



snippets

Review of Developments in Intellectual Property Law

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Welcome to the Inaugural Issue of snippets™!

MBHB enters a new era with the introduction of snippets™ MBHB's Review of Developments in Intellectual Property Law. snippets™ will provide MBHB's clients with current information on legal developments directly related to their industries, as well as legal developments that span industries. Our coverage will focus on the practical effects of judicial, legislative and political developments in patent, trademark, trade secret, and copyright law, on both the domestic and international fronts. We also hope that through snippets™, our clients and friends will achieve a greater familiarity with the attorneys of MBHB and see another example of MBHB's commitment to providing highlevel, highvalue client service.

We want you to benefit as much as possible from snippets™, and we would therefore appreciate your input on how we can make this publication most useful for you. Please fill out the form at the end of this issue or email us at snippets@mbhb.com to let us know what you would like to see in snippets™.

We hope that you enjoy the inaugural issue of snippets™!

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From Doha to Baghdad via DC: U.S. Pharmaceutical Policy in a Troubled World

Perhaps no other area so clearly exemplifies the inherent conflict between incentives for innovator companies and public access to technology as that of innovator versus generic drugs. As the military action in Iraq winds down and the U.S. is faced with building a health care system in a developing country; as new diseases such as SARS (severe acute respiratory syndrome) and monkeypox attack both developed and developing nations; and as presidential election activity gets underway in earnest, the conflict will return to the forefront of the political landscape in the form of a debate over the cost and availability of prescription medications. A number of pending and recently-enacted initiatives, both domestic and international, will inevitably become the centerpieces of the debate. The various initiatives are different in focus and respond to different issues, but one consistent theme

emerges from them: innovator pharmaceutical companies will have to expend more resources than ever waging battles on multiple fronts to recoup their investments in bringing new drugs to market and generic companies will have more opportunities for early access to the market.

The International Front: The Doha Offensive and the Rebuilding of Iraq

Long before it staged Iraqi-war updates, Doha, Qatar was the staging area for one of the most ambitious health care reform agendas ever undertaken by the international community. In November 2001, the World Trade Organization met in Doha and adopted the Ministerial Declaration on TRIPS and the Public Health ("the Declaration"). WT/MIN(01)/DEC/2

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Drafting the Technology Game-Plan Part 1: Patent Searches

Patent searches come in more forms and scopes than many realize. By utilizing appropriate searches as part of its overall intellectual property game plan at various stages, including idea and product development, patent procurement, and litigation, an intellectual property owner can gain an advantage over its competitors.

Training Camp: Rules of the Patent Game

To fully appreciate the various types of searches and their uses, we should first understand the concept of a patent and the rights it affords its owner. Although this may seem to be overly simplistic, many businesspeople dealing with intellectual property issues are unfamiliar with the process of obtaining patent rights or with the scope of the rights they receive with the patent. Thus, a review of fundamental patent principles is in order.

An inventor applies for a patent by filing a patent application. Each patent application has a description of the invention, which is likely to include one or more figures along with text describing how to practice the invention, alternative embodiments of the invention, and the context in which the invention is used. Also accompanying the application is a set of claims, which are numbered sentences setting the boundaries of the proposed protection. The U.S. Patent and Trademark Office, upon receiving such an application, will undertake an examination of the application, which consists of a check for formalities (appropriate signatures and fees) and a substantive technical review. The Patent Examiner assigned to the application typically conducts one or more searches of technical literature, which may include, for example, patents, published patent applications, and technical articles. The Patent Examiner either allows or, more often, rejects the claims of the application, based upon the search results. In response to rejected claims,

the Applicant may make arguments and/or claim amendments, and the process will continue until the claims are allowed or the Applicant abandons the application.

An issued patent grants its owner the right to exclude others from making, using, selling, offering for sale, or importing the invention defined by the issued claims. This right to exclude is different from a right to practice the invention. Thus, a patent owner should not necessarily expect to begin (or continue) to make, use, sell, offer for sale, or import his or her patented invention without threat of a patent lawsuit. If, by practicing the patented invention, the patent owner would be doing something covered by another's patent, he or she is at risk of being subject to license discussions or even litigation. This will often be the case with "improvement" patents, in which minor patentable advances are made to previously patented technology.

Without knowledge of relevant patents and/or prior art, the inventor and/or businessperson is at a disadvantage when it comes to playing the patents game. During the application process, unknown prior art that might otherwise have been anticipated and planned for, can extend the application process and make it more expensive. After a product has been manufactured and/or sold, unknown and unaccounted for patents can be disastrous if the product is found to infringe and the infringers are enjoined from making, using, selling, offering for sale, and importing the product, and/or are liable for money damages.

The Playbook

To avoid being blindsided at game time, a little pre-game prep is in order. In addition to making sure you have the right team (e.g., informed inventors, patent counsel, etc.), it often pays to initiate an appropriate patent search. Depending on what part of the game (i.e., inventing,

applying for patents, manufacturing, enforcing patents, or defending patents) is approaching, a patent search may save money down the road and could be the difference between victory and defeat.

Pre-Game Prep: Technology Survey, Patentability Search

An ideal time to get a feel for the playing field is before a patent application is written and/or filed. Two types of searches — a technology survey and a patentability search — can be helpful at this stage.

Technology Survey

A technology survey may be helpful where an inventor or business is considering entering a new technical area or market segment. Once they identify a problem or need, they can develop solutions to address the problem or need. The technology survey moves development of the solution forward by showing the approaches of others. Discovery of others' solutions may, in turn, help to kindle new ideas, possibly resulting in one or more feasible inventive ideas. Because of the self-learning that accompanies such a search, the end-users of the technology survey are often the best ones to do the actual searching.

Resources for a technology survey will obviously vary from one industry to the next, but the Internet is generally a good starting place. If necessary, a few broad query searches will help to provide relevant terminology in the pertinent field. The searcher can then use that terminology to perform more focused searches on industry-specific databases, such as those maintained for IEEE, ACM, ACS, or ASME. The U.S. Patent and Trademark Office website (<http://www.uspto.gov>) is another place to learn about a technology area, because most patents describe needs and their accompanying solutions. Yet another effective way to get a feel for the state of the art is to determine the key players in an industry and browse

their Web sites. Many sites offer technical primers, such as white pages. Due to the amount of information companies are now making available, the scope of a technology survey is typically limited only to the time and patience of the person doing the searching and reviewing.

Patentability Search

The patentability search, sometimes simply called a "patent search," is often used to evaluate inventions, to assess risks in pursuing patent protection on those inventions, and to formulate strategies for drafting patent applications to avoid problems with prior art and to ensure the broadest possible coverage. The theory is that a little time and money spent up front can make a worthwhile difference later.

In a patentability search, the main goal is to determine whether an invention is already known or obvious. The scope of such a search can vary from doing a simple search of patent titles to a full-blown search of U.S. and foreign patents and published patent applications, articles, conference proceedings, and other secondary sources. Deciding the extent of a patentability search is not unlike determining how much insurance to obtain: more extensive searching is likely to prevent problems in the future, but it comes at a price. The business and the searcher should work together to determine an appropriate balance between scope and cost.

A patentability search that approximates the search done by a typical patent examiner is likely to include some key word searches in patent databases, perhaps with a review of patents falling within the same patent classification as the invention. Such a patentability search would provide some assurances about what an examiner is likely to find. A search simulating what an accused infringer would do in litigation to try to prove a patent invalid is at the other end of the

spectrum. Due to the large damage amounts typically at issue in patent suits, an accused infringer is often more willing to leave no stone unturned in attempting to locate invalidating prior art. The cost of a search should be balanced with the cost of actually preparing the application and the potential value of any issued patent. Sometimes it makes financial sense to go with a more limited search and assume some risk that an unknown, troublesome article or patent might appear later during examination or in litigation.

Offense: Investigative Search, Assignee Search

Upon issuance of a U.S. patent, the patent holder can begin implementing an offensive strategy, which the patent holder may have formulated long before filing of the application. While in some cases the best offensive strategy is to passively hold the new patent in a portfolio of patents, to be used upon receiving a charge of infringement by another company or upon determining that a competitor is gaining ground by using the patented invention, in other situations, a more proactive approach is appropriate. A number of patent searches are also useful tools in a proactive intellectual property enforcement game plan.

Investigative Search

An investigative search can start in several ways: through intelligence gathered by company employees, by a Web search, or by reviewing product catalogs or trade journals, for example. The goal, of course, is to identify entities that are practicing the patented invention, as defined by the claims. While companies often tout their products' features in ways that make identification of infringing products easy, in many cases, it can be difficult to determine infringement without reverse-engineering. Because patents held by a company often correspond to technologies in which the company does

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Without knowledge of relevant patents and/or prior art, the inventor and/or businessperson is at a disadvantage when it comes to playing the patents game.

Drafting the Technology Game-Plan Part 2: Opinions of Counsel

In an age of increasingly large damages verdicts, willful infringement and the potential for enhanced damages are sources of great concern for businesses. While there is no magic formula for obtaining an opinion of counsel that will avoid a willfulness finding, a large body of case law has developed that provides general guidance regarding what a business should expect when seeking an opinion.

In a patent infringement suit, 35 U.S.C. § 284 allows a court discretion to enhance damages up to three times the amount found or assessed by a jury. Courts look to the totality of the circumstances when exercising their discretion to enhance damages and factor heavily an accused infringer's willful infringement of the adverse patent.

A party with knowledge of an adverse patent has an affirmative duty of due care to avoid infringement, and must comply with this duty despite the oftentimes fast-paced schedule for development and commercialization of a product. See *Critikon, Inc. v. Becton Dickinson Vascular Access*, 120 F.3d 1253, 1259-60 (Fed. Cir. 1997). Failure to investigate infringement and form a good faith belief of noninfringement, invalidity, and/or unenforceability of the adverse patent can lead to a finding of willful infringement. At trial, an accused infringer can rebut an allegation of willful infringement through several types of evidence, including evidence that it relied on a competent opinion of counsel.

Willfulness is a question of fact. In litigation, an opinion of counsel used to rebut an allegation of willful infringement must satisfy two criteria: (1) the opinion must be competent, and (2) the accused infringer must have reasonably relied on the opinion. See, e.g., *Comark Communications v. Harris Corp.*, 156 F.3d 1182, 1191 (Fed. Cir. 1998); *Stryker Corp. v. Davol Inc.*, 234 F.3d 1252, 1259 (Fed. Cir. 2000).

Competency largely rests on the quality of the opinion and the effect that the opinion had on the actions of an accused infringer. *Amsted Indus. v. Buckeye Steel Castings Co.*, 24 F.3d 178, 181 (Fed. Cir. 1994). Juries and courts consider many factors in assessing the competency of opinions of counsel. As an initial matter, courts have based findings of non-willfulness on oral opinions as well as written opinions. See, e.g., *Radio Steel & Mfg. Co. v. MTD Prods., Inc.*, 788 F.2d 1554, 1559 (Fed. Cir. 1986). While an oral opinion can, in an appropriate case, satisfy the duty of care, it is more difficult to prove the competency of and reliance on oral opinions at trial. Opinions of non-infringement, invalidity, or unenforceability, therefore, are most often written. *Minnesota Mining & Mfg. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1580 (Fed. Cir. 1992).

A competent opinion should be thorough and objective. *SRI Int'l v. Advanced Tech. Lab.*, 127 F.3d 1462, 1464 (Fed. Cir. 1997); *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 829 n.9 (Fed. Cir. 1992). An opinion should not be conclusory or give the perception that it was created as a shield to be used exclusively for litigation. *Jurgens v. McKasy*, 927 F.2d 1552, 1562 (Fed. Cir. 1991). A competent opinion should include both legal and factual analyses that are tailored to the particular issues addressed by the opinion, and the legal conclusions of the opinion should be explained in light of the relevant law. *SRI Int'l*, 127 F.3d at 1467. But an opinion need not be written in certainties (e.g., "unequivocally no infringement"), rather it can reflect probabilities (e.g., "more likely than not"). *Read*, 970 F.2d at 829 n.9. Moreover, even if the conclusions reached in an opinion later prove incorrect at trial, an accused infringer's reliance on that opinion can still be evidence of good faith. *Graco, Inc. v. Binks Mfg.*, 60 F.3d 785, 793-94 (Fed. Cir. 1995).

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Properly done, a competent opinion of counsel is an accused infringer's best protection against a willfulness determination. An opinion that saves a party from treble damages liability is worth much more than its actual cost.

A competent opinion should be premised on the best information known to the accused infringer. A party seeking an opinion should, for example, provide the latest information on the accused or potentially infringing product(s), the latest design drawings, and access to employees who possess material information. *Comark*, 156 F.3d at 1191. If not, the opinion might be inaccurate, and the failure to provide the best information might compromise the perception that an accused infringer acted in good faith. *Id.*; *Goodwill Constr. Co. v. Beers Constr. Co.*, 991 F.2d 751, 758 (Fed. Cir. 1993). In addition, if the accused product is modified, then an updated opinion is helpful to establish continued good faith. *Comark*, 156 F.3d at 1192.

While there is no specific form an opinion must take to be found competent, a noninfringement opinion ideally includes an analysis of the scope of each relevant claim of the patent at issue, a claim construction analysis (including an analysis of any means-plus-function claims), and, generally, a review of the prosecution history. See *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1364 (Fed. Cir. 1998); *Critikon*, 120 F.3d at 1259-60; *Stryker*, 96 F.3d at 1414. Further, the opinion should include an analysis of at least literal infringement and, if necessary, infringement under the doctrine of equivalents. *Jurgens v. CBK, Ltd.*, 80 F.3d 1566, 1572-73 (Fed. Cir. 1996). It might also be helpful for an opinion to discuss the prior art considered by the examiner during prosecution of the adverse patent. *Id.*; *Westvaco Corp. v. Int'l Paper Co.*, 991 F.2d 735, 744 (Fed. Cir. 1993).

A competent invalidity opinion might demonstrate an accused infringer's good faith belief that prior art anticipates or obviates an adverse patent. See, e.g., *SRI Int'l*, 127 F.3d at 1464. A competent invalidity opinion might also undertake a full claim construction analysis and a

limitation-by-limitation comparison of prior art disclosures with the patent claims at issue. See *Johns Hopkins*, 152 F.3d at 1364. If relevant, and if sufficient facts are available, an invalidity opinion might set forth the standard of one of ordinary skill in the art. *In re Hayes Microcomputer Prods. Patent Litig.*, 982 F.2d 1527, 1543 (Fed. Cir. 1992). And when analyzing obviousness, an analysis of the "objective indicia" or "secondary considerations" of obviousness also might be helpful, if the drafting attorney has sufficient facts to perform the analysis. See *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1571 (Fed. Cir. 1996); *In re Hayes*, 982 F.2d at 1543.

A competent unenforceability opinion might demonstrate an accused infringer's good faith belief that an adverse patent is unenforceable due to, for example, inequitable conduct. See, e.g., *SRI Int'l*, 127 F.3d at 1466. In such a case, the opinion should include a full inequitable conduct analysis, including a discussion of the materiality of the alleged withheld references and the nature of the alleged misrepresentations. See *id.* at 1466.

A competent noninfringement, invalidity, or unenforceability opinion does not provide carte blanche, however. A party's actions preceding the opinion, such as deliberate copying of a patented product, might adversely affect a jury's determination of willfulness, notwithstanding the existence of a competent opinion. See, e.g., *Bott v. Four Star Corp.*, 807 F.2d 1567, 1572 (Fed. Cir. 1986). In contrast, a good faith effort to design-around patent claims supports a lack of willfulness. See, e.g., *Spindelfabrik Suessen-Schurr Stahlecker v. Schubert*, 829 F.2d 1075, 1084 (Fed. Cir. 1987). Further, a party that "fully" involves patent counsel "during all stages of the design process" can more easily establish due care and good faith in avoiding infringement. *Braun, Inc. v. Dynamics Corp. of Am.*, 975 F.2d 815, 823 (Fed. Cir. 1992).

Circumstances surrounding the opinion might also influence a jury's determination of willfulness. For example, a jury might consider the amount of communication between the author of the opinion and the accused infringer and how much time and money were spent on the opinion. See *SRI Int'l*, 127 F.3d at 1467. Further, a jury might consider whether an accused infringer also investigated related patents and applications, such as continuations or divisionals. See *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 944 (Fed. Cir. 1992). Perhaps most importantly, an opinion and the circumstances of its authorship should exude an air of genuineness and should not seem contrived or merely self-serving. See, e.g., *id.*; *Johns Hopkins*, 152 F.3d at 1364. However thorough and competent an opinion may be, a jury might still discount an accused infringer's assertion of good faith reliance on an opinion of counsel. See, e.g., *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1379 (Fed. Cir. 2001).

Properly done, a competent opinion of counsel is an accused infringer's best protection against a willfulness determination. While a thorough, competent opinion may involve significant expense, an opinion that saves a party from treble damages liability is worth much more than its actual cost.

Eric R. Moran's practice focuses on representing and counseling clients in the mechanical, electrical-mechanical, telecommunications, and software arts. Eric's practice includes preparing and prosecuting patent and trademark applications, preparing opinions of counsel, procuring and providing licensing rights, and litigating patent and trademark issues in federal courts.

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Festo: The Federal Circuit Hears Oral Argument

In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 122 S. Ct. 1831 (2002), the Supreme Court reversed the Federal Circuit's attempt to provide a predictable standard for determining if prosecution history estoppel precludes a finding of infringement under the doctrine of equivalents. On remand, the Federal Circuit solicited the views of the parties in order to better determine how it should proceed in light of the Supreme Court's reversal. Regardless of whatever view the Federal Circuit now adopts, the doctrine of equivalents remains as unpredictable and intractable an issue as ever.

Festo's Long And Winding Road

Festo, the holder of two patents relating to magnetically coupled rodless cylinders, prevailed in an infringement suit against Shoketsu Kinzoku Kogyo Kabushiki ("SMC"). SMC appealed, but the Federal Circuit affirmed. The Supreme Court vacated and remanded for further consideration in light of its *Warner-Jenkinson* decision relating to the doctrine of equivalents. On remand of *Festo* from the Supreme Court, the Federal Circuit initially affirmed in part, vacated in part, and remanded. On rehearing *en banc*, the Federal Circuit held that (1) any reason for amendment to a patent claim that is related to patentability gives rise to prosecution history estoppel; (2) voluntary amendments are treated the same as other amendments for purposes of prosecution history estoppel; (3) when an amendment creates prosecution history estoppel, there is no range of equivalents available for the amended element on which to base an allegation of infringement under the doctrine of equivalents; (4) unexplained amendments are not entitled to any range of equivalents; and (5) prosecution history estoppel barred any finding that the magnetizable cylindrical

sleeve and sealing ring elements of the patents at issue were infringed under the doctrine of equivalents. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558 (2000).

On its second grant of writ of certiorari, the Supreme Court reversed the Federal Circuit's holding that where a claim element was narrowed during prosecution for a reason affecting patentability, prosecution history estoppel completely barred application of the doctrine of equivalents as to the amended element. The Supreme Court noted that there are some cases where an amendment cannot reasonably be viewed as surrendering a particular equivalent, including situations where (1) the equivalent was unforeseeable at the time of the amendment; (2) the rationale underlying the amendment bears no more than a tangential relation to the equivalent in question; or (3) some other reason suggests that the patentee could not reasonably be expected to have described the insubstantial substitute in question. Rejecting the Federal Circuit's complete bar rule, the Supreme Court held instead that a narrowing amendment raises a rebuttable presumption that the complete bar applies, but that a patentee can overcome such a presumption by showing 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. The Supreme Court remanded the case to the Federal Circuit for further proceedings, but did not specify the manner of determining whether and what subject matter was surrendered during prosecution.

In order to decide what further action to take, the Federal Circuit ordered the parties to submit briefs addressing several issues, including: (1) whether rebuttal of

the presumption of surrender, including issues of foreseeability, tangentialness, or reasonable expectations of those in the art, is a question of law or one of fact—and what role a jury should play in determining whether a patentee can rebut the presumption; and (2) what factors are encompassed by the criteria set forth by the Supreme Court. On February 6, 2003, the Federal Circuit heard the parties' oral arguments on these issues.

SMC: Rebuttal Of Presumption Of Surrender Is A Strict Question Of Law

SMC argued that determining whether the presumption of surrender has been rebutted is a strict question of law, and hence that there is no role for the jury to play. In SMC's view, deciding the question requires considering only the prosecution history and the excuse(s) offered by the patentee as to why s/he could not have drafted a claim that covered the asserted equivalent.

Several judges were openly skeptical of SMC's view that there are no factual issues that arise in deciding whether a patentee has rebutted the *Festo* presumption, variously noting that:

(1) determining the issue as a matter of law would "keep digging [the] hole" started by the *Markman* "charade" of declaring that facts are law and then pretending to review them *de novo*;

(2) determining the issue as a matter of law would seem [incongruously] to mean that there would be no point in having the district court developing facts on the issue;

(3) a patentee's proffered excuse could implicate what was known in the art at the time, and therefore involve a *Graham v. John Deere*-type analysis of the scope and content of prior art, which is a question of fact;

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It seems clear, however, that regardless of the view announced by the federal circuit, the doctrine of equivalents remains as unwieldy and unpredictable as ever.

(4) to attempt rebutting the presumption by showing that after-arising technology would not be foreseeable would require knowing the state of the art to one of ordinary skill at the time of claim drafting, which again is a question of fact under *Graham v. John Deere*; and

(5) the Supreme Court has already instructed that if an alleged insubstantial substitute did not exist either at the time the claim was filed or was amended, then the substitute couldn't have been foreseeable, and whether or not something existed at the relevant time is a question of fact.

With respect to foreseeability, SMC argued that if the patentee originally claimed subject matter encompassing the accused equivalent, but then narrowed the claim in response to a rejection, then he cannot argue that the surrendered territory was an unforeseeable equivalent at the time of the amendment. Here, again, at least one panelist voiced doubt, noting that to adopt this view would burden a claim drafter with the extremely difficult task of trying to be sure not to give up linguistically (such as by adding a modifier to a claim term to overcome an indefiniteness rejection) something that does not yet exist at the time of the amendment.

Festo: Rebuttal Of Presumption Is A Question Of Law Based On Underlying Facts

Festo argued that issues of foreseeability, tangentialness, and any other question that may be appropriate to determining whether a surrender of subject matter occurred in a particular case, are questions of fact that should be decided by the jury, except where a district court can make a determination without sending it to a jury.

Festo's views also met strong criticism. One *en banc* panelist noted that to adopt Festo's view would mean that interpretation of the prosecution history would be a question of fact for the jury, which contradicts a long history of

precedent and established law assigning prosecution history estoppel to the province of the court. Certain panelists also noted that adding a *Festo* factual hearing on prosecution history estoppel on top of the already-existing *Markman* "trial-within-trial" hearing on claim construction would be to introduce a further undesirable complexity in patent litigation.

A Likely Outcome

During SMC's argument, one *en banc* panelist suggested that, rather than the *Markman* hearing model, or for that matter the *Graham v. John Deere* model, the model most analogous to the equities underlying prosecution history estoppel would be an inequitable conduct analysis, in which the ultimate question of fraud is a question of law based on underlying factual determinations. Other panelists endorsed and appeared willing to embrace this view. It seems likely that the Federal Circuit's eventual decision will follow the general contours of this view. In future appeals involving rebuttal of the presumption of surrender, the tug-of-war between parties will then be whether the alleged error is most properly characterized as one of law, entitled to little deference, or one of fact, entitled to much greater deference. It seems clear, however, that regardless of the view announced by the Federal Circuit, the doctrine of equivalents remains as unwieldy and unpredictable as ever.

Jeremy E. Noe's practice comprises preparing and prosecuting patent applications before the U.S. Patent and Trademark Office, preparing opinions concerning the validity and infringement of patents, procuring or providing licensing rights, and litigating in federal courts in the areas of chemistry, biochemistry, and biotechnology. Before joining MBHB, Jeremy spent nearly 15 years in a research environment developing and commercializing new consumer products. Jeremy is the inventor of several currently marketed consumer products.

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“Reach Through” the *Searle* Decision... by Michael S. Greenfield, Ph.D.

In a decision involving the validity of so-called “reach-through” claims, the District Court for the Western District of New York rendered a summary judgment of invalidity of University of Rochester’s U.S. Patent No. 6,048,850 (“the ‘850 patent”), directed to methods of treatment employing COX-2 inhibitors. *Univ. of Rochester v. G.D. Searle & Co.*, 249 F. Supp. 2d 216 (W.D.N.Y. 2003) (“*Searle*”). These pain-relieving compounds had more than \$5 billion in sales last year in the United States alone.

Reach-through claims seek to patent downstream research products (e.g., drug compounds) discovered or developed using a biological research tool before the particular product has been identified. Thus, the discoverer of a gene encoding a biologically important enzyme may seek to claim not only the gene and enzyme but also yet-to-be-discovered small molecule inhibitors of the enzyme and methods of treatment employing the small molecule inhibitors.

This was the exact situation underlying *Searle*. The inventors of the ‘850 patent had discovered the gene encoding the mammalian prostaglandin H synthase-2 (PGHS-2) and its expression product. PGHS-2 was discovered to be responsible for increased prostaglandin synthesis associated with inflammation. The claims of the ‘850 patent were directed to methods of inhibiting PGHS-2. Claim 1 is representative:

1. A method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a human host in need of such treatment.

This is a classic reach-through claim in that it encompasses methods of treatment employing any PGHS-2 inhibitor. The ‘850 patent taught methods of assaying for PGHS-2 inhibitors and disclosed tests of a few compounds, all well known (e.g., aspirin, ibuprofen, and naproxen). However, the ‘850 patent did not identify any other particular inhibitors in structural terms or in any manner that would permit one of ordinary skill in the art to envision the inhibitor without first testing it for inhibitory activity.

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“Scientific discoveries, and theories based on those discoveries, frequently lay the groundwork for later inventions, but that does not make the discoverer the inventor as well.”

Relying primarily on the written description triumvirate of *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir.1993), *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998), and *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316 (Fed. Cir. 2002), the *Searle* court held:

The patent does no more than describe the desired function of the compound called for, and it contains no information by which a person of ordinary skill in the art would understand that the inventors possessed the claimed invention. At best, it simply indicates that one should run tests on a wide spectrum

of compounds in the hope that at least one of them will work.

The court further noted that nowhere did the ‘850 patent specify which compounds were selective inhibitors of PGHS-2; only a method of finding the compounds was disclosed. The court poignantly noted:

I recognize that the inventors and the research teams of which they were a part did apparently make some significant discoveries in this field. They realized, in light of the discovery of PGHS-2, that it would be quite beneficial if one could find a compound that would specifically target the activity of PGHS-2, but not that of PGHS-1.

What the inventors did not do, however, is succeed in taking the last, critical step of actually isolating such a compound, or at least of developing a process through which one skilled in the art would be directly led to such a compound. Absent that step, their discoveries, valuable though they might have been, did not blossom into a full-fledged, complete invention. Scientific discoveries, and theories based on those discoveries, frequently lay the groundwork for later inventions, but that does not make the discoverer the inventor as well.

The court rejected the patentee’s assertion that *Fiers*, *Eli Lilly*, and *Enzo* were limited to DNA or nucleic acids. Based on the foregoing, the court held the claims of the ‘850 patent were invalid for failing to satisfy the written description requirement.

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...And Show Me The Chemistry by Stephen H. Docter

Having had the privilege of toiling in the *Searle* labs on the COX-2 inhibitor program in the early 1990s, and seeing the hard work come to fruition, I felt great satisfaction as a result of the *Searle* decision. In *Searle*, the district court granted summary judgment of invalidity of a patent which attempted to claim a method of selectively inhibiting COX-2 activity by administering a non-steroidal compound, or, in other words, nearly every molecule under the sun.

The *Searle* decision is a reminder of, and is consistent with, the long-standing line of precedent arising from the “cancer treatment cases,” *In re Buting*, 418 F.2d 540, 163 U.S.P.Q. 689 (C.C.P.A. 1969), *In re Jolles*, 628 F.2d 1322, 206 U.S.P.Q. 885 (C.C.P.A. 1980) and *In re Brana*, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995). The cancer treatment cases support the principle that to claim methods for treating a certain indication using a broad genus of compounds, some specific chemical structural characteristic must be provided within the specification to satisfy the enablement requirement of 35 U.S.C. § 112. In the patents-at-issue in *Buting*, *Jolles*, and *Brana*, the patentees described the structural genus of the claimed compounds and disclosed only a few limited examples. The patent-at-issue in *Buting* asserted activity of the structurally-specified genus of compounds against many different types of cancers; the patent-at-issue in *Jolles* asserted activity of the structurally-specified genus against only acute myeloblastic leukemia; and the patent-at-issue in *Brana* claimed a novel, structurally-specified genus of compounds based on comparative data with known and related anti-tumor agents. Ultimately, the claims of the applications in *Jolles* and *Brana* were found to be enabling and those of the application in *Buting* were not. The different result in

Buting can be explained at least in part by the differing scope of the claimed method, namely, the applicant in *Buting* attempted to claim a method for treating several different types of cancers. In addition, the later *Jolles* and *Brana* cases reflected the advancement of cancer treatment over time and illustrated the dynamics of the enablement requirement—i.e., the more that is known, the less need be disclosed.

snippets

The bottom line is that claims drawn to a method of using a compound must define the compound in such a way that would allow one skilled in the art to identify the compound, and a chemical structure seems to presently be the most logical way to proceed.

The ‘850 patent at issue in *Searle* taught methods of selectively inhibiting COX-2 activity in a human host and what to do with any “identified compounds” once they had themselves been identified as selective COX-2 inhibitors. In addition, the ‘850 patent disclosed the testing of a few known, non-steroidal compounds, such as aspirin, ibuprofen, and naproxen. Based on this limited disclosure, the patentee attempted to claim a method employing every non-steroidal compound possible, whether then known or not, that had selective COX-2 inhibitory activity. The claims were exactly the opposite of the type found valid in the cancer treatment cases, and the court properly found them invalid

for violating the enablement requirement of section 112. The *Searle* court also held that the specification of the ‘850 patent failed to comply with the written description requirement, noting that the claimed method could not be practiced until one had discovered a compound that was not in the possession of the inventors themselves, similar to the ancient “philosopher’s stone.”

Unfortunately, the ‘850 patent does not stand alone. Many patents now in force and many more pending applications contain similar, non-enabled claims. The lesson to be learned from *Searle* and the cancer treatment cases is that a claimed method of treatment must contain some guidance as to what entity is accomplishing the treatment. In other words, an applicant must disclose some boundary for chemical structure, be it a small organic molecule, a small inorganic molecule, a polypeptide molecule, or otherwise. Simply defining a compound by a function or a desired result of administering the compound, e.g., inhibition of COX-2 activity, is unacceptable and would defeat the very purpose of patent law.

It is said that a picture is worth a thousand words. As imperfect as language is, the simplest solution to the problem is to include a generic chemical structure within the specification, and, preferably, within the body of the method claim itself. The claim is then just a few working examples (which disclose the claimed method employing one or more species falling within such genus) away from enabling. Simple? Yes. Painfully limiting? No, just fair.

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“Reach Through” the Searle Decision... continued from p. 8

The court relied on similar reasoning in dealing with the enablement issue, holding that whereas the ‘850 patent disclosed an assay for identifying a compound as a PGHS-2 inhibitor, the ‘850 patent merely identified broad categories of compounds that might work. The court held that without more, this merely amounted to providing a starting point for further re-

search, enabling a person of ordinary skill in the art to attempt to discover how to practice the claimed invention. That, the court concluded, was not enough.

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Substituents may need to be defined; and perhaps more importantly, the skillful balance of “obtaining the broadest claim coverage vs. obtaining a valid claim” will then rest with how broad the genus can be and how many species need be taught before the claim is enabling.

The chemical arts are often characterized as “unpredictable,” and a higher level of disclosure may be necessary for chemical inventions than with other arts; but, what level of disclosure will suffice? On the one hand, not every detail need be described, yet on the other hand, the invention claimed must be fully capable of being reduced to practice. Enter the “undue experimentation” analysis and the *Wands* factors. See *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988) (outlining eight factors of undue experimentation).

Applying the eight *Wands* factors to patent applications having claims drawn to a method of using a compound, and assuming an applicant provides at least one working example, a claim drafting strategy should consist of a series of method claims with different levels of protection. In other words, an initial claim directed to a method of using a large genus of compounds should be followed by a series of claims directed to a method of

using a smaller subgenus of compounds. The claim scope of these latter claims will depend on the compounds in question and the examples disclosed, and should eventually lead to claims with single species. This will guarantee enablement of at least some, if not all, of the claims. As an added bonus, this claiming strategy also helps address *Festo* issues that may arise along the way.

The *Searle* decision is good for patent law and, like the cancer treatment cases before it, tells a good story in the area of chemical-pharma patent law. The bottom line is that claims drawn to a method of using a compound must define the compound in such a way that would allow one skilled in the art to identify the compound, and a chemical structure presently seems to be the most logical way to proceed. So, when drafting an application, we should dust off those chemistry books, bring on the chicken wire drawings, and draft some valid claims. In so doing, we rid ourselves of patents that impermissibly claim subject matter not yet in the possession of the inventors. The chemical arts are unique in patent law in that drawings truly can replace words. Why not take advantage of this? Show me the chemistry, and let’s not worry about enablement any more.

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Drafting the Technology Game-Plan Part 1: Patent Searches continued from p. 3

business, a search of patents in relevant areas of technologies will often provide clues about potential targets and their products. A target company’s detailed description of its product in a patent might provide details to justify a patent suit.

Assignee Search

Before pulling the trigger on a patent infringement suit, a patent holder should review the patent portfolio of the alleged infringer to avoid potential retaliatory suits. Searching patents and patent applications by assignee name will often yield a fairly complete list. Complications may arise where the target company has made or has been the subject of one or more acquisitions, or when early patents were not originally assigned to the company, but were instead listed in the inventors’ names. In such a case, additional research may help to determine names of related companies, company founders, etc.

Defense: Product Clearance Search, Invalidity Search

Many businesses end up on the other side of patent suits as accused infringers. This position often can be avoided by conducting a product clearance search, or improved by conducting an invalidity search.

Product Clearance Search

A product clearance search, often called a right-to-manufacture/use or a freedom to operate search, begins with a proposal to start making, using, selling, offering for sale, or importing a product or using a certain method. By searching for patents that might be implicated by conducting such business, these patents potentially can be avoided by designing around them or by deciding to not proceed with the proposal. While the search itself should focus on issued patents (and possibly patent applications) in the jurisdictions in which activity is likely to occur, analysis of the patents to determine applicability should focus on the claims of the

identified patents. A product clearance search is often followed by an opinion that analyzes the pertinent patents and non-infringement and/or invalidity issues related to the patents.

Invalidity Search

Because invalidity is a defense to patent infringement, an accused infringer should consider conducting one or more searches to identify potentially invalidating prior art references. This type of search will closely approximate a thorough patentability search. Names of inventors, authors, and companies associated with identified references should also be investigated, because they may be the source of other potentially invalidating evidence, such as deposition testimony or product technical documents that might be subpoenaed.

Duty of Disclosure

The rules underlying patent law require every person associated with the filing and prosecution of a patent application to disclose to the patent office “all information known to that individual to be material to patentability.” Although the rules do not require that an applicant perform a search to obtain a patent, any search results actually obtained before a patent issues must be disclosed, to the extent they are material and are not cumulative of other items already before the patent examiner. Thus, the duty of disclosure is yet another factor to consider in the cost-benefit analysis for a given search.

Conclusion

Appropriate searches can help in pre-game preparation (technology surveys and patentability searches), and on both offense (investigative searches, assignee searches) and defense (product clearance searches, invalidity searches). To help ensure victory, a solid intellectual property management game plan should include one or more of these patent searches.

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From Doha to Baghdad via DC: U.S. Pharmaceutical Policy in a Troubled World continued from p. 1

(Nov. 20, 2001). Paragraph 6 of the Declaration ostensibly provides those least developed countries (“LDCs”) having “insufficient or no manufacturing capacities in the pharmaceutical sector” with a mechanism to ensure an adequate and affordable supply of medication for “public health problems.” Under the Declaration as written, “public health problems” include diseases such as HIV/AIDS, tuberculosis and malaria – diseases that have decimated the populations of the LDCs, particularly on the African continent.

The Doha Declaration was sufficiently vague, however, as to immediately trigger a number of objections. Left unresolved were serious questions regarding a definition for the scope of diseases covered by the Declaration; the types of countries, if any, that would be allowed to manufacture and export patented medications to an affected LDC; the types of treatments covered by the Declaration, and the appropriate remuneration to the patentee for any compulsory licenses granted under the guise of a Paragraph 6 program. To no one’s surprise, the developed world and the developing world staked out markedly different positions on these questions.

One source of concern was the potentially unlimited scope of the Declaration. Although the U.S. government initially called for a detailed list of diseases that would qualify for purposes of Paragraph 6, it had dropped that demand as of June 22, 2003, and no compromise position has yet been reached. “US Drops Demand For List Of Diseases Covered By Drug Pact,” Dow Jones Newswires (June 22, 2003). Because the Declaration currently contains no useful definition for a “disease affecting public health,” the emergence of SARS presents an interesting case study. Rapidly classified as an epidemic by the

World Health Organization, through June 25, 2003, SARS cases have primarily occurred in a developed nation (Canada) and a developing nation (China/Hong Kong). The question remains as to what would happen if a SARS outbreak occurred in a lesser developed nation. How many cases of a particular disease are needed to activate the implementation provisions for the Declaration? Even with China’s recently revised numbers, the total percentage of the population affected is a small fraction of 1 percent. Similarly, how does fatality rate affect the determination? Again, the total number of SARS-related deaths as a percentage of total number of cases was less than 10% as of June 25. If SARS qualifies under the Declaration, what would prevent the LDCs from designating other diseases that have higher incidence but are more responsive to treatment as eligible diseases affecting the public health? Where should the line be drawn?

The Declaration also failed to define a mechanism for implementing Paragraph 6. Developing countries envisaged a mechanism of parallel compulsory licensing, whereby countries other than an LDC needing a drug could manufacture and export a patented medication under a compulsory license, and the LDC itself would have a compulsory license for its distribution and use of the drug. The developed world naturally balked at this suggestion, viewing it as inconsistent with obligations under Article 31(f) of the TRIPS agreement, which provides for compulsory licensing “predominantly for the supply of the domestic market” rather than a foreign market. Instead, the United States, followed by Switzerland, proposed a moratorium on invoking WTO dispute settlement mechanisms in such situations.

Innovator pharmaceutical companies are in a particularly unenviable position in this debate. Notwithstanding the substantial philanthropic efforts of these companies to address “diseases that affect the public health,” by arguing for more details and more stringent controls on implementation of the Doha Declaration, the pharmas are seen as valuing profit and stock price over human life. This stigma (along with the developing countries’ failure to recognize existing philanthropic efforts) was clearly seen in comments made by the Egyptian delegate at Doha, who argued:

What needs now to be emphasized, however, is the need to persuade R & D, most of which is conducted ... in the laboratories of the [multi-national corporations], to pay greater attention to the health problems of the poor in the developing world. Such contributions will pay great dividends in the long run and will certainly help in dismantling the wall of fear and suspicion that is sometimes visible.

At least on this front, however, the U.S. government is still making efforts to provide innovator companies with substantial protection for their intellectual property rights.

Months after the Declaration was to have been fully implemented, no consensus has been reached on implementing the Declaration, and none is readily foreseeable. The only decision officially reached has been to allow LDC’s until 2016 to implement patent protection for pharmaceuticals. Innovator companies, however, should be prepared to respond to a wide range of compulsory licensing programs implemented under the auspices of the Doha Declaration.

The Domestic Front: The Bush Administration and Rep. Schumer Lay Siege to Hatch-Waxman

On the domestic front, attention has been focused on ease of access for generics under the Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman”). In a surprising bipartisan effort to speed generics to market, both the Bush administration and the Democrats have proposed amendments to Hatch-Waxman and the FDA rules implementing Hatch-Waxman. Each proposal ostensibly attempted to address problems associated with the abuse of Orange Book patent listing procedures and the 30-month stay on FDA approval of a generic drug application following the filing of an infringement suit by an innovator company.

The Bush Feint: The Republican Attack on Hatch-Waxman

The FDA outlined its plan for addressing problems allegedly associated with Hatch-Waxman, in particular multiple 30-month stays, in a proposed rule published on October 24, 2002. 67 Fed. Reg. 65,448 (Oct. 24, 2002) (to be codified at 21 C.F.R. pt. 314).

The proposed FDA rules affected the types of patents that could be listed in the Orange Book and current listing procedures, and eliminated the possibility of a patentee obtaining multiple 30-month stays. Under the proposed rules, a generic applicant would have no duty to notify the patent holder of an amendment to its new drug application to include certifications against later-issued patents. With respect to patent listings in the Orange Book, the rule specified that patents claiming processes, packaging, metabolites and/or intermediates could not be listed, but that product-by-process patents could be listed. The proposed

rule also included a certification that the patentee must submit with its patent listings, in which the patentee would verify that the patents were properly listed.

The response to the proposed rule was significant. During the two-month comment period, more than 30 corporations, associations and individuals submitted comments. Although the comments were quite varied, one consistent response was that the proposed rules as drafted would not achieve the intended goal of preserving the balance between innovators rights and generic access.

On June 18, 2003, the FDA issued its final rule, which was substantially the same as the proposed rule. 68 Fed. Reg. 36,676 (Jun. 18, 2003) (to be codified at 21 C.F.R. pt. 314). Under the final rule, only one 30-month stay is available for any given generic ANDA. The final rule adopts the same categorization of patents that can and cannot be listed in the Orange Book. With respect to product-by-process claims, the final rule provides for a line in the new Orange Book listing certification form that requires the patentee to verify that the product of the product-by-process claims is novel.

The final rule will apply to all patent information submitted for an NDA on or after August 18, 2003. It remains to be seen whether the rule will have any impact on the perceived deficiencies of Hatch-Waxman.

The Gregg-Schumer Offensive: a Multi-Pronged Attack on Patent Rights

On January 7, 2003, Sen. Charles Schumer (D-New York), along with a large group of co-sponsors, including Sen. Hillary Clinton (D-New York), introduced a bill entitled the “Greater Access to Affordable Pharmaceuticals Act of 2003.” S. 54,

108th Cong. (2003) (“S. 54”). The stated purpose of S. 54 was to substantially amend the Hatch-Waxman Act to ensure “expand[ed] access to generic pharmaceuticals.” The overall gist of these amendments was simple: an innovator company must provoke early resolution of a patent infringement dispute with a potential generic or risk losing its right to sue for infringement.

Among the major provisions of S. 54 was one requiring that a patent holder must not only file an infringement suit upon receiving notice of a generic’s ANDA, but must also concurrently file a motion for a preliminary injunction. The 30-month stay would then be abrogated by a decision denying the motion for preliminary injunction. Failure to file a PI motion would result in a waiver of rights to sue for infringement of the patent(s). The bill required patent holders to file suit within 45 days of notice or forever waive their right to sue for infringement. In an attempt to appear even-handed, the bill also included a section entitled “Fairness to Innovators” that modified the standard for preliminary injunction by precluding a court from considering the ability of a generic to pay monetary damages in making its determination. S. 54 also sought to eliminate the possibility of multiple 30-month stays with a provision which precluded application of the 30-month stay to patents listed after an initial paragraph IV certification by a generic. Finally, in a response to the FDA’s position that the FDA has neither the responsibility nor the ability to assess the propriety of patent listings, the bill expanded potential litigation in this area by creating a cause of action to correct improper listing of patents and force delisting of patents.

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From Doha to Baghdad via DC: U.S. Pharmaceutical Policy in a Troubled World continued from p. 14

S. 54 was referred to the Committee on Health, Education, Labor and Pensions, chaired by Sen. Judd Gregg (R-New Hampshire). On June 10, 2003, Sen. Gregg sponsored, with Sen. Schumer as a co-sponsor, a compromise bipartisan position. S. 1225, 108th Cong. (2003) (“S. 1225”). S. 1225 not only eliminates the possibility of a multiple 30-month stay, but also provides that the 30-month stay applies only with respect to patents published by the Secretary pursuant to 21 U.S.C. 355 (b)(1) or (c)(2) at least one day before a generic files its ANDA. While a generic would have to amend its certification to include later issued patents, no additional 30-month stays would result. S. 1225 leaves unclear whether a generic would have to provide the innovator with notice of the amended certification and a detailed description of its basis for the amended certification; however, because the intent of the notice provision is to trigger the 30-month stay, notice presumably would not be required for the amended certification.

S. 1225 also contains a section entitled “Civil Action to Obtain Patent Certainty.” This portion of the bill provides a generic with a declaratory judgment cause of action if the innovator does not sue the generic for infringement within 45 days of receiving notice of a Paragraph IV certification. In addition, the bill provides the generic with the right to file a counterclaim for improper listing of a patent. The bill expressly precludes monetary damages for the counterclaim, but instead provides for an order “requiring the patent owner to correct or delete patent information....”

The bill further contains provisions that attempt to restrain generics from filing ANDA’s if they are not in a position to commercialize the drug, or if they reach

launch position through an agreement with the innovator. Specifically, the bill provides a list of actions resulting in forfeiture of the 180-day exclusivity granted to the first generic to successfully challenge the innovator’s patents. Among the “forfeiture events” contained in the bill are: failure to bring a product to market within the later of 60 days after FDA approval or 60 days after a final, non-appealable (except for writ of certiorari) decision of invalidity or non-infringement, conversion of the Paragraph IV certification to a Paragraph III certification, and failure to certify against a later-issued patent. In addition, in response to the recent spate of FTC antitrust proceedings against innovator-generic marketing agreements, the bill provides for forfeiture of the 180-day exclusivity period if the generic and the innovator enter into an agreement regarding the patent(s)-at-issue that the FTC “determines has violated the antitrust laws....”, defined as Section 1 of the Clayton Act and Section 5 of the Federal Trade Commission Act.

S. 1225 passed the Senate, and is expected to pass in similar form in the House.

Designing the Counteroffensive

The net effect of the current initiatives and ones that will inevitably come is that the average lifespan of a blockbuster drug will be reduced and generics will have earlier access to the market. So what can innovator companies do to effectively respond to this multi-pronged attack on pharmaceutical IP rights and preserve the balance? First, they will have to continue their worldwide philanthropic efforts, especially in the areas of treating widespread communicable diseases that affect poor countries. Moreover, they will need to more consistently and more effectively publicize these efforts and

the amount of money that is being spent on these efforts. In addition, innovators must continue to educate the public regarding the amount of time, effort and money that goes into bringing one drug to market, and provide the public with an understanding of the differences between the resources expended by the innovators and the generics. Finally, innovators must consider how to address generic entry much earlier in the drug lifecycle. As an example, innovators may consider co-marketing arrangements with generic providers. As seen in S. 1225, however, these types of arrangements come with their own set of problems, particularly on the antitrust side. Finally, innovator companies must adapt their intellectual property planning to consider these issues much earlier in the pharmaceutical lifecycle. Patent portfolio planning should now include assessments of (1) the potential impact from implementation of the Doha Declaration and (2) the potential impact of Orange Book issues and Paragraph IV litigation before a patent application is ever filed.

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McDonnell Boehnen Hulbert & Berghoff recognizes the ever-increasing importance of intellectual property. That is why our mission is to enhance the value of our clients’ businesses by creating and defending their intellectual property assets. We have built our reputation guiding our clients through the complex web of legal and technical issues that profoundly affect these assets. We are keenly aware of the trust placed in us by our clients Fortune 100 corporations, universities, individuals, and start-up companies and we always remain focused on their ultimate business goals.

With offices in Chicago and Washington state, MBHB provides comprehensive legal services to obtain and enforce our clients’ intellectual property rights, from navigating patent office procedures to litigating complex infringement actions. However, we don’t merely procure rights and litigate cases; we craft winning strategies that achieve our clients’ business objectives.

Our entrepreneurial spirit, combined with the wealth of our legal experience and technological expertise, permits McDonnell Boehnen Hulbert & Berghoff to achieve success for our clients.

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Review of Developments in Intellectual Property

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