

KELLY CASEY MULLALLY, GREGORY CASTANIAS &amp; FRANKLIN E. GIBBS\*

*MedImmune v. Genentech*

LAWRENCE SUNG: Moderating our second panel this morning is Professor Kelly Casey Mullally, Assistant Professor of Law here at the law school. Professor Casey Mullally received her B.S. in chemistry with highest honors from Georgia Tech and her J.D. *summa cum laude* from the University of Georgia School of Law, where she graduated first in her class and served on the Georgia Law Review.

Following law school, Professor Casey Mullally clerked for Judge J.L. Edmondson of the U.S. Court of Appeals for the Eleventh Circuit as well as Judge William C. Bryson of the U.S. Court of Appeals for the Federal Circuit. She is a registered patent attorney and practiced law with the firm of Finnegan, Henderson, Farabow, Garrett & Dunner, and while at Finnegan she specialized in appellate litigation of intellectual property matters. Before joining us here at the University of Maryland, she was a visiting professor at the University of Georgia School of Law where she taught patent law and international intellectual property.

KELLY CASEY MULLALLY: Thank you, Professor Sung. Thank you everyone for being here today. Welcome back for everyone who is rejoining us from the break and welcome to anyone who is just now coming in to the conference. As Professor Sung mentioned earlier, this conference is very much intended to generate broad-ranging discussions about important developments in intellectual property law. Our scope is not going to be limited in any way, but we will focus in particular on the Supreme Court's recent decision in *MedImmune v. Genentech*,<sup>1</sup> decided in January of last year. This case is very much a part of the trend that we have noted, the trend away from any kind of patent law exceptionalism.<sup>2</sup> I am going to give a brief

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\* The annotations included in the footnotes are not the views of the individual speakers, but are provided for the reader's knowledge. The remarks were edited for clarity and readability.

1. 549 U.S. 118 (2007); see also Lawrence M. Sung, *In the Wake of Reinvigorated U.S. Supreme Court Activity in Patent Appeals*, 4 J. BUS. & TECH. L. 97, 109 (2009) (discussing the factual background, Court's reasoning, and holding in *MedImmune*).

2. The term "exceptionalism" indicates that courts treat the subject differently. Minutes from a Convention of the Federalist Society, *Intellectual Property: American Exceptionalism or International Harmonization?*, 3 N.Y.U. J.L. & LIBERTY 448, 478-79 (2008). An example of exceptionalism in patent law would be a court withholding antitrust liability because "'one of the parties owned a patent,' and that 'by their nature, patents create an environment of exclusion, and consequently, cripple competition.'" C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1601 (2006) (arguing that patent exceptionalism is grounded in provisions of the Patent Act itself). Rationales for antitrust patent exceptionalism have ranged from a monopolistic right inherent to a valid patent to a statutory right extended by the Patent Act, which eclipses antitrust interests as expressed in the Sherman Act. *Id.* at 1600-01.

sketch of the facts before introducing our speakers, who will give you more detail and start off our discussion.

The case involved a license agreement between Genentech, the patentee, and MedImmune, negotiated in 1997, that covered an issued patent and a then-pending patent application. MedImmune agreed, pursuant to the license, to pay royalties on sales of licensed products. In 2001, the application that had been pending at the time the license agreement was reached was issued, at which time Genentech notified MedImmune that it believed that one of MedImmune's products, a high revenue earner for the company, fell within the scope of this second patent.

MedImmune disagreed that it owed the royalties under the second patent, and rather than expose itself to treble damages, attorneys' fees, and the threat of being enjoined from producing one of its most profitable products, it continued to pay royalties pursuant to the license agreement and sought a declaratory judgment action, challenging the validity and infringement of its product. The issue ultimately went to the Supreme Court, which had to resolve the question of whether or not MedImmune, without repudiating its license, could establish the existence of an Article III case or controversy.<sup>3</sup> The Court answered that question in the affirmative.

To discuss this case and its impact in more detail, and to lend the perspective of those actually dealing with the issue on behalf of a wide variety of clients, the effects of this decision and the other cases, we are really fortunate to have with us two experienced lawyers in private practice, Greg Castanias and Gene Gibbs.

Greg is a partner at Jones Day in Washington, DC, and is a member of that firm's Issues and Appeals and Intellectual Property group. He coordinates the firm's Federal Circuit and IP appeals practice. He has appeared in over seventy-five cases in the Federal Circuit where he has argued over a dozen appeals for clients such as DirecTV, Boston Scientific, and MathWorks. He has argued numerous other non-IP appeals in the federal appellate courts and three in the U.S. Supreme Court. Mr. Castanias is the co-author of a newly published West Nutshell, *Federal Appellate Practice and Procedure*,<sup>4</sup> and he has written and spoken widely on matters pertaining to appellate litigation and intellectual property. He graduated *summa cum laude* from the Indiana University-Bloomington School of Law in 1990 and *summa cum laude* from Wabash College in 1987. He also serves as an adjunct professor of law at the Indiana University-Bloomington School of Law.

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Critics of patent exceptionalism question why holders of intellectual property, having rights equal to holders of tangible property, face reduced scrutiny of monopolistic behavior. *Id.* at 1604.

3. In *MedImmune*, Justice Scalia, relying on *Altwater v. Freeman*, 319 U.S. 359 (1943), ruled that the licensee, MedImmune, was entitled to declaratory relief under the coercive circumstances of the case, and he stated that MedImmune's continuing royalty payments did not preclude it from challenging the patent's validity. *MedImmune*, 549 U.S. at 131.

4. GREGORY A. CASTANIAS & ROBERT H. KLONOFF, *FEDERAL APPELLATE PRACTICE AND PROCEDURE IN A NUTSHELL* (2008).

We are also joined by Mr. Gene Gibbs, who is from the firm of Wang, Hartmann, Gibbs & Cauley, joining us from Newport Beach, California. He is a registered patent attorney with the U.S. Patent and Trademark Office. His practice includes patent prosecution and litigation. He has advised numerous corporate clients on the development and implementation of intellectual property policies and procedures that include the identification and trademarking of trade secrets. His clients range from individual inventors to multi-million dollar aerospace companies in complex license negotiations with entities such as NASA.

We are very pleased to have you both with us today. Thank you.

GREGORY CASTANIAS: Thank you very much, Professor Casey Mullally and Professor Sung. This is just a great conference and I have just been amazed at the hospitality and the interest level that I have seen at this law school.

Let me start with a disclaimer: I practice law. I represent plaintiffs and defendants in patent litigation, among other things that I do. What you hear today are my views only; they are not to be attributed to Jones Day, they are not to be attributed to any of my clients—unless it is particularly helpful to one of them. But, that is the standard disclaimer that goes along with talking about these things while also practicing in the public space like I do.

I would like to address a couple of things that Thomas Woolston said. The first is to thank him for noting the value of the generalist to intellectual property litigation. I am, despite the claims of seventy-five cases in the Federal Circuit and all this patent litigation experience, a generalist. And that, I think, colors some of the themes that Professor Casey Mullally just mentioned, including that the Supreme Court keeps reminding patent lawyers that patent law is patent *law*, not *patent* law. The Supreme Court also keeps reminding us that they are still supreme.

Now, despite the fact that I have promised to talk about *MedImmune*, I would like to begin by continuing to talk about *eBay*.<sup>5</sup> I think that you have heard a very powerful argument, or set of arguments, in the first panel about why the *eBay* decision is terrible. Whether I agree with that or not, I will make some of the contrary arguments that I think were not made in the earlier session.

First of all, the old rule that is referred to is a Federal Circuit created rule and that rule said, “If you win a judgment of infringement of a patent, you are almost conclusively entitled to an injunction following that verdict.” Well, if you step back and take the emphasis off of the *patent* and go to the *law* part of it, this is not the way injunctions get adjudicated in every other space in the law. There is a long-standing, traditional, four factor equitable test<sup>6</sup> and what you can read the *eBay*

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5. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

6. An injunction is an equitable remedy, which courts use to “protect property rights against injuries otherwise irreparable.” *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982) (quoting *Cavanaugh v. Looney*, 248 U.S. 453, 456 (1919)). Congress may enact legislation which controls the court’s discretion. *Id.* at 313. However, “[n]othing in the Patent Act indicates that Congress intended” to control the courts’ discretion in relation to patent law. *eBay*, 547 U.S. at 391–92.

decision to say is that patent cases are just like every other case that we see in the courts. Namely, if you are going to resort to equity, you are going to have to meet the four factors of the long-standing, traditional equitable test: irreparable harm, you balance the harms, you look to the public interest, and so forth.<sup>7</sup> And that, the Court said, in the—to be fair—terse majority opinion by Justice Thomas, was not consistent with an almost conclusively presumptive rule that you always get an injunction.

Now, the argument that was made primarily by the MercExchange side and a lot of *amici*, including Scott, is that a patent is a property right, but it is a sort of special kind of property right. It has one right of the bundle of rights that is paramount above all others—it has the right to exclude. A U.S. patent does not give the holder any rights to make, or use, or sell, or offer to sell, or import anything. That document only gives the holder the right to exclude *others* from the space defined by the patent. So, for example, if I have a patent for carrot cake, that patent does not give me a right to make a carrot cake, any kind of carrot cake. It only allows me to exclude others from making that particular type of carrot cake, as it is defined by the patent.

Now, the argument for automatic or almost automatic injunctions in patent cases is, the patent holder cannot have an effective right to exclude if he or she cannot go to the court and get an order to exclude all others. That is a strong argument, but there is another argument that I want to make. A violation of any right can be compensated in at least a couple of ways. It can be stopped by an injunction, or compensated by money. In some cases, money compensation is better, fairer, and more equitable for all concerned.<sup>8</sup> To me, that is what the *eBay* case said.

Even in real property we heard the example of kicking somebody out of a living room. That is a famous and widely-used closing argument, which is, “They came

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7. The four factor test adopted by the court was set forth in *Virginia Petroleum Jobbers Association v. Federal Power Commission*, 259 F.2d 921, 925 (D.C. Cir. 1958). *Croskey St. Concerned Citizens v. Romney*, 459 F.2d 109, 111–12 (3d Cir. 1972). The test has been adopted in many different types of disputes in the last fifty years. See, e.g., *MicroStrategy Inc. v. Motorola, Inc.*, 245 F.3d 335, 339 (4th Cir. 2001) (agreeing with the district court’s application of the four factor test in the context of a trademark dispute); Klitzman, Klitzman and Gallagher v. Krut, 744 F.2d 955, 958–59 (3d Cir. 1984) (using the four factor test to find that a law firm’s requested preliminary injunction for the return of documents seized by the government must be granted); *A. O. Smith Corp. v. FTC*, 530 F.2d 515, 525 (3d Cir. 1976) (applying the four factor test in the context of industry pre-enforcement actions against the Federal Trade Commission).

8. See David L. Applegate, *A Mark, a Yen, a Buck, or a Pound: Damages Make the World Go Round*, PAT. LITIG. 2008, Sept.–Nov. 2008, at 473, 511 (arguing that in some cases, such as when a patent holder irrationally refuses to license an important medication, a money damages remedy, which is, in effect, a compulsory license, would be more equitable than an injunction). However, in practice, the balance of equities is never as clear as in this example, and courts have tended toward categorically-based tests for whether injunctions will be granted. *Id.* In post-*eBay* decisions, patent holders who have manufactured their own inventions have generally received injunctive relief, while patent holders who have only licensed their patents have received money damages. *Id.* at 512. Where a patent covers only a component of a larger product, courts more often granted injunctive relief where the patented element was central to the whole product. *Id.* at 513.

in, they took my property, they camped out in my living room, they are watching my TV, and they are raiding my refrigerator. How do you feel about that, jury?" That is a powerful argument, but it is not exactly accurate because with patents, unlike with real property, I do not have the right to use that property in the sense that though I hold a patent, I do not have the right to make that carrot cake, because there might be another patent covering that process. A patent does not grant any right other than the right to exclude. And so, even in real property, you have a seemingly absolute right to exclude others from your property. You could compensate also for a violation of that right. You can compensate for that by paying for an easement<sup>9</sup> or even in the case of a constitutional taking, with just compensation.<sup>10</sup> Which leads us to the question of what is just compensation? What ought to be the default rules for the marketplace?

Now, Professor Beckerman-Rodau, Professor Kieff, and Mr. Woolston all made powerful arguments that this rule of *eBay* really diminished value. And it did diminish value for a patent holder, but only insofar as you are measuring the change in value between what a patent holder got under the old law, where he or she could have an automatic exclusion when he or she got a judgment of infringement, and the new law under *eBay*. All the Court is doing, so the argument would go, is altering the baseline rules in a way that is a course correction, taking the specialized patent-law rule that grew up out of the Federal Circuit with automatic injunctions,

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9. "An easement is an interest in property that confers on its holder an enforceable right to use another's property for a specific purpose." *Burlison v. United States*, 533 F.3d 419, 426 (6th Cir. 2008) (quoting *Bradley v. McLeod*, 984 S.W.2d 929, 934 (Tenn. Ct. App. 1998)). Easements are of two kinds: in-gross and appurtenant. *Fruth Farms, Ltd., v. Vill. of Holgate*, 442 F. Supp. 2d 470, 475 (N.D. Ohio 2006). An easement in-gross is assigned to a person, while an appurtenant easement runs with the land and may be transferred and assigned. *Id.* Easements may be created in many ways, including by "express grant, reservation, implication, prescription, estoppel, and eminent domain." *Burlison*, 533 F.3d at 426. In *Burlison*, a landowner sought to quiet title to an access road over a federal wildlife refuge. *Id.* at 440. The court found that the landowner possessed an easement by reservation on which the federal government could exercise reasonable limitations. *Id.* In *Fruth Farms*, the court held, in part, that a municipality's use of an express easement on a private landowner's property for a sewage treatment plant was consistent with the language of the easement which provided for construction of a sewage line. *Fruth Farms*, 442 F. Supp. 2d at 477–78; *see also* *Modern, Inc. v. Florida*, 444 F. Supp. 2d 1234, 1240–41, 1243 (M.D. Fla. 2006) (holding that, where the federal government blocked landowners' drainage ditches, the landowners had not received an easement through dedication, an implied easement, or a common law flow easement).

10. A constitutional taking involves loss of private property rights due to government "intrusion, interference or encroachment . . ." *Fla. E. Coast Props., Inc. v. Metro Dade County*, 572 F.2d 1108, 1111 (5th Cir. 1978). Under the Takings Clause of the Fifth Amendment, constitutional takings deprive private property of virtually all beneficial use. *Devines v. Maier*, 665 F.2d 138, 146–47 (7th Cir. 1981). "The Takings Clause of the Fifth Amendment of the United States Constitution states that 'private property [shall not] be taken for public use, without just compensation.'" *Huntleigh USA Corp. v. United States*, 525 F.3d 1370, 1377 (Fed. Cir. 2008) (quoting U.S. CONST. amend. V). The Takings Clause prevents "[g]overnment from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole." *Id.* (internal citations and quotation marks omitted). Courts use "a two-part test for determining whether 'fairness and justice' require compensation for burdens imposed by a particular governmental action." *Id.* Courts determine whether a property owner is due just compensation by asking (1) whether the property owner had a valid property interest at the time of the taking, and (2) "whether the governmental action at issue amounted to a compensable taking of that property interest." *Id.* at 1377–78 (internal citations and quotation marks omitted).

and bringing it back to ordinary equitable principles of injunctive relief. If that is the baseline rule, then it is unfortunate that at the beginning of the litigation, MercExchange had a potential giant windfall from getting a patent-infringement verdict. But, it is not illegal or unconscionable; it is just bringing the law back to where it should have been in the first place.<sup>11</sup> Likewise, there is an argument that under the Federal Circuit's rule of automatic injunctions, the old rule of automatic injunctions, there was a systematic overvaluing of patent property.<sup>12</sup>

The question is, where do you start? Where is your baseline? I think the answer is now, and our baseline is where we currently are after *eBay*. Patents are still valuable property—they still have an exclusionary right attached to them, in appropriate circumstances there are going to be injunctions, but in other circumstances there will be some other form of compensation. Tom Woolston also mentioned a case where I was the defense lawyer. It was a case called *Finisar v. DirecTV Group, Inc.*<sup>13</sup> and I represented the DirecTV Group defendants. Along with a number of my partners, I argued an injunction motion in the court in the Eastern District of Texas. The court imposed a compulsory royalty system<sup>14</sup> in lieu of an injunction,

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11. In *eBay*, the Supreme Court held that courts must use discretion in granting equitable relief consistently and cannot apply a specialized standard when considering patent disputes. 547 U.S. at 394. Chief Justice Roberts concluded that, although injunctions have often been granted in cases of patent infringement, the presumptive injunction rule used by the Federal Circuit was unsupported by the history of equitable relief in general and in the context of patent disputes. *Id.* at 395 (Roberts, C.J., concurring). Justice Kennedy explained that the four factor rule comports with precedent which used the presumptive rule, because those cases present a pattern that “simply illustrates the result of the four-factor test in the contexts then prevalent.” *Id.* at 396 (Kennedy, J., concurring). Kennedy further stated that district courts have the flexibility, under the Patent Act, to “determine whether past practice fits the circumstances of the cases before them.” *Id.* at 397.

12. Justice Kennedy's concurrence in *eBay* suggests that in some cases, the purposes of patent law will be better served by the imposition of a compulsory license than an injunction. Keith E. Broyles & William Hubbard, *Repelling Patent Trolls After eBay*, INTELL. PROP. & TECH. L.J., Sept. 2006, at 5, 8. Where an injunction has been granted, a patent holder may force the infringing manufacturer to pay licensing fees which far exceed the actual value of the patent. *Id.* In such cases, the injunction allows the patent holder to receive a substantial windfall. *Id.* Thus, judicially prescribed royalty damages, which often suffer from large margins of error, may prove a better estimation of the actual value of the patented invention. *Id.* The larger the windfall which the patent holder stands to receive, the greater the balance of interests weighs against the granting of an injunction, because windfalls do not advance technology. *Id.* at 9.

13. 523 F.3d 1323 (Fed. Cir. 2008). *Finisar* involved a patented invention concerning the transmission of audio-visual content by satellite or cable. *Id.* at 1326. A jury found that DirecTV had infringed Finisar's patent. *Id.* The district court, rejecting Finisar's request for an injunction, imposed a compulsory license and \$25 million in damages. *Id.* On appeal, the Federal Circuit vacated the district court's infringement verdict, because the court below had misconstrued an important term in a patent claim and had misinterpreted the prior art. The Federal Circuit remanded the case for a new trial concerning the issues of patent infringement and patent validity. *Id.* Thus the grant of a compulsory license was also vacated. *Id.* at 1339. (Speaker's note: the Federal Circuit handed down this decision at the moment this symposium was occurring.)

14. A compulsory royalty, or compulsory license, is “an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the state.” Brian T. Liberis, *Compulsory Licensing and the TRIPS Agreement: A Solution to High Drug Prices in the United States?*, 28 SUFFOLK TRANSNAT'L L. REV. 57, 65 (2004) (quoting Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 IDEA 349, 349 (1993)). A compulsory royalty system “allows a generic manufacturer to legally produce patented goods against the will of the patent holder” in return for a royalty paid by the manufacturer to the patent holder. *Id.* at 65–66. Some critics argue that compulsory licenses reduce the incentive to innovate. *Id.* at 66.

noting in particular that EchoStar, which is the DISH TV network, and DirecTV, once tried to merge, but the antitrust authorities stopped the merger. Judge Clark was quite appropriately concerned in that case with the question of, “What happens if I, by patent law fiat, create a monopoly where the antitrust authorities said there should not be one?” That is a public interest factor.<sup>15</sup> I think it is fair to say that under the previous regime under the Federal Circuit of almost automatic injunctions, that argument would not have carried the day. But it did in the *Finisar* case, which came just after *eBay* was decided. I think that Tom Woolston, the most passionate and the most personally invested of those who do not like the *eBay* decision, said that the court in the Eastern District of Texas got it right.

Now, why did I start there? Was it just to be fair? Was it just to defend my own client’s faith? No. I wanted to use that as a jumping-off point for talking a little bit more about how *MedImmune* came to us and how it fits into a broader context of a discussion that has been going on between the United States Court of Appeals for the Federal Circuit and the United States Supreme Court. Presumably, most of you know a little bit about what the Federal Circuit is—we heard some about it today. It was created in 1982, by the Federal Courts Improvement Act,<sup>16</sup> signed by Presi-

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The district court in *Finisar* ordered DirecTV to pay Finistar \$1.60 per “set top box” activated by DirecTV for the remaining life of the patent. Final Judgment at 1–2, *Finisar Corp. v. DirecTV Group, Inc.*, No. 1:05-CV-264, 2006 WL 2037617 (E.D. Tex. July 7, 2006). The parties could agree to “more comprehensive or convenient terms,” so long as they notify the court, which retained jurisdiction over the royalty system. *Id.* at 2.

15. Because the word “monopoly” implies “the giving of an exclusive privilege for buying, selling, working or using a thing which the public freely enjoyed prior to the grant” of the monopoly, the inference is that something is taken away from the people. *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186 (1933). Thus, if monopoly conditions exist, there is evidence that public interests are affected. Arnold B. Kanter & Stephen D. Sugarman, *British Antitrust Response to the American Business Invasion*, 22 STAN. L. REV. 433, 466 (1970). For example, nineteen references were made to the Monopolies Commission between 1960 and 1968, and “[i]n 11 of the 15 matters the Commission found a monopoly that in some way was operating against the public interest.” *Id.* at 465–66. Ambiguity is a natural result because the word “monopoly” is used in different contexts in patent and antitrust law. Simone A. Rose, *Patent “Monopolyphobia”: A Means of Extinguishing the Fountainhead?*, 49 CASE W. RES. L. REV. 509, 526 (1999). The term also evokes negative reactions that cloud an objective analysis of patent law matters because of its antitrust connotations and association with illegality. *Id.* This ambiguity has created confusion with the courts as the chances of patents being held invalid and negatively impacting patent filings are increased, which in turn can inhibit technological innovation and growth that impacts the public. *See id.* at 527.

16. In 1979, the Senate Judiciary Subcommittee on Improvements in Judicial Machinery was charged with two tasks: to relieve the caseload burden on the federal appellate system and to achieve uniformity in difficult areas of the law, like patents and taxes. Dennis DeConcini, *The Federal Courts Improvement Act of 1982: A Legislative Overview*, 14 GEO. MASON U. L. REV. 529, 529 (1992). These practice areas were of particular interest because the law was difficult to ascertain and often varied from circuit to circuit, creating an inefficient process and increased litigation. *Id.* at 529–30. Indeed, it appeared that the scattered court system itself contributed to the problems, as there was no single court that could provide definitive statements of the law. *Id.* at 531–32. The Supreme Court would have been the logical choice as the ultimate voice in these types of cases, but a significant backlog of cases rendered this nearly impossible. *See id.* at 531. With the goal of efficiency in mind, the Federal Courts Improvement Act of 1982 was passed. The Act helped address the critical issues facing the Subcommittee by consolidating the Court of Customs and Patent Appeals and the Court of Claims and creating the Court of Appeals for the Federal Circuit and the United States Claims Court. *See id.* at 529–30. The Federal Circuit would help to alleviate the caseload burden confronting appeals courts, create uniformity in nebulous areas of the law, and remain deferential to the Supreme Court. *Id.* at 532–33.

dent Reagan, but pushed in bipartisan manner. Why did it come to be that all patent appeals went to this special court? Well before the Federal Circuit existed, patent infringement and validity challenges in ordinary district court litigation went to the regional circuits, just like every other kind of case. The problem was that there were some circuits that were so hostile to patents, that the lore was that certain circuits had not even upheld the validity of a patent for many years. So, patents were basically of no worth in certain circuits. This created all sorts of incentives for declaratory-judgment plaintiffs to bring their suits in the appropriate circuits, so that they could get their patent validity challenge heard by the circuit that hates patents. That hatred of patents that cropped up in several circuits was really the result of a hostility to patents that the Supreme Court showed in the 1930s and 1940s on the heels of an overall distrust of monopolies in general, and the vigorous enactment and enforcement of antitrust laws. This is why a lot of people who spend a lot more time thinking about these issues than I do, do not like using the term “patent monopoly,”<sup>17</sup> because a patent’s right is not a monopoly right; it is a right to exclude.

Now, very quickly, what has happened in the Supreme Court with these Federal Circuit patent cases since 1982? Well, in another article that I and three of my partners wrote last year in the *American University Law Review*,<sup>18</sup> we identified three waves in the history of Supreme Court review of Federal Circuit patent decisions. The first one, from 1982 to 1994, was effectively a hands-off period: “We created the specialized court, they are going to harmonize patent law, and we are going to let them do it.” The interventions were modest and around the edges. The

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17. A “patent monopoly” is a phrase that has generally become accepted without argument. See Giles S. Rich, *Are Letters Patent Grants of Monopoly?*, 15 W. NEW ENG. L. REV. 239, 239 (1993). But the term “monopoly” usually carries with it negative connotations. See *id.* at 251. Thus, marrying the words “patent” and “monopoly” automatically confers upon patents the same prejudice associated with monopolies, resulting in distaste for the term by many. See *id.* at 239. Some schools of thought have put forth the idea that patents and monopolies are intertwined and that this mix can be conducive to both the public good as well as provide a benefit to inventors. See *id.* at 240. Others have argued the opposite viewpoint—that patents and monopolies are mutually exclusive. See *id.* The root of the disagreement lies in the notion that a monopoly takes away something of value from the public while a patent simply grants someone a right of exclusion. *Dubilier*, 289 U.S. at 186. Courts have occasionally wavered on which interpretation to follow, but generally speaking, the Federal Circuit has taken the stance that the phrase “patent monopoly” is unacceptable because it implies disapproval. See Rich, *supra*, at 252; *Schenck v. Nortron Corp.*, 713 F.2d 782, 786 n.3 (Fed. Cir. 1983).

18. Gregory A. Castanias et al., *Survey of the Federal Circuit’s Patent Law Decisions in 2006: A New Chapter in the Ongoing Dialogue with the Supreme Court*, 56 AM. U. L. REV. 793 (2007). From 1982 to 1994, the Supreme Court took a largely hands-off approach to patent law cases, letting the Federal Circuit decide a number of patent issues and only intervening periodically. See *id.* at 800. During the next seven years, from 1995 to 2002, the Court reviewed a number of cases that touched upon the biggest issues in patent litigation. *Id.* at 802. Although more aggressive in granting certiorari to cases, the Court stood by many of the Federal Circuit’s decisions. See *id.* at 802–03. Then, starting in 2002, the Court’s approach to the Federal Circuit’s rulings appeared to change. See *id.* at 808. The Court began actively reviewing the decisions of the Federal Circuit, and its fidelity to the lower court’s rulings was replaced by stern language and an enhanced interest in patent law matters. See *id.* at 809; see also Sung, *supra* note 1, at 99 (discussing the Supreme Court’s changing approach to patent appeals).



first case to get the Court on the merits was *Christianson against Colt*.<sup>19</sup> It was fundamental—it had to do with whether the case was properly appealed to the Federal Circuit. What happens when you have a case that has a patent issue sort of buried in one of the claims? The answer was, if the well-pleaded complaint says there is a claim arising under the patent law and you go to the Federal Circuit on your appeal and if the complaint does not, you go to the regional circuit. This comes up not infrequently when a patent-law issue becomes an essential part of a claim, but you are not actually bringing a patent-law claim. Those cases have to go to the Federal Circuit if a patent-law issue is a fundamental part of the claim being asserted. Other cases, like *Eli Lilly against Medtronic*,<sup>20</sup> involve the interpretation of a particular section of the patent laws dealing with medical devices: narrow, around the edges sort of things.

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19. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800 (1988). Colt Industries holds patents for the M16 and requires others to agree to a nondisclosure agreement when manufacturing M16 parts and accessories. *Id.* at 804. Christianson was a former Colt employee who agreed to such an agreement. *Id.* Christianson later formed his own company and began selling M16 parts to third parties. *Id.* at 804. Christianson brought an action in the U.S. District Court for the Central District of Illinois against Colt for damages, injunctive and equitable relief, violations of antitrust laws, and tortious interference with business relations. *Id.* at 805.

The district court agreed with Christianson's contention that Colt's patents were invalid from their inception for failure to meet certain statutory requirements, and granted Christianson's motion for summary judgment, holding that (1) nine of Colt's expired M16 patents were invalidated from their inception, and (2) all of Colt's trade secrets regarding the M16 were void and unenforceable. *Id.* at 806. Colt appealed to the Federal Circuit, which concluded that it lacked jurisdiction and transferred the appeal to the U.S. Court of Appeals for the Seventh Circuit. *Id.* The Seventh Circuit concluded the Federal Circuit had been wrong in transferring the case and transferred it back. *Id.* On retransfer, the Federal Circuit reversed the district court's grant of summary judgment. *Id.* at 807.

On certiorari, the Supreme Court held that the Federal Circuit did not have jurisdiction because a patent law issue was not necessary to the overall success of either claim. *Id.* at 809. The Court also held that antitrust claims against Colt did not "arise under" patent law. *Id.* at 815. In addition, the Court decided that the Federal Circuit was not obliged to adopt the Seventh Circuit's analysis of the jurisdictional issue because "the law of the case was that the Seventh Circuit had jurisdiction, and it was the Seventh Circuit, not the Federal Circuit, that departed from the law of the case;" once the Federal Circuit "concluded that the prior decision was 'clearly wrong' it was obliged to decline jurisdiction." *Id.* at 817.

20. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990). In 1983, "the predecessor-in-interest of . . . Eli Lilly & Co. filed an [infringement] action against . . . Medtronic Inc., in the United States District Court for the Eastern District of Pennsylvania to enjoin [their] testing and marketing of an implantable cardiac defibrillator . . ." *Id.* at 664. Medtronic argued that its activities were "reasonably related to the development and submission of information under" the Federal Food, Drug, and Cosmetic Act ("FDCA"), and were thus exempt. *Id.* The district court rejected Medtronic's "argument, concluding that the exemption does not apply to the development and submission of information relating to medical devices." *Id.*

On appeal, the Federal Circuit reversed and remanded, holding that Medtronic's actions could not constitute infringement if those actions were intended to develop information reasonably related to the development and submission of information necessary to obtain approval under FDCA regulations. *Id.*

The Supreme Court granted certiorari and affirmed the Federal Circuit's ruling. *Id.* at 664, 679. The Court held that Medtronic's use of the inventions to develop and submit information for marketing approval of medical devices under the FDCA was not infringement because, even though the text is not "plainly comprehensible on anyone's view," the provision more naturally reads as the Federal Circuit determined when the structure of the Drug Price Competition and Patent Term Restoration Act of 1984 is taken as a whole. *Id.* at 669. The Court felt that to construe the statutory provision differently would take a "good deal of legislative imprecision" and "an implausible substantive intent as well." *Id.* at 679.

The second wave—lasting from 1994 to 2002—shows the Court as a little bit more aggressive, but only on the biggest issues. This is when the Supreme Court decides cases like *Markman*.<sup>21</sup> Can a jury get a claim-construction dispute?<sup>22</sup> Is that compelled by the Seventh Amendment cases like *Warner-Jenkinson*?<sup>23</sup> Should there

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21. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). Markman owned the patent to a clothes-tracking system that aided in the dry-cleaning process by generating transaction records and bar codes readable by optical detectors. *Id.* at 374. Westview's product used a similar data processor and listed dry-cleaning charges on bar codes as well. *Id.* Markman brought an infringement action and the jury found that Westview's product had infringed Markman's patent. *Id.* at 374–75. However, the district court directed a verdict for Westview on the ground that its device was unable to track “inventory” as that term was used in the claim. *Id.* at 375. The Federal Circuit affirmed, holding that the interpretation of the claim was the exclusive province of the court. *Id.* at 376.

The Supreme Court granted certiorari and affirmed, holding that the construction of a patent, including terms of art within its claim, was exclusively within the province of the court and rejecting the notion that a jury could determine the meaning of any disputed term of art subject to a Seventh Amendment guarantee. *Id.* at 391. The Court reasoned that “judges, not juries, are the better suited” to decipher the meanings of patent terms, as “[t]he construction of written instruments is one of those things that judges often do and are likely to do better than jurors unburdened by training in exegesis.” *Id.* at 388. The Court supported its decision by emphasizing the importance of uniformity in the treatment of patents. *Id.* at 390.

22. Along with a brief summary of the invention, an inventor must include a specification section in the patent application that fully describes, among other things, the invention itself and the “part, improvement, or combination which he claims as his own.” Kyle J. Fiet, Comment, *Restoring the Promise of Markman: Interlocutory Patent Appeals Reevaluated Post-Phillips v. AWH Corp.*, 84 N.C. L. Rev. 1291, 1296 (2006) (quoting the Patent Act of 1836, § 6, 5 Stat. 117, 199 (repealed 1870)). These patent claims define the exact boundaries of patent protection. *Id.* Claim construction is the term used to describe the process of interpreting and translating the meaning of the patent claims that have allegedly been infringed. *See id.* Essentially, the goal of claim construction is to figure out what the claim means. *Id.* This phase of patent litigation is significant because the outcome of the case can hinge on how the court defines a specific term. *Id.* at 1297. Indeed, in *Markman*, the Supreme Court held that interpreting the construction of a patent and the terms within its claim were purely legal issues that fell within the exclusive province of the court. 517 U.S. at 391.

23. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997). Warner-Jenkinson and Hilton Davis both manufactured dyes. *Id.* at 21. Hilton Davis held a patent that disclosed a dye-purification process involving “ultrafiltration.” *Id.* Warner-Jenkinson developed a similar ultrafiltration process, and Hilton Davis sued Warner-Jenkinson for patent infringement. *Id.* at 23. “As trial approached, Hilton Davis conceded that there was no literal infringement, and relied solely on the doctrine of equivalents.” *Id.* “The jury found that the . . . patent was not invalid and that Warner-Jenkinson infringed upon the patent under the doctrine of equivalents.” *Id.* The district court granted a permanent injunction forbidding Warner-Jenkinson's ultrafiltration method. *Id.*

The Federal Circuit affirmed, holding that “the doctrine of equivalents continues to exist and that its touchstone is whether substantial differences exist between the accused process and the patented process.” *Id.* The court also held that the equivalence matter is one left to the jury. *Id.* Furthermore, it found little difference between the Warner-Jenkinson process and the Hilton Davis patent. *Id.*

The Supreme Court granted certiorari and reversed and remanded. *Id.* at 24. The Court held that the history of the doctrine of equivalents does not conflict with the Patent Act. *See id.* at 28. It also held that the doctrine of equivalents must be applied to individual elements of the claim and not to the invention in its entirety, in order to avoid an overly broad application that would “effectively eliminate that element in its entirety.” *Id.* at 29. The Court reasoned that “[w]here the reason for the change was not related to avoiding the prior art, the change may introduce a new element, but it does not necessarily preclude infringement by equivalents of that element.” *Id.* at 33. The Court emphasized the importance of prosecution history estoppel and “preservation of some meaning for each element in a claim,” holding that “[p]rosecution history estoppel continues to be available as a defense to infringement.” *Id.* at 40, 41. Therefore, “if the patent holder demonstrates that an amendment required during prosecution had a purpose unrelated to patentability, a court must consider that purpose in order to decide whether an estoppel is precluded.” *Id.* at 40–41. However, if the patent

be a doctrine of equivalents<sup>24</sup> in patent law, or should we overrule it? Petitioners argument was that the 1952 Act had abolished the doctrine of equivalents, since it expressly provided for equivalents only for claims written under Section 112, Paragraph 6.<sup>25</sup> Of course, asking the Court to do that in 1994 about the 1952 Act did not really work, and the argument failed. But still, in both of those two waves, the Federal Circuit did really well, and their affirmance rate was high in both of those waves. There was not a lot of data in either of them because there were not a lot of cases that the Supreme Court agreed to take.

But starting in 2002, the tide turned. In 2002, in a period of a couple of days, the Supreme Court decided two cases: *Festo*<sup>26</sup>—another case, like *Warner-Jenkinson*, involving the doctrine of equivalents—and a case called *Holmes Group* against *Vornado*,<sup>27</sup> dealing with basically the same issue that the Supreme Court had taken

holder fails to “establish such a purpose, a court should presume that the purpose behind the required amendment is such that prosecution history estoppel would apply.” *Id.* at 41. The lower court failed to give due recognition to this principle, leading the Supreme Court to reverse its findings. *Id.*

24. Under the doctrine of equivalents, a device or process that does not fall within the literal scope of patent infringement may still be found to infringe if there is “equivalence” or a lack of substantial difference to the claimed invention. *Id.* at 17; *see also* *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1218 (Fed. Cir. 1995). The core of the doctrine of equivalents is that a person “may not practice a fraud on a patent.” *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950). The basis on which the doctrine is founded is that “if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form or shape.” *Id.* at 608 (citing *Mach. Co. v. Murphy*, 97 U.S. 120, 125 (1878)). The goal of the doctrine is to protect patent owners from unfair infringements. *Id.* (citing *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 42 (1929)). Equivalency is not a static measure—it must be defined by taking into account the context and purpose of the patent, the prior art, and the unique circumstances of each case. *Id.* at 609.

25. 35 U.S.C. § 112, ¶ 6 (“An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described on the specification *and equivalents thereof.*”) (emphasis added).

26. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002) (chastising the Federal Circuit for “ignor[ing] the guidance of [Supreme Court precedent],” taking on a responsibility that “rests with Congress,” and applying a new rule without justification). *Festo*, the holder of two patents for an improved magnetic rodless cylinder, brought an action against *Shoketsu* for infringement when it entered the market with a similar device to the ones disclosed by *Festo*’s patents. *Id.* at 728–29. Although *Shoketsu*’s device did not fall under the exact scope of *Festo*’s patents, *Festo* argued that the similarities between the devices were enough to invoke the doctrine of equivalents. *Id.* at 729. In response, *Shoketsu* argued that *Festo* was estopped from such a claim because *Festo*’s prosecution history involved multiple amendments narrowing the prior applications. *Id.* Reviewing these arguments, the Court held that prosecution history estoppel may apply to “[any] narrowing amendment made to satisfy any requirement of the Patent Act . . .” *Id.* at 736. The Court also held that estoppel does not necessarily bar suit against every equivalent to the suit as “the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question.” *Id.* at 740.

27. *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826 (2002). The Court was purposeful in noting the Federal Circuit’s disregard for Supreme Court precedent and “longstanding policies.” *Id.* at 830–31. In *Holmes*, *Vornado*—a manufacturer of patented fans and heaters—sued *Duracraft*, a competitor, for patent infringement. *Id.* at 827–28. Even though the U.S. Court of Appeals for the Tenth Circuit found for *Duracraft*, *Vornado* initiated a similar complaint with the United States International Trade Commission against *The Holmes Group*. *Id.* at 828. *Vornado* argued that *Holmes*’s sale of fans and heaters with a spiral grill design infringed their patent and trade dress—the same dress held unprotected in the prior case. *Id.* *Holmes* then filed an action for declaratory judgment and an injunction prohibiting *Vornado* from claiming infringe-

up in 1983 or 1984 with the *Christianson* case. Basically, in both of these opinions, the Supreme Court used some pretty harsh language, and pointed at the Federal Circuit, saying, “You are not reading our opinions. You are not following the law. You need to listen. You are interfering with our right to make the law.” Since 2002, eleven patent cases have been decided by the Supreme Court of the United States.<sup>28</sup> The Federal Circuit’s record in those eleven cases? 0-11. What is happening here is the Supreme Court is saying, basically, “We are going to reform patent law.” While Congress is fiddling with patent-law reform, as they have been for numbers of years, and every time you think it is close, it never happens. There are a lot of interests. The political waves in an election year are not with patent-law reform right now. So the Supreme Court is left to reform—to adjust—patent law. What I see the Court saying to the Federal Circuit is, “Look. You have gone and given too many advantages to the patent holders. You have made patents too strong. We need to step back and mediate and moderate a little bit.” But again, patent law is still patent law, not *patent* law, and the Supreme Court is still supreme. Those are the two lessons that you take out of all of that.

So that brings us to *MedImmune*. The old law in the Federal Circuit said you had to have a reasonable apprehension of an imminent suit to sue for declaratory judgment. Now this basically gave the playing field to the patent holder because you could style your licensing discussions, your charge letters, and that sort of thing in such a way that you could never give the potential defendant the right to go seek out their own forum, to go file somewhere really slow just to hold this thing up. Likewise, maybe you want to file somewhere really fast, like the Eastern District of Virginia or the Eastern District of Texas, because that is really advantageous to plaintiffs. So the whole *MedImmune* case really ends up being a discussion of the contract, because the contract said, “You only have to pay license fees if the patent is valid.” The question was whether they could challenge the validity while continuing to pay the license fees to protect themselves. The Supreme Court says that you do not have to bet the farm to seek out a declaratory-judgment action. But the real potential for mischief, the really interesting portion of the *MedImmune* decision, is

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ment. *Id.* The district court granted the declaratory judgment and the injunction, explaining that “the collateral-estoppel effect of [Vornado’s prior case] precluded respondent from relitigating its claim of trade-dress rights” in the design. *Id.* On appeal, the Federal Circuit remanded the case “for consideration of whether the ‘change in law’ exception to collateral estoppel applied.” *Id.* at 829. The Supreme Court held that the Federal Circuit erred in that it lacked jurisdiction over the case. *Id.* at 830. The Court explained that the Federal Circuit’s jurisdiction hinges on whether the plaintiff’s well-pleaded complaint asserts a claim arising under federal patent law. *Id.* It also held that a “counter claim . . . [cannot] serve as the basis for a district court’s ‘arising under’ jurisdiction.” *Id.* The claims at issue were not based on patent law, and as such, the court lacked jurisdiction. *Id.*

28. *Quanta Computer, Inc. v. LG Elecs., Inc.*, 128 S. Ct. 2109 (2008); *Microsoft Corp. v. AT&T Corp.*, 127 S. Ct. 1746 (2007); *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007); *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006); *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 546 U.S. 394 (2006); *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005); *Holmes Group*, 535 U.S. 826; *Festo Corp.*, 535 U.S. 722; *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124 (2001).

in a footnote—footnote 11.<sup>29</sup> The footnote gets rid entirely of this “reasonable apprehension of imminent suit” test. So, this is how it has changed the law as to licensees—this is what the *MedImmune* case is actually about, the actual license that was already in place. They had been using the Article III bar as they interpreted it to keep licensees from challenging patent validity, or challenging actual validity. Now that the jurisdictional bar is gone, it is going to be more difficult—you heard Professor Kieff talk about *Lear Inc. v. Adkins*<sup>30</sup>—that contractual provisions prohibiting validity challenges have been at least suspect since the *Lear* decision. Also they have been allowed in the context of settlement of litigation.

Now, the bigger effect of *MedImmune* is that when you are engaging in licensing discussions, you really cannot play the “magic words” game that you used to be able to play to keep people from going to court for the declaratory-judgment actions. Now, if you are having licensing discussions, saying, “I think you ought to take a license to my ’234 patent because you are not going to be able to make your widget without my ’234 patent,” and that might be enough, in a totality-of-the-circumstances test,<sup>31</sup> which now, after *MedImmune*, applies. That might be enough for the other party in the licensing discussion, the non-patent holder, to rush off to court, file a declaratory-judgment action, and say, “This patent stinks. It is invalid, and by the way I would not infringe it with my widget. Let us get this decided.” This

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29. *MedImmune*, 549 U.S. at 132 n.11. The footnote states:

Even if *Altwater* could be distinguished as an “injunction” case, it would still contradict the Federal Circuit’s “reasonable apprehension of suit” test (or, in its evolved form, the “reasonable apprehension of imminent suit” test, *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (2005)). A licensee who pays royalties under compulsion of an injunction has no more apprehension of imminent harm than a licensee who pays royalties for fear of treble damages and an injunction fatal to his business. The reasonable-apprehension-of-suit test also conflicts with our decisions in *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 . . . (1941), where jurisdiction obtained even though the collision-victim defendant could not have sued the declaratory-judgment plaintiff-insurer without first obtaining a judgment against the insured; and *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239 . . . (1937), where jurisdiction obtained even though the very reason the insurer sought declaratory relief was that the insured had given no indication that he would file suit. It is also in tension with *Cardinal Chemical Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 98 . . . (1993), which held that appellate affirmance of a judgment of noninfringement, eliminating any apprehension of suit, does not moot a declaratory judgment counterclaim of patent invalidity.

*Id.*

30. 395 U.S. 653, 672 (1969).

31. In patent infringement cases, the court must employ the “totality of the circumstances” test to evaluate whether a declaratory judgment action satisfies the Article III requirement that there exists an actual, and thus justiciable, controversy. See *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 879–80 (Fed. Cir. 2008); see also *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1290 (Fed. Cir. 2008) (quoting *MedImmune*, 549 U.S. at 127). Prior to the “totality of circumstances” test, the courts employed a “reasonable apprehension of suit test.” *Cat Tech*, 528 F.3d at 879. The Supreme Court overruled this test in *MedImmune* because it was unduly restrictive and because it conflicted with, and would contradict, several prior decisions in which it was found that a declaratory judgment plaintiff had a justiciable controversy. See *MedImmune*, 549 U.S. at 126–37. The Supreme Court has implemented a three part framework to guide an analysis under the “all the circumstances test.” Under that framework, “an action is justiciable under Article III only where (1) the plaintiff has standing, (2) the issues presented are ripe for judicial review, and (3) the case is not rendered moot at any stage of the litigation.” *Caraco Pharm.*, 527 F.3d at 1291 (citations omitted).

becomes not so much a question of *whether* there is going to be litigation, but *where* there is going to be litigation and who is going to get to choose the location. This gives more power to the potential defendant, to the non-patent holder. It is going to come up in the context of licensing discussions, it is going to come up in the context of inquiry or charge letters—where you send a letter to somebody and say, “You know, we have got a patent and we think we ought to discuss it with you.” Maybe you can make the letter so vague that it is not a sufficient threat of litigation that you need to settle your rights. I would be skeptical about how vague you can be and still send a useful letter. “We might have something that you might be interested in; we should talk.” That probably is not enough for declaratory-judgment in a jurisdiction, but it is closer to the line than it was before the *MedImmune* decision.

It is also really interesting how this is playing out in pharmaceutical patents, because the Federal Circuit is increasingly holding that just merely listing your patents in the Orange Book<sup>32</sup> may very well be enough to sustain declaratory-judgment jurisdiction; it may be enough of a threat to a potential generic manufacturer that the generic can go in and file a declaratory-judgment action.

Next, I will review very quickly what has happened in the Federal Circuit since *MedImmune*, so that we have some time to talk about this and how it fits in. The first post-*MedImmune* case, *SanDisk v. ST Microelectronics*, was decided March of last year and the holding was: where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without a license, then there is a case or controversy.<sup>33</sup> In Judge Bryson’s concurrence, he points out that this is going to apply to virtually any case involving licensing discussions—and he is probably right. The next one is a pharmaceutical case: *Teva*.<sup>34</sup> There is a special provision of the Hatch-Waxman Act that allows for a declaratory-judgment type suit to obtain patent certainty. This is where the Orange Book notion comes into play. The court says in *Teva* that the controversy was created when

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32. Officially entitled the “Approved Drug Products with Therapeutic Equivalence Evaluations,” the Orange Book is a listing of all FDA-approved drugs and pertinent patents covering those drugs. See Julie Dohm, Comment, *Expanding the Scope of the Hatch-Waxman Act’s Patent Carve-out Exception to the Identical Drug Labeling Requirement: Closing the Patent Litigation Loophole*, 156 U. PA. L. REV. 151, 152 & n.2 (2007). The purpose of the Orange Book is to provide a reference where all pharmaceutical patents can be found. See Douglas A. Robinson, Note, *Recent Administrative Reforms of the Hatch-Waxman Act: Lower Prices Now in Exchange for Less Pharmaceutical Innovation Later?*, 81 WASH. U. L.Q. 829, 854 (2003). The types of patents that may be listed include “drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents.” See Dohm, *supra*, at 160. But more than just a reference, the Orange Book serves the interest of the Hatch-Waxman Act as it helps to “facilitate the resolution of patent-related disputes over pharmaceutical drugs by creating a streamlined mechanism for identifying and resolving patent issues related to the proposed generic products.” *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1338 (Fed. Cir. 2003).

33. *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372 (Fed. Cir. 2007); see also Sung, *supra* note 1, at 111 (discussing the Federal Circuit’s treatment of the *SanDisk* case).

34. *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007); see also Sung, *supra* note 1, at 112 (highlighting the court’s reasoning in *Teva*).

Novartis listed its family of patents over Famvir® in the Orange Book. They said that merely listing in the Orange Book represents that a claim of patent infringement could reasonably be asserted. Judge Friedman, concurring, thought this would be enough. The Federal Circuit majority in this case actually went through several factors, like the fact that Teva had filed an ANDA—an abbreviated new drug application.<sup>35</sup> They also pointed to the statutory provision for certainty, the statutory provision providing for ANDA, the overall purposes of the Hatch-Waxman Act, the fact that there was already a pending suit involving one of this family of patents between these two companies, and the prospect of future litigation. So all of this sort of went into the soup of saying, “Yeah, there is a case or controversy.” Judge Friedman would just cut through it and say, “That listing in the Orange Book is enough.”

So, then you get to *Benitec Australia*,<sup>36</sup> an interesting case because even after *MedImmune*, it still held there was no controversy. The patent holder sued for infringement; defendant counter-claimed for declaratory judgment of invalidity and unenforceability. The Supreme Court had decided the *Merck* case,<sup>37</sup> deciding that there was a broad safe harbor under § 271(e)(1).<sup>38</sup> Benitec argued that there was no present case or controversy and asked for dismissal without prejudice. This left open the possibility that the patent holder could sue again. Nucleonics asserted that they had a counter-claim for invalidity, and that the court could not just get rid of that claim by dismissing. The court sided with Benitec and dismissed.<sup>39</sup> Judge

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35. ANDA is a process designed to provide independent generic drug companies with a strong incentive to develop and produce lower-costing generic drugs for the benefit of public consumption. See Bryan A. Liang, *Regulating Follow-on Biologics*, 44 HARV. J. ON LEGIS. 363, 365 (2007). To reduce costs while simultaneously developing generic drugs, ANDA eliminates the repetitive tests that the FDA previously required before approving generic drugs. *Id.* at 386. Under this system, the FDA looks to testing of the earlier brand name product. *Id.* In essence, ANDA allows manufacturers to make generic drugs as long as they “establish[] bioequivalence with an already approved” drug. Edward Hore, *A Comparison of United States and Canadian Laws as They Affect Generic Pharmaceutical Market Entry*, 55 FOOD & DRUG L.J. 373, 374 (2000).

36. *Benitec Austl., Ltd., v. Nucleonics, Inc.*, 495 F.3d 1340 (Fed. Cir. 2007); see also Sung, *supra* note 1, at 113 (laying out the Federal Circuit holding in *Benitec*).

37. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

38. *Id.* at 201–02. In *Merck*, the Supreme Court relied upon the safe harbor provision of 35 U.S.C. § 271(e)(1), which states in part that “[i]t shall not be an act of infringement to . . . use . . . or import into the United States a patented invention solely for uses reasonably related to the development and submission of information under a Federal law which regulates the . . . use . . . of drugs.” *Id.* at 202. Specifically, the Supreme Court found that the “exemption from infringement” must extend to all research conducted in both clinical and preclinical trials, contrary to claims by the respondent that the breadth of the exemption does not extend to “preclinical studies related to a drug’s efficacy, mechanism of action, pharmacokinetics, and pharmacology . . . .” *Id.* at 203.

39. The *Benitec* court found that under the standard of declaratory judgment jurisdiction, “[t]he residual possibility of a future infringement suit based on Chase’s future acts is simply too speculative a basis for jurisdiction over Chase’s counterclaim for declaratory judgments of invalidity.” 495 F.3d at 1346 (alteration in original) (quoting *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1060 (Fed. Cir. 1995)). The court found that, per *MedImmune*, a counterclaim for declaratory judgment of invalidity is only justiciable if it meets both an “immediacy and reality” requirement. *Id.* at 1348–49 (citing *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007)).

Dyk dissented, and he said that *Cardinal Chemical*<sup>40</sup>—a Supreme Court case back from 1993—requires the Federal Circuit to go on and decide an invalidity counterclaim even if the infringement counterclaim becomes moot. He asserts that *Cardinal Chemical* compels the declaratory judgment be adjudicated. Interestingly, Justice Scalia, in that footnote 11 in *MedImmune*, pointed out the *Cardinal Chemical* problem with the old Federal Circuit rule of reasonable apprehension of imminent suit. I do not know where *Benitec Australia* stands, or if somebody is trying to get it to the Supreme Court, but it does strike me as at least in tension with *MedImmune*.

Then you get *Sony* against *Guardian*,<sup>41</sup> which says that a combination of adverse positions and explicit identification of the patents and the products is enough, that this is sufficiently concrete to create a case or controversy. The fact that you are saying, as the defendant, “Oh no, I just want to negotiate a business transaction, I do not want to sue”—that was the old trick before *MedImmune* came down—that is not enough; you are still going to be hauled into court in a declaratory-judgment action.

And then the *Micron* case,<sup>42</sup> one of the more recent ones, is really the one that exhibits that this *MedImmune* issue is usually not about *whether* there is going to be litigation, but *where* it is going to be. Because MOSAID, the defendant in this declaratory-judgment suit, sent all of these letters, they sent all of these warnings

Here, Nucleonics was found not to have satisfied either the immediacy or reality requirements for three reasons. *Id.* at 1349. First, Nucleonics offered nothing but circumstantial evidence of its intent to begin work on “potentially-infringing animal research,” thereby failing to satisfy the immediacy requirement. *Id.* Second, the court found that Nucleonics had done nothing to introduce information that would tend to show “whether Nucleonics’s possible future animal work would be infringing or not.” *Id.* Third, the court found that Benitec had conceded the fact that animal testing for human use and animal testing for animal use fell within the protection of 35 U.S.C. § 271(e)(1). *Id.* Therefore, the court concluded that “there [was] no evidence of a justiciable controversy between Benitec and Nucleonics over Nucleonics’s vaguely defined potential expansion to animal husbandry and veterinary products.” *Id.*

40. *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83 (1993). In *Cardinal*, the Supreme Court answered the question of “whether the affirmance by the Court of Appeals for the Federal Circuit of a finding that a patent has not been infringed is a sufficient reason for vacating a declaratory judgment holding the patent invalid.” *Id.* at 85. The Supreme Court found that the Federal Circuit’s current practice is to declare “that the issue of patent validity is ‘moot’ if it affirms the district court’s finding of noninfringement and if, as in the usual case, the dispute between the parties does not extend beyond the patentee’s particular claim of infringement.” *Id.* at 95. However, the Supreme Court found that this rule should not be applied in such a uniform manner. *Id.* at 96.

This conclusion follows the Supreme Court’s reasoning that “[a] party seeking a declaratory judgment of invalidity presents a claim independent of the patentee’s charge of infringement.” *Id.* Therefore, for two reasons, the Court rationalized that “[i]f the District Court has jurisdiction (established independently from its jurisdiction over the patentee’s charge of infringement) to consider that claim, so does (barring any intervening events) the Federal Circuit. . . . First, the Federal Circuit is not a court of last resort,” and the Supreme Court should be given the opportunity to “consider[ ] the question of validity.” *Id.* at 96–97. Second, once the burden of establishing jurisdiction has been met in the trial court, following courts “are entitled to presume, absent further information, that jurisdiction continues.” *Id.* at 98.

41. *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271 (Fed. Cir. 2007); see also *Sung*, *supra* note 1, at 114 (discussing the Federal Circuit’s holding in *Sony*).

42. *Micron Tech., Inc. v. MOSAID Techs., Inc.*, 518 F.3d 897 (Fed. Cir. 2008); see also *Sung*, *supra* note 1, at 115 (highlighting the court’s reasoning in *Micron*).



and invitations to negotiate. Then they sued three of the four players in the D-RAM [computer memory] industry. They got settlements against two of them, and Micron then filed a declaratory-judgment suit. And MOSAID said, “Hey, we were just talking.” The court said, “No, not under *MedImmune*. You cannot do that anymore.” Whether intended or not by the Supreme Court—here the Federal Circuit used the *MedImmune* holding to sort of tweak the Supreme Court a little bit—the now more-lenient legal standard facilitates or enhances the availability of declaratory-judgment jurisdiction in patent cases.<sup>43</sup> The interesting part about this is that the court goes through this 1404(a) transfer analysis,<sup>44</sup> because the day after Micron filed its declaratory-judgment action and MOSAID said, “We were just talking,” MOSAID filed a patent-infringement suit against Micron in a different district. So *Micron* was not a case about whether, but *where*. The court went through the 1404(a) analysis and said, “The case should stay where you filed the declaratory judgment suit.”

Finally, *Forest Laboratories v. Ivax*, another, more recent, pharmaceutical case<sup>45</sup> with a weird fact pattern, a weird holding, and a dissent. It had to do with a pro-

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43. *Micron*, 518 F.3d at 902. The Declaratory Judgment Act was designed “to provide the allegedly infringing party relief from uncertainty and delay regarding its legal rights.” *Id.* (quoting *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 956 (1987)). However, a court still retains some discretion over whether or not the case will be heard even if jurisdiction has been found to be proper. *Id.* (citing *Wilton v. Seven Falls Co.*, 515 U.S. 277, 289 (1995)). But, the court here goes on to state that if the trial court finds that the purpose of the Declaratory Judgment Act has been fulfilled, “dismissal is rarely proper.” *Id.*

44. 28 U.S.C. § 1404(a) (2000) (“For the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought.”). The court in *Micron* reasoned that although “[t]he general rule favors the forum of the first-filed action,” the trial court could make exceptions when considering numerous factors including but not limited to: “the convenience and availability of witnesses, the absence of jurisdiction over all necessary or desirable parties, and the possibility of consolidation with related litigation.” *Micron*, 518 F.3d at 904 (quoting *Genentech Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993)). Applying these convenience factors, the court noted that both Micron and MOSAID conducted business in California and Texas, witness availability was not favorable to either jurisdiction, and consolidation was unnecessary. *Id.* at 904–05. As such, the court found that the Northern District of California, the forum in which the declaratory judgment action was first filed, was the more appropriate forum for the dispute between Micron and MOSAID. *Id.* at 905.

45. *Forest Labs., Inc. v. Ivax Pharm., Inc.*, 501 F.3d 1263 (Fed. Cir. 2007). The Federal Circuit in *Forest Laboratories* reviewed the district court’s finding of no invalidity and affirmed. *Id.* at 1272. In affirming the lower court’s judgment, the court examined four arguments made by the challengers. *Id.* at 1267–72. First, the court found that the element of “anticipation” is a question of fact in which the general question is whether any references could have enabled “a person of ordinary skill in the art” to obtain or create the results claimed in the patent. *Id.* at 1267. Second, the court held that “obviousness” is a question of law in which the general question on appeal is whether the district court was clearly erroneous in finding “that a person of ordinary skill in the art would [not] have had a reasonable expectation” of obtaining or creating the results claimed in the patent. *Id.* at 1269. Third, the court found that “claim 11” of the reissue patent did not impermissibly broaden the scope of the claims in the original patent. *Id.* at 1270. Finally, the court examined the issue of scope with respect to the injunction ordered by the district court. *Id.* at 1271.

The Federal Circuit found in part that the scope of the district court’s injunction was overly broad and amounted to an abuse of discretion because it covered products other than those claimed in the patent. *Id.* at 1271–72. However, the court agreed with the inclusion of Cipla in the scope of the injunction because Cipla “actively induced the acts of Ivax that [would] constitute direct infringement” on the reissue patent, “and it was thus not inappropriate for the district court to include Cipla within the scope of the injunction.” *Id.* at 1272.

posed 180-day exclusivity period for another company called Ivax before anybody else could get into the generic market. So Forest, who had the patent, had beaten Ivax. Ivax was still the first filer and the exclusivity provision provided that when the patent expired, they had the first 180 days. But, they could not challenge validity again—that would be *res judicata*. A third company comes in and wants to challenge validity; they do that, and, the district court dismissed it. The Federal Circuit reversed, holding that there is a case or controversy here because if they challenge and successfully settle the validity of the patent, they can accelerate the time in which they can get to market. The Federal Circuit reasoned that if the patent is declared invalid, then the 180-day period starts for Ivax promptly, instead of when the patent expires. Judge Schall, dissenting, said,<sup>46</sup> “No. This is too speculative,” and it is just not enough for him. It is interesting, by the way, that Judge Friedman is in the majority in *Forest Laboratories*. It is interesting—probably just a coincidence—that a judge who is senior and sits on only half—at most—of the cases that other judges do, has shown up so frequently in the first wave of these post-*MedImmune* cases.

So, here is what we know after *MedImmune*. It is easier for licensees to bring suit; but how much easier? It is beginning to play out. If you already are a licensee, you can stop paying royalties and challenge validity. You can pay royalties under protest and challenge validity if there is otherwise a sufficient threat of litigation. That is what *MedImmune* says. Beyond that, it is still playing out.

Quickly, I will address some suggested strategies, either for the patent owner or for the defendant, or the other party engaged in a potential licensing negotiation. How do you prevent this litigation from happening? If you are already in a license, maybe you can negotiate a term of the license that says the licensee will not challenge validity. There is some question as to whether that would be upheld under the public policy ruling in *Lear, Inc. v. Adkins*.<sup>47</sup> Alternatively, maybe you could negotiate a penalty clause, saying if you challenge, you pay double. Assuming you

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46. *Id.* at 1272 (Schall, J., dissenting). In his dissent, Judge Schall disagreed with the inclusion of Cipla in the injunction. *Id.* Judge Schall reasoned that the language of § 271(e)(1) stating that “[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products” protected Cipla’s actions. *Id.* at 1273 (alterations in original) (quoting 35 U.S.C. § 271(e)(1) (2000)). Specifically, Judge Schall stipulated that Cipla did nothing more than provide Ivax with information that was already included in the ANDA as opposed to the actions of Ivax which warranted injunction. *Id.*

47. 395 U.S. 653, 672 (1969). The Court found that federal policy can override a contract between an inventor and a company, which would allow the inventor to accrue royalties irrespective of the validity of the patent ultimately issued. *Id.* at 673. The Court refused to allow the inventor to recover royalties because it would ultimately “permit inventors to negotiate all important licenses during the lengthy period while their applications were still pending at the Patent Office, thereby disabling entirely all those who have the strongest incentive to show that a patent is worthless.” *Id.* at 672. The controlling issue was “whether overriding federal policies would be significantly frustrated if licensees could be required to continue to pay royalties during the time they are challenging patent validity in the courts.” *Id.* at 673. In the Court’s opinion, “such a requirement would be inconsistent with the aims of federal patent policy.” *Id.*

can get those things in negotiation though, this strategy still raises the potential *Lear* problem. Maybe you can do it in a lump-sum payment up front that does not get refunded even if or whether there is a successful challenge. Or, maybe you provide in the license that there is a termination of the license itself or increased royalties if you challenge. You could front-load the royalty obligations or take equity in the company up-front; require the licensee to pay litigation costs. This one is probably more realistically going to be upheld. The fee-shifting strategy is common in non-patent contracts. Or, maybe you just do not bother licensing; only license after litigation is settled. That is an expensive proposition, so you better have a valuable patent for that to be the case. You could consider arbitration. Section 294 says that you can send patent disputes to arbitration. Maybe insist on confidentiality provisions saying the licensee cannot use the communications from arbitration after the license in a judicial proceeding. That was a suggestion made by the court in the *SanDisk* case. Or maybe, in the end, do not even bother licensing—just sue.

On the other side, you want to make sure you can bring this challenge and so it is really just the mirror image of what I just went through. You insist on defining the royalty obligations based on validity. You attempt to get lower royalty rates in exchange for any promises you might make not to challenge validity. Then, ultimately over all this, you have to do a business reality check. And this is where I am trying to bring the theme of this conference back to you, which is how you can use contracts to privately order your intellectual property rights. You have to evaluate your chances of winning a validity challenge upfront. Why upset a good business deal if you do not have to?

So, if you are on the other side, maybe you are trying to avoid a non-licensing situation; you are trying to avoid having your patents put in jeopardy. You could give them a covenant not to sue,<sup>48</sup> but you are giving away the farm if you do that. Even if you do not give away the farm, you probably have not given away enough to avoid declaratory-judgment jurisdiction. Maybe you just sue first; this is a litigation-encouraging ruling out of the Supreme Court in the *MedImmune* case. Sue first so you get your choice of forum. Maybe sue first and then negotiate. Why does choice of forum matter? Speed kills. These districts with so-called “rocket dockets”—you could be in trial in eleven months after you file your complaint. That does not give the defendant much time to mount an invalidity challenge, to do the sort of prior-art search and analysis with expert witnesses that is necessary to really

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48. A covenant not to sue is “a contract by the plaintiff not to sue the settling tortfeasor.” *Batteast v. Wyeth Labs., Inc.*, 560 N.E.2d 315, 318 (Ill. 1990). A covenant not to sue differs from a release in that a covenant not to sue is a contract that is “enforceable between the parties, but [does] not . . . release other tortfeasors.” *Id.* Therefore, if the plaintiff has elected to enter into a covenant not to sue with one tortfeasor but not the second, he retains the right to file suit against the second tortfeasor who did not enter into the covenant not to sue. *Id.* However, the plaintiff would retain no such right if he had entered into a release with the initial tortfeasor because a release nullifies all joint tortfeasors with respect to a particular claim. *Id.*

mount a good invalidity challenge. You can get to trial really quickly, it is good leverage for patentees, but it is bad for costs: if the price of negotiating a license is that you have to file suit first, that is a huge transaction cost right up front.

So, in the end, what have we learned? *MedImmune* gave prospective and actual licensees an additional lever as a result of the Supreme Court tilting the playing field a little bit back to what it perceives to be more even between plaintiffs and defendants, patentees and potential licensees. It is consistent with that theme. You see, *KSR* makes obviousness of a patent easier to prove; we talked about *eBay*—injunctions are harder to get; and *MedImmune* gives you as a potential defendant a lot easier opportunity to establish declaratory-judgment jurisdiction.

A couple of other lessons out of this: the Hatch-Waxman cases<sup>49</sup> may yield distorted results because it is a funny statute with funny provisions. There are lots of creative ways and there is a lot of literature emerging out of business people about how to get around these *MedImmune* problems, but they have not been tested much yet—we are only just over a year out of the *MedImmune* decision. But still, even if you are that person who wants to bring a declaratory-judgment suit, you have to have significant and likely gains if you are going to risk it.

FRANKLIN E. GIBBS: Well, I want to thank the University of Maryland School of Law for inviting me here today. I anticipate this is going to be a much more pleasurable experience for me than I am used to. When a case like *MedImmune* comes out, a number of our corporate clients will ask us to go over and explain to them what happened. I get about two or three lines into the explanation and the first question pops up, “So what are we going to do about it? What can you do for me to help me get around this or to deal with this problem?” I have already gone quite a few seconds into this presentation—not a single question—that is refreshing.

I am going to take it from a different point of view here—I am going to take it from the point of view of, what do you do with *MedImmune*? What do you do with these cases when they come up? How do you handle them? Recently, there was another case in the Federal Circuit—*Agrizap*<sup>50</sup>—which drove home the point that if

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49. “A so-called ‘Hatch-Waxman case’ is one brought pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 (1994)).” Keith Leffler & Cristofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F. L. REV. 33, 35 n.10 (2004). It has been found that 73% of those cases result in the court finding that the manufacturer did not infringe a valid patent. *Id.* In one such case, Justice Edwards explained that the Hatch-Waxman Amendments “emerged from Congress’ efforts to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.” *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting). The majority in *Abbot* found the FDA’s interpretation of the Drug Price Competition and Patent Term Restoration Act ambiguous and unreasonable. *Id.*

50. *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337 (Fed. Cir. 2008). *Agrizap* sued Woodstream for “fraudulent misrepresentation and infringement” of a patent “which pertain[ed] to an electronic rodent-killing device.” *Id.* at 1339. The court found that “the patent law aspects of this case [could] be decided entirely on the grounds of obviousness.” *Id.* at 1342. The court further examined the evidence and found that the electronic rodent-killing device, although highly successful in the market, differed very slightly from a previous patent for

you have very simple inventions, you are going to have a hard time proving they are not obvious. So, with *Agrizap* behind us, we look at *MedImmune*. I tell my clients, “You know if you are going to talk about invalidity challenges, you are going to have to start considering reexaminations.” Because, if none of these cases start to come to light, it is going to be a viable alternative to go before the Patent Office again and see if you can invalidate these patents. I have seen licenses where judicial invalidity is spelled out, but everything else is left open.

So whenever we are talking about *MedImmune*, *eBay*, *KSR*—any of the other cases, for our firm—it really has to come down to, what can you give the client? As importantly, when the client does not take your advice, what can you do to cover yourself to make sure that if, in the future, they say, “You should have told me,” you can point out, “Yes we did, and it was your choice not to do it.”

Now as a practical matter, with a lot of the clients I am seeing, they tend to fall into two general categories, at least for us. The first is the clients who do not have a very large operation, and frankly do not care. They do not think they are going to be in business that long with this particular product, they do not think that their competitor is going to mount an offense against them, they just want to get on with business and they want to avoid the cost of going to litigation or an expensive licensing campaign. With the ones who are a little larger, who have more resources, they care, but they care about very specific things. Sometimes what they care about is not what you think they should care about under *MedImmune*. In those cases, you go with your client and you have to identify what you would recommend, document what you are going to recommend for them, let them turn it down, and then move on and do the best you can. Then we have that class of client that wants it all. They want to know, “How I can protect myself every which way from a case like this?” For that class of clients, I find some of their ideas are running a gambit between amusing to being pretty valid alternatives.

One client, for example, told me, “Well I am going to go ahead and license this patent, and we will give them a dollar for the licensing, for the patent itself, unless the patent is found to be invalid.” They have the patent, and they go and do the licensing, and what they want to do is, after the licensing, abandon the patent or dedicate it to the public. You are not going to get a judicial finding that the patent is invalid if you do not have a patent. But you do have a license that is still running, only a dollar of which went to the patent. Ideas like that are fascinating, because where they may have some problems, they open up your mind as to some alternatives in a practical sense that you can apply to help your client in cases like this.

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an electronic gopher-killing device. *Id.* at 1344. Because of the heavy similarity between this patent and previous patents, the court held that the evidence produced “a strong prima facie case [for] obviousness” and found that *Agrizap*’s “asserted claims [we]re invalid.” *Id.* at 1344–45.

Now, there are a number of things you can do. You can ask for arbitration. You can ask for a change of venue.<sup>51</sup> You can ask for all types of things that help out the client. You can start to move a little further out and you can start to look at some things that might work and some things that might not, and make sure that if they do not work, they do not take down your license. For instance, you may consider putting a clause in the contract that says: “You shall not argue invalidity.” The Federal Circuit seems to be saying that there is some kind of a policy consideration here,<sup>52</sup> at least with that type of clause. Imagine, if you are in the bankruptcy statutes, if you have got a clause in the contract that says this contract becomes null and void because one of the parties becomes insolvent. That statute says that the clause is not enforceable, and it is done. So, if you are going to play around with a policy issue, you have to draft the license in such a way that if a court does not uphold your language, you do not lose the whole license.

F. SCOTT KIEFF: I would like to make two comments, one broad and one narrow. On the broad point, I agree, you can come up with a whole set of approaches that will walk around the letter of the case that was written yesterday. I agree that if a court says I cannot put a clause in that says, “I won’t challenge the validity,” I can instead put a clause in that says, “If I do challenge, I will do it standing on my left foot, and I will promise not to do so with sugar on top, and I will pay damages and put a needle in my eye even if I do.” The problem is that what is motivating the Court is not balancing, but a fundamental view that it knows the right set of rules. That, I think, is problematic because the folks who have to deal with this stuff are private orderers, the plaintiffs and defendants, the patentees and alleged infringers.

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51. A change of venue is a change in the location of a trial and is defined in 28 U.S.C. § 1404 which provides the following:

- (a) For the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought.
- (b) Upon motion, consent or stipulation of all parties, any action, suit or proceeding of a civil nature or any motion or hearing thereof, may be transferred, in the discretion of the court, from the division in which pending to any other division in the same district. Transfer of proceedings in rem brought by or on behalf of the United States may be transferred under this section without the consent of the United States where all other parties request transfer.
- (c) A district court may order any civil action to be tried at any place within the division in which it is pending.
- (d) As used in this section, the term “district court” includes the District Court of Guam, the District Court for the Northern Mariana Islands, and the District Court of the Virgin Islands, and the term “district” includes the territorial jurisdiction of each such court.

28 U.S.C. § 1404(a)–(d) (2000). The Supreme Court has further found that “the purpose of this section of the Revised Judicial Code was to grant broadly the power of transfer for the convenience of parties and witnesses, in the interest of justice, whether dismissal under the doctrine of *forum non conveniens* would have been appropriate or not.” *Norwood v. Kirkpatrick*, 349 U.S. 29, 31–32 (1955) (quoting *Jiffy Lubricator Co. v. Stewart-Warner Corp.*, 177 F.2d 360, 362 (4th Cir. 1949)). It can be inferred, therefore, that a change in venue is relatively simpler to obtain than dismissal under *forum non conveniens* as it gives the court broader powers to serve the interests of justice. *See id.* at 32.

52. The policy consideration is the encouragement of experimentation through the use of patents. *See* U.S. Constr. art. I, § 8, cl. 8 (providing Congress with the authority “[t]o promote the [p]rogress of [s]cience and useful [a]rts” through issuing patents to inventors).

They are the ones that have to figure out over time that they want or do not want to structure their affairs in any one particular way. Allowing them infinite flexibility; that is why we have contract law.

So the broad comment is, first, I do not think actually any of the suggestions made today will work for tomorrow. They might work for 20 hours, 24 hours, for 23 1/2 hours, but courts are smart and what they are really trying to do is tell the parties what you can and cannot do. I think that is problematic and we should not lose sight of that. And even if the ideas work, the courts recognize that they are just imposing a whole set of very large set of costs on people. They pretend to be doing what is not what they really want to be doing, so that has got to be bad for society.

The narrow comment is about the response to *eBay*. I am a pro-patent guy. Yet I do not think the remedies are about compensation, while everyone seems to be talking about compensation as do courts when they talk about measuring damages. Rather, I think that we need to recognize that what we want people to do is strike agreements with each other and plan business models for themselves and each other, privately or cooperatively, and go forth and do business. The compensation mindset is a mindset that says we lawyers, who sit in courts or sit in agencies, can always figure out how better to do for somebody else what they are already doing for themselves. A benefit of a strong right to exclude backed up by an injunction and backed up by enhanced damages is not that they do a better job figuring out value and not that they do a better job compensating, but rather that they force the private parties to figure out how they want to plan their affairs, and since they are the ones who know how to do that stuff, we ought to force them to do it.

FRANKLIN E. GIBBS: Let me say I understand your position, but for the most part I disagree. If, in fact, the Federal Circuit and the high court are saying that contract law does exist and allows people to enter into bargained for exchanges, then these types of clauses are going to have some effect. They have to. Otherwise, the Court is going to have to impose some sort of a policy-based reason to say you have to go this way, and they really have not been very proactive in that sense, at least I do not think.

The second point is, when you are dealing with a client, they want results. Now, we can talk to them about the underlying reason for *Lear*; we can talk to them about all sorts of things they do not really care about. In my perspective, clients want to know what you can do for them now in light of this case. Granted, some of these suggestions might not last twenty hours. Some might not last ten hours. But some may last and if they do, you have done the job for your client, which is where I am coming from. It is all in the negotiation. The whole thing is a negotiation of what you are going to give and take. What we have had here in the Supreme Court is a changing of some factors. But it is still a negotiation. Ultimately, these parties are going to have to come to some type of resolution.

GREGORY CASTANIAS: I would add to that, Scott, when the Court changes or restores the law, whichever way you want look at it, we will use *eBay* as the example

here, the Court has said there is going to be this multifactor equitable balancing test that in some cases when you find infringement are going to result in injunctions and in other cases are not. Now, your certainty is the other side's unconscionable lever,<sup>53</sup> and there are cases—Tom Woolston talked earlier about the old equitable cases involving injunction. Well, there are lots of old cases, you go back to the old dusty equity treatises that say that you cannot use a patent as a tool of coercion. The flip side of your argument is simply that, “Well yes the old doctrine is certain.” It is certain like having the death penalty for everything from parking violations to murder.

On the other hand, just to make sure that both sides of the arguments are made and ventilated, it is true that the Court did decrease some certainty so that if you are representing a defendant immediately after an infringement verdict comes down, the outcome is more uncertain. Under the old regime, the other side would come to you and say, “Negotiate or die, because the injunction is coming.” The dance would be, “Well, I have got a design around or I do not need your technology; I can do without it entirely, so just go ahead and have the injunction go in, because I am not going to pay you for it.” Alternatively, now, under the current regime we just have another piece of risk which is what precedes all contracts and so now that risk is just early in the game. *eBay* has been out for two years and we have to now establish what the risks are, and we are learning in these cases.

I think that there has been some effort on the first panel to sort of divine a grand unifying principle: if you are a competitor you can get an injunction, if you are a non-practicing entity you cannot. I think that is a little simplistic. I think there are non-practicing entities that are much like the *Continental Paper Bag* non-practicing entity where they said, “We have a patent. We have a right to exclude people from using this thing, but it is a benefit to us because we are in the market with this other thing and being able to legally keep out competition is a good thing and it gives value to our enterprise.” The fact that the court in *eBay* specifically asked the parties to brief the question of whether *Continental Paper Bag* should be overruled, and ultimately decided not to, but rather viewed its decision as consistent with

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53. In *H. Lubovsky, Inc. v. Esprit De Corp.*, the court suggested that the best way to avoid providing an unconscionable lever would be to award a limited injunction with minimal provisions. 627 F. Supp. 483, 486–92, 497 (S.D.N.Y. 1986). The court reasoned that such an award would “not excessively deprive defendant of the benefit of the valuable goodwill it has built up (and, accordingly, does not give plaintiff a lever for unconscionable extortion), but [would] require[ ] the defendant to take more effective steps to distinguish its [patent] . . . and to avoid potential confusion.” *Id.* at 497. Ultimately, the court felt that such an approach would leave plaintiff with a “wider scope for exercise of its trademark rights but would not [give the plaintiff] the benefit of high extortion value premised on the loss inflicted on defendant by the injunction.” *Id.* To reach this conclusion regarding the award of recovery for infringement, the court considered the following factors: (1) the strength of plaintiff's mark; (2) the degree of similarity between plaintiff's and defendant's marks; (3) the proximity of products; (4) the sophistication of buyers; (5) bridging the gap; (6) the quality of defendant's products; (7) actual confusion; (8) defendant's good or bad faith; (9) the relative harm to the parties from grant or denial of a remedy; and, (10) the likelihood of confusion. *Id.* at 486–92.



*Continental Paper Bag*, leaves a lot more room for injunctions than I think some who have spoken today have given it credit for.<sup>54</sup>

LAWRENCE SUNG: Scott, I think that I agree with you in part about the mechanisms that were described here for being inserted within licenses going forward at this point in time. But, I wonder whether or not there are multiple possibilities involved. For example, if all we care about is crafting licenses to get around *MedImmune*, that is silly. It is no different than saying we are going to now put in provisions that say, “If a meteor strikes the earth, you are off the hook.” I mean, we just do not worry about that. But, I think it is a separate precision pricing structure that people can now account for, because otherwise, prior to *MedImmune*, we would sit here and negotiate a price that we thought was appropriate. Now that there is a spotlight on the fact that the licensee can raise a challenge, the price can change, and the controls that we put in the penalty clause might not be a good term to use here, but one that really gives you another option that would in fact allow the deal to go through, because it would go through on a cheaper price at some point in time but yet allocate the risk on some level. So, I am not ready to wholesale say that the suggestions advanced today do not work. But, I agree with your point, that if all you are trying to do is contract around the Supreme Court decision, that is obviously the wrong motivation.

KELLY CASEY MULLALLY: Okay, now we will continue to hear from the remaining members of our first panel before we open it to all your questions. Professor Beckerman-Rodau.

ANDREW BECKERMAN-RODAU: I think it is interesting that you have to keep in mind that ultimately, you do want the patent to be used and everyone wants to make money because if you have a great license deal, what is the use if you cannot make money? I think I tend to agree with what was said by the panel that this really just alters the negotiation. I mean if you had the ability to get a permanent injunction, well you make a leap. You have to get damages and we are not talking about twelve cents for damages—there is something substantial. All of these cases simply alter the negotiation. Now, the issue to me is: will it alter the negotiations such that the innovators are going to have a disincentive to pursue patents? If the disincentive is not there, then it is still going to be working the patent system. Speaking this

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54. The Court in *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 422–30 (1908), “rejected the contention that a court of equity has no jurisdiction to grant injunctive relief to a patent holder who has unreasonably declined to use the patent.” *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393 (2006). The Court upheld the lower court’s ruling in *eBay*, holding that “the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards.” *Id.* at 394. The Court upheld the *Continental* ruling after noting that the Patent Act calls for the principles of equity to govern the granting of injunctive relief. *Id.* at 392. The Court also noted that it “has consistently rejected invitations to replace traditional equitable considerations with a rule that injunction automatically follows a determination that a copyright has been infringed.” *Id.* at 392–93. In the Court’s opinion, such a categorical rule would directly contradict the notions of equity that are inherent in the Patent Act. *Id.*

morning was Tom, and he was talking about how much money he could have made with an injunction. Well, it is not like he is not going to make a substantial amount of money with his patent. Consider the RIM case,<sup>55</sup> where the patent holder did walk away with over \$600 million. That is still probably an incentive for someone to seek a patent and to engage in innovation. That is the public policy of the argument. So, I think I do agree that you have to reallocate the negotiations, but I am not sure you are going to be able to do any more than that.

LAWRENCE SUNG: But is that not just a prospective answer? I mean, what happens to the retroactive effect for what the expectations might have been and you are going into these, and now the Court basically is eviscerating all that, saying that we are not going to allow you to honor your deal because there are other competing considerations.

ANDREW BECKERMAN-RODAU: No, I think that is a significant issue but I guess I come at that saying that is not a patent lawyer issue. Because outside the criminal courts, the law is almost always applied retroactively. A great example is the '60's revolution in residential leases. In those cases, the courts applied the warranty of habitability release.<sup>56</sup> You used to be able to use self-help, and you could not do that because most of those cases applied retroactively and so you hold the parties to the bargain. I think that is a problem. I am just not sure it is a patent law problem. I think it is a general problem in the way patents apply.

KELLY CASEY MULLALLY: I think the effect on pre-*MedImmune* licenses is very clear. The licensee has much more power. The licensors in that situation did not

55. *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1292 (Fed. Cir. 2005) (vacating the award of a final judgment totaling \$53 million to NTP from Research in Motion (RIM)). On March 3, 2006, NTP and RIM agreed to a final settlement of \$612 million for a longstanding dispute over the BlackBerry device. Rob Kelley, *BlackBerry Maker, NTP Ink \$612 Million Settlement*, CNNMONEY.COM, Mar. 3, 2006, [http://money.cnn.com/2006/03/03/technology/rimm\\_ntp/](http://money.cnn.com/2006/03/03/technology/rimm_ntp/). The settlement was reached after the two companies had battled in court over RIM's alleged infringement of NTP's patent. *Id.* The terms of the settlement allow for a onetime payment of \$612 million to NTP in exchange for NTP's agreement to allow RIM to "keep running its BlackBerry business." *Id.*

56. In the 1960s and 1970s, there was an enormous shift in which courts "abolished the doctrine of *caveat emptor* in residential leases and judicially adopted the implied warranty of habitability." 15 RICHARD A. LORD, WILLISTON ON CONTRACTS § 48:11 (4th ed. 2008) (citing *Pugh v. Holmes*, 405 A.2d 897 (Pa. 1979)). One example of this trend was a landmark decision by the Supreme Court of Pennsylvania in *Pugh v. Holmes* in which the court held that "the doctrine of *caveat emptor* has outlived its usefulness and must be abolished, and that, in order to keep in step with the realities of modern day leasing, it is appropriate to adopt an implied warranty of habitability in residential leases." 405 A.2d at 900.

In *Pugh*, the Court explained that, at its beginning, "[t]he doctrine of *caveat emptor* comported with the needs of the society in which it developed." *Id.* This doctrine placed upon the lessees the burden of inspecting the premises and demanding express warranties from landlords. *Id.* at 901. However, much has changed and this doctrine is no longer practical in today's society. *Id.* "Today, the doctrine of the implied warranty of habitability has attained majority status in the United States . . . ." *Id.* This warranty "recognizes that the modern tenant is not interested in land, but rather bargains for a dwelling house suitable for habitation." *Id.* at 901-02. As such, "[t]he implied warranty is designed to insure that a landlord will provide facilities and services vital to the life, health, and safety of the tenant and to the use of the premises for residential purposes." *Id.* at 905.

even have the opportunity to come up with some of these creative solutions. But, maybe that sums to renegotiating it if at all possible.

Questions from the audience for our panel members?

QUESTION: Might we consider licensing whereby the licensee is encouraged or required to conduct its own independent due diligence or pay independent opinion counsel for which invalidity should be examined of some nature, and if they do not that is a waiver of their opportunity and chance to raise that? Practical or not is a separate question. If that opportunity was given and a licensee fails to, or does not, or does it, and accepts the terms of the license agreement, whereby licensing the contract, agrees not to subsequently challenge the invalidity of the contract. How do you think the court would consider that kind of shifting of the dynamics?

GREGORY CASTANIAS: Well on some level that is a question that I have not thought much about. It is an intriguing idea. I listened to the question and my mind immediately went to another aspect of the declaratory-judgment statute—the aspect of the statute that says a court *may* (not *must*) entertain a declaratory-judgment action.<sup>57</sup> That “may” language as we know from *eBay* and lots of other cases and as we now know from *MedImmune*, means that a court has some discretion to decline to entertain a declaratory-judgment action even where there is a case or controversy. This issue keeps coming up in the post-*MedImmune* cases, but it has not been decided yet by the Federal Circuit. So I wonder whether, in a situation like what you have just described, there would probably still be a case or controversy even if they did not do their due diligence. But, it might be enough of a factor to encourage a court in its discretion to decline to exercise declaratory-judgment jurisdiction.

LAWRENCE SUNG: This really does bring us full circle and it is a good point to actually close the conference on. That is, this underlying tension will continue to be in place on a number of issues as we go forward. What we are now seeing is now maybe a business court and the Roberts Supreme Court looking at it and again coming back and asking the question why the predominant balance between those two tensions is not swinging in favor of what private parties do, and to the extent they do not do it they are really bringing the risk onto themselves.

I want to take this opportunity to thank everybody for joining us today and again for us to express our appreciation to the experts that we have had an opportunity to meet today. We can carry on some parts of this conversation over the luncheon. Again, thank you very much for sharing your time with us today and have a very nice weekend.

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57. 28 U.S.C. § 2201(a) (2000) (“In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, *may* declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.”) (emphasis added).

ELLEN SMITH: On behalf of the Journal of Business and Technology Law I want to thank everyone for coming and especially to thank our distinguished panelists and our two faculty moderators who took time out of their schedule to help us put this on. So, thank you so much for everything.