Shell's "Spirit" oil drilling platform, the `918 patent relates to a method of construction and installation of fixed offshore drilling platforms. A fixed offshore drilling platform is essentially comprised of foundational pilings imbedded into the sea floor, a tower or "jacket" going to the surface and an above-water "deck." Prior to the `918 patent, "mud mats" were typically used to temporarily level and support the jacket while it was anchored to the sea floor with foundation pilings. According to the invention in the `918 patent, pilings were imbedded first and then the jacket was attached to the pilings. The two main advantages afforded by this method were a cost savings resulting from the exclusion of the mud mats and the use of less jacket material due to improved structural support. At the conclusion of the trial, the jury returned a verdict of infringement and awarded Riles $8.7 million in damages.

The Damages Case

Riles' damages expert prepared three economic models which he used to support his damages position. In ruling on the case, the Federal Circuit could have relied on any of the three models as support for the jury's award, but found insufficient evidence to support any of the three models.

Economic Model #1

The first model calculated damages by applying a 2 to 5 percent royalty rate to the entire cost of Shell's platform. The model was based on the assumption that Shell's construction of a platform utilizing the patented method could result in an injunction on behalf of Riles, thus forcing Shell to either abandon the $84 million platform or pay a percentage of the total cost as a royalty.

Economic Model #2

The second model claimed that Riles deserved a 2 to 5 percent royalty on the gross revenue generated by the platform in its first year of production. Similar to the first economic model, the second model assumed that Riles could enjoin Shell from using the platform. Under such a scenario, Shell would have been willing to pay a percentage of its revenues for use of the patent.

Economic Model #3

The third model simply added the first two models together while providing no actual basis for their combination.

In dismissing the first two models, the Federal Circuit identified two key flaws. First, assuming that an injunction would be granted was legally incorrect. There was insufficient evidence to support an injunction on the use of the Spirit platform, merely because of its method of construction. Second, and more economically important, the Court concluded that the "market" would pay Riles only for his patented product. Therefore, it was incorrect to apply a royalty rate to the entire cost of the platform or the platform's overall revenues. The Court rightly stated that there was no relationship between the patented method and the total cost of the platform or its revenues. In forming its opinion, the Federal Circuit found that, in a hypothetical negotiation, Shell would have had non-infringing alternative methods for installing the platform. Thus, the negotiation would have been driven by the economic relationship between the patented method and the non-infringing alternative methods. Finally, the Federal Circuit found that the third model compounded the errors in the first two models and therefore found no basis on which it could be supported.

This case is an excellent example of the need and importance of a fully supported and economically sound damages model. In complex cases involving complex business decisions, such as today's patent infringement cases, it is of utmost importance that damages calculations and their related issues are not looked at in a vacuum. Rather, a well-rounded, defensible opinion must consider all the relevant facts, evidence and circumstances of each particular situation surrounding the alleged infringement. From that perspective, this case contains many examples of critical facts/pieces of evidence that were indeed relevant to properly determine economic damages.

Economic Relationships

The Federal Circuit emphasized that there must be an economic relationship between the patent-in-suit and the damages model. In today's patent infringement lawsuits, the plaintiff can no longer propose an exorbitant damages claim in hopes of receiving a windfall from the jury. The Federal Circuit recognizes that the ownership of a valid patent does not necessarily mean that the alleged infringer can be "held up for ransom." The damage figure must be tied to sound economic and accounting principles in assessing what monetary damages are due to the plaintiff.

In this case, it is clear that this economic relationship is based on the cost

"…[T]here must be an economic relationship between the patent-in-suit and the damages model. In today's patent infringement lawsuits, the plaintiff can no longer propose an exorbitant damages claim in hopes of receiving a windfall from the jury."

savings that the patent offers. Clearly, the appropriate damages model should be grounded in an analysis of the cost savings achieved by Shell through its use of the `918 patent. By ruling that Riles could not hold Shell "over a barrel" through the enforcement of its patent, the Court concluded that the value of the benefits provided by the invention must be limited to the invention itself and not the cost and/or benefit of the entire platform.

However, under a different set of facts and circumstances, a patented component may equate to greater economic value. Often discussed as the "entire market value rule," this concept addresses situations where a patent covers only part of a product, but a part that is of such paramount importance that it substantially creates the value of the entire product. In such cases, it may then be appropriate for the patentee to recover damages based on the entire product. Again, the key is to analyze the substantive relationship between the patent-in-suit and the infringing product and to consider all relevant evidence and facts related to each specific case.

Next Best Alternative

The Federal Circuit also identified the critical importance of determining the alternatives available to each of the parties at the time of the hypothetical negotiation. In that regard, it is assumed that both parties would have had knowledge of those alternatives and, as such, would have negotiated a royalty that is consistent economically with those options. Generally, when the value of the invention is limited to the cost savings it produces, the additional cost to the infringer for using its "next best alternative" creates an economic cap to the amount it would pay for use of the patented invention. Although this basic concept is straight forward, the analysis quickly becomes very complex in infringement lawsuits, as the factual evidence must determine the alternatives' total cost, availability, quality, market acceptance, timing, *etc.*

Again, the *Riles* case provides a useful example. Although some evidence was presented at trial that mud mats were an available alternative and would have cost Shell an additional $350,000; there was conflicting evidence that, due to certain geological conditions of the sea floor, mud mats were not an alternative. An appropriate economic model would have pursued this critical information through additional documents, deposition testimony, or market research. At a minimum, there also would be more questions to answer related to the additional material cost savings the patented method may provide in determining the complete value afforded to Shell.

Analyzing the parties' "next best alternative" is an important step and a simple concept to convey. However, the facts and evidence of each case make this economic principle extremely complex and difficult to model in many patent infringement cases.

Licensing History

Another important piece of economic evidence that the damages models did not incorporate was the historical licensing practices of the plaintiff, Riles. Although evidence was presented to suggest that Riles' past royalty rate agreements were based on either a percentage of savings that the licensee would have realized or a fee based on platform depth (potentially related to the cost savings associated with the invention), the plaintiff's damages models calculated a royalty based on the cost/benefit of the entire platform. Every damages model must be thoroughly grounded in the facts of the case. The plaintiff simply cannot belie certain facts and evidence so as to create an inconsistent economic model. In this case the calculation not only ran contrary to the factual evidence, but it also was inconsistent with the first of the 15 factors set forth in *Georgia Pacific v. United States Plywood Corp.,* which is focused on "the royalties received by the patentee for the licensing of the patent-in-suit (proving or tending to prove an established royalty)." From the Federal Circuit's opinion it is clear that all available evidence must be considered in developing economic and accounting damages models.

Other Lessons From the *Riles* Decision

- Understand the key assumptions that drive any damages model. Be aware of the source of those assumptions along with their defensibility and potential impact on the damages calculation. Question and critically challenge key assumptions whenever possible.
- Monitor the analysis throughout the entire process to understand the direction and general methodology employed. Also, be prepared to obtain additional discovery if required so that legal schedules and deadlines do not preclude the collection of valuable economic and accounting information.
- Question any alternative theories that may have been considered. Understand why those alternative theories are not applicable. Inquire into and challenge the ultimate conclusions of the damages model.

Conclusion

The Federal Circuit's decision in this case is an excellent reminder to professionals responsible for working with damages models. As has been addressed in previous decisions, this opinion stresses the importance of creating strategically sound damages models that are not only supported by the specific facts, circumstances and evidence present, but also grounded in economic principles and "real world" analyses. ■

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Messers James E. Malackowski and Robert M. Hess are Chief Executive Officer and Chief Financial Officer, respectively, for Ocean Tomo, LLC, an integrated intellectual capital merchant bank providing finance, asset and risk management, M&A advisory and valuation, diversity and expert services. *www.oceantomo.com*

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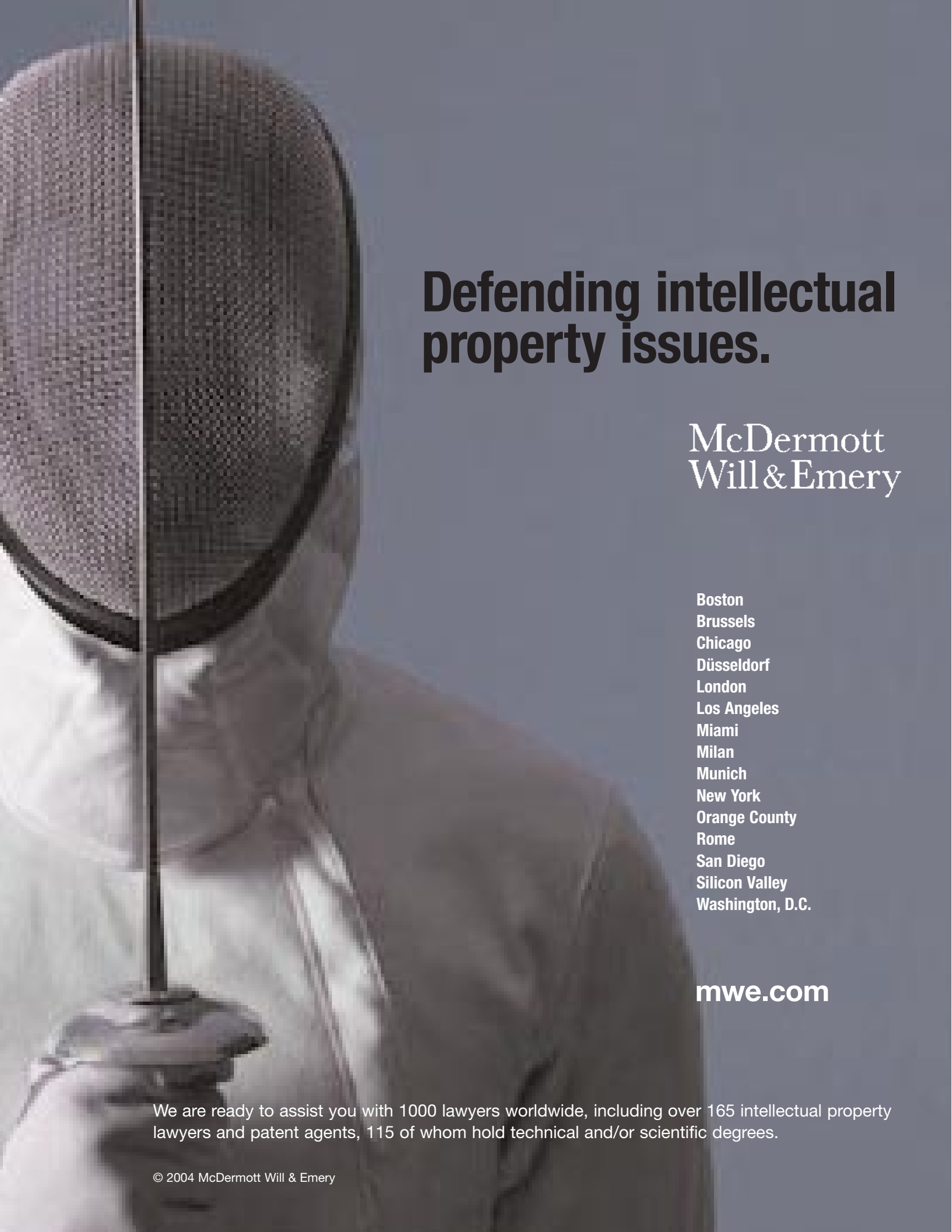

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