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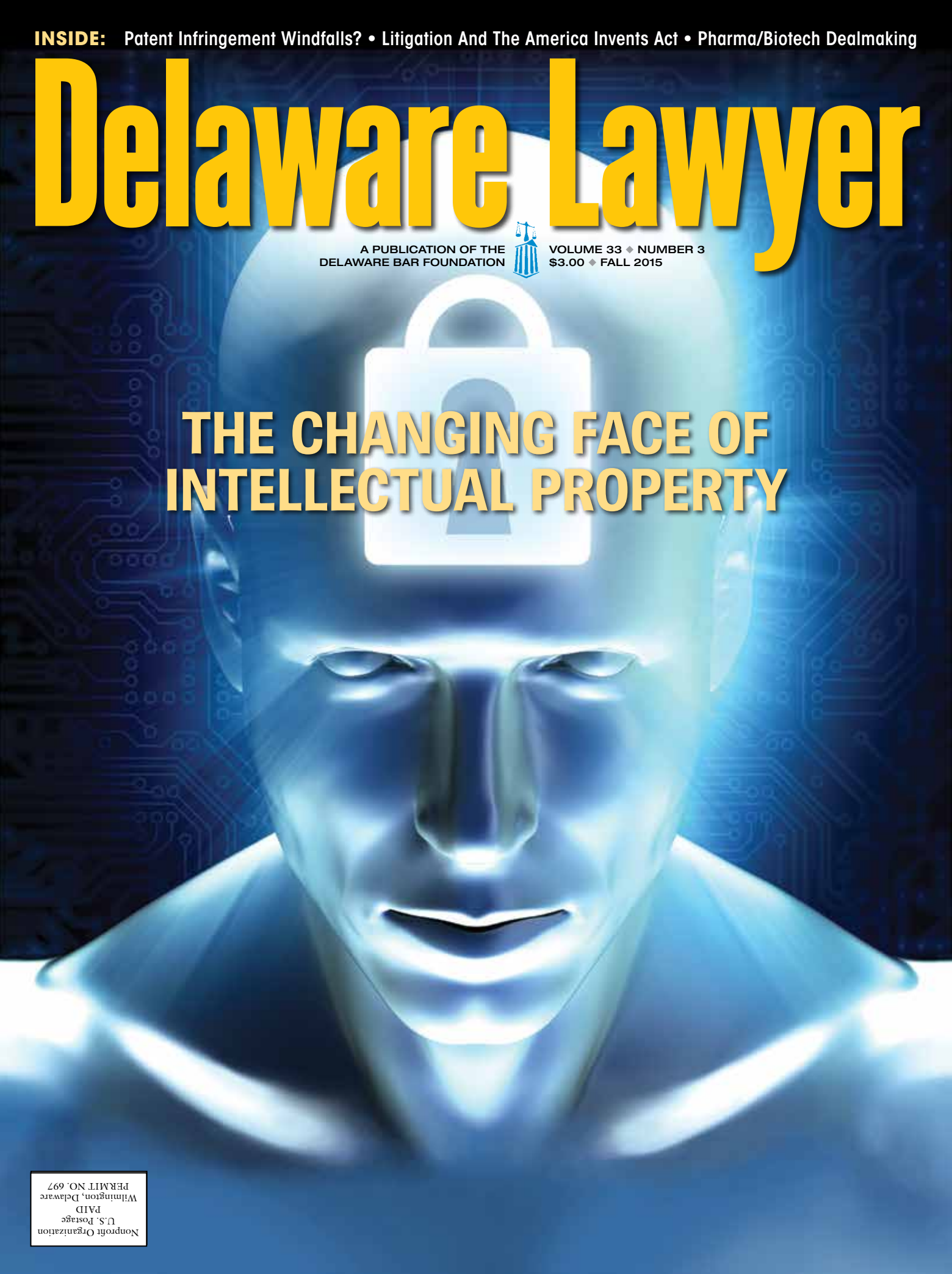

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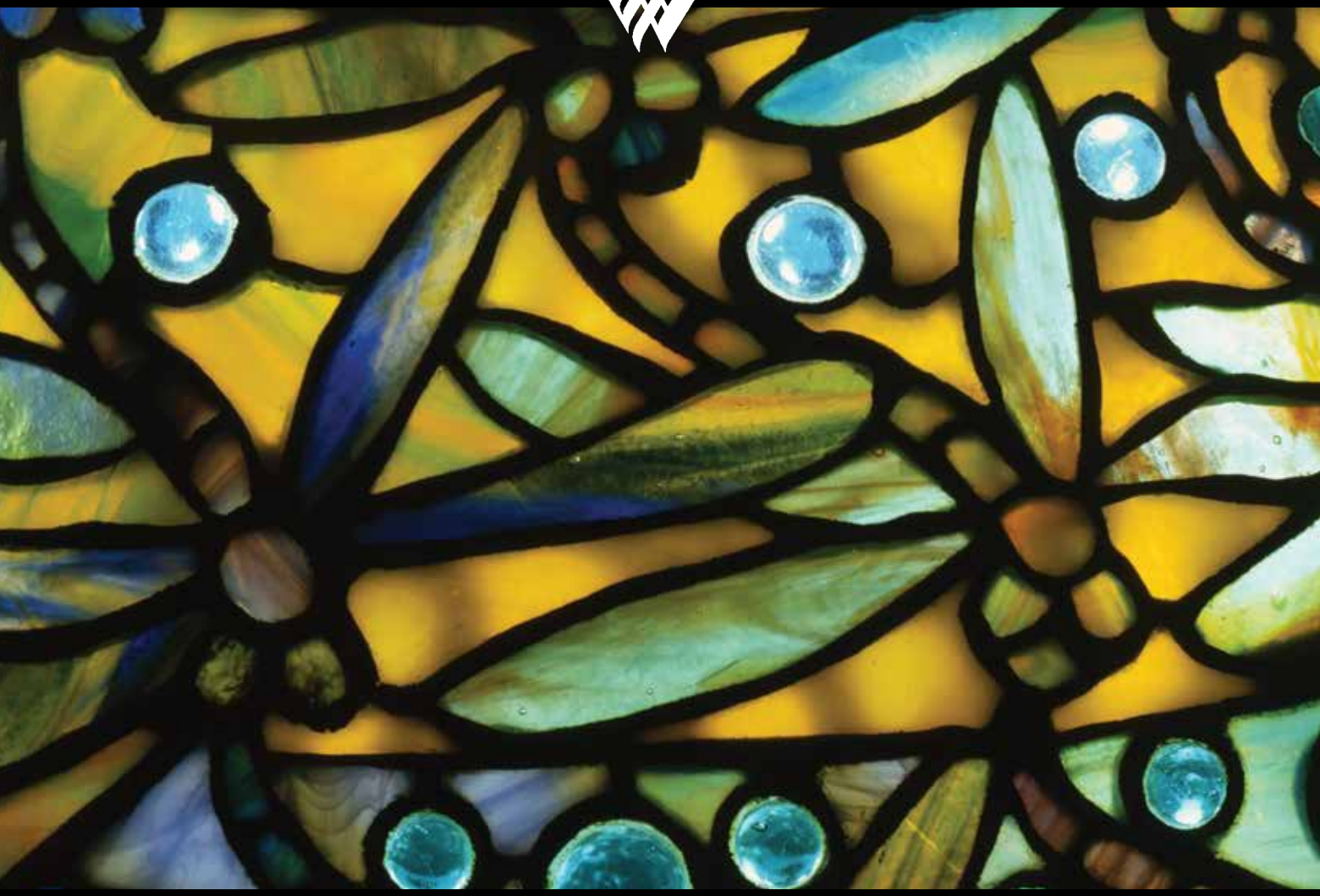

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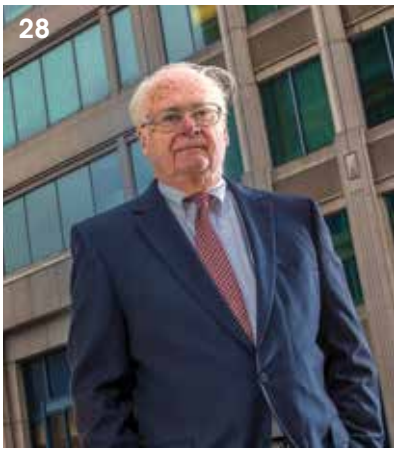

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EDITOR'S NOTE

Dominick T. Gattuso

Today, the term "intellectual property" is well known, even outside of legal circles. Simply put, intellectual property is the product derived from original, creative thought, and encompasses art, literature, music, machines and compositions of matter, among other things.

The idea of intellectual property is not new. Indeed, the concept of protecting the product of a person's intellectual effort has been around for hundreds of years, with one of the earliest known references coming around 500 B.C.

Perhaps not surprisingly, the American system of intellectual property protection is derived from the English system. The Statute of Monopolies, enacted in England around 1624, provided a 14-year monopoly to inventors and authors. Roughly 80 years later, England enacted the Statute of Anne, arguably one of the first modern copyright statutes. Other European countries followed.

The United States Constitution, drafted at the height of the Industrial Revolution, expressly provides for the protection of intellectual property: "The Congress shall have the power ... [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Thus, Article I, Section 8, Clause 8, of the U.S. Constitution is the base upon which our intellectual property laws have been built.

The scope and complexity of our intellectual property system, like those of many other countries, have grown considerably since that time. Today, our intellectual property system encompasses patents, copyrights, trademarks, trade dress and trade secrets, as well as ideas (that have not received other protection) and even the value of one's identity (think celebrities). That growth is a recognition of the importance we place on the benefit to society of encouraging and protecting original, creative works in various forms.

Thus, it is with great pleasure that I introduce several outstanding authors.

In our first article, Dan Brean addresses the often hotly debated topic of damages in patent infringement cases.

Next, Laura Lydigsen addresses how federal district courts are handling motions to stay patent infringement cases when a petition is filed with the U.S. Patent and Trademark Office under the Leahy-Smith America Invents Act challenging the same patents.

In our third feature, Jaime d'Almeida, Rick Schwartz and David Nadell discuss the challenges facing the pharmaceutical/biotechnology industry in recent years, and provide insight on mergers and acquisitions and other transactional forms that have resulted from these challenges.

In our fourth article, Adam Poff discusses trade secret law in Delaware, and the possibility that a federal trade secret law could be enacted this year.

Finally, Pat Rogowski has written a profile of Rudy Hutz. He is an exceptional Delaware lawyer who has blazed a trail in the field of intellectual property for more than three decades.

It has been a pleasure working with these authors. I sincerely hope you enjoy reading their articles.

Dominick T. Gattuso

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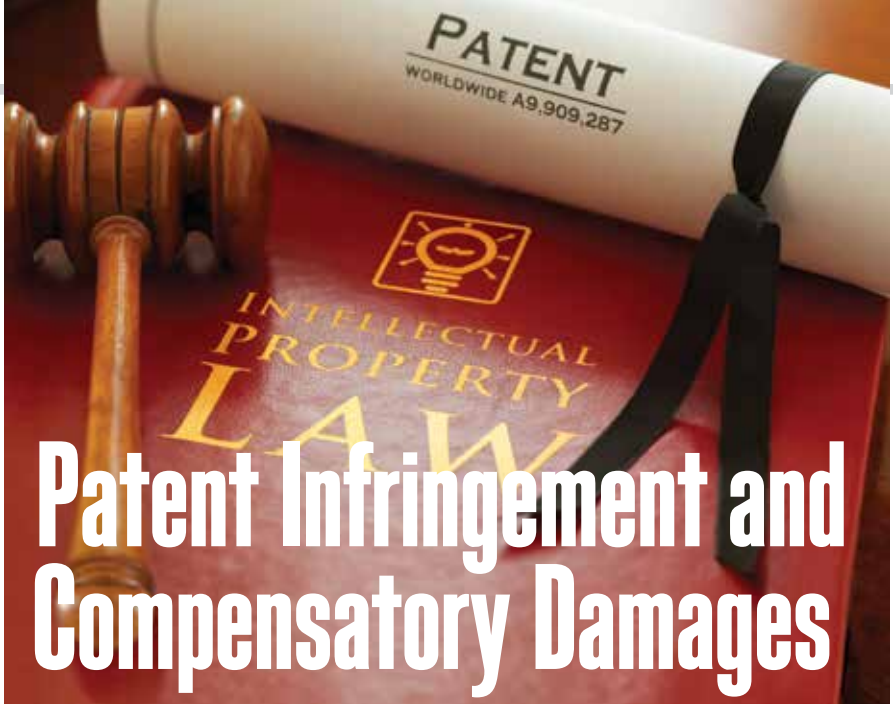
Daniel H. Brean



Unreasonable Royalties: Patent Infringement and Compensatory Damages

Decisions that ignore legal principles, legislative intent, and controlling damages precedent have wrongly generated windfall payments for patentee plaintiffs.

Damages are supposed to be compensatory. In the event of an injury, damages are intended to put a plaintiff back in the position the plaintiff would have been had the injury never occurred. The extent of cognizable harm to the plaintiff is thus the measure of what the law calls "damages."

In the patent infringement context, however, the law has dramatically departed from these bedrock legal principles. Although the plain text, legislative history, and Supreme Court's interpretation of the patent damages statute (35 U.S.C. § 284) are all clear that damages must constitute compensation for actual harm suffered, subsequent errant case law effectively endorses windfalls and calls them damages.

Patent infringement causes a legal harm to a patentee, but it does not cause actual harm in every instance. Historically, absent proof of "actual loss," only nominal damages were awarded.[1] The same is true for the analogous tort of trespass on land – unless some actual damage occurs to the land or landowner due to the trespass, no more than nominal damages would be owed.[2]

Yet today patentees who suffer no actual harm (most notably, patent assertion entities) are regularly obtaining considerable amounts of money from infringers as purported damages. A fresh review of the controlling damages law, and how it has gone awry, can hopefully help put an end to the *status quo* in which many patent owners are being routinely overcompensated for infringement.

History and Background of the Damages Statute

Section 284 of the 1952 Patent Act, entitled "Damages," provides that "[u]pon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but *in no event less than a reasonable royalty* for the use made of the invention by the infringer." The emphasized language of this statute has been interpreted to set a floor on damages. It has also been assumed that a reasonable royalty is something more than nominal and is necessarily a substantial sum.[3]

That assumption is mistaken. Indeed, the Federal Circuit very recently acknowledged that a zero or nominal reasonable royalty award might be appropriate in some cases. It held in *Apple Inc. v. Motorola, Inc.* that "[c]ertainly, if the patentee's proof [of damages] is weak, the court is free to award a low, perhaps nominal, royalty, as long as that royalty is supported by the record."[4]

The 1946 precursor statute to Section 284, which allowed for recovery of "damages ... not less than a reasonable royalty," was the first time the concept of a reasonable royalty was codified for patent cases. The notion of a reasonable

royalty had long before arisen in the common law as a way patentees could obtain damages when the evidence of the amount of damages stemming from the infringement was lacking.[5] While earlier statutes and cases allowed for the measure of reasonable royalty damages to include infringers' profits, the 1946 Act was intended "precisely to eliminate the recovery of profits as such and allow recovery of damages only."[6]

In 1952, Section 284 further clarified that "damages" must "*compensate* for the infringement." As the Supreme Court subsequently explained in *Aro Manufacturing* (1964), "the statute allows the award of a reasonable royalty, or of any other recovery, only if such amount constitutes 'damages' for the infringement," and emphasized that recoverable "damages" can only be losses to the patentee, not gains to the infringer ("'[i]n patent nomenclature what the infringer makes is 'profits'; what the owner of the patent loses by such infringement is 'damages.'").[7]

The Court went on to emphasize that pecuniary loss is the hallmark of damages, noting that "[damages] have been defined by this Court as 'compensation for the pecuniary loss he [the patentee] has suffered from the infringement, without regard to the question whether the defendant has gained or lost by his unlawful acts.'"[8]

Aro thus definitively held that any non-compensatory theories of damages seeking an infringer's profits – *e.g.*, restitutional or unjust enrichment theories – were prohibited by Section 284. The law was refreshingly clear that damages were limited to compensating for harms actually suffered by patentees.

The Georgia-Pacific Fallacy

Six years after *Aro* came *Georgia-Pacific Corp. v. United States Plywood Corp.*, a district court decision that set forth a 15-factor test that became the prevailing analytical framework for determining a reasonable royalty. Many of those factors sound in restitution, not compensation, however – *e.g.*, "[t]he effect of selling the patented specialty in promoting sales of other products of the licensee," "[t]he established profitability of the product made under the patent," "the benefits to those who have used the invention," and "the value of [the infringer's] use [of the invention]."[9] Post-*Aro*, such restitutional factors should not be considered as part of a reasonable royalty analysis, and yet they persist.

The fallacy of the *Georgia-Pacific* decision opened the floodgates for theories of damages that have nothing to do with any harm to the patentee and everything to do with seeking a windfall. The most frequent exploiters of this fallacy have been patent assertion entities ("PAEs," more pejoratively known as "patent trolls"), which exist solely to own and enforce patents. PAEs make and sell no products and offer no services. Their sole activity is to extract their supposed "damages" from operating companies that allegedly use the patented technologies, by seeking to license their patents under actual or threatened litigation.

Because PAEs suffer no lost sales, lost customers, price erosion, or other business injury as a result of infringement, they can adduce nothing showing that they are *worse off* because of the infringement than they would have been if the infringement never occurred. Although a PAE could have been in a *better* position had the accused infringer agreed to pay to use the patented technology instead of using the technology without a license, *Aro* was clear that this is not indicative of any damages within the scope of § 284.

Having no actual damages to speak of, PAEs generally point to the financial success of the infringer in relation to the patented technology, and claim credit (in the form of damages) for some portion of that success. For example, in the closing argument of the trial in *Soverain Software, LLC v. Newegg Inc.* – a case involving a notorious electronic "shopping cart" patent asserted against online retailer Newegg – Soverain's counsel asked the jury to award reasonable royalty damages as follows:

> $34 million. Yeah. That's real money. That's a lot of money. And why is it so much? Because this is the engine that their business runs on, and they're making a lot of money and doing a lot of business; 28 million transactions, totaled 12 million, I believe, last year and a couple of billion dollars.
>
> So the number value here is high, not because we're trying to steal from people. It's because of the use they've made of the licensed technology.[10]

Conspicuously absent from this plea is any indication that Soverain was harmed by the alleged infringement. Instead, Soverain relied exclusively on restitutional concepts from *Georgia-Pacific* such as the extent of use of the invention by Newegg and Newegg's profitability. This is typical of damages theories advanced by PAEs, and because *Georgia-Pacific* has overshadowed *Aro* in recent years, these non-compensatory theories are almost universally unchallenged in court.

These improper restitutional damages theories have been wildly successful for PAEs. Statistics show that PAEs "win both larger judgments and larger settlements than do 'practicing entities' – those that practice patents and are not principally in the business of collecting money from others that practice them."[11] According to a recent study by PricewaterhouseCoopers, over the past few years non-practicing entities have obtained, on average, approximately triple the damages awards of practicing entities.[12]

Simply stated, PAEs are obtaining considerably more damages from infringement of their patents than those who actually make and sell technology (and thus stand to lose something from infringement in the market).

Common Law Guidance

When enacting the first reasonable royalty statute in 1946, "Congress's attention was primarily focused on the evils attendant on the recovery of 'profits' rather than on the obstacle in the path of a patent owner seeking a reasonable royalty."[13] The 1946 Act was supposed to simplify and streamline patent litigation by replacing cumbersome profit-apportionment procedures with the ability to prove damages "by any relevant and competent evidence just as they can be proved in an action of tort."[14]

While it is clear that Congress was eliminating profits recovery in favor of

a general compensatory damages statute, Congress assigned no special or restrictive meaning to the term "reasonable royalty" or expressed a belief that such relief was required to be more than nominal. Because the common law formulation of reasonable royalty damages at the time reflected consideration of infringers' profits,[15] it would be wrong to conclude that Congress intended that common law meaning to apply.

Testimony heard by Congress at the time suggested that "[i]n essence, the reasonable royalty approach is more consistent with the general doctrine of damages in other cases."[16] Looking to general common law principles, it is clear that tortious, but harmless, conduct resulted in only nominal damages. At common law, "harm" that justifies compensatory damages "denote[s] the existence of loss or detriment in fact of any kind to a person resulting from any cause."[17] One could not receive compensatory damages for "harm to property" – *e.g.*, a "wrongful taking" – unless there was proof of "pecuniary loss."[18]

As the tort most analogous to patent infringement, it is helpful to consider trespass law in particular.[19] At common law there was no liability for unintentional trespasses, but even reckless or negligent trespasses only gave rise to liability if there was "harm to the land" as a result.[20] If a person went so far as to intentionally trespass, the trespasser would be liable for the tort "irrespective of whether he thereby cause[d] harm to any legally protected interest."[21] The *extent* of such liability was limited to the actual harm done to the property, however.[22]

Thus, a harmless trespass, while still an actionable trespass, only entitled the land owner to recover nominal damages at common law.[23] As one court explained, upon a trespass "[t]he law implies damage to the owner, and in the absence of proof as to the extent of the injury, he is entitled to recover nominal damages."[24]

Like trespass to real property, while patent infringement always constitutes a *legal* harm, it does not necessarily *actually* harm the owner of the property rights. The extent of harm depends on the use to which the property has been put. Crashing one's car onto a vacant lot is harmless compared to crashing the same car into a commercial building erected on the lot. Likewise, while a practicing patentee might lose some enjoyment of the patent due to an infringing competitor's sales (via lost sales and reputation, for example), a PAE has no such interest in market or license exclusivity that can be negatively affected by infringement.

Again, the difference in harm depends on what the patent owner has done with the property (and, importantly, *not* on the identity of the owner of that property). Just as nominal damages are reasonable in trespass cases where "the owner is not substantially injured," they should be a reasonable result where a patentee likewise suffers no substantial injury.[25]

Precedent for this notion of nominal

recovery exists as recently as the *Apple* case noted above, but there are other corollaries within intellectual property law for the idea that not all violations of legal rights come with substantial remedies. For example, trademark infringement may result in nominal damages when the proof of harm is lacking.[26] Likewise, in the injunction context, a patentee must prove irreparable harm resulting from the infringement to obtain such equitable relief.[27]

Returning to Reasonableness

Section 284 is being seriously misread to support overcompensation. Instead of relying on the plain text of § 284 and *Aro* to ensure the damages are compensatory, courts and litigants are relying on *Georgia-Pacific* to enable windfalls under the guise of reasonable royalty damages.

While the *status quo* of PAEs best highlights the problem with the direction damages law has gone post-*Aro*, there are certainly other situations where patentees are not actually harmed by infringement. For all such cases lacking proof of actual harm, nominal damages would be more consistent with Section 284's language, in keeping with Congressional intent, and mandated by *Aro*.

A fresh reading of Section 284 would reaffirm its compensatory nature and discard legal constructs (primarily *Georgia-Pacific*) that restrict the plain meaning of the term "reasonable royalty." Essentially, reasonable royalties arose in the common law where actual harm was demonstrable, but was difficult to quantify. It was not intended to establish a separate form of "damages" disembodied from those that are "adequate to compensate for the infringement" under § 284.

Following the example of the Supreme Court's recent *Octane Fitness* decision (interpreting Section 285's "exceptional case" language),[28] the plain meaning from around the time of the 1946 Act should govern. To wit, a reasonable royalty should simply be a royalty that is "fair" and "sensible," provided that it meets the threshold requirement of being compensatory for actual harm suffered.[29] In appropriate cases where a patentee cannot show that it is somehow worse off due to infringement, nominal damages would constitute a reasonable royalty. ◆

The views expressed in this article, as well as any errors, are solely those of the author and should not be attributed to The Webb Law Firm or its clients. For additional reading on this topic, please see Daniel Harris Brean, *Ending Unreasonable Royalties: Why Nominal Damages are Adequate to Compensate Patent Assertion Entities for Infringement*, 39 Vermont L. Rev. 867 (2015).

FOOTNOTES

1. *See, e.g., Whittemore v. Cutter*, 29 F. Cas. 1123, 1121 (C.C.D. Mass. 1813) ("Every violation of a right imports some damage, and if none other be proved, the law allows a nominal damage."); *Seymour v. McCormick*, 57 U.S. 480, 489-90 (1854) ("Actual damages must be actually proved ...The question is not what speculatively he may have lost, but what actually he did lose.").
2. *See* Restatement (Second) of Torts, §§ 7, 162-

166, 902-906.

3. *See, e.g., Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1574 (Fed. Cir. 1995) (Nies, J., dissenting) ("[a] reasonable royalty is in fact a Congressional largesse for cases where a patentee might otherwise receive only nominal damages. A patentee is now statutorily entitled to a reasonable royalty even though it has not suffered or cannot prove a financial loss to its market in patented goods."); 1-20 Chisum on Patents § 20.07[e][iii][A] (expressing the view that awarding nominal damages for patent infringement "runs contrary to the purpose of the reasonable royalty standard, which is to set a substantial minimum measure of monetary recovery or patent owners whose rights have been violated").

4. 757 F.3d 1286, 1328 (Fed. Cir. 2014).

5. *See generally* Erick S. Lee, *Historical Perspectives on Reasonable Royalty Patent Damages and Current Congressional Efforts for Reform*, 13 UCLA J.L. & Tech. 2, at 3-31 (2009).

6. *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 504-05 (1964).

7. *Id.*

8. *Id.* at 507.

9. 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970).

10. *Soverain Software, LLC v. CDW Corp. et al.*, No. 6:2007-cv-511, ECF No. 395, at 52, 79 (E.D. Tex. May 13, 2010).

11. 34. Mark A. Lemley & A. Douglas Melamed, Missing the Forest for the Trolls, 113 Colum. L. Rev. 2117, 2119–20 (2014).

12. 2014 Patent Litigation Study, Price-WaterhouseCoopers (July 2014), at 2–3, *available at* http://www.pwc.com/en_US/us/forensic-services/publications/assets/2014-patent-litigation-study.pdf ("Our statistics indicate that only 20% of identified decisions in 2013 involved NPE patent holders, reflecting the much higher tendency for NPE-filed cases to settle or be dismissed. However, as further detailed in this year's study, NPEs' median damages award in recent years has been triple that of practicing entities.").

13. *Georgia-Pacific Corp. v. United States Plywood Corp.*, 243 F. Supp. 500, 547 (S.D.N.Y. 1965).

14. Recovery in Patent Infringement Suits, Hearing Before the Committee on Patents on H.R. 5231, 79th Cong., 2nd Sess., at 9 (January 29, 1946).

15. *See, e.g., Dowagiac Mfg. Co. v. Minnesota Moline Plow Co.*, 235 U.S. 641, 648-89 (1915) (holding that absent an established royalty "it was permissible to show the value by proving what would have been a reasonable royalty, considering the nature of the invention, its utility and advantages, and the extent of the use involved").

16. Recovery in Patent Infringement Suits, Hearing Before the Committee on Patents on H.R. 5231, 79th Cong., 2nd Sess., at 20 (January 29, 1946) (testimony of John Stedman of the Department of Justice).

17. Restatement (Second) of Torts, § 7(2).

18. *Id.* § 906(a).

19. *See, e.g., King Instruments Corp. v. Perego*, 65 F.3d 941, 958 (Fed. Cir. 1995) ("The right to exclude is not 'injured' by an infringer, anymore than a landowner's right to exclude is 'injured' by a trespasser. The right to exclude remains enforceable to its fullest. A trespasser can inflict injury only on the property on which the trespass is committed, for example by cutting the trees. Similarly, a patent infringer cannot injure the patent itself, but only property rights protected by the patent, namely, the patentee's exclusive market for patented goods.").

20. Restatement (Second) of Torts, §§ 165-66.

21. *Id.* § 158.

22. *Id.* § 162 ("A trespass on land subjects the trespasser to liability for physical harm to the possessor of the land at the time of the trespass, or to the land or to his things, or to members of his household or to their things, caused by any act done . . . .").

23. *Id.* § 163 cmt. e (discussing the availability of punitive damages "in addition to nominal damages for even a harmless trespass, or in addition to compensatory damages for one which is harmful.").

24. *Pfeiffer v. Grossman*, 15 Ill. 53, 54 (Ill. 1853).

25. *Id.*

26. *See, e.g., Downtowner/Passport International Hotel Corp. v. Norlew, Inc.*, 841 F.2d 214, 220 (8th Cir. 1988) (finding infringement but ordering entry of nominal damages because "any award greater than nominal damages would be based on sheer speculation").

27. *eBay, Inc. v. MercXchange, LLC*, 547 U.S. 388, 391, 394 (2006) (holding that "the decision whether to grant or deny injunctive relief ... must be exercised consistent with traditional principles of equity," which includes consideration of whether the plaintiff "has suffered an irreparable injury" and whether "remedies available at law . . . are inadequate to compensate for that injury").

28. *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1756 (2014).

29. The Pocket Oxford Dictionary of Current English, Oxford University Press, F.G. Fowler & H.W. Fowler (4th Ed. 1946), at 672; The American College Dictionary, Random House, Clarence L. Barnhart (1947), at 1009.

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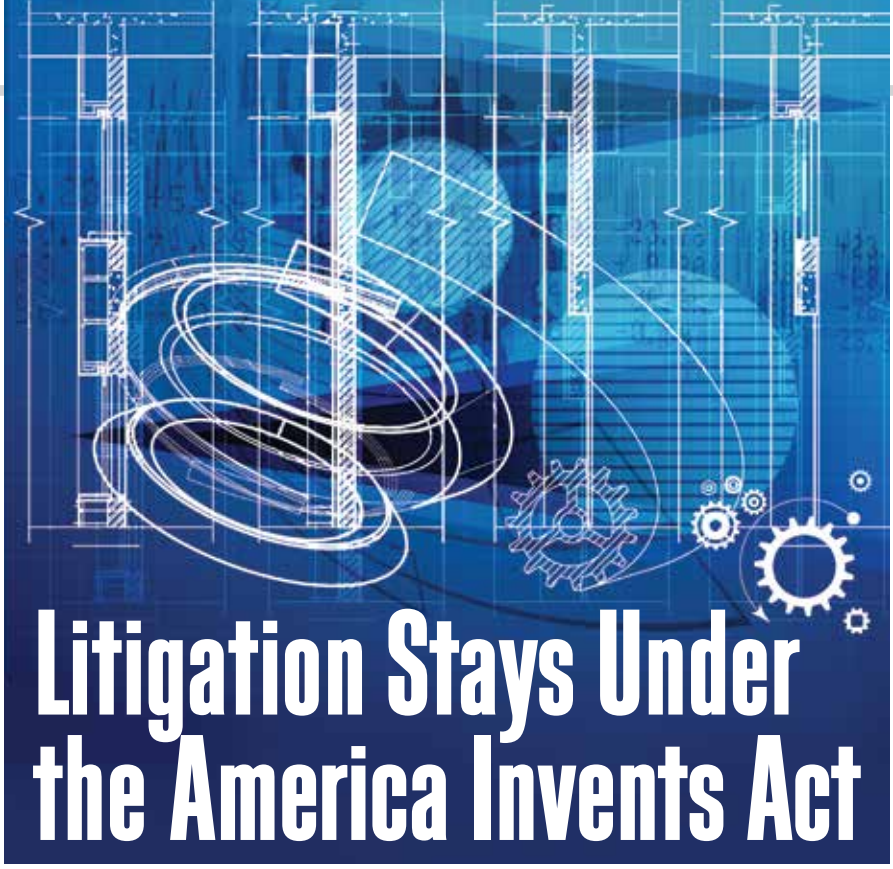

"Staying" Power: Litigation Stays Under the America Invents Act

An analysis of stay rules, motions and results suggests useful strategies for patent challengers and owners.

Between September 16, 2012, when new forms of patent validity review became available at the U.S. Patent and Trademark Office ("USPTO") under the Leahy-Smith America Invents Act ("AIA"), and July 16, 2015, patent challengers filed 3,610 petitions for review at the USPTO.[1]

Many of these petitions challenged patents subject to pending litigation, which accused infringers sought to stay during the USPTO's review. The majority of these stay motions have been successful, particularly where the USPTO has issued an initial decision instituting trial on at least one patent claim by the time of the decision on the stay motion.

The new reality for patent litigation thus often involves the patentee being forced to defend the validity of the patent at the USPTO – frequently against long odds – before pursuing claims for infringement in district court.

This article discusses: (i) the factors courts consider when evaluating stay motions pending AIA review; (ii) how particular districts have decided stay motions, with a focus on how institution of trial on at least one patent claim affects outcome; and (iii) practical tips relating to stays for both patent challengers and patent owners.[2]

USPTO Reviews Under the America Invents Act

The AIA[3] establishes three new types of USPTO review of issued patents:

(1) *Inter partes* review ("IPR");

(2) Post-grant review ("PGR"); and

(3) Covered business method patent review ("CBMPR").[4]

While there are many differences between these three new types of AIA patent review, all three share the same overall framework and strict statutory time limits. For each, a party seeking to challenge the validity of an issued U.S. patent may submit a petition to the USPTO's Patent Trial and Appeal Board ("PTAB") setting forth why particular claims of the patent are invalid.[5] The PTAB is statutorily required to issue an institution decision within six months of the petition's filing.[6]

In the institution decision, the PTAB must determine whether the petitioner has asserted sufficient grounds to institute trial. Once instituted, the PTAB is

statutorily required to issue a final decision within one year.[7]

Thus, by statute, all three types of AIA review must be completed within 18 months of the filing of a petition, with limited exceptions.[8]

District Court Litigation and AIA Patent Review

District courts must frequently determine whether to stay litigation pending the outcome of an AIA review. The AIA recites factors for courts to evaluate whether a stay of district court litigation is appropriate when a patent is subject to CBMPR. Specifically, AIA § 18(b)(1) provides that courts shall decide whether to stay an action pending CBMPR based on:

> (A) whether a stay, or the denial thereof, will simplify the issues in question and streamline the trial;
>
> (B) whether discovery is completed and whether a trial date has been set;
>
> (C) whether a stay, or the denial thereof, would unduly prejudice the nonmoving party or present a clear tactical advantage for the moving party; and
>
> (D) whether a stay, or the denial thereof, will reduce the burden of litigation on the parties and on the court.

As a result of statutory provisions expressly providing for immediate interlocutory appeal to the Federal Circuit for CBMPR stay decisions,[9] the Federal Circuit has provided substantial guidance on how to evaluate these four factors.

The first factor concerns whether a stay will simplify the issues and streamline trial. Although this factor weighs more heavily in favor of a stay when all asserted patent claims and all invalidity defenses in the litigation are undergoing review at the USPTO, a court may stay the case even when the CBMPR does not address all asserted patents, claims or invalidity defenses.[10] There is no categorical rule that all claims be challenged in a CBMPR proceeding for a stay to be warranted.

In addition, when evaluating this factor, it is improper for the district court to reevaluate the merits of PTAB's initial decision, if one exists at the time of the motion. Accordingly, this factor does not weigh against granting a stay where the district court disagrees with the PTAB's institution of trial.[11]

The second factor, "whether discovery is completed and whether a trial date has been set," is evaluated as of the date the motion to stay is filed – not the time of the decision on the stay motion.[12] Discovery and litigation activity that occur between the filing of the stay motion and the date the motion is decided do not weigh against a stay.

The third factor requires courts to examine whether undue prejudice or tactical advantage exists. The types of prejudice asserted by parties and considered by the courts include price erosion, lost market share, direct competition by the alleged infringer, plaintiff's loss of its chosen forum, impact on the ability to license the patent-in-suit, and spoliation considerations such as the possibility of stale evidence, faded memories and lost documents.[13]

The fourth factor calls for consideration of whether the stay would reduce the burden of litigation on the parties and court. This factor "often points in the same direction" as the first, as the stay's potential to simplify the issues and streamline the trial is tied to litigation burden. Nonetheless, at least with respect to CBMPRs, courts must consider this fourth factor separately under the statute.[14]

Unlike CBMPRs, the factors for evaluating stay motions based on pending IPR and PGR proceedings are not codified in the AIA. However, district courts have adopted a similar set of considerations when evaluating these motions, which are based on the same pre-AIA reexamination stay decisions that formed the basis for the codified CBMPR factors.[15] Specifically, the courts usually rely on three factors in the IPR and PGR context: (1) whether discovery is complete and a trial date has been set; (2) whether a stay will simplify the issues in question and trial of the case; and (3) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party.[16]

Role of Motions to Stay Pending AIA Review

For a party sued for patent infringement, seeking PTAB review of the validity of the asserted patent claims via an IPR, PGR or CBMPR may be an attractive option for several reasons:

- The PTAB limits discovery and only evaluates invalidity, making AIA review a less expensive option for challenging validity than district court litigation.
- The PTAB operates under an accelerated 1.5-year schedule from petition to completion.[17]
- The presumption of validity does not apply at the PTAB. Patent challengers must only prove invalidity by a preponderance of the evidence before the PTAB.[18]
- The PTAB construes claims according to their broadest reasonable interpretation, which may make it easier to identify claim features in the prior art.
- The PTAB's historical institution and cancellation rates are favorable to patent challengers. Excluding patent claims subject to dismissal of the petition (*e.g.*, as a result of settlement), the PTAB has cancelled 61.5% of patent claims for which review was instituted.[19] Another 22.5% of claims upon which the PTAB instituted review have been cancelled or disclaimed by the patentee. As of April 30, 2015, just 16% of patent claims subject to AIA review survived. Between September 2012 and March 2014, the percentage of claims surviving review was even lower – less than 5%.[20]

Challenging a patent before the PTAB is particularly attractive where the district court litigation is stayed. Moving the battle to the PTAB puts the patentee on the defensive; the patentee must defend the patent's validity against unfavorable odds before even being permitted to present the case for infringement.

The power dynamic changes somewhat where the district court declines to stay litigation during an AIA review. The parties' dispute then becomes a complicated multi-front war. The accused infringer still will enjoy the advantages of the PTAB's lower burden of proof,

more favorable claim construction and accelerated schedule, but without the efficiencies of a single proceeding with limited discovery and limited issues. Given this dynamic, accused infringers routinely seek stays of district court litigation when pursuing AIA review.

District Courts' Evaluation of Stay Motions

Review of decisions on stay motions in the five district courts with the highest volume of new patent suits indicates the probability of obtaining a stay varies dramatically between districts. The Northern District of California has granted, extended or renewed stays pending AIA proceedings with the greatest frequency – 75.4% of the time.[21] The rates at which the District of Delaware and Central District of California opted to grant, extend or renew stays were similar at 56.9% and 56.0% respectively. The Eastern District of Texas and District of New Jersey were strikingly lower, at 38.5% and 33.3%, respectively.

It should be no surprise that a major factor in whether a court grants a stay pending AIA review is whether the PTAB has instituted trial at the time of the stay decision. In the first 2.5 years of AIA review, courts granted stay motions more frequently when the PTAB had already instituted an AIA review proceeding at the time of the stay. Of the 202 orders reviewed, courts granted, extended or renewed stays 69.5% of the time where the PTAB had instituted trial on at least one claim of one of the patents-in-suit. The rate of grants, extensions and renewals fell to 48.7% absent institution on at least one claim.

In the Eastern District of Texas in particular, the existence of a PTAB institution decision on at least one claim is a near-prerequisite for a successful stay motion. Of the 52 relevant orders reviewed in the Eastern District of Texas, movants were only successful in obtaining a stay 8% of the time where the PTAB had not yet instituted trial on any claim. By contrast, the Eastern District of Texas granted, extended or renewed 66.7% of stay requests where the PTAB had instituted on at least one claim.

Indeed, Judge Bryson, sitting by designation, commented in his decision denying a stay based on a pending IPR petition that "it is the universal practice" in the Eastern District of Texas to deny stay motions where the PTAB has not yet acted on a petition for IPR.[22]

Motions to stay in Delaware and the Northern District of California also have been more successful where the PTAB instituted trial on at least one claim at the time of the decision. Specifically, the District of Delaware granted, renewed or extended stays 51.7% of the time where the PTAB had not instituted trial on any claim and 63.6% of the time where the PTAB had instituted trial on at least one claim – an 11.9% difference. The Northern District of California granted, renewed, or extended stays 71.1% of the time where the PTAB had not instituted trial on any claim and 81.5% of the time where the PTAB had instituted trial on at least one claim – a 10.4% difference.[23]

Interestingly, the Central District of California has granted, extended or renewed stays with greater frequency (61.9%) where the PTAB has not yet instituted trial than when the PTAB has instituted trial at the time of the stay decisions (25.0%).

There are other factors that may influence a court's willingness to grant a stay such as the type of AIA review involved, type of technology, and whether the patent owner is a non-practicing entity. However, the outcome of stay motions in the districts reviewed appears to have been heavily influenced by whether the PTAB instituted trial at the time the stay motion was decided.

Practical Tips for Stay Motions

Pre-Institution Denials Frequently Do Not Foreclose Stays. District courts often deny stay motions *without* prejudice, particularly when stays are sought prior to institution. The motion may be renewed once the PTAB makes it decision, at which time the "balance of factors bearing on the appropriateness of a stay may be very different, and issuance of a stay may be appropriate."[24] An early stay motion, even if denied, may be appropriate to ensure the success of a subsequent post-institution stay motion.

File a Stay Motion Early. Although courts are more likely to grant a stay motion where the PTAB has already instituted trial, stay motions should still be filed early. As noted above, even if the motion is denied due to lack of an institution decision, such denials are frequently issued without prejudice to renewal. Moreover, many of the relevant factors are likely to weigh in favor of a stay where a motion is filed early in the case. For example, the first and fourth of the CBMPR factors, which concern whether a stay will simplify the issues and reduce the burden of litigation, are more likely to point toward a stay early in the case where significant discovery and other litigation activity may be avoided.

Movants are also likely to be best positioned with respect to the second CBMPR factor (whether discovery is completed and a trial date has been set) shortly after suit is filed. As noted previously, this factor is measured at the time of the motion – not the decision. Filing a motion to stay promptly ensures that the case is at the earliest possible stage for purposes of this factor.

An early stay motion also best positions a patent challenger with respect to the third CBMPR factor, whether a stay would unduly prejudice the nonmoving party or present a clear tactical advantage. By filing early, the petitioner minimizes the possibility of delay that may result in lost evidence. Further, an early motion makes it more difficult for the patentee to blame the petitioner for any ensuing delay.

Consider Districts' Practices with Respect to Stays Before Filing Suit. Patent owners should carefully consider the practices of various district courts with respect to stays before deciding where to file suit. The statistics reported here suggest that some courts are less inclined to grant stays pending AIA review than other districts.

Conclusion

Through the AIA's establishment of IPR, PGR and CBMPR, Congress has given accused infringers powerful tools to attack patents as invalid. Accused

infringers opting to petition for review under the AIA frequently call upon the courts to decide whether to stay concurrently pending district court litigation involving the same patents. Notwithstanding the standard factors considered by courts in evaluating these motions, the top five district courts differ in their handling of these motions. ◆

FOOTNOTES

1. USPTO, Patent Trial and Appeal Board AIA Progress Statistics (as of 07/16/2015), http://www.uspto.gov/sites/default/files/documents/aia_statistics_07-16-2015.pdf.

2. The author extends special thanks to James Stephens for his research assistance. James is a 2016 J.D. candidate at Northwestern University School of Law.

3. Pub.L. 112-29, 125 Stat. 284

4. 35 U.S.C. §§ 311-319 (IPR), 321-329 (PGR); AIA § 18 (CBMPR).

5. 35 U.S.C. § 311(a), 325(a); AIA § 18(a)(1).

6. 35 U.S.C. §§ 313, 314(b), 323, 324(b).

7. *Id.* § 316(a)(11), 326(a)(11).

8. ***Id.*** § 316(a)(11); 37 C.F.R. § 42.300(c).

9. AIA § 18(b)(2).

10. *Versata Software, Inc. v. Callidus Software, Inc.*, 771 F.3d 1368, 1372 (Fed. Cir. 2014), *vacated on jurisdictional grounds*, 780 F.3d 1134 (Fed. Cir. 2015).

11. *VirtualAgility Inc. v. Salesforce.com, Inc.*, 759 F.3d 1307, 1313-14 (Fed. Cir. 2014).

12. *Versata*, 771 F.3d at 1373.

13. *E.g., Evolutionary Intelligence, LLC v. Apple, Inc.*, No. C 13-04201 WHA, 2014 WL 93954, at *3 (N.D. Cal. Jan. 9, 2014); *Benefit Funding Sys. LLC v. Advance Am., Cash Advance Centers, Inc.*, No. 12-801-LPS, 2013 WL 3296230 (D. Del. June 28, 2013); *Progressive Cas. Ins. Co. v. Safeco Ins. Co. of Illinois*, No. 1:10-cv-1370, 2013 WL 1662952, at *2 (N.D. Ohio. Apr. 17, 2013).

14. *VirtualAgility*, 759 F.3d at 1313.

15. *Progressive Cas. Ins. Co. v. Safeco Ins. Co. of Illinois*, No. 1:10-cv-1370, 2013 WL 1662952, at *2 (N.D. Ohio. Apr. 17, 2013).

16. NuVasive, Inc. v. Neurovision Med. Prods., No. 15-286, 2015 U.S. Dist. Lexis 85894 (D. Del. June 23, 2015); *Trover Grp., Inc. v. Dedicated Micros USA*, No. 2:13-cv-1047, 2015 U.S. Dist. Lexis 29572 (E.D. Tex. Mar. 11, 2015); *Aylus Networks, Inc. v. Apple, Inc.*, No. C-13-4700, 2014 WL 5809053, at *1 (N.D. Cal. Nov. 6, 2014); *Black Hills Media LLC v. Pioneer Elecs. (USA) Inc.*, No. 14-00471, 2014 WL 4638170, at *5 (C.D. Cal. May 8, 2014).

17. 35 U.S.C. §§ 316(a)(11), 326(a)(11); AIA § 18.

18. 35 U.S.C. §§ 282, 316(e), 326(e).

19. USPTO, *"Inter Partes Review Petitions Terminated to Date (as of 4/30/2015),"* http://www.uspto.gov/sites/default/files/documents/inter_partes_review_petitions_%2004%2030%202015_0.pdf.

20. Rob Sterne & Gene Quinn, PTAB Death Squads: Are All Commercially Viable Patents Invalid?, IPWatchdog (Mar. 24, 2014), available at http://www.ipwatchdog.com/2014/03/24/ptab-death-squads-are-all-commercially-viable-patents-invalid/id=48642/

21. The surveyed districts constitute the top five district courts for new patent cases between August 2014 and May 2015, with the following number of new complaints: Eastern District of Texas (1,475), District of Delaware (531), District of New Jersey (303), Northern District of California (220), and the Central District of California (213). Brian Howard, *Spring 2015 Patent Case Filing Trends*, Lex Machina (June 10. 2015), https://lexmachina.com/spring-2015-patent-case-filing-trends-2/. A search was conducted on Docket Navigator using the following parameters: (1) Type of court document: Motion to Stay Pending Post-Grant Review, OR Motion to Stay Pending Inter Partes Review, OR Motion to Stay Pending CBM Review; (2) Posture of motion: Motion by a Party OR Renewed Motion; (3) Court/Agency: Delaware District, OR New Jersey District, OR California Central District, OR California Northern District, OR Texas Eastern District; and (4) Order filed date: on or after January 1, 2012. The January 1, 2012 date restriction was chosen in order to capture the possibility that some stay motions may have been filed, and possibly even decided, prior to the September 16, 2012 effective date for AIA provisions governing IPR, CBMPR and PGR based on an accused infringer's plans to file a petition upon the AIA taking effect. *See* AIA § 6. Orders. The content of the 202 relevant orders were categorized as either: (i) granting, extending or renewing stay requests; or (ii) denying or lifting stays. Results were tallied based on the number of orders rather than by case. Thus, the E.D. Tex.'s separate orders denying stays in *Smartflash LLC v. Apple, Inc.*, No. 6:13-cv-447, 014 WL 3366661 (E.D. Tex. July 8, 2014) and *Smartflash LLC v. Samsung Elecs. Co.*, No. 6:13-cv-448 (E.D. Tex. May 15, 2014), were counted as two denials. However, the court's subsequent combined order denying stays as to *Apple, Inc.*, and *Samsung Electronics, Inc.*, but granting stays as to Google, Inc., and Amazon.com, Inc. were counted as a single grant, extension or renewal. *See Smartflash LLC v. Apple, Inc. et al.*, No. 6:13-cv-447, 2015 WL 3453343 (E.D. Tex. May 29, 2015). As illustrated by the author's categorization of *Smartflash*, an order was generally categorized as a grant, extension or renewal if the court granted a stay as to any party or any aspect of the litigation. Although the statistics reported here would undoubtedly vary somewhat if results were tallied by case rather than order, the number of affected cases was relatively small and thus the general trends reported should hold true regardless of whether results are tallied by order or case.

22. *Trover Grp., Inc. v. Dedicated Micros USA*, No. 2:13-cv-1047, 2015 WL 106179, at *6 (E.D. Tex. Mar. 11, 2015).

23. The sample set for denials of stay motions in New Jersey and Central District of California was not sufficiently large to draw conclusions about how these denials relate to PTAB institution.

24. *Trover*, 2015 WL106179, at *7.

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Drug Development R&D: New Transaction Structures

As drugs come off patent, biosimilar drugs gain traction, and companies grapple with bringing new drugs to market, creative funding and deal-making take center stage.

Looking at transactions in the pharmaceutical/biotech industry one might reasonably conclude that the book *Getting To Yes* must be generating record sales.[1] Fisher and Ury's book is a perennial top-seller that outlines how a reader can negotiate without giving in. In the pharma/biotech industry, buyers and sellers have been negotiating at a prolific pace, generating transaction activity that has not been seen in a number of years.

Transaction Activity

The statistics are impressive. According to S&P Capital IQ, worldwide merger and acquisition ("M&A") transactions involving targets in the health care sector were valued at $464 billion in 2014, more than double the $193 billion in 2013.[2] Three deals alone accounted for more than 31 percent of the worldwide health care M&A activity in 2014 – two acquisitions by Actavis and one by Medtronic.

Last year was also a record for M&A activity involving an S&P 1500 company as a buyer, seller or target, with almost $300 billion in transactions. That amount exceeded the previous all-time high of $173 billion in 2009 when Pfizer acquired Wyeth.

A review of transactions, however, should not be limited to M&A activity. Licensing activity is equally important, and in fact, equally robust. According to BioPharm Insight, the fourth quarter of 2014 saw the largest dollar volume of licensing agreements in biotech and pharma since 2009, peaking at $13.6 billion in licensing deals.[3]

Industry Challenges

So what is causing all of these transactions? While there is no single explanation, there are a number of challenges currently facing industry players that have helped fuel the growth in transactions. For example, many drugs have come off patent, with competing generics capturing significant market share and eroding industry profits. In 2013, several large drugs (representing $33 billion in revenues) came off patent, including Cymbalta® and Humalog®. In 2014, another 11 major drugs came off patent, with just four drugs accounting for almost $13 billion in worldwide revenues (Copaxone®, OxyContin®, NovoRapid® and Symbicort®).[4] This year rep-

resents another patent cliff, when drugs generating worldwide annual sales of almost $66 billion will come off patent.

In addition, biologic drugs, another class of high-value pharmaceuticals, also face competition due to the introduction of biosimilar drugs, which are similar, but not exact copies, of the biologic drugs. Biosimilars are yet another facet of the competition between branded and generic companies. Like other generic drugs, biosimilars involve a separate FDA approval process despite their similarity to a marketed, FDA-approved, biological product.[5] In March 2015, the first biosimilar, Zarxio®, was approved by the FDA.[6] Thus, after a great deal of discussion and speculation as to when the technical and regulatory hurdles would be overcome, biosimilars have hit the market, and pose a new competitive challenge similar to that already posed by other generic pharmaceuticals.

Industry players are also facing increased pressure from payors and regulators, with greater focus on drug pricing. While drugs represent only a small proportion of overall healthcare costs, the high profitability of pharmaceutical companies creates a target for healthcare payors trying to reduce costs.

Perhaps most importantly, large industry players are faced with narrowing product pipelines. While there has been a sizeable drop in money spent on research and development ("R&D") as a percentage of revenue since the early 1990s, the real culprit of narrowing pipelines has been the increased cost of bringing a drug to market. For example, between 2004 and 2013 the estimated cost of bringing a new chemical or biological product to market more than trebled from $451 million to $1.5 billion. As opposed to the long and costly process of bringing a drug to market, M&A activity provides an opportunity for large pharmaceutical companies to increase their pipeline instantaneously.

Besides industry challenges, the need for (and availability of) cash also drives transactions in the pharma/biotech space as much as, if not more, than in other industries. Small companies often have only one product in development and simply do not generate sufficient cash to fund the necessary R&D expenses, particularly as their product moves toward launch. While the IPO market has become a more serious consideration for many small pharmaceutical firms to raise capital, licensing and M&A transactions still remain a fertile ground for obtaining the capital necessary to carry a drug through the end of development.

Complementing the need for capital is the availability of cash, which many of the larger drug companies have available. In fact, some companies have been generating enough cash to begin paying dividends, as Gilead Sciences, Inc. did beginning in 2015, alongside dividends paid by Amgen, Inc., and GlaxoSmithKline plc. This availability of cash coupled with the need for cash by smaller drug companies looking to develop a single drug creates a strong environment for M&A transactions.

Types of Transactions

As the number of transactions has increased, so too has transaction complexity. With more opportunities available, it is only reasonable that buyers would allocate resources to differentiating good from bad opportunities, and to identifying ways to reduce the risk of good opportunities. Specifically, buyers are realizing that there are alternatives to a straight-forward sale that can help align incentives and reduce risk.

Companies, for example, are using "contingent consideration" transactions in the pharma/biotech space with greater frequency. These types of transactions, often termed "complex" deal structures, typically provide for payment from a buyer to a seller over time if certain milestones or thresholds are met, such as success in clinical development and regulatory approval or achievement of revenue targets.

These types of deal structures can help create a performance incentive for the sellers that might not exist if they only received a large, up-front payment.

The types of deals themselves are also varied. For example, transaction activity includes traditional mergers and acquisitions, venture capital transactions, licensing deals, asset swaps, and option-to-buy transactions. The last example, option-to-buy transactions, has become more prevalent in the last five years. The buyer provides funding for the target's research efforts in exchange for an option to acquire the assets at a pre-negotiated price in the future. These transactions can focus on a single asset or they can be outright purchases of the whole company. For example in June 2011, Genentech, Inc., acquired from Forma Therapeutics, Inc., the option to buy the rights to an early-stage cancer drug in exchange for financing the research and development costs. In addition to the purchase price, Forma would receive milestone payments contingent on meeting sales goals, but would not receive any royalties for the drug.[7]

Option-to-buy transactions can address key concerns specific to buyers and sellers in the pharma/biotech industry. For example, early-stage biotech companies have a need for liquidity, while large pharmaceutical companies are understandably wary of acquiring high-risk projects. Option-to-buy transactions enable larger pharmaceutical companies to acquire smaller biotech firms at a less risky stage in their life cycle, while the biotech firms receive the financing required to navigate the more risky stages. A drawback of these types of deals involving a venture capital firm is that the firm may realize a lower overall return if they exit through an option-to-buy transaction.

There also has been an uptick in R&D collaboration agreements in the pharma/biotech industry. Instead of an outright sale, smaller companies are increasingly pursuing these agreements to reduce their own risk and generate value for shareholders more quickly. A simple example helps illustrate the benefits of such collaborations.

First, consider a pre-revenue company focusing on developing one product that is entering phase I. Using common benchmarks, the drug has only a 9% chance of launch:

- 63% chance of completing Phase I

- 33% chance of completing Phase II, assuming Phase I success
- 55% chance of completing Phase III, assuming Phase II success
- 90% chance of FDA approval assuming Phase III success

The cost of each phase increases rapidly as the drug moves forward in development. If Phase I costs $15 million, Phase II can be three times as much. Phase III can cost eight to ten times as much as Phase I for a typical product, and the costs can be significantly higher in some cases. Table 1 (see below) shows the NPV of the product at various points in its development. In each case, there is no recovery of any investment until the product launches.

An alternative strategy to going-it-alone would be for the company to find a partner. For example, assume the company strikes a 50:50 sharing agreement in exchange for an up-front payment. As shown in Table 2 (see below), in this simplified case, the company is able to reduce costs and risk without giving up any value. The company receives an immediate return on investment with the up-front payment and can pursue the costlier stages at a lower cost. In this example, the company is able to recover its full investment no matter the final outcome if it partners prior to Phase III.

Of course, in exchange for the reduced risk, the company would need to give up some value. However, in exchange for giving up value, the company receives access to resources and expertise that may not otherwise be available. The outside capital could enhance the likelihood that the company's product succeeds, resulting in a higher net present value for both partners.

While this example focuses on the smaller partner, the structure offers significant advantages for the larger partner. A collaboration agreement may allow for more limited investment in the product than an outright purchase, enabling the larger partner to pursue multiple collaborations. These collaborations work for both sides, because the smaller partner is looking to reduce the risk of a single asset while the larger partner may be looking to reduce the risk of a portfolio of assets.

Two acquisitions by public companies help illustrate how these types of deals can differ when the risks and uncertainties around the acquired assets are different. In April 2012, Jazz Pharmaceuticals plc acquired EUSA Pharma, Inc.[8] EUSA's lead product, Erwinaze®, had received FDA approval six months prior to the transaction. The deal structure included a large up-front payment and a smaller milestone payment (10% of total value) tied to 2013 sales, reflecting market acceptance as a key uncertainty surrounding deal value.

In contrast, Zogeneix, Inc., acquired Brabant Pharma Limited in late 2014.[9] At the time of the deal, Brabant's lead product was in development and expected to enter Phase III clinical trials in the next six to nine months. The deal terms included a smaller up-front payment with larger milestone payments worth potentially up to 2.7x the up-front payment. In this second example, the key risk for the partners was whether the product would reach the market. Thus, a majority of the consideration was tied to launch of the product.

Valuation Issues

All companies have growth and business strategy objectives. In considering different paths for achieving these objectives, it is common to begin with a broad perspective and value a wide range of potential paths. While virtually every market participant has both internal paths (*e.g.*, through organic growth) and external paths (*e.g.*, through transactions), a broad perspective can provide a rationale for a transaction strategy and help focus the pursuit of collaboration partners. Understanding value is critical to deciding upon, negotiating and executing any transactions, including, for example, an R&D collaboration agreement as discussed above.

In considering potential targets, a valuation model can help identify, screen and prioritize opportunities. To support this stage of the process, the model should be kept lean and high-level, capturing key drivers of value and risk, while maintaining overall consistency with the approach that will be used in evaluating a specific transaction. Ultimately, a discounted cash flow ("DCF") model is typically used to help price and negotiate a "live" transaction. At the

TABLE 1: Go-it-Alone Strategy

Stage	NPV (millions)	R&D Cost Incurred to Date (millions)	Remaining R&D Cost to Bring to Market (millions)	Probability of Recovering All R&D Cost (Launch Required)
Pre-Phase I	$6	$0	$180	9.1%
Pre-Phase II	$32	$15	$165	14.5%
Pre-Phase III	$238	$55	$125	44.0%

TABLE 2: Collaboration Strategy

Stage	NPV (millions)	R&D Cost Incurred to Date (millions)	Remaining R&D Cost to Bring to Market (millions)	Probability of Recovering All R&D Cost (Launch Required)
Pre-Phase I	$6 ($3 upfront)	$0	$90	9.1%
Pre-Phase II	$32 ($16 upfront)	$15	$82.5	14.5%
Pre-Phase III	$238 ($119 upfront)	$55	$62.5	100.0%

screening stage, a simplified DCF can be useful in considering whether to pursue an opportunity further, or to compare one opportunity against another.

If a large number of opportunities are being considered, it may be overwhelming to develop many DCFs. In such instances, a simpler approach may be useful, such as a scoring matrix that captures the main elements of a DCF analysis, including potential revenue growth, incremental cost and probability of successful product launch.

Prior to negotiating and closing a specific transaction, a robust valuation model typically supports the pricing of the deal, understanding and addressing purchase accounting and tax issues, negotiating contingent consideration and other deal terms, and preparing for post-deal execution. When the deal closes, the valuation model facilitates communication with stakeholders and supports financial reporting activities, issuance and valuation of equity, and ongoing tracking of progress against the execution plan.

R&D collaboration agreements offer other complexities. So how might someone value such an agreement? Ideally, one would look for the prices paid for similar transactions, such as the up-front, milestones and royalties in prior announced transactions, or the price paid for outright acquisition of a similar R&D program or product platform. From those reference points, one might infer a "market value" for the collaboration.

It is rarely easy to find comparable transactions, however, and often the reported pricing information and terms of the deal are incomplete. Even with good information, valuing R&D collaboration agreements often involves applying probability assessments against the contingent elements such as milestones and royalties, and making adjustments for differences between these transactions and the collaboration being valued.

Given the challenges with this "Market Approach," a second method, the "Cost Approach," is sometimes considered, which values an asset based on what has been spent to create it or how much would need to be spent to recreate it. In an R&D collaboration in which a partner receives rights to intellectual property ("IP") in exchange for an up-front payment, R&D funding and potential milestones and royalties, the value of the IP should equal at least what the partner would pay to avoid the cost to create the IP from scratch.

Here, too, challenges exist. It may be difficult to identify relevant historical costs, particularly where the IP is part of a broader effort or where there were false starts. Estimating the cost to replace the IP may be equally difficult. More importantly, the value of the IP may be substantially greater than the cost to create it, due to potential profitability and the strategic value of faster product development, reduced R&D

risks and other factors.

A third approach, the "Income Approach," overcomes many of the challenges mentioned above by valuing the collaboration based on projected incremental cash flows. Given the uncertainties inherent in an R&D collaboration and the future revenues that may result, multiple scenarios are considered (*e.g.*, depending upon R&D and regulatory outcomes and levels of commercial success), which are weighted by their corresponding likelihoods of occurrence. The resulting probability-weighted or "expected" cash flow is then present-valued by applying a discount rate that reflects the riskiness of the expected cash flow.

The Income Approach is typically the best practice when valuing R&D collaboration arrangements as it applies a robust and transparent methodology that ties the value specifically to the potential cash flows that may result and the likelihood of such results.

Examples

Two examples illustrate how Income Approach valuation models can be used. In one example, a small pharmaceutical company entered into four licensing agreements for various compounds in development and needed to value these agreements for financial reporting purposes and to value their privately held equity shares. The agreements included payments contingent upon achieving certain developmental milestones, regulatory milestones, sales milestones and sales (*i.e.* royalties).

The clinical development path for one of the products was contingent upon the outcome of the trials for another of the compounds. The valuation models captured these flexible development options for the various compounds. The value of each of the company's classes of equity shares was estimated under each of the potential future cash flow scenarios driven by clinical and regulatory outcomes, with the scenario results then probability-weighted to estimate the overall value of each share class.

In another example, a small biotech was planning to restructure once their key asset, an oncology drug undergoing Phase II trials, was sold. Potential tax consequences from the restructuring placed significant constraints on the terms of the sale of the asset. The proposed terms included payments contingent upon achievement of certain developmental, regulatory and sales milestones. Valuation models were used to explore the tax implications of the potential deal. In this case, the structure of the final deal was guided by tax considerations that resulted in decisions to shift payments between up-front cash and contingent milestones.

In both examples, risk had a crucial impact on value. Indeed, risk has a crucial impact on most valuations, whether risks involve pre-clinical uncertainties around the number of viable candidates, the developmental risks around success and product profile, regulatory approval risks, launch timing or post-launch commercial success risks. To quantify these risks, best practice is to apply an Income Approach that utilizes observable inputs such as industry benchmarks or company experience.

Within the pharmaceutical industry there are many sources of data against which to benchmark key assumptions and probability assessments for R&D timing, cost, success rates, regulatory approval and timing, market sizing, peak share, uptake rates, price/share erosion, sales and marketing expense, and other factors. Critical review of benchmarks is essential. For example, in ascertaining the probability of Phase I, II and III clinical trial success, one can consider success rates reported by multiple studies and results that are specific to a given therapeutic area, in-licensed vs. self-originated products, small molecule vs. large molecule products, and other relevant subsets.

Ultimately, even when benchmarks are available, judgment may be needed regarding which benchmark is most relevant, whether to aggregate several benchmarks, when to adjust from a certain benchmark given the specifics of the program being valued, or whether there is simply no reasonable benchmark. When obtaining probabilities and other inputs, a formal assessment process can help ensure that the assumptions used are accurate and defensible.

Critically, the individual providing the assessment must be the right "expert," have sufficient motivation (*e.g.*, by demonstrating that the valuation is sensitive to the assumption), be permitted to provide assessments in a way that overcomes biases (*e.g.*, through training, providing benchmarks, and playing "devil's advocate"), and not be overwhelmed by being asked for too broad an assessment (*e.g.*, assess price and peak market share separately instead of assessing peak revenues at once).

Conclusion

As this article goes to the publisher, additional transactions in the pharma/biotech industry continue to be announced. More and more industry participants are "getting to yes" and closing the deal. Indeed, it is not clear when, or even if, the activity will subside. The industry challenges discussed above do not appear to be short-term, nor do they appear to be avoidable. As a result, it is likely that we will see more and more creative transactions, aligning the interests of buyers and sellers alike, and posing interesting and complex valuation issues. Fortunately, that is what makes working in the pharma/biotech industry so interesting. ◆

FOOTNOTES

1. Roger Fisher, William Ury and Bruce Patton, *Getting to Yes: Negotiating Agreement Without Giving In*, May 2011 (Penguin Books).
2. S&P Capital IQ, Biotechnology, March 26, 2015.
3. BioPharm Insight, Licensing Activity Report 1Q15.
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Adam W. Poff

Changes On the Horizon for Trade Secret Misappropriation

Proposed federal legislation will add protections beyond current state laws and potentially alter the role of state courts.

Trade secrets are the only major type of intellectual property not civilly protected by federal law. That, however, may be about to change. Bills creating a new federal cause of action for trade secret misappropriation were introduced in 2014 in both chambers of Congress. While neither passed – the Senate bill (the "Defend Trade Secrets Act of 2014") stalled in the Judiciary Committee, while the House version (the "Trade Secrets Protection Act of 2014") made it out of the Judiciary Committee, but did not receive a full House vote – both bills received wide bipartisan support with no major opposition and were reintroduced this year.

Today, the Uniform Trade Secret Act (UTSA) is the only civil enforcement mechanism for trade secret owners, and because it differs from state to state, trade secret owners have difficulty instituting nationwide non-disclosure policies and cannot protect their trade secrets in the federal courts. One of the goals of federal trade secret legislation is to provide uniformity by bringing trade secrets into line with the other types of intellectual property already protected by federal statute (*e.g.*, patents, copyrights, trademarks and trade dress), thus providing both a consistent standard for non-disclosure policies and access to the federal courts.

If and when the proposed federal legislation becomes law (and most believe it is just a matter of time), the role of state courts, including Delaware's courts, in the development of trade secret jurisprudence will likely change dramatically.

Delaware State Courts: A Long History of Trade Secret Misappropriation Cases

In 1979, the Uniform Law Commission drafted the UTSA,[1] which was subsequently adopted, in whole or in part, by almost every state. However, Delaware state courts were deciding significant trade secret cases and developing substantive trade secret law long before the UTSA was enacted. In the 1950s, the Delaware Court of Chancery recognized that certain patterns and drawings "constituted know-how of the type that the law treats as a prop-

erty right" and enjoined the defendant from using them.[2]

The next decade saw the extension of these protections to the employee/employer relationship. For example, in *E. I. duPont de Nemours & Co. v. Am. Potash & Chem. Corp.*, the employer sought a temporary restraining order and preliminary injunction to stop a former employee from disclosing its trade secrets and "undertaking any employment" that related to the manufacturing process comprising the plaintiff's trade secrets.[3] The Court of Chancery did so, notwithstanding that there was no covenant not to compete.

The 1970s marked the beginning of the rise of computer technologies. In one case, the Court of Chancery permanently enjoined a defendant from using drawings that disclosed the design for the plaintiff's "compacted minicomputer[ ]."[4] In doing so, the court rejected the defendant's argument that the minicomputer was reverse engineered, finding instead that the defendant had relied upon plaintiff's design drawings.

Over the next two decades, the increasing sophistication of computer and chemical technologies led to a number of significant trade secret decisions in Delaware. In *Bunnell Plastics, Inc. v. Gamble*,[5] the court granted a permanent injunction against a former employee who signed a non-compete agreement which demanded he not disclose "any confidential information or any other material related to the business or operation of [the plaintiff corporation]." Despite this agreement, the defendant disclosed information regarding a chemical coating for pulp and paper rollers to a company he founded. The court upheld the non-compete agreement and enjoined the defendant's use of plaintiff's trade secrets for two years, finding that the covenant to protect the trade secrets was reasonable with regard to time, geography and subject matter.

In another case, *Technicon Data Systems Corp. v. Curtis 1000 Inc.*,[6] the court preliminarily enjoined the defendant corporation from misappropriating the plaintiff's claimed trade secrets related to its product – the "Medical Information System" – a computerized system that stored, transmitted and displayed hospital data.

In 1994, the Court of Chancery decided *Miles Inc. v. Cookson America, Inc.*,[7] a case that illustrated the court's ability to fashion specific and significant equitable remedies to protect trade secrets. The defendant corporation hired several of the plaintiff's ex-employees and misappropriated many of the plaintiff's trade secrets regarding processes to manufacture "high performance pigments." The court found that several of the pigment processes were "inextricably connected" to the "defendant's manufacture" of the high performance pigment and issued production injunctions with regard to these pigment processes.

The production injunctions, one of which lasted three years, prohibited the defendant from manufacturing the high performance pigment related to the misappropriated pigment process, even if the defendant was able to discover a legally permissible pigment process to manufacture the high performance pigment during the period of the injunctions.

In 1999, the Court of Chancery granted injunctive relief in *Merck & Co., Inc. v. SmithKline Beecham Pharmaceutical Co.*,[8] finding that the defendants misappropriated the plaintiff's trade secrets regarding a "process for producing a vaccine to prevent varicella (commonly known as chicken pox)." In fashioning a remedy, the court noted that "the development of a commercial process" typically "takes many years," and in this case, the defendant gained "a time advantage of three to five years as a result of its misappropriation." Accordingly, the court enjoined the defendant "from marketing its varicella vaccine in the United States or Canada for a period of three years from the date it receive[d] approval to market its vaccine in those countries."

More recently, the Delaware Superior Court and the Court of Chancery have issued several significant trade secret decisions. In 2002, the Superior Court of Delaware held that a doctor misappropriated trade secrets when he improperly solicited patients from his former employer using the former employer's protected "super bills," which were written compilations of patient data.[9]

In a 2006 case, *W.L. Gore & Associates, Inc. v. Wu*,[10] the Court of Chancery granted additional injunctive relief to the plaintiffs, supplementing the permanent injunction to which the defendant had already consented. Specifically, the court enjoined the defendant, a former scientist-employee of plaintiff, from working with any polymers with which he worked during his employment for 10 years, and also enjoined him from working with any "TFE-containing polymers" for a period of five years. The court relied on the defendant's "lack of trustworthiness and the likelihood of inevitable disclosure" in reaching its determination. A few years later, the court held the defendant, Wu, in contempt of court for failing to abide by the terms of that injunction and ordered him to pay a "fine of $5,000 per day" until he demonstrated compliance with the injunction.[11]

In 2010, in *Agilent Technologies, Inc., v. Kirkland*,[12] the Court of Chancery found that three defendants, each a former employee of the plaintiff, had improperly taken plaintiff's trade secrets with them to their new employer. The trade secrets related to technologies used to create "particles and solvents for use in reversed phase high performance liquid chromatography columns." In addition to awarding more than $4.5 million for unjust enrichment and lost profits, the court granted injunctive relief requiring, *inter alia:* (1) the return of all property of plaintiff, including any "copies or records" derived therefrom; (2) a prohibition against conducting research on or disclosing the trade secrets; and (3) the withdrawal of pending patent applications that dealt with the misappropriated technology.

Unquestionably, Delaware state courts have had a significant impact on

the development of trade secret law. Whether Delaware's courts continue to have such an impact will be determined, in large part, by how the federal trade secret legislation on the horizon ultimately fares.

A Potential Federal Trade Secret Misappropriation Law

The proposed federal trade secret legislation does not differ significantly from the Delaware Uniform Trade Secret Act (DUTSA) or the decisional law discussed above with respect to the requirements for trade secret protection and the acts that would constitute misappropriation.[13]

The proposed legislation would, however, remake the procedural landscape. To start, the proposed federal legislation would create original federal jurisdiction, but would not preempt state trade secret claims. Trade secret owners would therefore have to choose between pursuing a misappropriation action in state court, based solely on state law, or in federal court, based on federal law or a combination of federal and state law. That may be a difficult choice, given several key differences between the proposed federal legislation and the current trade secret laws in most states, including Delaware, which are largely based on the Uniform Trade Secret Act.

Like most states, the DUTSA has a three-year statute of limitations. The proposed federal legislation has a five-year statute of limitations, creating a two-year window when only a federal claim could be asserted by a trade secret owner.

The proposed federal legislation also provides for punitive damages for willful and malicious misappropriation of up to three times actual damages, whereas the UTSA limits punitive damages to two times actual damages.

However, the most controversial provision of the proposed federal legislation provides for the *ex parte* seizure of property "necessary to preserve evidence" or to "prevent dissemination of the trade secret," if the trade secret owner can show "clearly … from specified facts" that: (1) injunctive relief under Federal Rule of Civil Procedure 65 is inadequate; (2) the plaintiff will suffer "immediate and irreparable injury"; (3) the harm to the plaintiff outweighs the harm to both the defendant and any third parties who may be affected by the order; (4) the plaintiff is likely to show both misappropriation and that the defendant is in possession of the trade secret; (5) a particular description of the subject of the seizure and its location; (6) the defendant would move, hide or destroy the materials if notice were provided; and (7) the plaintiff has not "publicized" the requested seizure.

The proposed legislation does provide for some constraints on the breadth of an *ex parte* seizure order. For instance, a court may limit any *ex parte* order by minimizing disruption to the defendant, issuing specific legal and factual findings, holding a hearing within seven days, and requiring that the plaintiff post an appropriate bond. Further, a court may protect the defendant from "publicity" relating to the seizure order "by or at the behest of the person obtaining the order." And, if the defendant is somehow damaged by the seizure order, the defendant can recover lost profits, loss of good will, punitive damages and reasonable attorney's fees through a cause of action for a "wrongful or excessive seizure."

Perhaps the most distinguishing feature of the proposed federal legislation when compared to the UTSA are provisions addressing the theft of trade secrets occurring abroad. Not surprisingly, U.S. companies doing business abroad and multinational companies are increasingly concerned with protecting their intellectual property. Under the proposed federal legislation, within one year of the enactment of the legislation, and biannually thereafter, the Attorney General shall submit to the House and Senate Judiciary Committees a report addressing, among other things, the scope and breadth of trade secret thefts occurring outside the U.S.; whether those thefts are being sponsored by foreign governments or other foreign instrumentalities; the economic threat posed by such thefts; the status of foreign trade secret laws or other protections available to U.S. and multinational companies; the ability and limitations of trade secret owners to prevent the misappropriation of their trade secrets outside the U.S. and to enforce any judgment against foreign entities for theft of trade secrets; and a recommendation of additional actions that could be taken by the legislative and executive branches of the federal government to further protect the trade secrets of U.S. and multinational companies doing business abroad.

These reporting requirements, if enacted into federal law, are seen by some as a crucial, first step in addressing foreign misappropriation in the U.S. courts.

Criticisms of Proposed Federal Trade Secret Misappropriation Legislation

Critics of the proposed federal trade secret legislation argue that an effective and uniform body of trade secret law already exists and, therefore, a federal law is unnecessary.[14] However, a federal trade secret statute likely would not alter the substantive law of trade secrets. Rather, a federal statute would only enhance the protective procedures available to a trade secret owner *(e.g.*, seizure orders, longer statute of limitations, increased punitive damages cap, additional protection for companies doing business abroad). Proponents of a federal trade secret law argue that any fear of inconsistency between state and federal law is overstated.

Critics of the proposed federal legislation also point to the *ex parte* seizure provision, arguing, among other things, that the provision is unnecessary because litigants already can request preliminary relief in trade secret cases, that *ex parte* seizure orders will be granted too frequently, thereby causing defendants undue harm, and that it will be difficult for a trade secret owner to show that the preliminary relief available under Rule 65(b) of the Federal Rules of Civil Procedure is inadequate and, therefore, the rem-

edy of *ex parte* seizure is superfluous. They also argue that the "protection from publicity" requirement is unclear and necessitates a level of secrecy about court rulings that is unprecedented.

Supporters of the proposed legislation respond that such concerns are unfounded, given that similar seizure provisions already exist in other federal statutes directed at protecting trademark owners from counterfeit use of their registered marks. Moreover, as detailed above, the procedures for obtaining an *ex parte* seizure order are far more onerous than the requirements for obtaining a temporary restraining order.

Perhaps most importantly, the *ex parte* seizure order is a remedy of last cause. Courts are often reluctant to grant such relief in the trademark area, and typically only do so when injunctive relief is insufficient. And, in the event a seizure order is wrongfully obtained, punitive damages would be available to remedy any harm to the defendant.

Critics of the proposed federal legislation also argue that it could be used for anti-competitive purposes, in that injunctions granted under a federal trade secret law would not be limited to the lead time advantage of the party accused of misappropriation. Such interminable injunctions could impede fair competition, employee mobility and innovation.

Proponents of the legislation counter that judges are better situated to determine the appropriate length of an injunction in any particular case, and that setting the duration of injunctions by statute would restrict that flexibility in a negative way.

Accidental disclosure of trade secrets is another concern espoused by critics of the legislation. They argue that a federal trade secret statute would give rise to more challenges to subject matter jurisdiction. That, in turn, would require earlier disclosure of the trade secrets in dispute in order to establish their existence and a jurisdictional basis. In trade secret actions in state courts, plaintiffs frequently delay identifying and disclosing the alleged trade secrets to avoid the risks inherent in the exchange of confidential information. Critics contend that the proposed federal legislation would enable defendants to demand earlier disclosure of the alleged trade secrets, resulting in a greater risk of inadvertent disclosure.

Supporters of the federal legislation view the disclosure issue differently. Avoidance of inadvertent disclosure is a reason plaintiffs delay identifying alleged trade secrets, but it may not be the most significant reason. Indeed, a plaintiff may obtain a strategic advantage by delaying the identification of the alleged trade secrets until after it has taken discovery of the defendant and, presumably, learned more about what proprietary information the defendant may be using.

Some courts view this delay by plaintiffs as prejudicial to defendants, and require earlier identification of alleged trade secrets to level the playing field. Accordingly, proponents of the proposed federal legislation argue that earlier identification of alleged trade secrets will happen regardless of any increase in challenges to subject matter jurisdiction.

How Federal Trade Secret Misappropriation Law Will Impact State Courts

New trade secret bills were introduced in both the House and the Senate in July 2015. Those bills are substantially similar to the trade secret bills introduced in 2014. Given the broad bipartisan support and lack of significant opposition to those 2014 trade secret bills, passage of a federal trade secret statute in 2015 is a realistic possibility, if not a probability. If and when that occurs, the part played by state courts in the development of trade secret law may change dramatically.

Multiple factors, including the appeal of truly uniform trade secret and misappropriation standards, a longer statute of limitations, the ability to obtain higher punitive damages and the *ex parte* seizure procedure, will create a strong incentive for plaintiffs to file trade secret misappropriation claims in the federal courts.

As a result, the role of state courts – including the important role played by the Delaware state courts to date – in the development of substantive trade secret law may change significantly in the very near future. ◆

FOOTNOTES

1. *See generally* Unif. Trade Secrets Act (amended 1985), 14 U.L.A. 437, *et seq.* (1979).
2. *Gronemeyer v. Hunter Mfg. Corp.*, 106 A.2d 519 (Del. Ch. 1954).
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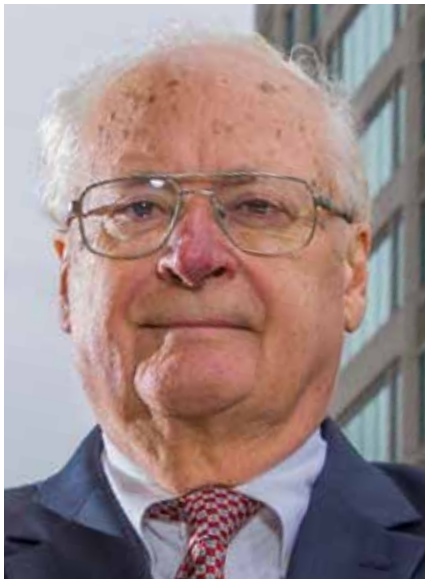
6. C.A. No. 7644, 1984 Del. Ch. LEXIS 588 (Del. Ch. Aug. 21, 1984).
7. C.A. No. 12,310, 1994 Del. Ch. LEXIS 221 (Del. Ch. Nov. 7, 1994).
8. C.A. No. 15443-NC, 1999 Del. Ch. LEXIS 242 (Del. Ch. Aug. 5, 1999).
9. *Total Care Physicians, P.A. v. O'Hara*, C.A. No. 99C-11-201, 2002 Del. Super. LEXIS 493 (Del. Super. Ct. Oct. 29, 2002).
10. C.A. No. 263-N, 2006 Del. Ch. LEXIS 176 (Del. Ch. Sept. 15, 2006).
11. *W.L. Gore & Associates, Inc. v. Wu*, C.A. No. 7964, at 5 (Del. Ch. Nov. 2, 2012).
12. C.A. No. 3512-VCS, 2010 Del. Ch. LEXIS 34 (Del. Ch. Feb. 18, 2010).
13. Unless stated otherwise, references to the potential or new federal law refer to a new law in the form of the Defend Trade Secret Act of 2014, H.R. 5233.
14. Criticisms of the proposed federal law come mainly from the "Professors' Letter in Opposition to the 'Defend Trade Secrets Act of 2014' (S. 2267) and the 'Trade Secrets Protection Act of 2014' (H.R. 5233)."

Patricia Smink Rogowski

OF COUNSEL: Rudolf E. Hutz

Delaware's most celebrated and accomplished patent attorney for a generation, Rudolf E. Hutz is a model to all lawyers for his advocacy, focus, integrity, mentoring and civility under pressure.



BobCraigPhoto

With his J.D. from Georgetown Law Center, and a degree from Princeton University, Rudy initially worked as a patent examiner, examining patents for firefighting chemicals and gasoline additives. In private practice, Rudy specialized in intellectual property, mainly patent law, with his father, Werner Hutz, and with Arthur G. Connolly in Wilmington.

In 1980, Rudy argued and won an important patent case before the United States Supreme Court. That victory upheld as lawful Rohm and Haas's licensing program for Propanil, an herbicide used to inhibit weeds from growing in rice crops, and established an important exception to the antitrust laws for control of unpatented products under contributory infringement standards. That year, the partnership honored Rudy by adding "Hutz" to the firm name to form Connolly Bove Lodge & Hutz.

In 1980, the Supreme Court issued opinions in only two patent cases. Rudy instantly was propelled to rock star status as a patent litigator. Rudy's client list became the Who's Who of Fortune 500 companies, including Pfizer, Scott Paper, Steelcase, FMC, Ethyl, Albemarle, Bayer AG and Henkel KGaA. Directors of major companies sought and continue to seek Rudy's counsel.

In 1990, Rudy and a team from Connolly Bove again represented Rohm and Haas, this time in a case against Rhone-Poulenc and Mobil Oil. Each side had its own patents covering the active chemical of a very successful herbicide to kill weeds in soybean crops. This highly contested case turned on proofs of who invented what and when. Rohm and Haas's two patents were upheld as valid and infringed, while all three of Mobil's patents were held invalid. After Judge Latchum's decision was affirmed on appeal, the President of Rohm and Haas wrote to Rudy with thanks, calling the case "the largest legal victory" in the company's 50-year history.

For many years, Pfizer relied on Rudy and a team from Connolly Bove to sue companies seeking to introduce generic versions of Pfizer's patented drug Lipitor. Those victories maintained Pfizer's exclusivity through the full term of the patents, which meant billions of dollars to Pfizer.

There are so many reasons that clients put their trust in Rudy. He personifies the qualities to which great attorneys should aspire. First, he is smart, really smart. And he remembers the details that matter. His cross-examinations of technical and expert witnesses in complex cases are legendary.

Second, he is trustworthy. Colleagues and clients seek out and gratefully accept Rudy's counsel on patent and law practice matters, not just because he has a lot of experience, but also because he has excellent judgment. He has never been afraid to tell a partner or a client "no" when circumstances warrant. That takes a lot of guts, and it earns much respect. When the answer is "no," however, he also does his best to find an alternative path to "yes," which is a hallmark of a great counselor.

Third, he is genuine. When I asked Rudy to share a favorite case, he immediately recounted *Scott Paper v. Moore Business Forms.* Scott Paper acquired its patent from independent inventor, Chester Davis, who had taught chemistry at MIT until he went deaf. Davis moved to his mother's house, and continued to tinker with chemistry in the attic. There, he invented an essential agent for carbonless carbon paper that he patented. After winning the case for Scott Paper (and Dr. Davis), Rudy was so pleased that one-half of the significant recovery was shared with Davis. And Davis, who had been living essentially in poverty, immediately gave a very large sum to his old high school to improve its chemistry labs. A personal triumph for the little guy in which Rudy took great pleasure, too.

Finally, he is tough but kind. Many of us learned how to practice law, really how to be better lawyers, working with Rudy. He ripped apart our first drafts with color-coded comments. He met with us following a deposition or a court day to go over what we had done well (and not so well). His critiques could hurt, but he was always fair. Through the years, he has mentored many successful attorneys who now serve as judges, managing partners and patent examiners.

He leads by example, showing civility and courtesy to all, especially to adversaries. His kindness perhaps has surprised young attorneys the most, who sometimes begin practice wrongly believing that litigation is "war" and scorched earth is the best recipe to success. Rudy shows us a better way. ◆

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