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Review of Developments in Intellectual Property Law

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Patent Litigation Under a Future Biosimilars Act

Biopharmaceuticals, such as Erbitux® (cetuximab) and Cerezyme® (imiglucerase), are becoming increasingly important for the treatment of disease. U.S. sales of such drugs were about $40 billion in 2006 and are expected to rise to over $90 billion in 2009. Accordingly, political pressure is building to allow the sale of "biosimilar" drugs (also called "follow-on biologics").

Inspired by the success of the Hatch-Waxman Act, which has led to the wide use of generic "small molecule" drugs, four different biosimilars bills have been introduced in Congress in the past fifteen months. Three of the proposed bills would establish a complex scheme for patent litigation between brand-name and generic biopharmaceutical companies, especially as compared to the Hatch-Waxman Act.

Hatch-Waxman Act

The Hatch-Waxman Act, passed by Congress in 1984, amended the Food, Drugs and Cosmetic Act to establish an abbreviated pathway for FDA approval of small molecule drugs. Under the Act, a company seeking to market a generic small molecule drug must demonstrate only that the generic is "bioequivalent" to the corresponding brand-name drug; it need not conduct large scale clinical trials demonstrating safety and efficacy. The Hatch-Waxman Act, however, did not amend the Public Health Service Act, under which biopharmaceuticals are approved, and therefore it did not create an abbreviated pathway for the approval of biopharmaceuticals.

The Hatch-Waxman Act established a relatively straightforward scheme for patent litigation. In a New Drug Application, a brand-name drug

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Follow-on Biologic Drugs and Patent Law: A Potential Disconnect?

Biologic drugs, the pharmaceutical embodiments of the biotechnology revolution, are an important part of the current pharmaceutical armamentarium, and the trend is a rising one. Biologic drugs are generally peptides and proteins, particularly monoclonal antibodies, but can also include vaccines. Currently-available biologic drugs include Epogen® (recombinant human erythropoietin) and Gleevac® (anticancer monoclonal antibody), among others. At present, there are 150 approved biologic drugs in the U.S., contributing $40 billion to U.S. drug costs in 2006; these costs are expected to increase to $90 billion by 2009. The average cost of biologic drug treatment is about $72,000/year (compared to about $1,000/year for conventional "small molecule" pharmaceuticals). Part of the difference in cost reflects the difficulties in bringing these drugs to market, as well as the greater complexity of biologic drugs and the methods by which they are produced. Because of this, biologic drugs have become a legislative target, promoting generic (more properly, "follow-on") drugs to reduce costs.

Legislative efforts include several bills introduced in Congress relating to follow-on biologics; none of these bills have been acted upon, in the face of intensive lobbying from both sides of the follow-on debate. (*See* "Patent Litigation Under a Future Biosimilars Act" in this edition.) The bills are different, but have in common leaving responsibility

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Patent Litigation Under a Future Biosimilars Act

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company is required to inform the FDA of any patents claiming the drug or methods of using the drug "with respect to which a claim of patent infringement could reasonably be asserted." The patent information is listed in the FDA's "Orange Book," which the FDA updates regularly and publishes on the Internet. When a generic drug company submits an Abbreviated New Drug Application ("ANDA"), it is required to file one of four different patent certifications with respect to any patents listed in the Orange Book for the brand-name drug. Upon filing a Paragraph IV certification (indicating that a listed patent is invalid, unenforceable, or not infringed), the generic drug company is required to provide notice to the patent owner. If the patent owner brings suit within 45 days of receiving notice, then the FDA may not grant final approval of the ANDA for 30 months. This last feature – the automatic 30-month stay – is conspicuously absent from all of the proposed biosimilars bills.

Access to Life-Saving Medicine Act

Rep. Henry Waxman introduced the first of the four biosimilars bills, the Access to Life-Saving Medicine Act (H.R. 1038), on February 14, 2007. The Waxman bill is regarded as the one most favorable to the generic drug industry. It establishes a complicated system for the private exchange of patent information between brand-name and generic biopharmaceutical companies, and contains unusual provisions regarding patent litigation.

The Waxman bill states that a biosimilar applicant or prospective applicant may, at any time, send a written request for patent information to the holder of the approved application for the brand-name biopharmaceutical, who then must respond within 60 days by providing a list of all those patents it believes "in good faith relate to the reference product." Moreover, the brand company must, for the following two years, update its response by identifying all relevant patents issued or licensed after the initial response. A biosimilar applicant may make additional requests for patent information at any time.

Unlike the Hatch-Waxman Act, the Waxman bill does not require (or even allow) biosimilar applicants to file any kind of patent certification with the FDA. Instead, the bill states that a biosimilar applicant may send notice of its application to the holder of the application for the approved biopharmaceutical, including a detailed statement of the factual and legal basis for its belief that one or more of the patents is invalid, unenforceable, or not infringed. That company may then bring an action for infringement, but only based on a patent in the notice, and only in a judicial district identified by the biosimilar applicant as one in which it consents to being sued. The bill also states that the recipient of the notice may not, prior to the commercial marketing of the biosimilar drug product, bring a declaratory judgment action for infringement, validity, or enforceability of any patent that was not identified in the notice.

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Conspicuously absent from the four biosimilars bills is a provision for an automatic 30-month stay.

The Waxman bill also would add a new 35 U.S.C. § 271(e)(6) to the patent statute, stating that in certain cases, the sole and exclusive remedy that may be granted by a court, upon a finding of infringement, shall be a reasonable royalty. In other words, neither any other measure of damages nor an injunction could be awarded. This new paragraph would apply to actions where: (1) the patent-in-suit was identified in response to a request for patent information by a biosimilar applicant; (2) notice of filing of a biosimilar application was provided; and (3) the action was brought either after the expiration of the 45-day period following the notice of filing or before expiration of the 45-day period but where the action was dismissed without prejudice or was not prosecuted to judgment in good faith.

Patient Protection and Innovative Biologic Medicines Act of 2007

The Patient Protection and Innovative Biologic Medicines Act of 2007 (H.R. 1956), introduced by Rep. Jay Inslee on April 19, 2007, does not contain any provisions for exchanging patent information or conducting litigation between brand-name and generic biopharmaceutical companies. Accordingly, patent litigation would proceed under an existing provision – for example, 35 U.S.C. § 271(a), (b) or (c). In most cases, such actions would not be filed until after the generic company begins marketing its biosimilar drug product, though in certain cases the brand company might have sufficient warning to file a declaratory judgment complaint.

Biologics Price Competition and Innovation Act of 2007

The Biologics Price Competition and Innovation Act of 2007 (S. 1695), introduced by Sen. Edward Kennedy on June 26, 2007, contains the most complex provisions for exchanging patent information and conducting patent litigation of any of the four biosimilars bills. It includes many of the features of the Waxman bill, and many additional provisions as well.

Like the Waxman bill, the Kennedy bill would establish a system for the exchange of patent information between brand-name and generic biopharmaceutical companies. Unlike the Waxman bill, however, the Kennedy bill mandates participation in the exchange. The Kennedy bill states that a generic biopharmaceutical company shall, within 20 days of being notified by the FDA that the FDA has accepted its biosimilar application, provide a copy of its application to the holder of the approved application for the brand-name biopharmaceutical. Within 60 days of receiving the biosimilar application, the brand company shall provide a list of patents covering the biopharmaceutical. In turn, the generic company shall provide, with respect to each listed patent: (1) a detailed statement describing the factual and legal basis of its opinion that such patent is invalid, unenforceable, or would not be infringed by the commercial marketing of its biosimilar drug product; or (2) a statement that the generic company does not intend to begin commercial marketing of its product before the patent expires. Then, the brand company is to provide a detailed statement describing the factual and legal basis of its opinion that each patent in the first category would be infringed by such marketing.

The Kennedy bill contains detailed provisions for "patent resolution negotiations" and patent litigation between brand-name and generic companies. After exchanging the information described above, the companies "shall engage in good faith negotiations to agree on which, if any patents listed" shall be the subject of a patent infringement action. If the companies agree, then the brand company is to file suit on the patents within 30 days. If they do not agree, then provisions to minimize the number of patents-in-suit must be followed, after which litigation may be initiated. In addition, a biosimilar applicant must provide notice to the brand company at least 180 days before commercial marketing of the biosimilar drug product, after which the brand company may seek a preliminary injunction. Moreover, like the Waxman bill, the Kennedy bill includes provisions relating to newly issued or licensed patents and limitations on declaratory judgment actions.

Pathway for Biosimilars Act

Recently, on March 13, 2008, Rep. Anna Eshoo introduced the Pathway for Biosimilars Act (H.R. 5629). Compared to the Waxman and Kennedy bills, the Eshoo bill would establish a relatively simple scheme for exchanging patent information and conducting patent litigation.

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Patent litigation under any of the proposed bills would be much different than under the Hatch-Waxman Act.

Like the Kennedy bill, the Eshoo bill states that a biosimilar applicant shall provide the brand-name company with a copy of its application after the FDA has accepted the application for review. Within 60 days of receiving the application, the brand company shall provide the generic company with a list of patents covering the biopharmaceutical, explaining why it believes each patent would be infringed if the biosimilar application were approved. Within 45 days of receiving the list, the generic company shall, with respect to each patent, either (1) state that it will not commence marketing of the biosimilar drug before the expiration of the patent; or (2) provide a detailed written explanation of the reasons why it believes the manufacture, use, or sale of the biosimilar drug would not infringe the patent. The brand company then has 60 days within which to bring an action for infringement of any patent on the list. Finally, the bill states that a biosimilar applicant may not bring an action for declaratory judgment of invalidity, unenforceability, or noninfringement of any patent on the list until at least 120 days after the applicant provides its detailed written explanation.

Conclusion

It appears unlikely that any biosimilars bill will be enacted before the new Administration takes office next year. However, with healthcare costs steadily rising, Congress is expected to begin working again in earnest to pass biosimilars legislation shortly thereafter. Any new biosimilars law will probably incorporate some of the elements described above, meaning there will likely be a dramatically different patent litigation scheme for biosimilars than there currently is for small molecule drugs under the Hatch-Waxman Act.

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It's Not Easy Selling Green

When Kermit the Frog first sang "It's not easy being green" on Sesame Street in 1970, he probably never anticipated the environmental impact of his lyrics. Today, however, we are starting to realize the effect that we have on our environment. Thanks in part to Al Gore's efforts to draw attention to global warming[1], it is becoming increasingly common to know your carbon footprint and to "go green." It should come as no surprise, then, that corporate America has picked up on this trend and responded with a surge of "green marketing," which is intended to capitalize on these environmental initiatives.

It is not entirely clear if consumer demand is the driving force behind green marketing, or rather if green marketing is changing consumer attitudes and perceptions. It is likely that both are true to some extent. As environmental issues become more mainstream, many companies have increasingly taken steps to take advantage of, and promote, their environmental awareness; green marketing is becoming trendier, and perhaps consumers are becoming more and more persuaded to lessen their individual impact on the environment. This article highlights some green-marketing efforts and explains why it is still not easy being green.

Who is Going Green?

It is impossible to surf the Web, pick up a magazine or newspaper, listen to the radio, or watch TV without being bombarded with examples of green marketing. For instance, many of the major automakers have some sort of environmentally-related link on their respective Web sites. On Honda's site, the Civic GX NGV is listed as the American Council for an Energy-Efficient Economy's "America's Greenest Car."[2] Toyota announced that, by the end of May, 2007, it had sold one million hybrid vehicles globally.[3] Furthermore, in March of this year, Audubon and Toyota announced a five-year alliance to promote conservation action, "Together Green," (USPTO Trademark Serial No. 77/324,911).[4] And, in April of this year, Toyota awarded the National 4-H council $1.48 million to "Engage 1.3 Million Youth Participating in 4-H Environmental Programming."[5]

General Motors has also taken the leap, touting a line of its cars as "gas friendly to gas-free."[6] GM claims that, by the end of 2008, it will offer eight hybrid models, and that, since 2003, more than 800 GM hybrid-powered buses have been delivered to cities across the country.[7] GM has also dedicated a Web page to describing its "Environmental Commitment."[8]

Moreover, Volkswagen has also launched a new environmental advertising campaign to promote their "green credentials."[9] Volkswagen's Web site now currently discusses "mobility and sustainability" to explain to its customers, shareholders, and other stakeholders how VW is improving their products and production processes with regard to environmental performance, and what the company has achieved in that respect.[10] In particular, VW is focusing on tracking the fuel efficiencies of new models over older models.

In 2005, General Electric launched its Ecomagination® (UPSTO Registration Nos. 3,395,783, 3,319,647, and 3,096,771, with 16 other applications currently pending) campaign[11], and GE's Web site lists four commitments: double investments in clean R&D, increase revenues from Ecomagination® products, reduce greenhouse-gas emissions, and keep the public informed. As of the summer of 2007, GE is offering its Earth Rewards℠ credit card (USPTO Registration No. 3,367,001), dedicated to reducing U.S. cardholders' carbon emissions.[12] GE's efforts appear to be paying off: according to a November 12, 2007 *Fortune* article, GE's improvement in brand recogni-

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In particular, companies should be careful when considering a "green" marketing campaign, because "green" claims – like other claims – must be substantiated.

tion over the last three years is due almost entirely to its environmental efforts.[13] GE also plans to launch a "go green" campaign for the 2008 Olympic Games.[14]

BP, ExxonMobil, and Shell have also jumped on the "green" bandwagon. BP began its Beyond Petroleum® (USPTO Registration No. 2,787,889) campaign in 2003. ExxonMobil has dedicated a Web page to "current issues," including climate change, energy outlook, and reducing emissions[15] and, along with GE and Toyota, is the "lead developer and sponsor" of the Global Climate and Energy Project (GCEP), touted as the "world's largest private research initiative" on alternative energy technologies.[16] Shell has devoted part of its Web site to environmental issues[17], including a page devoted to measuring Shell's performance with respect to metrics such as use of fresh water, discharge of oil effluents, and greenhouse-gas emissions.[18] As a final example, Dow Chemical's "Human Element" (USPTO Trademark Application No. 77/028,960) campaign includes themes such as "Fueling Better Gas Mileage" and "Alliance to Save Energy."[19]

Are You Going Green?

Are you inspired? Are you ready to go green? Are you ready to launch some trendy new green marketing for your company? Great. Just be careful. Going green – like being green – is not so easy.

In particular, companies should be careful when considering a "green" marketing campaign, because "green" claims – like other claims – must be substantiated. The Federal Trade Commission (FTC) is charged with protecting customers from deceptive and unfair advertising in the marketplace, and, as part of that responsibility, issued Environmental Guides[20] (a.k.a. the "Green Guides") in 1992 (revised in 1998).[21] The Environmental Guides are "administrative interpretations of laws administered by the Commission for the guidance of the public in conducting its affairs in conformity with legal requirements."[22] If the FTC becomes aware of conduct that is inconsistent with the positions of the Environmental Guides, it may investigate, and, if it has reason to believe that conduct violates prohibitions against unfair or deceptive acts or practices, such conduct may result in corrective action.[23]

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The FTC's Environmental Guides apply to all forms and modes of marketing.

The Environmental Guides apply to all forms of marketing, including logos and brand names, and to all modes of marketing, including Internet marketing. They help companies understand how marketing messages are often interpreted by consumers, so that companies can avoid making false or misleading claims, and they also establish standards for environmental performance.

The Guides do address some environmental claims specifically, such as requirements for claims like "biodegradable," "compostable," "recyclable," and "recycled content." For those not specifically addressed, FTC law requires substantiation for all reasonable interpretations of an ad.[24] In particular, companies must be wary of making general claims that products or services benefit the environment, as such claims are difficult to interpret, and may convey a wide range of meanings to consumers. General environmental-benefit claims must be substantiated or qualified as necessary to prevent deception about the specific nature of the environmental benefit being asserted.[25]

As an aside, there are some indications that the prevalence of "green marketing" has caused some consumer confusion. One study found that 64% of responders could not name a "green" brand, and 51% of those who considered themselves to be environmentally conscious were unable to name a "green" brand.[26] Furthermore, while green-advertising campaigns are costing companies a great deal of money, it is not entirely clear that consumers are convinced that some companies are actually environmentally conscious.[27] Various magazines (online and in print) have tried to determine what makes a "green marketing" campaign work. For instance, Entrepreneur Magazine recently published an article entitled "Go for the Green: Check out these 4 essential tips for turning green marketing into gold."[28] The article focused on how to make "green marketing" an effective tool to attract customers, including motivating green shoppers, coupling environmentally-friendly consumerism with monetary savings, promoting safety and good health, and convenience.[29]

In summary, it seems apparent that environmental issues and "going green" will continue to become more and more a part of our collective consciousness, and that, in spite of some potential consumer confusion and skepticism, corporate America will increasingly look to launch environmentally-friendly initiatives and participate in green-marketing campaigns, both for the benefit of the world in which we live, and to increase their attractiveness to consumers. In so doing, these companies should be as conscientious about making environmental-benefit claims as they are about making all other claims, taking care to ensure that the claims being made can be properly substantiated. As always, it's best to listen to Kermit.

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Endnotes

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2. http://automobiles.honda.com/civic-gx/
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23. *Id. See* also, § 260.2, Guides for the use of Environmental Marketing Claims, http://www.ftc.gov/bcp/grnrule/guides980427.htm
24. http://www.ftc.gov/bcp/conline/pubs/buspubs/greenguides.shtm
25. *See* § 260.7(a), http://www.ftc.gov/bcp/grnrule/guides980427.htm
26. http://www.brandweek.com/bw/news/recent_display.jsp?vnu_content_id=1002878049
27. *Id.*
28. http://www.entrepreneur.com/magazine/entrepreneur/2008/march/190098.html
29. *Id.*

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Seagate: Reports of the Death of Opinions of Counsel Have Been Greatly Exaggerated

The Federal Circuit's *en banc* decision in *In re Seagate Tech.*, LLC[1] represents a shift in willful-infringement jurisprudence and effectuates key changes regarding the advice-of-counsel defense to willful-infringement allegations, as well as waiver of attorney-client privilege. In the end, however, the decision likely will not change the degree to which opinions of counsel are obtained, as accused infringers are still in a much better position with an opinion than without.

Willfulness

Seagate represents, at least semantically, a significant change in what constitutes willful infringement. While the court explicitly abandoned the affirmative duty of due care, along with the affirmative obligation to obtain an opinion of counsel[2], the post-*Seagate* waterfront is murky at best, and still surprisingly treacherous for patentees and accused infringers alike.

What the Court Actually Did

In *Seagate*, the Federal Circuit explicitly overruled *Underwater Devices v. Morrison-Knudsen Co.*[3], and held that proof of willful infringement, which would permit enhanced damages, requires at least a showing of "objective recklessness."[4] In doing so, the court essentially removed negligent infringement from the range of activities that qualify for enhanced damages. As a part of this move, the court explicitly stated that accused infringers have no affirmative obligation to obtain an opinion of counsel.[5] Thus, it appears that the failure to obtain advice of counsel does not per se qualify as willful infringement.

The court conceded that the term "reckless" is not self-defining, but noted that a person who acted in the face of an unjustifiably high risk of harm that is either known or so obvious that it should be known is generally considered reckless by civil law.[6] To provide some guidance in the post-*Seagate* era, the court provided a two-part test for a patentee to establish willful infringement:

> (1) A patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent. The state of mind of the accused infringer is not relevant to this objective inquiry.
>
> (2) If this threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding), was either known or so obvious that it should have been known to the accused infringer.[7]

On its face, the decision appears to be a big deal – a precedent is overruled, affirmative duties are eliminated, and a new test is born. Without a doubt, the process a patentee must now follow for obtaining enhanced damages is more difficult and perhaps more dangerous. However, despite the alleviation of an affirmative duty or two, it is unclear what practical effect *Seagate* has for accused infringers.

What About Formal Opinions?

The *Seagate* opinion begs the question: Do I need a formal opinion from patent counsel? After *Seagate*, the answer seems to be "no," at least to the extent that failing to obtain an opinion will not, in and of itself, constitute willful infringement. There is no affirmative duty to obtain a formal opinion describing in detail why a patent is invalid, unenforceable, and/or not infringed. However, just because obtaining an opinion is no longer a requirement does not mean that it is not still a good idea. In fact, after *Seagate*, an accused infringer with a pre-suit formal opinion has some weight to throw around. For example, the first part of the *Seagate* willfulness test establishes a threshold issue, where a patentee must show by clear and convincing evidence that an accused infringer acted despite an objectively high likelihood that its actions infringed a valid patent. A pre-suit formal opinion held by the accused infringer would seem to make it extraordinarily difficult, if not impossible, for a patentee to meet this threshold.

Preliminary Injunctions and the Formal Opinion

A formal opinion may also help accused infringers avoid a preliminary injunction. The court noted that an accused infringer can avoid a preliminary injunction by showing "only a substantial question as to invalidity, as opposed to the higher clear and convincing standard required to prevail on the merits."[8] A formal opinion can raise just such a question.

The *Seagate* decision also provides the real payoff behind avoiding a preliminary injunction. The court noted that, if a patentee fails to secure an injunction, it is unlikely that the infringement was reckless.[9] The court also effectively barred a patentee from obtaining enhanced damages for post-filing reckless conduct if the patentee does not seek an injunction. Simply put, if a party's pre-suit formal opinion can raise a substantial question of invalidity, the likelihood of a finding of willfulness against that party drops.

The tension between seeking a preliminary injunction and foregoing enhanced damages forces the patentee to make an important strategic decision early in the litigation process. If the accused infringer has a pre-suit opinion in hand, the patentee must either wage a difficult battle to show that, despite a formal opinion to the contrary, the accused infringer knew or should have

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known that there was a high likelihood that it was infringing a valid patent, or essentially concede the issue of willfulness.

Will Courts Just Move the Goal Posts?

The court left little ambiguity in its opinion regarding the affirmative duty to acquire an opinion. Post-*Seagate*, the failure to obtain an opinion is not sufficient by itself to constitute willfulness.[10] However, in defining willfulness and recklessness, the court looked to a variety of cases outside the realm of patent law, and left it to the district courts to sort out the details.

This of course presents the question – what is reckless? The court's opinion does not foreclose the possibility that the failure to acquire an opinion could be considered in light of other actions or indications as part of a larger analysis of recklessness. Also, by looking beyond the bounds of patent law to examine the meaning of willfulness and recklessness, the Federal Circuit invites litigants to do the same. Thus, it is likely that future cases will witness a range of arguments exploring and analogizing a variety of reckless behaviors from a variety of legal areas.

Should Plaintiffs Get an Opinion?

As noted above, Plaintiffs bear a significant burden in establishing willfulness, and have some significant strategic decisions to make even before filing suit. To fulfill the second prong of the willfulness test, the Plaintiff has to show that the accused infringer knew or should have known about the risk. The easiest, if not the only, way for Plaintiffs to meet this burden is to give the infringer a relatively detailed pre-suit notice.

It seems fairly implicit that a short cease-and-desist letter with bald accusations of willful infringement will not satisfy the second willfulness prong. The patentee has to show that the accused infringer knew or should have known of the objectively high risk of infringement, not just that the patentee is asserting willful infringement. However, post-*SanDisk*,[11] pre-suit notice can confer declaratory-judgment jurisdiction to the accused infringer, putting them in the driver's seat with respect to venue.

Given some of the significant tactical and strategic decisions that must be made by the patentee early in the litigation process, it may be wise for patentees to obtain an opinion to determine the strength of their case before running head-long into a full-blown patent-infringement case.

The Elephant in the Room

While it is unclear whether Congress will pass patent reform legislation this term, and what the final legislation may wind up including, draft versions from both the House and Senate have included their own standards and limitations for willfulness that would supersede the *Seagate* opinion.

Waiver

With regard to waiver of attorney-client privilege, the court in *Seagate* first stated that disclosing the opinions of patent opinion counsel is not a waiver of privilege between the client and trial counsel.[12] Second, the court stated that relying on opinion counsel's work product is not a waiver of work-product immunity as it applies to trial counsel.[13]

While these changes seem to significantly reduce the ability of plaintiffs to argue for waiver of privilege, the *Seagate* opinion leaves two questions open: First, it is unclear how *Seagate* applies to in-house counsel. Second, the court indicated that despite the holding in *Seagate*, privilege and work-product immunity may be waived based on a party's conduct, including "chicanery" by counsel.[14]

To the extent that *Seagate* fails to address the privilege held by in-house counsel, it appears that *In re Echostar Communs. Corp.*[15] is still in effect. In the Federal Circuit's 2006 decision in *Echostar*, the court held that a party's reliance on in-house counsel's advice to refute allegations of willfulness waived privilege.[16]

In summary, the court in *Seagate* removed a harm of disclosing or relying on an opinion of counsel during trial. And, while it seems that the court eliminated many reasons for obtaining an opinion of counsel by removing the strict, formalistic application of the opinion-of-counsel defense to a charge of willful infringement, an opinion of counsel still remains a valuable asset.

Endnotes

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2. *Id.* at 1371
3. 717 F.2d 1380 (Fed. Cir. 1983)
4. *Seagate*, 497 F.3d at 1371
5. *Id.*
6. *Id.*
7. *Id.*
8. *Id.* at 1374
9. *Id.*
10. *Id.* at 1371
11. 480 F.3d 1372, 1375 (Fed. Cir. 2007)
12. *Seagate*, 497 F.3d at 1374
13. *Id.* at 1376
14. *Id.* at 1374, 1376
15. 448 F.3d 1294 (Fed. Cir. 2006)
16. *Id.* at 1304

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with the FDA for approving follow-on biologic drugs that are "comparable" or "biosimilar" to the innovator biologic drug. They also each provide for some amount of market and data exclusivity for the innovator.

The bills differ in the requirements for showing biosimilarity. The scientific issue behind the concern for biosimilarity is the capacity for a follow-on biologic to be equivalent to the innovator drug, specifically, how difficult it may be to make a "biosimilar" biologic drug. Innovators maintain that it is virtually impossible to make a truly "generic" biologic, as the term is used for conventional drugs, and offer a number of bases for this position: Unlike conventional pharmaceuticals that are made using well-defined and controlled chemical reactions, biologic drugs are almost always made by a living cell (bacterial, yeast, or mammalian), and the cells used by the innovators are rarely available. Cells, even cells of the same type, are expected to have phenotypic variability that may influence the structure of the biologic drug product they make. Also, different formulations of biologic drugs can have different properties. Potential consequences of this type of variability include changes in bioavailability, biological activity, solubility (including the propensity for agglomerization), and immunogenicity.

Biologic drugs (more properly, pharmaceutical composition claims comprising a biologic compound) must comply with the same standards of patentability as conventional drugs, and U.S. patent law does not require disclosure of clinical trials or safety and efficacy data for pharmaceutical composition claims. However, the extent of disclosure required for a claim depends on claim scope, since 35 U.S.C. § 112, first paragraph, has been interpreted to require disclosure of how to make and use an invention throughout the full scope of the claim. It is not unreasonable to expect that pharmaceutical composition claims for biologic drugs will require disclosure sufficient to enable one of ordinary skill in the art to produce a useful biologic drug (*see In re Wands*, 858 F.2d 731 (Fed. Cir. 1988)). Indeed, in *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202 (D. Mass. 2004), the trial court disqualified prior art (that must also be enabling) relating to purification of human urinary erythropoietin based on testimony that the method did not yield uEPO in sufficient quantities or purity to have a biological effect.

These considerations have become more important, since the Federal Circuit has shown a penchant recently to give significantly closer scrutiny to the correspondence between claim scope and disclosure. Examples include: *Pharmaceutical Res. Inc. v. Roxane Labs, Inc.*, 253 Fed. Appx. 26 (Fed. Cir. 2007), where the patent was invalidated on non-enablement grounds for claiming formulations of megastrol acetate with a flocculating agent, supported by disclosure of only three flocculating agents; and *Monsanto Co. v. Syngenta Seeds Inc.*, 503 F.3d 1352 (Fed. Cir. 2007), where a patent to methods for transforming "plant cells" was invalidated in view of uncontroverted testimony that, at the time the application was filed, the art recognized methods for transforming dicotyledonous but not monocotyledonous plants.

In this climate, conventional claims to pharmaceutical compositions encompassing biologic drugs may be at risk. For biotechnology claims, patent disclosures typically contain specific information relating to isolating a gene encoding the biologic compound and methods for producing a sufficient amount of a protein to determine its properties. Disclosure relating to producing a pharmaceutical from such a biologic com-

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The scientific issue behind the concern for biosimilarity is the capacity for a follow-on biologic to be equivalent to the innovator drug.

Follow-on Biologic Drugs and Patent Law: A Potential Disconnect?

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pound tends to be more generic. In addition, deposits of functional cell lines for producing the biologic are rarely made, in part to protect against a competitor, particularly a foreign competitor, obtaining a sample of the cells once a patent is granted in the U.S. The question is whether this disclosure will be deemed sufficient to support pharmaceutical composition claims for biologic drugs; the consequences to innovator biotechnology and pharmaceutical companies in the event that the trend toward requiring greater supporting disclosure is extended to these types of claims is also at issue.

The capacity for a skilled artisan to use the patent disclosure to produce a biologic drug implicates the "quid pro quo" nature of the patent grant. The inventor obtains the exclusive right only because she fully discloses her invention, with the expectation that the skilled worker will be able to practice the full scope of the claimed invention once the patent has expired. Assertions suggesting that a skilled worker could not practice a pharmaceutical composition claim to a biologic, either because of the inherent complexity of the drug, differences in cell lines used to produce the drug, or a failure to disclose necessary methods for producing or formulating the drug, could result in an invalidation of such claims. And as the number of "position papers" and other publicly-available sources of such claims increase, so does the potential for savvy Examiners to use such statements to make procuring pharmaceutical composition claims for biologic drugs more difficult.

To address these assertions, it may be appropriate to focus on whether follow-on biologic drug producers are of "ordinary skill" in the art. Alternatively, patent claims may more productively be directed toward the biologic agent per se rather than to pharmaceutical compositions, avoiding any negative implications between claim scope and sufficiency of disclosure. Considerations that keep an innovator from depositing its commercial strain or cell line remain sufficiently compelling to preclude cell deposits as a solution, but it may be possible to deposit an equivalent (or at least sufficient) cell line (albeit carrying the risk that a competitor might obtain the cells). As with some conventional pharmaceuticals, it also may be possible to patent particularly advantageous synthetic or formulation methods around a patented biologic drug. Finally, the extent of patent disclosure relating to actual production of a biologic drug can be increased, but this is not guaranteed to be sufficient in every case.

No matter how it is done, additional disclosure is an important part of an effective response to the changing requirements, for a number of sound policy reasons. Post patent expiry, disclosure is in the public interest and satisfies the patent quid pro quo. Innovators are protected by data exclusivity, since the patent disclosure is the minimum that is required, and there is a wealth of information relating to the regulatory process that is not required to be contained in a patent specification. Also, providing increased disclosure can be used as leverage for obtaining political concessions, such as increased market and data exclusivity.

And finally, it is just good corporate citizenship, at a time when many voices are inclined to blame drug companies for the reality that producing new drugs, particularly biologic drugs, is a capital-intensive enterprise requiring sufficient return on investment to obtain the necessary capital. Such efforts to convince policymakers of these economic realities, in the face of the political clarion call for lower drug costs at any price, will be more and more important as the cost for new drugs increases.

Kevin E. Noonan has extensive experience in biotechnology and the chemical arts. Dr. Noonan brings more than 10 years of experience as a molecular biologist working on high-technology problems to his legal work. He has wide experience in all aspects of patent prosecution and client counseling on validity, infringement, and patenting strategy matters. He represents pharmaceutical and biotechnology companies both large and small, and he is particularly experienced in representing university clients in both patent prosecution and licensing to outside investors. Dr. Noonan is an author of the Patent Docs Blog (http://www.patentdocs.us./).

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