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Marvel, Cisco, and *Teva:* The U.S. Supreme Court Decides Three Patent Cases in 2015, Respecting *Stare Decisis*

Sue Ann Ganske*

I. Introduction

Congress has the power "[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[1]

The United States Supreme Court decided three patent cases in 2015: *Teva Pharmaceuticals USA, Inc. v. Sandoz*,[2] *Commil USA, LLC v. Cisco Systems, Inc.*,[3] and *Kimble v. Marvel Enterprises, Inc.*[4] In *Teva*, on January 20, 2015 the Supreme Court held, seven to two, that the appropriate standard of review of findings of fact in patent claim construction is the clear error standard, not a de novo review, vacating the decision of the Court of Appeals for the Federal Circuit and remanding.[5] In *Cisco*, on May 26, 2015 the Court held, seven to two, that there is no defense of a good faith belief in the patent's invalidity to an allegation of induced patent in-

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1 U.S. CONST., art. I, § 8, cl. 8.

2 Teva Pharm. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831 (2015). *See infra* notes 22 - 60 and accompanying text.

3 Commil USA, LLC v. Cisco Sys., Inc., 135 S. Ct. 1920 (2015). *See infra* notes 61 – 98 and accompanying text.

4 Kimble v. Marvel Entm't, LLC, 135 S. Ct. 2401 (2015). *See infra* notes 99 - 145 and accompanying text.

5 *Teva*, 135 S. Ct. at 835-43.

fringement.[6] In *Marvel*,[7] the Supreme Court held, six to three, that a patent holder may not charge patent royalties beyond the patent term, upholding the Court's 1964 precedent in *Brulotte v. Thys Co.*[8] In *Marvel*,[9] the Court of Appeals for the Ninth Circuit was affirmed, the only case of the three where an appellate court was affirmed.

The three patent decisions of 2015 were half of the record-setting six patent decisions by the Court in 2014,[10] but in the 2013-14 term, the appellate court, the Court of Appeals for the Federal Circuit in every case, was also affirmed only once.[11] In the patent cases decided by the Court in 2015, there were dissents in each case, while all six patent decisions in 2014 were unanimous.[12] In *Teva*,[13] Justices Thomas and Alito dissented. In *Cisco*,[14] Justice Scalia and Chief Justice Roberts dissented. In *Marvel*,[15] Justices Alito and Thomas and Chief Justice Roberts dissented.

The theme of the Supreme Court in the three patent decisions in 2015, if there is a theme, is that, in patent cases, the Court is respecting stare decisis. In *Teva*,[16] both the majority and the dissent relied heavily on the Court's decision in *Markman v. Westview Instruments, Inc.*[17] In *Cisco*,[18] the Court reaffirmed its decision in *Global-Tech Appliances v. SEB S.A.*[19] Finally, in *Marvel*,[20] the Court, adhering to

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6 *Commil*, 135 S. Ct. at 1931.

7 *Kimble*, 135 S. Ct. at 2405.

8 Brulotte v. Thys Co., 379 U.S. 29 (1964).

9 *Kimble*, 135 S. Ct. at 2405-06.

10 *See generally* Sue Ann Ganske, *The U.S. Supreme Court Decides Six Patent Cases in 2014, Culminating in* Alice Corp. v. CLS Bank International, 23 TEX. INTELL. PROP. L.J. 183 (2015).

11 In Medtronic, Inc. v. Mirowski Family Ventures, LLC, 134 S. Ct. 843, 852 (2014), the Supreme Court unanimously reversed the Court of Appeals for the Federal Circuit, and remanded. In Octane Fitness, LLC. v. Icon Health & Fitness, Inc., 134 S. Ct. 1749, 1758 (2014), the Court unanimously reversed the Federal Circuit and remanded. In Highmark Inc. v. Allcare Health Management System, Inc., 134 S. Ct. 1744, 1749 (2014), the Court unanimously vacated the Federal Circuit's decision and remanded. In Limelight Networks, Inc. v. Akamai Technologies, Inc., 134 S. Ct. 2111, 2120 (2014), the Supreme Court unanimously reversed the Federal Circuit and remanded the case. In Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2131 (2014), the Supreme Court unanimously vacated the decision from the Court of Appeals for the Federal Circuit and remanded. In Alice Corp. v. CLS Bank International, 134 S. Ct. 2347, 2360 (2014), affirmed the Court of Appeals for the Federal Circuit unanimously.

12 *See id.* (discussing cases).

13 *Teva*, 135 S. Ct. at 844.

14 *Commil*, 135 S. Ct. at 1931. Justice Breyer took no part in the consideration or decision in this case, so the vote was six to two.

15 *Kimble*, 135 S. Ct. at 2415.

16 *Teva*, 135 S. Ct. at 845 (citing Markman v. Westview Instruments, 517 U.S. 370 (1996)).

17 *Infra* notes 43 and 51 and accompanying text.

18 *Commil*, 135 S. Ct. at 1926 (discussing Global-Tech Appliances, Inc. v. SEB S.A., 131 S. Ct. 2060 (2011)).

19 *Infra* note 78 and accompanying text.

20 *Kimble*, 135 S. Ct. at 2415.

principles of stare decisis, did not overrule its decision in *Brulotte,*[21] leaving any change in the law to Congress.

This article reviews and analyzes the three Supreme Court patent decisions of 2015. This article concludes with implications of this series of important cases.

II. Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.

The legal question in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.* is, what is the appropriate standard of review of a district court's findings of facts when conducting patent claim construction?[22] The U.S. Supreme Court ruled seven to two that the clear error standard should be used, not a de novo review, citing precedent and practical considerations.[23]

The plaintiff, Teva Pharmaceuticals,[24] holds patents for a multiple sclerosis pharmaceutical sold under the brand name Copaxone®. The patents specifically address an improved composition of copolymer-1 with a lower molecular weight to treat multiple sclerosis.[25] Prior to the expiration of Teva's patents, the defendant Sandoz, Incorporated[26] filed an Abbreviated New Drug Application under the Hatch-Waxman Act[27] to make and sell a generic version of Copaxone®. Teva filed suit against Sandoz for patent infringement concerning the claims of four Teva patents.[28] Sandoz counterclaimed, seeking a declaratory judgment of noninfringement, and the unenforceability and invalidity of nine of Teva's patents.[29]

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21 Brulotte v. Thys Co., 379 U.S. 29 (1964).

22 *Teva,* 135 S. Ct. at 835.

23 *Id.*

24 *See* Teva Pharm. USA, Inc. v. Sandoz, Inc., 876 F. Supp. 2d 295, 303 (S.D.N.Y. 2012) (explaining that the plaintiffs were a group of companies: Teva Pharmaceuticals USA, Inc., a Delaware corporation, Teva Pharmaceutical Industries, Ltd., an Israeli company,Teva Neuroscience Inc., a Delaware corporation, and Yeda Research and Development Co., an Israeli company (collectively, "Teva")).

25 *Id.* at 305.

26 *Id.* at 303-05 (clarifying that the remaining Sandoz defendants, after Teva voluntarily dismissed two other defendants, were Sandoz, Inc., a Colorado corporation, and Momenta, a Delaware corporation). Initially, two suits were filed, against Sandoz and Momenta, but these were combined, and collectively the defendants are called the "Sandoz" defendants. *Id.*

27 *See id.* at 303 (citing 21 U.S.C. §§335, 360cc (2003), 35 U.S.C. § 156 (2002), 35 U.S.C. § 271 (2003)).

28 *See id.* at 304 (explaining that Teva alleged that the claims of patents No. 7,199,098, No. 6,939, 539, No. 6, 054, 430, and No. 6,620, 847 were infringed by defendants Sandoz. Teva alleged that the claims of those four patents, and the claims of three additional patents, patents No. 5, 981, 584, No. 6,342,496, and No. 6,362, 161 were infringed by Momenta. These were consolidated by the court into the present case.).

29 *Teva,* 876 F. Supp. 2d at 303. These nine patents have 78 claims, and included the seven that Teva alleged were infringed by Momenta, plus patents No. 5,800,808 and 6,048,898.

Sandoz alleged that the term "molecular weight" was indefinite, as there are different ways to ascertain average molecular weight.[30]

In 2011, the district court denied the defendant's motion for summary judgment on the indefiniteness allegation, finding that the claims could be construed.[31] Claim construction and indefiniteness are each a matter of law,[32] and indefiniteness must be proven by clear and convincing evidence, according to the district court.[33]

The district court in 2012 held that Sandoz's proposed pharmaceutical product infringed on Teva's patent claims.[34] Further, none of the challenged claims were either invalid or unenforceable.[35] Sandoz appealed.

The Court of Appeals for the Federal Circuit in 2013 affirmed in part, reversed in part and remanded in part.[36] The appellate court affirmed that the patent claims which did not give an average molecular weight were not invalid or unenforceable.[37] Using a de novo review standard, the appellate court found that the claims that did specify an average molecular weight were indefinite, because those claims were ambiguous because the way to measure molecular weight was not specified, and there are multiple ways to calculate the average molecular weight.[38]

The U.S. Supreme Court agreed to hear the case,[39] to clarify which standard of review that the Federal Circuit must use when reviewing claim construction.[40]

On January 20, 2015, the U.S. Supreme Court held seven to two that the appellate court should use the clear error standard when reviewing factfinding in patent claim construction,[41] vacating the Federal Circuit's decision, and remanding.[42] Justice Breyer, writing for the majority, started his opinion by citing *Markman v. Westview Instruments, Inc.*,[43] which held that under the Seventh

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30 Teva Pharm., USA, Inc. v. Sandoz, Inc., 810 F. Supp. 2d 578, 587 (S.D. N.Y. 2011).
31 *Id.* at 596.
32 *Id.* at 581.
33 *Id.*.at 582.
34 *Teva*, 876 F. Supp. 2d at 363.
35 *Id.* at 419.
36 Teva Pharm. USA, Inc. v. Sandoz, Inc., 723 F.3d 1363, 1375-76 (Fed. Cir. 2013).
37 *Id.* at 1368-69.
38 *Id.* at 1369.
39 Teva Pharm. USA, Inc. v. Sandoz, Inc., 134 S. Ct. 1761 (2014).
40 *Teva,* 135 S. Ct. at 836.
41 *Id.* at 840.
42 *Id.* at 843.
43 *Id.* at 835 (2015) (citing Markman v. Westview Instruments, Inc., 517 U.S. 370, 376, 391 (1996)). *See generally,* Timothy Le Duc, Note, *The Application of Collateral Estoppel to* Markman *Rulings: The Search for Logical and Effective Preclusion of Patent Claim Constructions,* 3 MINN. INTELL. PROP. REV. 297 (2002); William F. Lee and Anita K. Krug, *A Prescription for the Timing of Claim Construction Hearings,* 13 HARV. J. L. & TECH. 55 (1999); Sue (Ganske) Mota, Markman v. Westview Instruments, Inc.*: Patent Construction is Within the Exclusive Province of the Court*

Amendment, a patent's construction, including claim construction, is solely in the province of the court, and not for the jury, even when the construction of a term of art has evidentiary underpinnings,[44] as in the *Teva* case. The Court in *Teva* held that the appellate court should regard the trial court's factfinding as correct unless clearly erroneous, as it does the factfinding in other cases under the Federal Rules of Civil Procedure,[45] and not under the de novo standard as an appellate court reviews questions of law.[46] The majority observed that it is practical to use the clearly erroneous standard of review as well, as the district court judge is more familiar with the case than an appellate panel.[47]

The Supreme Court also clarified how the Court of Appeals for the Federal Circuit is to apply the clearly erroneous standard upon appeal. If only evidence intrinsic to the patent, such as the claims, the specification, and the prosecution history, is being reviewed by the appeals court, then the de novo standard is used, as this is a determination of law. But when extrinsic evidence is reviewed, the "evidentiary underpinnings" are reviewed under the clearly erroneous standard, as in *Markman.*[48] The Court thus vacated and remanded.[49]

Justice Thomas, joined by Justice Alito, dissented. The dissent argued that since patent claim construction does not involve findings of fact, the de novo standard is appropriate.[50] Also citing *Markman,*[51] the dissent analogized a patent closer to a statute, which is construed as a matter of law, than other factfinding review.[52] The need for uniformity in appellate review of claim construction also favors a de novo review, according to the dissent.[53] Since the district court didn't make findings of fact, according to the dissent, the appropriate standard was used by the appellate court.[54]

On remand, on June 18, 2015, using the appropriate standard of review, the Court of Appeals for the Federal Circuit affirmed that the claims which did not state an average molecular weight were not indefinite, but using the clear error standard

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Under the Seventh Amendment, 3 RICH. J. L & TECH. 3 (1997), *available at* http://law.richmond.edu/jolt/v3i1/mota.html.

44 *Teva,* 135 S. Ct. at 835 (citing Markman v. Westview Instruments, Inc., 517 U.S. 370, 390 (1996)).

45 *Id.* at 836 (citing Federal Rule of Civil Procedure 52(a)(6)).

46 *Id.* at 835.

47 *Id.* at 838.

48 *Id.* at 841 (citing Markman v. Westview Instruments, Inc., 517 U.S. 370, 390 (1996)).

49 *Id.* at 843.

50 *Teva,* 135 S. Ct. at 844 (Thomas, J., dissenting).

51 *Id.* at 845. (Thomas, J. dissenting) (citing Markman v. Westview Instruments, Inc., 417 U.S. 370, 381 (1996)).

52 *Id.* at 849 (Thomas, J. dissenting) (citing the intellectual property clause of the Constitution, U.S. CONST. art. 1, § 1, cl. 8, *supra* note 1 and accompanying text, as an authority that patents are issued when statutory requirements are met). The dissent also opined that patents are less like contracts and deeds. *See id.* at 848.

53 *Id.* at 851 (Thomas, J., dissenting).

54 *Id.* at 853.

of review, held that the claims which did were indefinite, reversing the district court,[55] and coming to the same ultimate conclusion it had previously reached using the de novo standard of review.[56] The appellate court cited both the 2015 Supreme Court decision in *Teva*,[57] as well as the 2014 decision in *Nautilus, Inc. v. Biosig Instruments, Inc.*,[58] which held that a patent fails for indefiniteness if its claims fail to disclose with reasonable certainty about the invention to someone skilled in the art.[59]

Thus, the Court in *Teva* clarified the standard of review for factual issues in patent claim construction is the clearly erroneous standard, and not de novo review.[60] In *Teva,* under either standard, the result is the same; the patent claim must define the method of calculating average molecular weight to avoid indefiniteness.

III. Commil USA, LLC v. Cisco Systems, Inc.

In *Commil USA, LLC v. Cisco Systems, Inc.,* the question before the U.S. Supreme Court was "whether a defendant's belief regarding patent validity is a defense to a claim of induced infringement."[61] Justice Kennedy, writing for the majority, clearly answered that "[i]t is not,"[62] vacating the decision of the Court of Appeals for the Federal Circuit and remanding.[63]

Commil Ltd. is the assignee of a patent on an invention that relates to wireless communication systems (wi-fi) with a number of mobile devices, and short range base stations which allow the mobile units to pass from one base station to another.[64] This patent "relates to a method of providing faster and more reliable

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55 Teva Pharm. USA, Inc., v. Sandoz, Inc. 789 F.3d 1335, 1338 (Fed. Cir. 2015). While the case was pending, all the patents whose claims recited an average molecular weight, except one, No. 5,800,808, expired. *See also supra* note 2.

56 Teva Pharm. USA, Inc. v. Sandoz, Inc., 123 F.3d 1363, 1376 (Fed. Cir. 2013).

57 *Teva,* 135 S. Ct. at 836.

58 Nautilus Inc. v. Biosig Inc.,134 S. Ct. 2120, 2124 (2014).

59 Teva Pharm., USA, Inc. v. Sandoz, Inc., 789 F.3d 1335, 1338 (Fed. Cir. 2015).

60 *Teva*, 135 S. Ct. at 836.

61 *Commil*, 135 S. Ct. at 1928.

62 *Id.*

63 *Id.* at 1931.

64 U.S. Pat. No. 6,430,395, *available at* http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetahtml%2FPTO%2Fsearch-bool.html&r=1&f=G&l=50&co1=AND&d=PTXT&s1=6,430,395.PN.&OS=PN/6,430,395&RS=PN/6,430,395, (Technical Field of the Invention). This patent specifically claims a wireless communication system with method of communicating between mobile units and at least two base stations, and at least one switch. There is a low-level communication protocol which has accurate time synchronization, and a high-level protocol which does not. *Id.* at claim 1. There is a claimed method of the switch routing data from the high-level protocols to the low level protocols, and vice versa. *Id.* at claim 4. There is a claimed method of having a mobile device including telephones, cell phones, personal data devices, computers, and laptops, among others, connect to the Internet by a central remote access server, among other devices. *Id.* at claim 6. Commil alleges that Cisco

handoffs of mobile devices from one base station to another as a mobile device moves throughout a network area."[65] Cisco Systems, Inc. designs and sells Internet Protocol based networking products and services.[66] Commil alleged that Cisco committed patent infringement by making and using certain of Cisco's networking systems, and induced patent infringement by selling the infringing equipment.[67] In 2010, after a jury trial, Commil was awarded $3.7 million in damages for patent infringement, but Cisco prevailed on the issue of induced infringement.[68] Commil requested and got a new trial on induced infringement and damages, because Commil alleged that Cisco's legal counsel made statements during trial which impaired Commil's ability to get a fair trial.[69] At the second trial in 2011, Commil was awarded $63 million in damages, plus $10.3 million in interest, and nearly $18,000 in costs.[70] Cisco appealed.

The Court of Appeals for the Federal Circuit in 2013 affirmed the granting of the partial new trial,[71] but reversed and remanded on the jury instruction that Cisco committed induced infringement if "Cisco actually intended to cause the acts that constitute direct infringement and that Cisco knew or should have known that its actions would induce actual infringement."[72] Cisco argued, and the appellate court agreed, that this interpretation prevented Cisco from defending with its good-faith belief in the invalidity of Commil's patent.[73] The dissent, while agreeing that a partial new trial was within the district court's discretion, disagreed with the majority's reversal on the good faith defense.[74] Commil requested a rehearing *en banc,* which was denied.[75] The U.S. Supreme Court, however, did grant certiorari

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infringes, directly and indirectly, on claims 1, 4, and 6 of the '395 patent. Commil USA, LLC v. Cisco Systems, Inc., 720 F.3d 1361, 1364 (Fed. Cir. 2013).

65 Commil USA, LLC v. Cisco Systems, Inc., 720 F.3d 1361, 1364 (Fed. Cir. 2013).

66 *The World's Most Valuable Brands,* FORBES, *available at* http://www.forbes.com/companies/cisco-systems/. Forbes ranks Cisco Systems the fifteenth most valuable brand (last visited Aug. 23, 2015). *Id.* Cisco calls itself "the worldwide leader in IT . . ." Cisco Overview, *available at* http://newsroom.cisco.com/overview (last visited Aug. 23, 2015).

67 *Commil,* 135 S. Ct. at 1922.

68 Commil USA, LLC v. Cisco Systems, Inc., No. 2:07-CV 341, 2010 U.S. Dist. LEXIS 144014 at *3-4 (E.D. Tex. Dec. 29, 2010).

69 *Id.* at *3. Cisco's counsel, when questioning a co-owner of Commil during trial, made a comment about not eating pork. *Id.* at *6. Cisco's counsel apologized and an instruction was given by the judge. *Id.* Again, during closing statements, Cisco's counsel referred to the most important trial in history from the Bible, referring to the trial of Jesus. *Id.* at *7. These comments were sufficient to grant a new trial on indirect infringement and damages. *Id.* at *7-8.

70 *Commil* 720 F. 3d at1365 . Obviously, the comments mentioned in the prior footnote were very expensive to Cisco, until the Supreme Court vacated and reversed on a different issue. *Commil,* 135 S. Ct. at 1942.

71 *Id.* at 1372.

72 *Id.* at 1366-67.

73 *Id.* at 1367.

74 *Id.* at 1373 (Newman, J., dissenting in part) (a good faith belief of patent invalidity is not a defense to patent infringement, according to the dissent).

75 Commil USA LLC v. Cisco Sys. Inc., 737 F.3d 699, 700 (Fed. Cir. 2013) (per curiam).

to decide if a good-faith belief in patent infringement is a defense to induced infringement.[76]

The Supreme Court had to address a question of first impression, "whether knowledge of, or belief in, a patent's validity is required for induced infringement. . ."[77] The Court first reaffirmed its decision in *Global-Tech Appliances, Inc. v. SEB S.A.*,[78] which held that induced infringement occurs if the defendant knew of the patent and knew that the induced acts constitute patent infringement.[79] Thus, according to the majority, Commil's argument that induced infringement requires only knowledge of the patent, fails, because *Global-Tech* also requires "proof the defendant knew the acts were infringing.[80]

Writing for the majority in an opinion issued May 26, 2015, Justice Kennedy addressed the question before the Court, and answered that the defendant's belief of patent invalidity is not a defense to induced patent infringement.[81] "When infringement is the issue, the validity of the patent is not the question to be confronted."[82] To allow the "new defense" of good-faith belief of patent invalidity would destroy the well-established presumption that a patent is presumed valid.[83] The Court observed that an accused infringer who believes that the patent in question is invalid has many options, including filing a declaratory judgment requesting that a federal court declare the patent invalid,[84] seeking an *inter partes*

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76 Commil USA LLC v. Cisco Sys., Inc., 135 S. Ct. 1920, 1926 (2015).

77 *Id.* The Court first observed that infringement can be direct, induced, or contributory. *Id.* Direct infringement is a strict liability offense; no one else may make, use, or sell the patented invention during the patent term. *Id* (citing 35 U.S.C. § 271(a)). Induced infringement requires knowledge of the patent, and that the induced acts constitute patent infringement. *Id.* (citing Global-Tech Appliances, Inc. v. SEB S.A., 131 S. Ct. 2060, 2063 (2011)). Contributory infringement also requires knowledge of the patent and its infringement. *Id.*

78 Global-Tech Appliances, Inc. v. SEB S.A., 131 S. Ct. 2060, 2068 (2011). *See generally* John David Evered, *Inducement of Patent Infringement after* Global-Tech *and* Akamai, *A Deadly Weapon Against New Enabling Technologies?* 23 TEX. INTELL. PROP. L. J. 43 (2014); Jeremy Adler , *See No Evil: How the Supreme Court's Decision in* Global-Tech Appliances v. SEB *Further Muddles the Intent Element of Induced Infringement,* 11 NW. J. TECH. & INTELL. PROP. 559 (2013).

79 *Commil*, 135 S.Ct. at 1928.

80 *Id.* at 1928 (*citing* Global-Tek, 131 S. Ct. 2060). *See generally* Sue Ann Mota, *The Times They Are A'Changin':* Biliski v. Kappos, Global Tech v. SEB, Stanford v. Roche, *and* Microsoft v. I4I, 16 J. TECH. L. & POL'Y 257 (2011).

81 *Commil,* 135 S. Ct. at 1928. The issues of patent infringement and patent validity are in different parts of the Patent Act. *Id.* Justice Breyer took no part in the consideration or decision of this case.

82 *Id.*

83 *Id.* (*citing* 35 U.S.C. § 282(a)). It would also undermine a century of precedent. *Id.*

84 *Id.* at 1929 (citing MedImmune, Inc. v. Genentech, Inc. 549 U.S. 118, 137 (2007)). *See generally,* Sue Ann Mota, MedImmune, Microsoft, *and* KSR*: The Supreme Court in 2007 Tips the Balance in Favor of Innovation in Patent Cases, and Thrice Reverses the Federal Circuit*, 11 MARQ. INTELL.PROP. L. R. 181 (2007).

review at the Patent Trial and Appeal Board,[85] seeking a reexamination by the Patent and Trademark Office,[86] or raising the affirmative defense of patent invalidity.[87] As a practical matter, if such a defense was allowed, any accused inducer could raise a defense that they thought the patent was invalid.[88] Thus, the Supreme Court held seven to two that there is no defense to induced infringement of a belief in a patent's invalidity, and the Court of Appeals was vacated and the case remanded.[89]

After resolving the issue before the Court, in dicta, Justice Kennedy then addressed the recurring issue of patent non-practicing entities. "The Court is well aware that an 'industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees.'"[90] These patent assertion entities, according to Justice Kennedy, "use [their] patents as a sword to go after defendants for money, even when their claims are frivolous."[91] While there has been no such allegation of frivolity in this case, Justice Kennedy deemed it "necessary and proper to stress that district courts have the authority and responsibility to ensure frivolous cases are dissuaded,"[92] by such methods as sanctioning attorneys who bring such cases[93] and awarding attorney's fees to prevailing parties in exceptional cases.[94]

Justice Scalia, joined by Chief Justice Roberts, dissented on the issue of whether a good faith belief in the patent's invalidity is a defense to an allegation of induced patent infringement.[95] Justice Scalia concludes that the majority's decision "increases the *in terrorem* power of patent trolls,"[96] using the term "patent troll" for the first time in a Supreme Court decision.[97] Scalia observes that Justice Kennedy apparently was aware of that result in the last part of the majority decision, thus

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85 *Commil,* 135 S. Ct. at 1929 (*citing* 35 U.S.C. § 316); Aashish Kapadia, *Inter Partes Review: A New Paradigm in Patent Litigation,* 23 TEX. INTELL. PROP. L. J. 113 (2015).

86 *Commil,* 135 S. Ct. at 1929 (*citing* 35 U.S.C. § 302).

87 *Id* (*citing* 35 U.S.C. § 282(b)(2)).

88 *Id.*

89 *Id.* at 1922.

90 *Id.* at 1930 (citing eBay Inc. v. MercExchange, LLC, 547 U.S.388, 396 (2006)) (Kennedy, J., concurring). *See generally,* Sue Ann Mota, EBay v. MercExchange*: Traditional Four Factor Test for Injunctive Relief Applies in Patent Cases, According to the Supreme Court,* 40 AKRON L. REV. 529 (2007).

91 *Commil,* 135 S. Ct. at 1930.

92 *Id.*

93 *Id.* (citing Fed. R, Civ. P. 11).

94 *Commil,* 135 S. Ct. at 1930-1931 (citing 35 U.S.C. § 285)).

95 *Commil,* 135 S. Ct. at 1931 (Scalia, J., dissenting).

96 *Id.*

97 Jeff John Roberts, FORTUNE *Supreme Court Says "Patent Troll" for First Time in* Cisco *Ruling, available at* http://fortune.com/2015/05/26/scotus-cisco-patent-trolls/ (last visited August 23, 2015).

encouraging district courts to use measures to combat patent trolls,[98] short of a defense of good faith belief in patent invalidity.

IV. Kimble v. Marvel Entertainment, LLC

The legal issue in *Kimble v. Marvel Entertainment, LLC*[99] was whether the Court should reaffirm or overturn the holding in *Brulotte v. Thys Co.,*[100] which held that patent royalties may not continue after the patent term has expired. On June 22, 2015, the Supreme Court held, six to three, that stare decisis leads the Court to continue to use *Brulotte's* holding, and that any change needs to come from Congress, not from the Court.[101]

In 1990, Kimble obtained a patent for a toy web-shooting glove which allows one to mimic Spiderman by shooting foam string from a glove.[102] In late 1990, Kimble met with the President of Marvel Enterprises, Inc.'s predecessor, Toy Biz,[103] and the President verbally told Kimble that the company would pay royalties if it used Kimble's ideas. The company later told Kimble that there was no interest in the toy but, nonetheless, the company started making a similar Spider Man toy called a Web Blaster, so Kimble sued for patent infringement and breach of contract in 1997.[104] The district court granted Marvel's motion for summary judgment on the patent claim, and Kimble won on the contract claim; both parties appealed.[105] In 2001, the parties reached a settlement agreement, under which Marvel would purchase the patent for over $500,000 plus 3% of net product sales, with no expiration date.[106]

In 2006, Marvel entered into a licensing contract with Hasbro, under which Hasbro could make certain role-playing toys, and in 2007, Hasbro began making versions of the Web Blaster toy.[107] Hasbro paid Marvel 10% royalties on net sales,

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98 *Commil,* 135 S. Ct. at 1931.

99 Kimble v. Marvel Entm't., 135 S. Ct. 2401, 2405 (2015).

100 Brulotte v. Thys Co., 379 U.S. 29, 33-34 (1964). *See generally* Michael Koenig, *Patent Royalties Extending Beyond Patent Expiration: An Illogical Ban From* Brulotte *to* Sheiber, 2013 DUKE L. & TECH. REV. 5 (2003).

101 *Kimble,* 135 S. Ct. at 2409.

102 *Id.* (U.S. Pat. No. 5,072,856). The abstract states that this toy makes it possible for a player to act like a spider person by shooting webs from the palms of his or her hand. *Id.* This patent expired around May 25, 2010. Kimble v. Marvel Enter. Inc., 727 F.3d 856, 57-858 (9th Cir. 2013).

103 Kimble v. Marvel Enter. Inc., 727 F.3d 856, 867 n.2 (9th Cir. 2013) (explaining that Toy Biz, Inc. was the company Kimble met with initially and which was originally sued in 1997). Marvel Enterprises, Inc. acquired Toy Biz. Marvel Enterprises, Inc. was the predecessor of Marvel Entertainment, LLC (hereinafter Marvel).

104 *Id.* at 858.

105 Kimble v. Marvel Enter., Inc., 692 F. Supp. 2d 1156, 1164 (D. Ariz. 2009) (the district court awarded damages of a 3.5% royalty of net past, present, and future product sales, excluding refill royalties).

106 *Id.*

107 *Id.*

and Marvel paid the plaintiffs the 3% royalties,[108] "and then Marvel stumbled across *Brulotte.*"[109] In 2008, Marvel told Kimble that full royalties were not owed on certain items such as Web Blaster packaged with other items, and recalculated lower royalties dating back to 2007 which Marvel claimed they had overpaid.[110] In 2008, Kimble sued again, alleging breach of the settlement agreement. Marvel counterclaimed, stating that it was not obligated to pay royalties after the expiration of the patent.[111] Citing *Brulotte v. Thys Co.,*[112] the magistrate recommended to the district court that Marvel was entitled to summary judgment and did not have to pay royalties after the expiration of the patent.[113] The settlement agreement stated that the only rights being transferred were patent rights, and did not have provisions for non-patent rights.[114]

The Court of Appeals for the Ninth Circuit reviewed the district court's decision de novo, and affirmed.[115] Reviewing and applying *Brulotte,*[116] the appeals court did acknowledge that "our application of the *Brulotte* rule in this case arguably deprives Kimble of part of the benefit of his bargain based upon a technical detail that both parties regarded as insignificant at the time of the agreement."[117]But, the agreement had one royalty rate, and did not have a discount rate post-patent for any non-patent rights, and thus royalties must cease after the patent expires.[118]

The Supreme Court granted certiorari in 2014 on whether to overrule *Brulotte,*[119] and held that under stare decisis, it should not.[120] Justice Kagan stated that "[p]atents endow their holders with certain superpowers, but only for a limited time."[121] She observed that the Court also protected the patent end date in cases including *Brulotte,*[122] which held an agreement unlawful *per se* when it called for patent royalties after the patent term ended. Justice Kagan observed that "[r]especting *stare decisis* means sticking to some wrong decisions."[123] *Brulotte* is not "unworkable," according to the Court,[124] and Congress could statutorily fix this

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[108] *Kimble*, 692 F. Supp. 2d at 1158.
[109] *Kimble,* 135 S. Ct. at 2406 ("In negotiating the settlement, neither side was aware of *Brulotte.*").
[110] *Kimble,* 692 F. Supp. 2d at 1166.
[111] *Kimble,* 727 F.3d at 859.
[112] *Brulotte,* 379 U.S. at 32.
[113] *Kimble,* 692 F. Supp. 2d at 1174.
[114] *Id.* at 1168.
[115] *Kimble* 727 F.3d at 867.
[116] *Brulotte*, 379 U.S. at 29.
[117] *Kimble* 727 F.3d at 866.
[118] *Id.* at 864.
[119] Kimble v. Marvel Entm't., LLC, 135 S Ct. 781 (2014).
[120] *Kimble*, 135 S. Ct. at 2406.
[121] *Id.* This author also speculates whether Justice Kagan herself was endowed with certain superpowers while writing this opinion alluding to Spider Man.
[122] *Id.* at 2407-08, (explaining Brulotte v. Thys Co., 379 U.S. 29 (1964)).
[123] *Id.* at 2409.
[124] *Id.* at 2411.

problem, but it's not the Court's role.[125] While antitrust precedents have been overturned,[126] *Kimble v. Marvel Entertainment, LLC* is a patent case, according to the majority.[127] The Court views antitrust case precedents under the Sherman Act less strictly as economic analysis evolves under antitrust law.[128] Thus, the Court of Appeals for the Ninth Circuit was affirmed.[129]

Justice Alito dissented, joined by Chief Justice Roberts and Justice Thomas.[130] The dissent states that the Patent Act is silent on post-expiration royalties.[131] Thus, *Brulotte* did not involve statutory interpretation, but rather was a "bald act of policymaking,"[132] whose "only virtue is that we decided it,"[133] according to the dissent. *Brulotte* is "an antitrust decision masquerading as a patent case,"[134] and should be overturned, according to the dissent.[135]

There are several solutions to the *Kimble*[136] problem of royalties post-patent expiration. Congress could amend the Patent Act to allow royalties past the patent term, as suggested by Justice Kagan.[137] In the meantime, those negotiating such patent royalties need to be aware that without proper wording, royalties based entirely on patent rights expire at the end of the patent term.[138] Justice Kagan points out options in a patent license to avoid having royalties end with the patent's term. Pre-expiration royalties can be spread out into the post-expiration time, but this needs to be explicitly stated in the contract.[139] Post-expiration royalties could be for other rights, such as trademarks or copyrights or trade secrets, but again, the agreement must be explicit that the post-patent expiration royalties are for other rights and not for patent royalties after the patented invention is in the public domain.[140] Post-patent term royalties can also be for other business arrangements,

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[125] *Id.* at 2412-2413.

[126] *Kimble*, 135 S. Ct. at 2412-2416 (citing Leegin Creative Leather Products, Inc. v. PSKS, Inc., 551 U.S. 877 (2007) and Illinois Tool Works v. Independent Ink, Inc., 547 U.S. 28 (2006)). *See generally,* Randal C. Picker, Twombly, Leegin, *and the Reshaping of Antitrust,* 2007 SUP. CT. REV. 161 (2007); Sue Mota, *Antitrust, Limited: The Supreme Court Reigns in Antitrust Enforcement in 2007,* 7 FLA. ST. BUS. REV. 121, 126-29 (2007). *See generally,* Sue Mota, *The Untwining of Patent Law and Antitrust: No Presumption of Market Power in Patent Tying Cases in* Illinois Tool Works v. Independent Ink, 40 SUFFOLK U. L. REV. 58 (2006).

[127] *See Kimble*, 135 S. Ct. at 2412-13.

[128] *Id.* at 2413.

[129] *Id.* at 2415.

[130] *Id.*

[131] *Id.*

[132] *Kimble*, 135 S. Ct. at 2415.

[133] *Id.* at 2417.

[134] *Kimble*, 135 S. Ct. at 2418.

[135] *Id.* at 2419.

[136] Kimble v. Marvel Entm't, LLC, 135 S. Ct. 2401 (2015).

[137] *Id.* at 2409-10.

[138] *See id.* at 2403. In *Kimble*, neither party knew of this, and fortunately for Marvel, they discovered *Brulotte* before the expiration of Kimble's patent.

[139] *Id.* at 2408.

[140] *Id.*

such as joint ventures, just not for patent royalties, according to Justice Kagan.[141] But, patent holders must be aware of *Kimble v. Marvel Entertainment, LLC,*[142] and *Brulotte v. Thys Co.,*[143] and how to negotiate post-patent expiration royalties which will stand scrutiny.

V. Conclusion

The U.S. Supreme Court in the 2014-15 term decided three important patent cases in *Teva,*[144] *Cisco,*[145] and *Marvel,*[146] vacating decisions from the Court of Appeals for the Federal Circuit in both cases before the Court, but affirming the Court of Appeals for the Ninth Circuit.

Perhaps the theme of this term is the importance of precedent in patent law. Both the majority and the dissent in *Teva* cited *Markman v. Westview Instruments, Inc.*[147] The Court in *Cisco* reaffirmed *Global-Tech Appliances, Inc. v. SEB S.A.*[148] The Court in *Marvel* upheld the precedent of *Brulotte v. Thys Co.*[149] to the detriment of the plaintiff Kimble, even though neither party was aware of the ramifications at the time of their contract.[150] The dissent in *Marvel* would have overturned *Brulotte,* as it was deemed bad law not based on the Patent Act.[151] Congress could fix the problem in *Marvel*[152] of extending royalties beyond the patent term, if it so agreed between the parties, but in the meantime, patent licensors need to be aware that purely patent royalties end at the end of the patent term.[153]

Possibly a second theme of the Court in patent cases in 2015 is the justices giving suggestions on how to deal with ramifications of two of the holdings. Justice Kagan in *Marvel* made suggestions for extending royalties beyond the patent term, such as explicitly stating in an agreement that patent royalties are reduced over the patent term and spread out over a longer term, or basing royalties post-patent expiration on other forms of intellectual property used, such as copyrights and trademarks, or making post-patent royalty payments based upon some other business venture.[154] Justice Kennedy in *Cisco* encouraged district courts to dissuade

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[141] *Id.* at 2408.
[142] Kimble v. Marvel Entm't, LLC, 135 S. Ct. 2401 (2015).
[143] Brulotte v. Thys Co., 379 U.S. 29 (1964).
[144] Teva Pharm. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831 (2015).
[145] Commil USA, LLC v. Cisco Sys., Inc., 135 S. Ct. 1920 (2015).
[146] Kimble v. Marvel Entm't, LLC, 135 S. Ct. 2401 (2015).
[147] Teva v. Sandoz 135 S. Ct. 831, 835; *id.* at 845 (Thomas, J., dissenting); *see supra* note 43 and accompanying text.
[148] Global-Tech Appliances, Inc. v. SEB S.A., 131 S. Ct. 2060, 2068 (2011); Cisco, 135 S. Ct. at 1928; *see supra* note 78 and accompanying text.
[149] Brulotte v. Thys Co., 379 U.S. 29 (1964).
[150] Kimble, 135 S.Ct. at 2406.
[151] *See supra* notes 126-137 and accompanying text.
[152] Kimble v. Marvel Entm't, LLC, 135 S. Ct. 2401 (2015).
[153] *Id.* at 2405.
[154] *Id.* at 2408.

frivolous patent cases by such methods as sanctioning attorneys who bring such cases and, citing *Octane Fitness, LLC. V. ICON Health and Fitness, Inc.*, decided by the Court in 2014, awarding attorney's fees to the prevailing party.[155]

The year 2015, like 2014, was not a good year for patent assertion entities at the United States Supreme Court, with the term "patent troll" actually used by Justice Scalia in the dissent in *Cisco*.[156] Justice Scalia, also citing *Octane Fitness,* would have allowed the defense of a good faith belief in patent invalidity,[157] which would have had the effect of even further deterring patent trolls. While *Cisco* did not reign in patent trolls as explicitly as the Court did in 2014 in *Octane Fitness.*[158] and *Highmark Inc. v. Allcare Health Management System, Inc.*,[159] which made attorney's fees easier to recover in patent infringement suits, and in *Alice Corporation v. CLS Bank International,*[160] where the Supreme Court held that "mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention," the Court in 2015 did again send a strong message on how to deal with patent trolls.

In all, in this author's opinion, the Court sent a clear, although not unanimous message in the area of patent law in the 2014-15 term, that precedent is important in patent law, and that Congress is the appropriate branch to enact or change law in this area, to promote the progress of science and useful arts.[161]

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[155] Commil USA, LLC v. Cisco Sys., Inc., 135 S. Ct. 1920, 1923 (2015); *see supra* notes 90 – 94 and accompanying text.

[156] Commil USA, LLC v. Cisco Sys., Inc., 135 S. Ct. at 11931 (Scalia, J., dissenting).

[157] *Id.*

[158] Octane Fitness, LLC v. ICON Health & Fitness,134 S. Ct. 1749 (2014).

[159] Highmark Inc. v. Allcare Health Management Sys., Inc., 134 S. Ct. 1744 (2014).

[160] Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2358 (2014).

[161] U.S. CONST., art. I, § 8, cl. 8.

A New Era for Patent Infringement Pleading: *Twombly*, *Iqbal*, and the Demise of Form 18

Jun Zheng*

I. Introduction

Every civil action begins with the filing of a complaint.[1] Thus, pleading is the first battle that a plaintiff must fight to get any civil action into the courts. Consequently, "[f]ew issues in civil procedure jurisprudence are more significant than pleading standards, which are the key that opens access to courts."[2]

Since the beginning of the twentieth century, the pleading standard for patent infringement cases has gone through several major changes. The adoption of the Federal Rules of Civil Procedure in 1938 established the "notice pleading" standard and ended the era of code pleading.[3] Seven decades later, the Supreme Court in its landmark decisions, *Twombly* and *Iqbal*, replaced the notice pleading standard with a plausibility pleading standard.[4] After *Twombly* and *Iqbal*, the lower courts wrestled with the continued validity of Form 18 in the Appendix Forms of the Federal

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1 Fed. R. Civ. P. 3 ("A civil action is commenced by filing a complaint with the court.").

2 Phillips v. Cnty. of Allegheny, 515 F.3d 224, 230 (3d Cir. 2008).

3 Jonathan L. Moore, *Particularizing Patent Pleading: Pleading Patent Infringement in A Post-Twombly World*, 18 TEX. INTELL. PROP. L.J. 451, 471-72 (2010).

4 Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007); Ashcroft v. Iqbal, 556 U.S. 662 (2009).

Rules of Civil Procedure.[5] Now, we are at another important turn of the law on patent infringement pleading, with the recent abrogation of the Rule 84 and Form 18.[6]

This essay reviews the evolution of patent infringement pleading standards, makes recommendations on what the courts should require for the heightened pleading standard under *Twombly* and *Iqbal*, and argues why these changes would be good for businesses and promote innovation. Section II reviews the start of the plausibility pleading standard under *Twombly* and *Iqbal*, and the complications caused by Form 18. Section III summarizes the current divided standards for different types of patent infringement pleading. Section IV summarizes the district courts' experiments to hash out what the heightened standard requires. Finally, in Section V, I make several recommendations on what the courts should require under the heightened pleading standard, and their potential impacts on several major players in patent litigation.

II. *Twombly, Iqbal,* and Form 18

Rule 8 of the Federal Rules of Civil Procedure provides: "A pleading that states a claim for relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief."[7] The Federal Rules of Civil Procedure were adopted in 1938 as a response to the pitfalls of code pleading and were intended to provide a new standard for the level of detail needed in a complaint.[8] In general, the new pleading standard was considered as the start of "notice pleading" for civil actions. The goal of the new notice pleading standard was that "pleadings would merely put a party on notice and that facts, as well as the specifics of claims, would be fleshed out through the discovery process."[9] The "notice pleading" standard essentially encourages pleading with simplicity, and a plaintiff's complaint is arguably less vulnerable to a Rule 12(b)(6) motion to dismiss than under the "code pleading" standard before 1938.[10]

In its landmark case *Conley v. Gibson*, the Supreme Court took a liberal interpretation of the notice pleading standard as required by Rule 8.[11] The Court explained that "[s]uch simplified 'notice pleading' is made possible by the liberal opportunity for discovery and the other pretrial procedures established by the Rules to disclose more precisely the basis of both claim and defense and to define more nar-

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5 Fed. R. Civ. P. Form 18; *see also, e.g.*, In re Bill of Lading Transmission & Processing Sys. Pat. Lit. (R+L Carriers, Inc. v. DriverTech LLC), 681 F.3d 1323 (Fed. Cir. 2012).

6 *See* Administrative Office of the U.S. Courts, Summary of the Report of the Judicial Conference Committee on Rules of Practice and Procedure, at Rules-13 (September 2014), *available at* http://www.uscourts.gov/uscourts/RulesAndPolicies/rules/Reports/ST09-2014.pdf.

7 Fed. R. Civ. P. 8(a).

8 Moore, *supra* note 3, at 471.

9 *Id.* at 472.

10 Fed. R. Civ. P. 8(12(b)(6) (A pleading may be dismissed for "failure to state a claim upon which relief can be granted.").

11 Conley v. Gibson, 355 U.S. 41 (1957).

rowly the disputed facts and issues."[12] According to the Court, Rule 8's requirement of only "a short and plain statement of the claim" is to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests."[13] More importantly, the Supreme Court sets an extremely liberal standard of notice pleading: "[A] complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove *no set of facts* in support of his claim which would entitle him to relief."[14] This "no set of facts" standard would govern the pleading for all civil actions in the federal courts for 50 years until the Supreme Court changed course in 2007.

A. From notice pleading to plausibility pleading

In 2007, five decades after the *Conley* ruling, the Supreme Court eventually decided in *Bell Atlantic Corp. v. Twombly* that the "no set of facts" language from *Conley* had "puzzl[ed] the profession for years" and "earned its retirement."[15] The *Twombly* decision would again change the landscape of the pleading standard for civil actions.

1. *Twombly:* The start of plausibility pleading

After retiring the "no set of facts" language from *Conley*, the Supreme Court replaced the notice pleading standard with a plausibility standard.[16] The plausibility standard, the Court explains, requires that "[f]actual allegations must be enough to raise a right to relief above the speculative level," and there must be "enough facts to state a claim to relief that is plausible on its face."[17] The Court proclaims that:

> While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the "grounds" of his "entitlement to relief" requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.[18]

Consequently, to meet the "fair notice" requirement, a complaint must state at least factual allegations in order to make it "plausible" that later discovery will likely reveal sufficient evidence to prove the truth of the allegations.

2. *Iqbal:* Plausibility for all civil actions

The state of the law regarding the pleading standard was anything but clear im-

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12 *Id.* at 47-48.
13 *Id.* at 47.
14 *Id.* at 45-46 (emphasis added).
15 Bell Atl. Corp. v. Twombly, 550 U.S. 544, 562-63 (2007).
16 *Id.* at 561-63, 570.
17 *Id.* at 555, 570.
18 *Id.* at 555 (internal citation omitted).

mediately after *Twombly*. The main concern of *Twombly* was discovery abuse. Throughout the opinion, the Supreme Court expressed its concerns about the "enormous expense" of antitrust discovery and the possibility of discovery abuse by a plaintiff's meritless claim.[19] Therefore, immediately after the high Court's ruling, the circuit courts split over how broadly to read the *Twombly* decision.[20] There were strong arguments that *Twombly* should be limited to antitrust cases, or complex civil actions which involve "potentially enormous expense of discovery."[21] Therefore, according to this argument, in non-complex cases where there was no threat of enormous expense of discovery, the notice pleading standard under *Conley* still applies. Adding to the strength of the argument was the fact that the Supreme Court never entirely overturned *Conley* in *Twombly*; rather, it only explicitly targeted the "no set of facts" language.[22] Moreover, the Court specifically stated that it was not creating a heightened pleading standard.[23]

This uncertainty among the appellate courts was settled two years later by the Supreme Court in another landmark case, *Ashcroft v. Iqbal*.[24] In *Iqbal*, the Court officially pronounced that the *Twombly* plausibility standard applies to not only antitrust or complex civil actions, but to all federal civil actions.[25]

B. Validity of Form 18 after *Twombly* and *Iqbal*

Because patent infringement actions are merely a specific type of civil action, the *Twombly/Iqbal* plausibility standard also applies to pleadings of patent infringement actions. However, complication arises when a plaintiff uses Form 18 included in the Appendix Forms of the Federal Rules of Procedures.

1. *Form 18 and Rule 84*

The Appendix Forms of the Federal Rules of Procedure have a number of forms, including Form 18, which is an illustrative form for "Complaint for Patent Infringement."[26] In essence, Form 18 requires the following information:

> (1) an allegation of jurisdiction; (2) a statement that the plaintiff owns the patent; (3) a statement that defendant has been infringing the patent "by making, selling, and using [the device] embodying the patent"; (4) a statement that the plaintiff has

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19 *Id.* at 559 ("[T]he threat of [enormous] discovery expense will push cost-conscious defendants to settle even anemic cases before reaching those proceedings.").

20 Jonathan L. Moore, *Particularizing Patent Pleading: Pleading Patent Infringement in a Post-Twombly World,* 18 TEX. INTELL. PROP. L.J. 451, 472, 475 (2010).

21 *See generally* Robbins v. Okla., 519 F.3d 1242, 1248 (10th Cir. 2008) (noting that *Twombly* involved the potential imposition of the "potentially enormous expense of discovery" on the defendants).

22 *See generally Twombly*, 550 U.S. 544.

23 *Id.* at 570.

24 Ashcroft v. Iqbal, 556 U.S. 662 (2009).

25 *Id.* at 684.

26 Fed. R. Civ. P. Form 18.

> given the defendant notice of its infringement; and (5) a demand for an injunction and damages.[27]

On its face, Form 18 appears to be insufficient under the *Twombly/Iqbal* plausibility pleading standard, because it does not require enough facts to move the case over the line of "plausibility." However, Rule 84 adds to the complication by stating that "[t]he forms in the Appendix suffice under these rules and illustrate the simplicity and brevity that these rules contemplate."[28] Because Form 18 and Rule 84 were developed when the notice pleading standard was adopted in 1938, long before *Twombly* and *Iqbal*, there is a potential contradiction between the two requirements.[29] Therefore, for a period after *Twombly* and *Iqbal*, the continued validity of Form 18 was frequently debated.

2. *McZeal:* Federal Circuit's first pass on continued validity of Form 18

Several months after *Twombly* but before *Iqbal*, the Federal Circuit was presented with the first opportunity to pass on the continued validity of Form 18 (then numbered as Form 16) under the plausibility standard.[30] McZeal, a *pro se* plaintiff, appealed the district court's granting of defendant's Rule 12(b)(6) motion to dismiss because the district court ruled that "there just aren't any facts" in the complaint for patent infringement.[31] The Federal Circuit vacated the dismissal and held that the plaintiff's "complaint contain[ed] enough detail to allow the defendants to answer and thus me[t] the notice pleading required to survive a Rule 12(b)(6) motion" and "nothing more is required."[32] More importantly, the Federal Circuit noted that Form 18 put the defendant on enough notice and was therefore consistent with the notice pleading standard: "It logically follows that a patentee need only plead facts sufficient to place the alleged infringer on notice as to what he must defend."[33] In doing so, the majority implied that direct patent infringement pleading does not have to comply with the *Twombly* plausibility standard.

Judge Dyk, however, took the position that the new plausibility standard pronounced in *Twombly* applies to patent infringement pleadings and that Form 18 is inconsistent with *Twombly*.[34] In his dissenting opinion, Judge Dyk argued that Form 18 could not pass the plausibility test for failure to state a patent infringement claim because of the lack of specificity it requires with respect to the infringing activity,

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27 McZeal v. Sprint Nextel Corp., 501 F.3d 1354, 1356-57 (Fed. Cir. 2007) (alteration in original) (citing Fed. R. Civ. P. Form 16 (2006) (renumbered Fed. R. Civ. P. Form 18)).

28 Fed. R. Civ. P. 84.

29 Adam Steinmetz, *Pleading Patent Infringement: Applying the Standard Established by Twombly and Iqbal to the Patent Context*, 13 COLUM. SCI. & TECH. L. REV. 482, 488 (2012).

30 McZeal v. Sprint Nextel Corp., 501 F.3d 1354 (Fed. Cir. 2007).

31 *Id.* at 1335, 1354-55.

32 *Id.* at 1357 (citation omitted).

33 *Id.* (citing Twombly, 550 U.S. at 1971 n.10).

34 *Id.* at 1360, 1362 (Dyk, J., dissenting in part).

and that both the patent claims being asserted failed to state a claim despite their compliance with Form 18.[35] On the other hand, Judge Dyk agreed that Rule 84, which endorses the sufficiency of Form 18, prevents the court from announcing that Form 18 is insufficient in view of the new plausibility standard.[36] Consequently, he called for the rulemaking process to either "eliminat[e] the form, or at least . . . revis[e] it to require allegations specifying . . . the features of the accused device that correspond to the claim limitations."[37]

3. Sharp divisions in district courts after *McZeal*

After *McZeal*, district courts were sharply divided on the continued sufficiency of Form 18 in view of *Twombly* and *Iqbal*. On the one hand, some district courts distinguished *McZeal* on the ground that *McZeal* involved a *pro se* plaintiff and therefore a lower pleading standard was applied there.[38] Some other courts took the position that the Supreme Court's later decision in *Iqbal* abrogated *McZeal*, which was decided before *Iqbal*.[39] Yet some other district courts went a step further to expressly decline to follow *McZeal* and Form 18, reasoning that *Twombly* and *Iqbal* practically invalidated Form 18, and that even a *pro se* plaintiff cannot rely on it.[40]

On the other hand, some district courts followed *McZeal* and held that allegations conforming to Form 18 are sufficient for pleading purposes.[41] These courts noted the difficulty of applying the plausibility standard because it creates a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense,"[42] but the "line between facts and legal conclusions is not always easy to draw."[43]

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35 *Id.* at 1360-61.

36 *McZeal*, 501 F.3d at 1360.

37 *Id.*

38 *See, e.g.*, Bender v. LG Electronics. U.S.A., Inc., No. C 09-02114 JF (PVT), 2010 WL 889541, at *2, *3 n.3, *6 (N.D. Cal. Mar. 11, 2010) (ruling that to put accused infringers on notice, a patentee must specifically identify an allegedly infringing product, such as "by name or number," and plead factual allegations to plausibly show infringement).

39 *See, e.g.*, Koninklijke Philips Elecs. N.V. v. The ADS Group, 694 F. Supp. 2d 246, 252 n.8 (S.D.N.Y. 2010) ("Of greater relevance, *McZeal* was decided before the *Iqbal* decision made clear that *Twombly*'s heightened pleading standard applied in all cases, not merely those like *Twombly* that assert antitrust violations.").

40 *See, e.g.*, Rovi Corp. v. Hulu, LLC, No. 11-665, 2012 WL 261982, at *2-3 (D. Del. Jan. 27, 2012); Pieczenik v. Abbott Labs., No. 10-2230, 2011 WL 1045347, at *20, *27 (D.N.J. Mar. 23, 2011), *aff'd*, 474 F. App'x 766 (Fed. Cir. 2012).

41 *See, e.g.*, Bedrock Computer Techs., LLC v. Softlayer Techs., Inc., No. 609 CV 269, 2010 WL 5175172, at *2 (E.D. Tex. Mar. 29, 2010) ("*Twombly* and *Iqbal* have not affected the adequacy of complying with Form 18."); Microsoft Corp. v. Phoenix Solutions, Inc., 741 F. Supp. 2d 1156, 1158, 1159 (C.D. Cal. 2010) (finding Form 18 sufficient).

42 Elan Microelectronics Corp. v. Apple, Inc., No. C 09-01531 RS, 2009 WL 2972374, at *1 (N.D. Cal. Sept. 14, 2009) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009)).

43 *Id.* at *2.

4. Federal Circuit's official endorsement of Form 18

The Federal Circuit attempted to resolve the non-uniformity on the sufficiency of Form 18 in *R+L Carriers*, where the court, relying heavily on Rule 84,[44] officially announced that Form 18 was sufficient under the *Twombly/Iqbal* plausibility standard.[45] Despite the potential inconsistency between Form 18 and *Twombly/Iqbal*, the Federal Circuit declined to rewrite the text of Form 18 because it felt that such an act would encroach on congressional authority,[46] and that any changes "must be obtained by the process of amending the Federal Rules, and not by judicial interpretation."[47] However, the court limited Form 18's application to direct patent infringement pleading only, because Form 18 does not include information about the mens rea required to prove indirect patent infringement.[48] Therefore, the pleading of indirect patent infringement should comply with the *Twombly/Iqbal* plausibility standard.[49]

Unlike the majority's reliance on Rule 84, Judge Newman, in her dissenting opinion, focused instead on the fundamental purpose of the Federal Rules—to "provide a uniform procedure for all civil actions."[50] Judge Newman argued that since Rule 8 was designed to "establish uniform rules" for all civil cases, except those subject to Rule 9, there should be no special treatment for direct patent infringement pleading just because there is an illustrative form.[51] Because the Supreme Court extended the *Twombly* plausibility standard to all civil actions in *Iqbal*, rather than limiting it to antitrust cases for the same reason of uniformity,[52] Judge Newman thought the majority's approach "absolve[d] patent infringement pleadings from the uniform requirements of the Federal Rules and Supreme Court precedent," and made useless the "judicial experience and common sense" of district courts.[53]

Despite Judge Newman's vigorous dissent in *R+L Carriers* that *Twombly/Iqbal* carved out no exception for pleading of direct patent infringement, the Federal Circuit reaffirmed its endorsement of Form 18 one year later in *K-Tech Telecommuni-*

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44 Fed. R. Civ. P. 84; *supra* note 28 and accompanying text; Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007).

45 R+L Carriers, Inc. v. DriverTech LLC (In re Bill of Lading Transmission & Processing Sys. Patent Litig.), 681 F.3d 1323, 1334-36 (Fed. Cir. 2012).

46 *Id.* at 1335 n.7.

47 *Id.* at 1334 (quoting Leatherman v. Tarrant Cnty. Narcotics Intelligence & Coordination Unit, 507 U.S. 163, 168 (1993)).

48 *See id.* at 1336 ("The Forms are controlling only for causes of action for which there are sample pleadings.").

49 *Id.* at 1337.

50 *Id.* at 1348.

51 *Id.* at 1349-50.

52 Ashcroft v. Iqbal, 556 U.S. 662, 684 (2009) (noting that *Twombly* was based on the interpretation and application of Rule 8).

53 In re *Bill of Lading*, 681 F.3d at 1347.

cations, Inc. v. Time Warner Cable, Inc., where the court again immunized a Form 18-like complaint for direct patent pleading from Rule 12(b)(6) attack.[54]

C. Choice of law issues and district courts' continued challenges of Form 18

Despite the Federal Circuit's repeated attempts to resolve the district courts' divided views on the sufficiency of Form 18 in *R+L Carriers* and *K-Tech Telecommunications*, some rebellious district courts continued to hold that Form 18 is insufficient under the *Twombly/Iqbal* standard.[55] These district courts were able to do so because the Federal Circuit's decisions on procedural issues are not necessarily binding for district courts.[56] While the Federal Circuit has exclusive jurisdiction over all cases arising under the Patent Act,[57] pleading is a procedural issue that arises under the Federal Rules of Procedure rather than the Patent Act. Therefore, "[t]he Federal Circuit applies its own law with respect to issues of substantive patent law and certain procedural issues pertaining to patent law, but applies the law of the regional circuits on non-patent issues."[58] Consequently, the Federal Circuit's rulings on the sufficiency of Form 18 in *R+L Carriers*, which applied Sixth Circuit law, and in *K-Tech Telecommunications*, which applied Ninth Circuit law, do not prevent district courts in other circuits from finding that Form 18 is insufficient under *Twombly* and *Iqbal*.

The first example was the Eastern District of Virginia in *Macronix*, decided in March 2014.[59] In *Macronix*, District Judge Payne criticized the Federal Circuit's endorsement of Form 18 in *McZeal* and *R+L Carriers*, stating that the Federal Court's rulings "simply exempted [direct patent infringement] cases from the reach of *Twombly* and *Iqbal* as if a rule change were necessary to implement a Supreme Court decision addressing application of a rule of procedure."[60] The district court further criticized the Federal Circuit's reliance on Rule 84, noting that "Rule 84 has been in effect since 1937"[61] and has lost its value in view of *Twombly* and *Iqbal*. The district court further reasoned that "[p]atent cases fit the same bill" as antitrust cases in *Twombly*, which is "a kind of litigation well-known for extensive discovery and high litigation costs," and patent cases are "perhaps even more so."[62] Therefore, "[i]t is not logical to exempt them from the reach of *Twombly* and *Iqbal*, whose prime purpose was to assure that such expense was not incurred unless the plaintiff

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54 K-Tech Telecommc'ns., Inc. v. Time Warner Cable, Inc., 714 F.3d 1277, 1283-87 (Fed. Cir. 2013).

55 *See, e.g.*, Macronix Int'l Co. v. Spansion Inc., 4 F. Supp. 3d 797, 802 (E.D. Va. Mar. 10, 2014); Regeneron Pharm., Inc. v. Merus B.V., No. 14–CV–1650 (KBF), 2014 WL 2795461, at *2-*3 (S.D.N.Y. June 19, 2014).

56 *See Regeneron Pharm.*, 2014 WL 2795461, at *1.

57 28 U.S.C. § 1295, 1338 (2006).

58 Invitrogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1378-79 (Fed. Cir. 2005).

59 *Macronix*, 4 F. Supp. 3d at 802.

60 *Id.*

61 *Id.*

62 *Id.* at 803.

had posited a plausible claim in the complaint."[63] Consequently, the district court held that a complaint complying with Form 18 is insufficient under the *Twombly/Iqbal* plausibility standard.[64]

Shortly after *Macronix*, several district courts followed the Eastern District of Virginia and held that Form 18 does not meet the *Twombly/Iqbal* plausibility standard,[65] while other district courts held on to the Federal Circuit's ruling and continued to honor Form 18.[66]

III. The Divided Patent Pleading Atandards After *R+L Carriers*

Because of the Federal Circuit's special treatment of pleading direct patent infringement based on Form 18, we are left with different pleading standards for various types of patent infringement actions after *R+L Carriers* and *K-Tech Telecommunications*. This section summarizes the various pleading standards in different contexts of patent infringement.

A. Direct infringement

As discussed above, the Federal Circuit has taken the position that Form 18 (which, as noted by Judge Dyk in *McZeal* and Judge Newman in *R+L Carriers*, on its face includes nothing more than legal allegations) is sufficient to put the defendants on "fair notice," even in view of *Twombly* and *Iqbal*.[67] Further, the Federal Circuit has also indicated that providing even less specific information than is detailed in Form 18 may still sometimes suffice to defeat a Rule 12(b)(6) motion to dismiss. For example, Form 18 states that the defendant is directly infringing by making, selling, and using a specific device (an electric motor).[68] However, the Federal Circuit does not read Form 18 to require a plaintiff to identify an accused device by name.[69] The court's reasoning is that such a requirement might serve to defeat a claim when the defendant operated in secrecy or when the defendant infringed through a system or method rather than by making a "device."[70] Thus, when the

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63 *Id.*

64 *Id.* at 803-04.

65 *See, e.g.*, Regeneron Pharm., Inc. v. Merus B.V., No. 14-CV-1650 (KBF), 2014 WL 2795461, at *2-*3 (S.D.N.Y. Jun. 18, 2014); Deerpoint Grp., Inc. v. Acqua Concepts, Inc., No. 1:14–CV–01503–SAB, 2014 WL 7178210, at *3 (E.D. Cal. Dec. 16, 2014).

66 *See, e.g.*, JDS Uniphase Corp. v. Coadna Photonics, Inc., No. 14–CV–01091–JST, 2014 WL 2918544 at *2-*3 (N.D. Cal. June 26, 2014); Ingeniador, LLC v. Lord's Co. of Orlando, Civ. No. 13–1655(SCC), 2014 WL 5460635, at *3, *4 n.5 (D.P.R. Oct. 24, 2014).

67 *See generally* McZeal v. Sprint Nextel Corp., 501 F.3d. 1354, 1361 (Fed. Cir. 2007); R+L Carriers, Inc. v. DriverTech LLC (*In re* Bill of Lading Transmission & Processing Sys. Patent Litig.), 681 F.3d 1323, 1348 (Fed. Cir. 2012); K-Tech Telecommc'ns., Inc. v. Time Warner Cable, Inc., 714 F.3d 1277, 1283 (Fed. Cir. 2013).

68 Fed. R. Civ. P. Form 18.

69 *K-Tech Telecommc'ns.*, 714 F.3d at 1286.

70 *Id.*

plaintiff cannot identify a specific "device," the complaint may suffice by providing "notice and facial plausibility" of the allegations, which is "not an extraordinarily high [bar]."[71]

The majority of district courts have followed the Federal Circuit's approach.[72] Therefore, in these district courts, a complaint for direct patent infringement complying with Form 18, or even complaints including less information as required by Form 18, will stand against Rule 12(b)(6) attacks. On the other hand, several district courts, such as the Eastern District of Virginia, have refused to recognize the continued sufficiency of Form 18 under the *Twombly* and *Iqbal* standard,[73] reasoning that "[t]here is no logical reason to exempt patent complaints from the plausibility requirements that apply to all other federal complaints."[74] Consequently, in these district courts, a complaint must plead more than what Form 18 requires and assert enough factual allegations "to state a claim to relief that is plausible on its face."[75]

B. Indirect infringement

There are two types of indirect infringement: induced infringement and contributory infringement.[76] Because both induced infringement and contributory infringement require the infringer to have knowledge of the asserted patent and to possess certain intent,[77] but Form 18 requires no such information, the Federal Circuit has ruled that Form 18 does not apply to indirect infringement cases, but only to direct patent infringement cases.[78] Therefore, a complaint pleading induced or contributory infringement must meet the *Twombly/Iqbal* plausibility standard.

Form 18 still plays a role in pleading indirect infringement though. Because a defendant's liability for indirect infringement of a patent requires direct infringe-

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71 *Id.*

72 *See, e.g.*, Light Transformation Techs. LLC v. Light Sci. Grp. Corp., No. 2:12–CV–826–MHS–RSP, 2014 WL 935354, at *2 (E.D. Tex. Mar. 5, 2014); Affinity Labs of Tex., LLC v. Toyota Motor North America, Inc., No. W:13–CV–365 , 2014 WL 2892285, at *3 (W.D. Tex. May 12, 2014); Boundaries Solutions Inc. v. CoreLogic, Inc., No. 5:14-CV-00761-PSG, 2014 WL 4954017, at *3 (N.D. Cal. Sept. 29, 2014); Unilin Beheer B.V. v. Tropical Flooring, CV 14–02209 BRO (SSX), 2014 WL 2795360, at *2-3 (C.D. Cal. June 13, 2014); Versata Software Inc. v. Cloud9 Analytics, Inc., Civ. No. 12–925–LPS, 2014 WL 631517, at *3 (D. Del. Feb. 18, 2014); Zond, LLC v. Toshiba Corp., No. 13–CV–11581–DJC, 2014 WL 4056024, at *2-3 (D. Mass. Aug. 14, 2014); Smartwater, Ltd. v. Applied DNA Scis., Inc., No. 12–CV–5731 (JS)(AKT) 2013 WL 5440599, at *3-4 (E.D.N.Y. Sept. 27, 2013); Ziemba v. Incipio Techs., Inc., No. 13–5590 (JLL), 2014 WL 7051782, at *2, 4 (D.N.J. Dec. 12, 2014).

73 *See, e.g.*, Macronix Int'l Co. v. Spansion Inc., 4 F. Supp. 3d 797, 803-80404 (E.D. Va. Mar. 10, 2014); Regeneron Pharm., Inc. v. Merus B.V., No. 14–CV–1650 (KBF), 2014 WL 2795461, at *2 (S.D.N.Y. June 19, 2014); Deerpoint Grp., Inc. v. Acqua Concepts, Inc., No. 1:14–CV–01503–SAB, 2014 WL 7178210, at *3 (E.D. Cal. Dec. 16, 2014).

74 Macronix Int'l Co. v. Spansion Inc., 4 F. Supp. 3d 797, 803-04 (E.D. Va. 2014).

75 Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007).

76 35 U.S.C. § 271(b)-(c) (2003).

77 *Id.*

78 *In re* Bill of Lading, 681 F.3d at 1334.

ment by a third party,[79] a plaintiff's plausible claim of the defendant's indirect infringement necessarily requires pleadings of direct infringement by a third party, but only in a level of detail that meets Form 18. However, the Federal Circuit does not require a plaintiff to "identify a *specific* direct infringer if it pleads facts sufficient to allow an inference that at least one direct infringer exists."[80]

1. Induced infringement

A defendant is liable for induced infringement of a patent when it actively and knowingly aided or abetted a third party to directly infringe the asserted patent, with knowledge of the asserted patent and with knowledge that "the induced acts constitute patent infringement."[81] Under the *Twombly/Iqbal* standard, a complaint for induced infringement must assert enough factual allegations to plausibly show that the defendant (1) induced a third party to directly infringe the asserted patent, (2) had knowledge of the asserted patent, and (3) possessed specific intent to encourage the third party's infringement, knowing that his action would induce actual infringement by the third party.[82]

District courts have split opinions on what is required for a plaintiff to plead that the accused infringer had knowledge of the asserted patent.[83] In a majority of district courts, a plaintiff can simply plead that the accused infringer has knowledge of the asserted patent by filing of the complaint.[84] In other courts, however, the complaint must assert facts showing that the accused infringer had knowledge of the asserted patent *before* the plaintiff's filing of the complaint.[85]

Whether the accused infringer possessed the specific intent to induce the direct infringement by a third party is a fact-specific question. Both the Federal Circuit and some lower courts have allowed for generous inferences in finding specific intent for induced infringement. For example, the Federal Circuit held that a plaintiff adequately pled specific intent by providing factual allegations that the defendants (1) issued advertising statements relating to their products' ability to operate in a manner similar to the claimed method and (2) hosted seminars targeting existing

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79 *Id.* at 1333.

80 *Id.* at 1336,

81 Commil USA, LLC v. Cisco Systems, Inc., 575 U.S. ____ (2015) (slip op., at 5) (quoting Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. ___ (2011) (slip op., at 10))

82 DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1303-05 (Fed. Cir. 2006); In re Bill of Lading, 681 F.3d at 1333, 1339.

83 M. Andrew Holtman, et al., *Avoiding Dismissal in Patent Infringement Cases: An Update On The Twombly /Iqbal Pleading Standard*, 26 NO. 5 INTELL. PROP. & TECH. L.J. 10, 11 (2014) (citing Rembrandt Social Media, LP v. Facebook, Inc., 950 F. Supp. 2d 876, 881-82 (E.D. Va. 2013)).

84 *Id.*

85 *Id.* at 12; *see also* Proxyconn Inc. v. Microsoft Corp., No. SACV 11-1681, DOC (ANx), 2012 WL 1835680, at *5-6 (C.D. Cal. May 16, 2012) (holding that knowledge after filing of a complaint is insufficient for pleading knowledge for indirect infringement).

and potential customers to demonstrate how its products could be used.[86] Similarly, a Delaware court ruled that a plaintiff sufficiently pled specific intent of inducement when it: "(1) provided the defendant with written notice that certain accused products infringed the patent-in-suit; (2) identified the general group of direct infringers who were asserted to have infringed the patent; and (3) set out facts explaining how the defendant was alleged thereafter to have interacted with those direct infringers in a way that would prompt the reasonable inference that [the] defendant encouraged the direct infringer to continue to infringe the patent."[87]

2. Contributory infringement

Contributory infringement is limited to sales or importation of components or materials without substantial non-infringing uses.[88] A defendant is liable for contributory infringement when (1) it contributed to a third party's direct infringement; (2) it had knowledge of the asserted patent; (3) the component has no substantial non-infringing uses and is a material part of the invention.[89] The accused infringer's required knowledge of the asserted patent is similar to that for induced infringement as discussed above.

To sufficiently plead the third element (no substantial non-infringing uses and material part), the complaint must provide factual allegations linking the asserted patent with use of the accused product. This is a very context-specific task that usually requires the court to make inferences based on the allegations. For example, the Northern District of California found that the complaint must contain allegations from which the court can infer that the accused product had no substantial non-infringing uses, and noted that this inference is possible only if the complaint explains how the accused product relates to the asserted patent.[90]

C. Willful infringement

Although a finding of willful infringement will impose punitive damages on a defendant,[91] willfulness is not considered as fraud. Therefore, "the pleading requirement for willful infringement does not rise to the stringent standard required by Rule 9(b)."[92] The majority of district courts have held that pleading willful in-

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86 In re *Bill of Lading*, 681 F.3d at 1341-46.

87 Advanced Optical Tracking, LLC v. Koninklijke Philips N.V., Civ. No. 12–1292–LPS–CJB, 2013 WL 4786463, at *4 (D. Del. Sept. 9, 2013).

88 35 U.S.C. § 271(c) (2003).

89 Fujitsu Ltd. v. Netgear Inc., 620 F.3d 1321, 1326 (Fed. Cir. 2010).

90 Redd Group, LLC v. Glass Guru Franchise Sys., Inc., No. 12-CV-04070, 2013 WL 3462078, at *5 (N.D. Cal. July 8, 2013).

91 35 U.S.C. § 284 (2003) (providing that "the court may increase the damages up to three times the amount found or assessed" if the defendant is found to have willfully infringed the asserted patent).

92 Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC, 350 F.3d 1327, 1343 (Fed. Cir. 2003).

fringement must meet the *Twombly/Iqbal* plausibility standard.[93] To plead willful infringement, a plaintiff must plausibly show that the accused infringer possessed knowledge of both (1) the asserted patent, and (2) that his actions directly or indirectly infringed the asserted patent.[94]

With respect to knowledge of the asserted patent, the Federal Circuit held in *In re Seagate Technology* that "a willfulness claim asserted in the original complaint must necessarily be grounded exclusively in the accused infringer's pre-filing conduct."[95] Thus, to plead willfulness, a plaintiff generally should provide some evidence that the defendant had pre-suit knowledge of the asserted patent.

With respect to knowledge of infringement, the Federal Circuit ruled in *Seagate* that an infringer must have acted "despite an objectively high likelihood that its actions constituted infringement of a valid patent."[96] However, lower courts are divided as to whether this must be alleged in a pleading for willfulness.[97] Some district courts have found that this is not required in a pleading for willful infringement.[98] Other courts require more in a pleading for willfulness: the complaint must, at the minimum, include facts "giving rise to at least a showing of objective recklessness of the infringement risk."[99] Still other courts have taken a middle ground, holding that *Seagate*'s "objective recklessness" standard "is not controlling for purposes of pleading [willfulness] under Fed. R. Civ. P. 8(a)," and that a "plaintiff must provide a pleading equivalent to 'with knowledge of the patent and his infringement.'"[100]

IV. The Race Between Congress and the Judiciary

Form 18 and Rule 84 have caused much trouble after *Twombly* and *Iqbal* in patent infringement cases. This was, to some extent, further complicated by the Federal Circuit's ruling in *In re Bill of Lading* and the line of cases following it, which essentially carve out a special treatment for pleading direct patent infringement. As has been discussed above, the Federal Circuit's rulings have stirred much criticism from the dissenters in the Federal Circuit, the lower courts, and commentators.[101]

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93 Holtman, *supra* note 83, at 14 (citing FuzzySharp Techs. Inc. v. Nvidia Corp., No. 12-CV-06375, 2013 WL 4766877, at *2 (N.D. Cal. Sept. 4, 2013)).

94 In re Seagate Tech., LLC, 497 F.3d 1360, 1374 (Fed. Cir. 2007).

95 In re *Seagate*, 497 F.3d at 1374.

96 *Id.* at 1371.

97 Holtman, *supra* note 83, at 14.

98 Va. Innovation Sci., Inc. v. Samsung Elecs. Co., No. 2:12CV548, 2013 WL 6053846, at *4-5 (E.D. Va. Nov. 15, 2013).

99 *See, e.g.*, Hand Held Prods., Inc. v. Amazon.com, Inc., No. 12-CV-00768, 2013 WL 507149, at *7 (D. Del. Feb. 6, 2013) (quoting St. Clair Intellectual Prop. Consultants, Inc. v. Hewlett–Packard Co., No. 10–425–LPS, 2012 WL 1134318, at *2–3 (Del. Mar.28, 2012); Execware, LLC v. Staples, Inc., No. 11-836, 2012 WL 6138340, at *6 (D. Del. Dec. 10, 2012).

100 Milwaukee Elec. Tool Corp. v. Hitachi Koki, Ltd., No. 09-C-948, 2011 WL 665439, at *3-5 (E.D. Wis. Feb. 14, 2011) (internal citation omitted).

101 *See, e.g.*, In re Bill of Lading, 681 F.3d 1323 (Fed. Cir. 2012) (J. Newman, dissenting); Macronix,

For example, as early as 2007, Judge Dyk, in his dissenting opinion in *McZeal*, pointed out the inconsistency between Form 18 and the new *Twombly* plausibility standard and noted: "One can only hope that the rulemaking process will eventually result in eliminating the form, or at least in revising it to require allegations specifying which claims are infringed, and the features of the accused device that correspond to the claim limitations."[102] However, five years later, the Federal Circuit had made it clear in *In re Bill of Lading* that it will not revise the content of Form 18, although it recognized the inconsistency between Form 18 and *Twombly/Iqbal* standard, explaining that revising the form is within Congress's exclusive power.[103] Consequently, the lower courts and patent litigants can only hope that the rulemaking process will step in and fix the problem. Fortunately, both Congress and the judiciary have attempted to address this troubling issue.

A. Patent reforms in the Congress

In the recently concluded 113th Congress, at least fourteen patent reform bills were introduced and three of these bills (the Innovation Act, the Patent Abuse Reduction Act, and the Patent Litigation and Innovation Act[104]) would have imposed a higher patent pleading standard.[105] Although none of these bills became law, the Innovation Act did pass the House of Representatives in December 2013,[106] and it was reintroduced in the 114th Congress on February 5, 2015.[107] In addition, a new bill introduced in the 114th Congress on March 3, 2015, the STRONG Patents Act of 2015, also calls for the elimination of Form 18.[108]

The Innovation Act, the Patent Abuse Reduction Act, and the Patent Litigation and Innovation Act all require long lists of information to be pleaded in the complaint. For example, Section 3(a) of the Innovation Act requires a plaintiff to plead, "unless the information is not reasonably accessible to such party," the following information in the complaint: (1) "an identification of each claim;" (2) "an identification of each accused process, machine, manufacture, or composition of matter (referred to in this section as an 'accused instrumentality') alleged to infringe the claim;" (3) "for each accused instrumentality . . . an identification *with particularity* . . . of . . . the name or model number . . . or . . . a description of each accused instrumentality;" and (4) "for each accused instrumentality . . ., a clear and concise statement of—where each element of each claim . . . is found within the accused instrumentality; and *with detailed specificity*, how each limitation of each claim . . . is

4 F. Supp. 3d 797 (E.D. Va. Mar. 10, 2014); *see also* Moore, *supra* note 3, at 451.

102 McZeal v. Sprint Nextel Corp., 501 F.3d 1354, 1360 (Fed. Cir. 2007) (Dyk, J., dissenting).

103 In re *Bill of Lading*, 681 F.3d at 1334-35.

104 Innovation Act, H.R. 3309, 113th Cong. (2013); Patent Litigation and Innovation Act of 2013, H.R. 2639, 113th Cong.; Patent Abuse Reduction Act, S. 1013, 113th Cong. (2013).

105 *See* Paul R. Gugliuzza, *Patent Litigation Reform: The Courts, Congress, and the Federal Rules of Civil Procedure*, 95 B.U. L. Rev. 279, 284 (2015).

106 *See* Innovation Act, H.R. 3309, 113th Cong. (2013).

107 Innovation Act, H.R. 9, 114th Cong. (2015).

108 *See* STRONG Patents Act of 2015, S. 632, 114th Cong.

met by the accused instrumentality."[109] Both the Patent Abuse Reduction Act, and the Patent Litigation and Innovation Act also require a similar specific list of information that must be pleaded.[110] In contrast, the STRONG Patents Act does not impose any of these requirements.

These bills also expressly addressed the continued sufficiency of Form 18. The Innovation Act and the STRONG Patents Act explicitly instruct the Supreme Court to eliminate Form 18 from the Appendix of the Federal Rules of Civil Procedure.[111] On the other hand, the Patent Abuse Reduction Act and the Patent Litigation and Innovation Act were less direct, only requiring the Court to "review and amend" Form 18 "to ensure that Form 18 is consistent with" the new pleading requirements adopted in the bill.[112]

B. The judiciary's move to abrogate Rule 84 and Form 18

Perhaps in response to the Federal Circuit's invitations and district courts' divided opinions on the continued sufficiency of Form 18, the Judicial Conference Committee on Rules of Practice and Procedure started to evaluate the possibility of revising Rule 84 and the forms in the Appendix of Federal Rules of Civil Procedure.

As early as August 2013, a lengthy package of proposed amendments including proposals to abrogate Rule 84 and Form 18 were released.[113] In September 2014, the 26-member Judicial Conference Committee voted for the proposed amendments and "unanimously approved . . . a proposed abrogation of Rule 84 and the Appendix of Forms." [114]

It is worth noting the Judiciary Conference Committee's rationales for proposing the abrogation of Rule 84 and Appendix of Forms. First, the Committee noted that "Rule 84 and the Appendix of Forms are no longer necessary."[115] This is because "Rule 84 was adopted when the Civil Rules were established in 1938 'to indicate, subject to the provisions of these rules, the simplicity and brevity of statement which the rules contemplate,'" and "[t]he purpose of providing illustrations for the rules . . . has been fulfilled" given that nowadays "there are many excellent alternative sources for forms, including the Administrative Office of the United States

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[109] Innovation Act § 3(a), H.R. 9, 114th Cong. § 3(a) (2015) (emphasis added).

[110] *See* Patent Abuse Reduction Act, S. 1013, 113th Cong. § 2(a) (2013); Patent Litigation and Innovation Act of 2013, H.R. 2639, 113th Cong. §2(a).

[111] Innovation Act § 6(c)(1); accord STRONG Patents Act of 2015 § 106.

[112] Patent Abuse Reduction Act § (2)(c); *accord* Patent Litigation and Innovation Act §2(c).

[113] Vin Gurrieri, *Judges Vote To Nix Rule Creating Patent Complaint Forms*, (Sept. 17, 2014, 5:50 PM ET), *available at* http://www.law360.com/articles/578149

[114] Summary of the Report of the Judicial Conference Committee on Rules of Practice and Procedure, at Rules-13 (Sept. 2014), *available at* http://www.uscourts.gov/uscourts/RulesAndPolicies/rules/Reports/ST09-2014.pdf.

[115] *Id.* at Appendix B-69.

Courts."[116]

Second, the Committee noted that "[m]any of the forms are out of date."[117] Most of the Appendix Forms were adopted in 1938 when the Civil Rules were established, and "[t]he sample complaints, for example . . . illustrate a simplicity of pleading that has not been used in many years."[118]

Third, the Committee noted that "[a]mendment of the civil forms is cumbersome," which requires "[a] process [that] ordinarily takes at least three years."[119] To amend the forms, the "amendments proposed by the Committee must be approved by the Standing Committee, the Judicial Conference, the Supreme Court, and Congress. Public notice and comment are also required."[120] Therefore, the better approach is to simply abrogate Rule 84 and the Appendix Forms rather than amending them.

The Committee's final argument was that "the Committee's perception was that the forms are rarely used."[121] In response to public comments arguing that "the forms assist pro se litigants and new lawyers," the Committee noted that "only one [of those commentators] stated that the writer had ever actually used the forms. The general lack of response to the Rule 84 proposal reinforced the Committee's view that the forms are seldom used."[122] It is interesting how the Committee reached its conclusion that the Appendix Forms are rarely used, given that there are abundant cases in the district courts and the Federal Circuit addressing the sufficiency of Form 18.[123]

On April 29, 2015, the Supreme Court adopted the Judiciary Conference's proposals and submitted it to Congress for final review and approval.[124] The new rule became effective on December 1, 2015in absence of Congress's objection.[125]

C. Congress should allow courts to experiment with the *Twombly/Iqbal* plausibility pleading standard

Although there are several pending bills, such as the Innovation Act, that call for a heightened pleading standard for patent infringement actions, Congress should afford courts the opportunity to at least experiment with the *Twombly/Iqbal* plausi-

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116 *Id.*
117 *Id.* at Appendix B-19.
118 *Id.*
119 *Id.*
120 *Id.*
121 *Id.*
122 *Id.* at Appendix B-20.
123 *See generally supra* Sections II and III.
124 *See* Pending Rules Amendments, USCOURTS.GOV, http://www.uscourts.gov/rules-policies/pending-rules-amendments (last visited, May 9, 2015).
125 28 U.S.C. § 2074. (2012).

bility pleading standard, instead of adopting the pleading "with detailed specificity" standard proposed by the Innovation Act. First, having a special pleading with detailed specificity standard for direct infringement pleading would once again bring direct patent infringement pleading out of line with other types of patent infringement pleadings and other types of civil pleadings, just like Form 18 did. This would go against the general rule of *Iqbal*'s spirit of treating all pleadings for civil cases with uniformity,[126] which is another reason why Form 18 should be abandoned.

Second, the Innovation Act's requirement to plead "with particularity" and "with detailed specificity" would affect a dramatic leap from the minimal pleading requirements of Form 18 to a new standard that is akin to the requirement of Rule 9(b) that plaintiffs plead fraud "with particularity."[127] In contrast, the *Twombly/Iqbal* plausibility pleading standard only modestly increases the amount of details required for direct patent infringement.[128] There is no compelling reason to heighten the pleading requirement for direct patent infringement to a similar level to pleading fraud, which has its own policy justifications.

Third, the inflexibility of the Innovation Act's pleading with detailed specificity will deprive district court judges of the ability to exercise discretion and make decisions on a case-by-case basis. Under the pleading with detailed specificity standard, some patent holders with legitimate infringement claims would be unable to survive the pleading stage because some patent infringement activities often occur in secret. For example, in the biotechnology industry, a patent holder with a genuine belief that its patent is being infringed often cannot obtain information about its competitor's potentially infringing manufacturing processes without discovery.[129] In these cases, a district judge should be given the discretion to allow limited discovery at the motion to dismiss stage so that the patentee would have a chance to discover key facts that were inaccessible to it.[130] The *Twombly/Iqbal* standard would grant district judges such discretion.

Fourth, although the Innovation Act may excuse a party from not providing certain detailed facts in the pleading when the relevant information "is not reasonably accessible," this seemingly safe harbor for plaintiffs will likely not lead to an efficient determination on the pleadings.[131] As one commentator pointed out, this

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[126] Ashcroft v. Iqbal, 556 U.S. 662, 684 (2009).

[127] *See* Fed. R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."); *see also* Paul R. Gugliuzza, *Patent Litigation Reform: The Courts, Congress, and the Federal Rules of Civil Procedure*, 95 B.U. L. REV. 279, 289 (2015).

[128] *See supra*, Section IV.B.2.

[129] *See* Gugliuzza, *supra* note 127, at 290.

[130] *See id.* at 290, 291, (citing Rice v. Murakami, No. 1:13-CV-441-BLW, 2014 WL 2780977, at *1-2 (D. Idaho June 18, 2014) (finding that the plaintiff's complaint failed to meet the requirements of Iqbal but ordering "limited discovery" to allow the plaintiff "a fair opportunity to amend his complaint to satisfy the Iqbal standards").

[131] *Id.* at 291.

standard would require the court to look beyond the pleadings to determine whether the facts absent in the plaintiff's pleading were "reasonably accessible."[132] This may invite additional and unnecessary litigation at the pleading stage and increase the cost of the already extremely expensive patent litigations. Thus, it would be simpler to allow district judges to evaluate the plausibility of the infringement pleadings based on "judicial experience and common sense," as required by *Twombly* and *Iqbal*.[133]

Finally, district courts have already been trying to hash out what should be required for pleading patent infringement under the *Twombly/Iqbal* plausibility standard,[134] and courts have long been applying the plausibility standard in indirect infringement (inducement and contributory infringement) cases.[135] Thus, it would be prudent to at least first see if the *Twombly/Iqbal* standard would solve the problem of overly vague direct infringement pleadings before requiring the much more drastic reform required by the Innovation Act.

V. District Courts' Experiments on Pleading Direct Infringement Under *Twombly* and *Iqbal*

Although it will likely take the lower courts several years to resolve what exactly should be required to plead direct infringement under the *Twombly/Iqbal* plausibility standard, the district courts' decisions after *Twombly* and *Iqbal* have raised three possible requirements for pleading direct infringement under the plausibility standard: whether the plaintiff should be required to (1) specify the particular patent claims that are allegedly infringed, (2) identify the specific allegedly infringing products, or (3) assert a theory of infringement.

A. Specifying the particular patent claims

Historically, a plaintiff must specify in its complaint the particular claims that were allegedly infringed.[136] However, prior to *Twombly*, most courts held that a plaintiff did not have to identify the specific infringed claims in the complaint.[137] These courts generally relied on the notice pleading standard and took the position that the notice function was satisfied without specifying the claims that were alleg-

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[132] *Id.*

[133] *See id.*; *see also* Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009).

[134] *See supra*, Section IV. *See infra*, Section V.

[135] *See supra*, Section III. B.

[136] *See* Jonathan L. Moore, *Particularizing Patent Pleading: Pleading Patent Infringement in A Post-Twombly World*, 18 TEX. INTELL. PROP. L.J. 451, 480 (2010) (citing, among others, J.D. Ferry Co. v. Macbeth Eng'g Corp., 11 F.R.D. 75, 76 (M.D. Pa. 1951) ("The general practice in patent infringement suits has been to require the plaintiff to state what claims of a patent he alleges to have been infringed.").

[137] *See id.* (citing, among others, Phonometrics, Inc. v. Hospitality Franchise Sys., Inc., 203 F.3d 790, 794 (Fed. Cir. 2000).

edly infringed.[138] After *Twombly*, courts are more split over whether the plaintiff should be required to assert the specific allegedly infringed claims in the complaint.

Shortly after *Twombly*, most district courts generally still do not require a plaintiff to identify the specific infringed claims in the complaint.[139] Some courts based their rulings on the ground that Form 18 continued to be valid under *Twombly* and *Iqbal*, and Form 18 does not require the plaintiff to specify the infringed patent claims. For example, the Northern District of California found in *Ardente* that the plaintiff's failure to identify the accused patent claims did not render the complaint inadequate, stating that "Form 18 . . . found in the appendix of forms in the Federal Rules of Civil Procedure does not indicate that a party must specify the particular claims thought to have been infringed."[140] Similarly, the District of Nebraska in *Prism Technologies* denied the defendant's argument that the plaintiff's "complaint is inadequate because Prism does not state which of the claims of each patent are allegedly being infringed upon," noting that "Form 18 does not require Prism to identify specific patent claims in its complaint."[141] The Eastern District of Texas and the District of Delaware have similarly held that the plaintiff is not required to specify particular claims in the complaint.[142]

On the other hand, more and more district courts have held after *Twombly* that the new plausibility standard requires the plaintiff to identify specific allegedly infringed patent claims in the complaint.[143] The Western District of Wisconsin in *Taurus* was the first district court after *Twombly* to require identification of allegedly infringed patent claims in the complaint.[144] In requiring the patentee to identify in its complaint which claims of the patent it asserted are infringed, the district court

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[138] *Id.*

[139] *See, e.g.*, Prism Techs., LLC v. AT&T Mobility, LLC, No. 8:12CV122, 2012 WL 3867971, at *3 (D. Neb. Sept. 6, 2012); Atwater Partners of Tex. LLC v. AT & &T, Inc., No. 2:10–CV–175–TJW, 2011 WL 1004880, at *3 (E.D. Tex. Mar. 18, 2011); Xpoint Techs., Inc. v. Microsoft Corp.,, 730 F. Supp. 2d 349, 353 (D. Del. 2010); Ardente, Inc. v. Shanley, No. C 07-4479 MHP, 2010 WL 546485, at *5 n.6 (N.D. Cal. Feb. 10, 2010); ASUSTek Computer Inc. v. Ricoh Co., Ltd., No. C 07-01942 MHP, 2007 WL 4190689, at *4 (N.D. Cal. Nov. 21, 2007).

[140] *Ardente*, 2010 WL 546485, at *5 n.6.

[141] *Prism Techs.*, 2012 WL 3867971, at *3.

[142] *Atwater*, 2011 WL 1004880, at *3 ("[T]here is no requirement that the complaint specify which specific claims the plaintiff is asserting. . . ."); *Xpoint Techs.*, 2010 WL 3187025, 730 F. Supp. 2d at 353 ("A plaintiff is not required to specifically include each element of the asserted patent's claims or even identify which claims it is asserting; nor is it required to describe how the allegedly infringing products work.").

[143] *See, e.g.*, Locata LBS, LLC v. Yellowpages.com, LLC, Nos. LA CV13–07664 JAK (SHx), LA CV13–07748 JAK (SHx), LA CV13–07743 JAK (SHx), LA CV13–07895 JAK (SHx), 2014 WL 2581176, at *4-5 (C.D. Cal. Apr. 18, 2014); Ingeniador, LLC v. Interwoven, 874 F. Supp. 2d 56, 66, 69 (D.P.R. 2012); Tetsuya v. Amazon.com, Inc., No. C11-01210 HRL, 2011 WL 2472557, at *1 (N.D. Cal. June 22, 2011); Tadayon v. Execubus, Inc., No. 3:11CV21311-5909, 2011 WL 7429453, at *1 (E.D. Va. June 15, 2011); Taurus IP, LLC v. Ford Motor Co., 539 F. Supp. 2d 1122, 1127 (W.D. Wis. 2008).

[144] *Taurus*, 539 F. Supp. 2d at 1127.

reasoned that the "plaintiff must do more than give clues to meet even the broad Rule 8 notice requirements," and "[i]n the context of alleged patent infringement, [notice] means at least that the plaintiff must tell the defendant which products allegedly infringe the plaintiff's patent."[145] Therefore, the court directed that:

> At the very least, a plaintiff's failure to specify which claims it believes are infringed by a defendant's products places an undue burden on the defendant, who must wade through all the claims in a patent and determine which claims might apply to its products to give a complete response. A plaintiff's failure to specify patent claims hinders the defendant's ability to prepare a defense.[161]

Based on this rationale, the court granted the defendants' motion for a more definite statement because "defendants cannot respond to plaintiff's allegations without undue burden and prejudice."[146]

The Eastern District of Virginia went a step further in *Tadayon*, requiring the plaintiff's complaint and the defendant's counterclaim to set forth "all aspects of each claim that is alleged to be infringed, claim by claim, and identifying the infringing product (by product, by claim) and describe how the infringing product is alleged to offend; and shall not use conclusory language."[147]

Similarly, in its recent decision in *Locata LBS*, the Central District of California found that a complaint failed to meet the *Twombly/Iqbal* plausibility standard where claims of the allegedly infringed patent were not identified, nor was the manner in which the end user's product infringed.[148]

B. Identifying the specific allegedly infringing products

Unlike the district courts' divided view over whether the complaint should identify particular patent claims, courts after *Twombly* and *Iqbal* have generally required the plaintiff to identify the infringing products with at least some level of specificity.[149] However, courts have not reached an agreement regarding with what level of

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[145] *Id.* (alterations in original).

[146] *Id.*

[147] *Tadayon,* 2011 WL 7429453, at *1 (E.D. Va. June 15, 2011).

[148] Locata, 2014 WL 2581176, at *4-5 (C.D. Cal. Apr. 18, 2014).

[149] *See, e.g.*, EmeraChem, Holdings, LLC v. Volkswagen Grp. of America, Inc., No. 3:14–CV–132–PLR–HBG, 2014 WL 5795027, at *2-3 (E.D. Tenn. Nov. 6, 2014); Courtesy Prods., L.L.C. v. Hamilton Beach Brands, Inc., No. 13–2012–SLR, 2014 WL 5780877, at *2 (D. Del. Nov. 5, 2014); Innovative Auto. LLC v. Vudu, Inc., No. 2:13–CV–1109–JRG, 2014 WL 4090528, at *2 (E.D. Tex. Aug. 19, 2014); Zond, LLC v. Renesas Electronics Corp., No. 13–11625–NMG, 2014 WL 4161348, at *4 (D. Mass. Aug. 15, 2014); Unilin Beheer B.V. v. Tropical Flooring, No. CV 14–02209 BRO (SSX), 2014 WL 2795360, at *3-4 (C.D. Cal. June 13, 2014); Infineon Techs. AG v. Volterra Semiconductor Corp., No. C–11–6239 MMC, 2012 WL 3939353, at *2-3 (N.D. Cal. Sept. 10, 2012); Prism Techs., LLC v. AT&T Mobility, LLC, No. 8:12CV122, 2012 WL 3867971, at *5 (D. Neb. Sept. 6, 2012); Oakley, Inc. v. 5.11, Inc., No. 11CV2173 WQH (CAB), 2012 WL 1327796, at *3 (S.D. Cal. Apr. 17, 2012).

specificity the plaintiff should identify the alleged infringing products.[150]

On the one hand, most courts have required only a general description of the alleged infringing products. These courts generally based their rulings on the ground that Form 18 requires only minimal identification of the infringing product, and that the Federal Circuit has read Form 18, in *K-Tech Telecomms*, to not require a plaintiff to identify an accused device by name.[151] For example, in *Innovative Automation*, the Eastern District of Texas found that the plaintiff's identification of infringing products as "Vudu content delivery product and service" with a reference to "the product's own webpage where it is generally described" was sufficient under the plausibility standard.[152] Similarly, the District of Delaware held in *Courtesy Products* that the accused product was adequately identified with a general description and identification of specific model numbers as an example.[153] Also, the Western District of Oklahoma held that even though a plaintiff's complaint did not identify a specific accused product, it was sufficient where it alleged the type of products.[154] Further, where the infringed patent claim is a method claim, the Federal Circuit has provided an additional reason to not require the plaintiff to identify accused products by name: when the accused infringers performed the method in secret, the plaintiff needs discovery to confirm its suspicion.[155]

On the other hand, some district courts have required more than just a general description of the alleged infringing products and have instead required the plaintiff to identify *specific* accused products.[156] For example, the District of Nebraska found that a plaintiff's identification of the accused products as "various wireless products and data services that implement authentication systems and methods for controlling access to protected computer resources as claimed in the . . . patent" was too broad and vague.[157] Similarly, the Southern District of California ruled in *Oakley* that the plaintiff's identification of the accused product as "eyewear" was insufficient because it "fail[s] to identify any specific products."[158]

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[150] *See supra* note 134.

[151] K-Tech Telecommc'ns., Inc. v. Time Warner Cable, Inc., 714 F.3d 1277, 1286 (Fed. Cir. 2013); *see also, e.g.*, Innovative Automation LLC v. Vudu, Inc., 2:13–CV–1109–JRG, 2014 WL 4090528, at *2 (E.D. Tex. 2014).

[152] *Innovative Automation*, 2014 WL 4090528, at *2.

[153] *Courtesy Prods.*, 2014 WL 5780877, at *2.

[154] Flow Valve, LLC v. Forum Energy Techs., Inc., No. CIV–13–1261–F, 2014 WL 3567814, at *4 (W.D. Okla. July 18, 2014).

[155] K-Tech Telecommc'ns., 714 F.3d at 1286 (Fed. Cir. 2013).

[156] *See, e.g.*, Tadayon, No. 3:11CV213, 2011 WL 7429453, at *1 (E.D. Va. June 15, 2011) (demanding that the plaintiff set forth in its amended complaint "all aspects of each claim that is alleged to be infringed, claim by claim, and identifying the infringing product (by product [sic] by product, by claim) and describe how the infringing product is alleged to offend. . . .").

[157] Prism Techs., LLC v. AT&T Mobility, LLC, No. 8:12CV122, 2012 WL 3867971, at *1, *5 (D. Neb. Sept. 6, 2012).

[158] Oakley, Inc. v. 5.11, Inc., No. 11CV2173 WQH (CAB), 2012 WL 1327796, at *1, *3 (S.D. Cal.

C. Asserting a theory of infringement

With regard to whether the plaintiff should be required to assert a theory of infringement in its complaint, there is no consensus among the district courts either. The Eastern District of Texas was the first district court that expressly refused to require the plaintiff to assert a theory of infringement in the complaint.[159] In *Actus*, the district court denied the defendant's invitation to require the plaintiff to "allege with specificity a theory of infringement for each element of the asserted claims," because the claims "have not yet been construed" in a *Markman* hearing, and thus a "motion to dismiss is premature" at this stage.[160] Consequently, the court proclaimed that "[t]he Court does not require that plaintiffs in a patent infringement lawsuit attach fully-developed infringement contentions to its complaint."[161] Several other district courts, including the District of Delaware and the Central District of California, have followed the Eastern District of Texas's approach in *Actus*, and refused to require the plaintiff to include a fully-developed infringement theory in the complaint.[162]

In contrast, other district courts have implicitly required the plaintiff to include some kind of infringement theory in the complaint, by requiring the plaintiff to allege in what manner or means the accused products have infringed the asserted patents. For instance, in *Tadayon*, the Eastern District of Virginia demanded the plaintiff to set forth "all aspects of each claim that is alleged to be infringed, claim by claim, and [to identify] the infringing product (by product by product, by claim) and describe *how the infringing product is alleged to offend.*"[163] Similarly, a California court required the plaintiff to amend the complaint to "allege with sufficient particularity: (i) the specific claim(s) of the [asserted patent] that are allegedly infringed by the [accused products]; and (ii) the *manner in which those claims are infringed* by the [accused products]."[164]

Apr. 17, 2012).

159 Actus, LLC v. Bank of Am. Corp., No. 2–09–CV–102–TJW, 2010 WL 547183, at *2 (E.D. Tex. Feb. 10, 2010).

160 *Id.*

161 *Id.*

162 *See, e.g.,* Pragmatus AV, LLC v. TangoMe, Inc., No. 11–1092–LPS, 2013 WL 571798, at *5, 7 (D. Del. Feb. 13, 2013); Network Signatures, Inc. v. Nestlé USA, Inc., SACV 11-1614 JVS (RNBx), 2012 U.S. Dist. LEXIS 189681, at *6-7 (C.D. Cal. Apr. 16, 2012); H-W Tech., L.C. v. Apple, Inc., No. 3:11–CV–651–G, 2012 WL 959316, at *7 (N.D. Tex. Feb. 23, 2012).

163 Tadayon v. Execubus, Inc., No. 3:11CV21311-5909, 2011 WL 7429453, *1 (E.D. Va. 2011) (emphasis added).

164 Locata LBS, LLC v. Yellowpages.com, LLC, Nos. LA CV13–07664 JAK (SHx), LA CV13–07748 JAK (SHx), LA CV13–07743 JAK (SHx), LA CV13–07895 JAK (SHx), 2014 WL 2581176, at *5 (C.D. Cal. Apr. 18, 2014) (emphasis added).

VI. Recommendations and Potential Impacts of the Heightened Pleading Standard

This section discusses what level of details should be required in direct patent infringement pleading under the *Twombly/Iqbal* plausibility standard, assuming that Congress will not adopt a more stringent pleading standard such as that proposed in the Innovation Act. This section also discusses some potential impacts of the plausibility pleading standard on several important patent litigation players.

A. What should be required to plead direct patent infringement under *Twombly* and *Iqbal*

After the abrogation of Rule 84 and Form 18, the lower courts need to resolve several issues in the coming years concerning what should be required to plead direct patent infringement under the *Twombly/Iqbal* standard. In this subsection, I propose several approaches for the courts to use in resolving several important issues.

1. Identification of particular patent claims should be required

In order to give defendants a "fair notice" under the *Twombly/Iqbal* plausibility standard, courts should require a plaintiff to identify specific claims of the patent that were allegedly infringed. As Judge Crabb pointed out in *Taurus IP, LLC v. Ford Motor Co.*, "a plaintiff's failure to specify which claims it believes are infringed by a defendant's products places an undue burden on the defendant, who must wade through all the claims in a patent and determine which claims might apply to its products to give a complete response. A plaintiff's failure to specify patent claims hinders the defendant's ability to prepare a defense."[165] Not requiring a plaintiff to identify the specific infringed patent claims is especially troublesome where there are a large number of claims in an asserted patent (some patents include almost 600 claims!).[166] In these cases, a plaintiff's failure to identify specific claims will unfairly prejudice the defendants and frustrate the very purpose of "fair notice" under Rule 8 and the spirit of *Twombly* and *Iqbal*.

2. At least a general identification of infringing products should be required

With regard to how specifically a plaintiff should be required to identify the infringing products in his complaint, courts should resolve the question on a case-by-case basis. Generally, courts should require the plaintiff to identify specific infringing products, by either model numbers or product types.[167] This requirement is most

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[165] Taurus IP, LLC v. Ford Motor Co., 539 F. Supp. 2d 1122, 1127 (W.D. Wis. 2008).

[166] *See e.g.*, Pat. No. U.S. 6,567,473 B1 (filed Mar. 10, 2000) (with 596 claims).

[167] *See* Prism Techs., LLC v. AT&T Mobility, LLC, No. 8:12CV122, 2012 WL 3867971, *5 (D. Neb. 2012).

consistent with the purpose of putting the defendants on "fair notice." Further, such a requirement makes sure that the plaintiff conducts at least some preliminary research of the case before filing the complaint and reduces the chance of frivolous filing sanctions under Rule 11.[168]

To the extent that in some cases it is impossible for the plaintiff to identify the specific infringing products, courts should allow the plaintiff to identify the infringing products with only general descriptions. This scenario arose in *K-Tech Telecomms.*[169] In that case, the plaintiff alleged that defendant's products infringed the method claims in the asserted patent; however, the plaintiff could not identify the specific infringing products because the defendant performed the method in secret.[170] Therefore, the Federal Circuit ruled that the plaintiff's general description of the infringing products was adequate in that case.[171] This approach strikes a good balance between giving the defendant a fair notice and at the same time does not unduly prejudice the plaintiff.

3. Assertion of a theory of infringement should be required

Unlike the Eastern District of Texas's approach in *Actus, LLC v. Bank of Am. Corp.*,[172] courts should require a plaintiff to assert a theory of infringement in the complaint, i.e., how the accused products infringed the asserted claims. Admittedly, at the pleading stage, the language of the claims has not been construed through a *Markman* hearing, but a court can nevertheless give the claims' language the broadest reasonable construction only for the purpose of evaluating the plausibility of the plaintiff's pleading. The "broadest reasonable construction" standard not only comports with the USPTO's long-time practice of giving the claims broadest reasonable interpretation in examining the patent,[173] but also functions similarly to the "assumption of truth" approach in normal pleading standard.

Some district courts, especially the Eastern District of Texas, have noted that the plaintiff's infringement theory will be disclosed to the defendant in infringement contentions after the filing of complaint, and thus the complaint does not need to include an infringement theory.[174] However, courts usually require the plaintiff to serve the defendant infringement contentions shortly after filing the complaint any-

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168 Fed. R. Civ. P. 11.

169 K-Tech Telecommc'ns., Inc. v. Time Warner Cable, Inc., 714 F.3d 1277 (Fed. Cir. 2013).

170 *Id.* at 1284-87.

171 *Id.*

172 Actus, LLC v. Bank of Am. Corp., No. 2–09–CV–102–TJW, 2010 WL 547183, at *2 (E.D. Tex. Feb. 10, 2010).

173 *See* M.P.E.P. §2111 (2013); In re Am. Acad. of Sci. Tech. Ctr., 367 F.3d 1359, 1364 (Fed. Cir. 2004).

174 *See, e.g.*, Innovative Automation LLC v. Vudu, Inc., No. 2:13–CV–1109–JRG, 2014 WL 4090528, *2 (E.D. Tex. 2014); Atwater Partners of Texas LLC v. AT & T, Inc., No. 2:10–CV–175–TJW, 2011 WL 1004880, *2-3 (E.D. Tex. 2011).

way.[175] Therefore, requiring the plaintiff to either assert the infringement theory in the complaint or supplement the complaint with infringement contentions does not place a great burden on the plaintiff. This requirement, like the requirement to identify specific infringing products in the complaint, forces the plaintiff and its attorney to conduct preliminary research of the case. This will not only reduce the chance of frivolous filing sanctions under Rule 11,[176] but also forces the plaintiff to evaluate the merits and value of its case, which encourages settlement and thus avoids potential litigation costs.

At least one commentator has raised the concern that by requiring the plaintiff to assert an infringement theory in the complaint, "the court might be limiting the potential arguments that the plaintiff could make if and when the claims are being construed" and "a judge who is ruling on what the claim language means may be inclined to rule based on what the plaintiff asserted in the complaint rather than allowing the plaintiff to subsequently argue for a larger scope."[177] However, the commentator's concern is misplaced. First, district court judges possess the required legal training and judicial experience to separate claim interpretations in different stages of the litigation. Further, as noted above, in many district courts, the plaintiff is required to disclose its infringement theory when serving the infringement contentions shortly after filing the complaint anyway, which is also usually before the claim construction in a *Markman* hearing proceeding. Thus, requiring the plaintiff to disclose an infringement theory in the complaint rather than waiting to disclose it in the infringement contentions does not make a significant difference in limiting the plaintiff's arguments or causing bias on the part of the district judges.

4. Amendment of complaint under Rule 15(a) should be liberally granted

The above recommended approach requires the plaintiff to identify specific infringed patent claims, specific infringing products, and to assert a theory of infringement in the complaint, but all these disclosures would take place before discovery, before the plaintiff has a chance to obtain the full scope of necessary information. One question that naturally arises from this approach is how closely should the plaintiff be tied to its allegations in the complaint?

One possible approach to resolve the issue is to employ Rule 15, which allows the court to grant leave to the plaintiff to amend its complaint.[178] To compensate for the plaintiff's lack of information in the pleading stage, courts should liberally grant the plaintiff's Rule 15(a) motion to amend the complaint when discovery of new ev-

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[175] *See, e.g.*, Patent Rules 3-1 U.S. District Court for the Eastern District of Texas (2005), *available at* http://www.txed.uscourts.gov/cgi-bin/view_document.cgi?document=1179.

[176] Fed. R. Civ. P. 11.

[177] Adam Steinmetz, *Pleading Patent Infringement: Applying the Standard Established by Twombly and Iqbal to the Patent Context*, 13 COLUM. SCI. & TECH. L. REV., 482, 505-06 (2012).

[178] Fed. R. Civ. P. 15.

idence warrants the amendment. However, courts should also be cautious of potential abuse of Rule 15(a) by the plaintiff, i.e., the possibility that the plaintiff purposefully asserts one set of allegations in the original complaint to mislead the defendant and then files a Rule 15(a) motion to amend the complaints asserting another set of allegations that it intended. Obviously, such abuse of Rule 15(a) motion will defeat the purpose of "fair notice" pleading and prejudice the defendant.

5. Choice of law on procedural issues in patent cases

As noted in Section II.C above, the Federal Circuit applies its own law with respect to issues of substantive patent law and certain procedural issues pertaining to patent law, but applies the law of the regional circuits on non-patent issues.[179] This choice of law rule has caused non-uniform results in the district courts. For example, after the Federal Circuit's official endorsement of the sufficiency of Form 18 in view of *Twombly* and *Iqbal*, several district courts continued to challenge the sufficiency of Form 18 because the Federal Circuit's rulings on pure procedural issues are not binding on the lower courts.[180] This result is at odds with the Patent Act's purpose of promoting uniformity and the very purpose of creating the Federal Circuit in the first place. Thus, the Federal Circuit should instead adopt a new test for choice of law to enforce uniformity of patent law among the circuits.

One possible approach is to replace the "patent issue or non-patent issue" test with an "outcome determinative" test. That is, if choosing the local circuit's law would lead to a different result than that if the Federal Circuit's law is applied, the lower court should apply the Federal Circuit's law. This approach would not only enforce the uniformity of patent law in different circuits, but also prevent possible forum shopping activities by the plaintiffs.

B. Why the heightened pleading standard is good on balance: potential impacts on several major patent litigation players

The heightened pleading standard under *Twombly* and *Iqbal* will inevitably change the strategies used by active players in patent litigation and the landscape of the game in the coming years. This section argues why the heightened pleading standard with the recommended requirements above will be effective in curbing frivolous patent lawsuits by patent trolls and promoting a healthier system for innovations and businesses. On this count, this section discusses the potential impacts of the heightened pleading standard on some important players such as patent assertion entities, small businesses, sophisticated corporations, and representative industries such as the information technology and pharmaceutical industries.

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[179] Invitrogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1378-79 (Fed. Cir. 2005).

[180] *See e.g.*, Macronix Int'l Co. v. Spansion Inc., 4 F. Supp. 3d 797, 801-02 (E.D. Va. Mar. 10, 2014); Regeneron Pharms., Inc. v. Merus B.V., No. 14–CV–1650 (KBF), 2014 WL 2795461, at *1 (S.D.N.Y. June 19, 2014).

1. Curbing frivolous lawsuits by patent trolls

Patent trolls, also known as patent assertion entities (PAEs) or non-practicing entities (NPEs), are generally regarded as entities that assert patent rights based on patents they own but do not practice any of the patented inventions.[181] Patent trolls have been increasingly blamed for the growing costs of patent litigation by aggressively asserting claims against not only manufacturers of allegedly infringing technology but also against businesses, organizations, and individuals who are the end users of that technology.[182] Patent trolls have been notoriously known to file frivolous lawsuits against a large number of small entities with the intention to extract settlement fees.[183] Some patent trolls filed numerous patent lawsuits against hundreds of defendants, but none of the cases even ever reached the claim construction stage.[184]

The behaviors of patent trolls have caused so many problems and have drawn so much attention that all branches of government have tried to decrease frivolous lawsuits by them in order to both encourage developing technology and allow businesses to utilize that technology without a looming threat of disruptive and costly litigation.[185] Indeed, the more than ten patent bills introduced in Congress in the recently concluded 113th session mainly targeted at reducing the undesirable effects of patent trolls,[186] and the heightened patent infringement pleading standard have been largely expected to be one of the major tools to reduce frivolous or meritless lawsuits by patent trolls.[187]

The high litigation cost of patent cases is one of the major factors that provide

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[181] *See* Jonathan L. Moore, *Particularizing Patent Pleading: Pleading Patent Infringement in A Post-Twombly World*, 18 TEX. INTELL. PROP. L.J. 451, 506, n.79. (2010).

[182] *See* Mark A. Lemley & A. Douglas Melamed, *Missing the Forest for the Trolls*, 113 COLUM. L. REV. 2117, 2118 (2013); Paul R. Gugliuzza, *Patent Litigation Reform: The Courts, Congress, and the Federal Rules of Civil Procedure*, 95 B.U. L. REV. 279, 280 (2015).

[183] Jason Rantanen, *Slaying the Troll: Litigation As an Effective Strategy Against Patent Threats*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 159, 164-69 (2006).

[184] *See*, e.g., *id.*

[185] *See, e.g.*, Exec. Office of the President, Patent Assertion and U.S. Innovation (2013), available at http://www.whitehouse.gov/sites/default/files/docs/patent_ report.pdf (calling for control of abusive litigation practices by patent assertion entities); *supra* note 182, Paul R. Gugliuzza, *Patent Litigation Reform: The Courts, Congress, and the Federal Rules of Civil Procedure*, 95 B.U. L. REV. 279, 281-82 (discussing various bills introduced in Congress targeting patent trolls in an effort to "impose heightened pleading requirements on plaintiffs, to limit discovery, and to create a presumption that the losing party should pay the winner's attorneys' fees."); John M. Golden, *"Patent Trolls" and Patent Remedies*, 85 TEX. L. REV. 2111 (2007).

[186] *See* Paul R. Gugliuzza, *Patent Litigation Reform: The Courts, Congress, and the Federal Rules of Civil Procedure*, 95 B.U. L. REV. 279.

[187] *See, e.g.*, Jonathan L. Moore, *Particularizing Patent Pleading: Pleading Patent Infringement in A Post-Twombly World*, 18 TEX INTELL. PROP. L.J. 451, 471-72 (2010).

patent trolls an incentive to file numerous nuisance-value infringement claims.[188] According to the American Intellectual Property Law Association, the legal costs of a patent infringement action range from $600,000 to $5 million, depending on the patentee's potential recovery.[189] Of the patent infringement cases that go to trial, the trial occurs over three years from the complaint's filing for one-third of the cases, and 12% of the cases take over five years to reach trial.[190] Unable to afford such formidably high litigation costs, small businesses would choose to settle in the early stages of litigation when faced with a patent infringement suit rather than taking the case to trial, even when the patent troll's claims are meritless.

In addition to the high litigation costs, innovation costs and business costs to potential defendants also contribute to patent trolls' practice of filing nuisance-value infringement claims. When faced with an infringement claim, inventors may choose to alter their research or products to simply avoid the scope of the asserted patent; but if they cannot easily design around, the threat of a lengthy lawsuit may be enough to cause them to cease the research on a technology or the manufacture of a product entirely.[191] Further, a pending patent infringement suit may affect a company's ability to obtain credit or, at a minimum, increase its credit costs.[192]

The heightened pleading standard under *Twombly* and *Iqbal* has a good prospect of reducing nuisance-value infringement claims by patent trolls for at least two reasons. First, under the recommended requirements in this section, pleading direct patent infringement would require the plaintiffs to (1) identify the particular claims that are allegedly infringed, (2) at least generally identify of the accused infringing products, and (3) assert how the accused products infringe the patent claims.[193] To meet these requirements in the complaint, the patentee is required to conduct at least preliminary investigations. The cost of such preliminary investigations would make it financially impractical, if not impossible, for a patent troll to file infringement claims against hundreds of potential defendants at the same time. Thus, the heightened pleading standard forces patent trolls to at least strategically choose which defendants they want to sue, instead of filing a suit against every potential defendant indiscriminately.

Second, even if a patent troll decides to invest some money in preliminary investigations and files the complaints, it still would need to withstand Rule 12(b)(6) motions to dismiss under the *Twombly/Iqbal* standard in order to trigger the costly litigation proceeding. District courts, acting as gatekeepers, will be able to exercise their discretionary power under *Twombly/Iqbal* to dismiss vague claims brought by patent trolls and relieve the defendants from further litigation costs. And with the

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188 *See id.*

189 *See* Am. Intellectual Prop. Law Ass'n, Report of the Economic Survey 2007, at 25 (2007).

190 *See* Moore, *supra* note 187, at 461.

191 *See id.* at 461-62.

192 *See id.* at 463.

193 *See supra*, Section IV.A.

"new" sword of Rule 12(b)(6) motions, defendants will be less likely than before to settle claims with patent trolls when their claims are meritless. This would further discourage patent trolls from filing batches of frivolous claims against small businesses with the intent of extracting licensing fees.

2. Protecting small businesses

Due to the potential chilling effect of the heightened pleading requirement on patent trolls' strategy of filing batches of nuisance-value infringement claims, as discussed above, small businesses named as defendants will greatly benefit from not having to defend themselves against frequent frivolous infringement lawsuits against patent trolls. The main concern, therefore, is whether the heightened pleading standard will cause undesired damage to small business patent holders when they try to enforce their patent rights against other corporations, especially large sophisticated corporations. Such concern is largely unwanted, however, under the *Twombly/Iqbal* pleading framework.

First, the heightened pleading standard does not add to the cost of meritorious litigation. Even before the heightened pleading requirement, many patentees, including small businesses, were already conducting pre-suit investigations to evaluate the value of their cases. Indeed, according to Rule 11, plaintiffs should be performing a pre-suit investigation anyway to avoid potential sanctions, at least to the extent possible.[194] A heightened pleading requirement would therefore only impose additional costs on those unscrupulous plaintiffs who take advantage of the lower pleading standard.

Further, the local rules in many district courts with large dockets of patent cases already require plaintiffs to disclose the information required in the complaint under the *Twombly/Iqbal* standard at a very early stage of the case. For example, in the Eastern District of Texas, a patent holder must provide detailed disclosures of its asserted claims and infringement contentions ten days before the initial case management conference,[195] and the Northern District of California requires a patent holder to provide that information immediately after the conference.[196] Thus, instead of requiring plaintiffs to discover more facts and disclose them shortly after filing the complaint, the heightened pleading standard merely requires that they put them into the complaint.

Finally, the *Twombly/Iqbal* standard would grant district judges the discretion to

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[194] Jonathan L. Moore, *Particularizing Patent Pleading: Pleading Patent Infringement in A Post-Twombly World*, 18 TEX. INTELL. PROP. L.J. 451, 502 (2010).

[195] E.D. TEX. LOCAL R. 3-1.; *see also* Paul R. Gugliuzza, *Patent Litigation Reform: The Courts, Congress, and the Federal Rules of Civil Procedure*, 95 B.U. L. REV. 279, 289-90 (2015).

[196] N.D. CAL. LOCAL R. 3-1 (disclosure required two weeks after the initial case management conference).

allow a small business plaintiff to conduct limited discovery for the purpose of meeting the heightened pleading standard when the plaintiff's claim shows sufficient merit. In some cases, due to the nature of the patented technology, it would be fair to allow a small business plaintiff with limited resources to discover a defendant's secret use of the patented claims rather than dismissing the claim up front. Indeed, at least one district court has recently allowed plaintiffs to undertake limited discovery at the motion-to-dismiss stage because evidence about key facts was inaccessible to them.[197]

One possible negative effect of the heightened pleading standard on small businesses, especially individual inventors, would be that with the decreasing business of patent trolls, it will be harder for small businesses to sell their patents to patent trolls. However, selling patents to patent trolls is not the only way that small businesses or individual investors could recoup their investment in their patents. Further, the heightened pleading standard only discourages infringement claims with nuisance value, but not those cases with true merit. Therefore, if a small business or individual investor has a strong patent, they still have a good market for sale. In this sense, the heightened pleading standard discourages small entities from filing weak patents for the purpose of selling them to patent trolls.

3. Comparatively less impact on large sophisticated corporations

Compared with small entities, large sophisticated corporations will likely be less affected by the heightened pleading standard under *Twombly* and *Iqbal*. Unlike small entities, large corporations have much more resources to defend themselves against nuisance-value infringement claims asserted by patent trolls. As a general strategy to deter future frivolous infringement claims against them, large corporations would not simply settle with patent trolls in the early stage but would take the case to trial and make every effort to invalidate the asserted patents.[198] Because of this, nuisance-value infringement claims by patent trolls are usually directed to small businesses, who are more willing to settle and take a license, rather than to large sophisticated corporations. This is especially true when the validity of the asserted patent is in doubt.

The heightened pleading standard will not have much impact on large sophisticated corporations as plaintiffs either. As discussed above, even before the heightened pleading standard, plaintiffs were already conducting pre-suit investigations to evaluate the value of their cases and to avoid possible Rule 11 sanctions,[199] and this

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[197] *See, e.g.*, Rice v. Murakami, No. 1:13-CV-441, 2014 WL 2780977, at *1-2 (D. Idaho June 18, 2014) (finding that the plaintiff's complaint failed to meet the requirements of Iqbal but ordering "limited discovery" to allow the plaintiff "a fair opportunity to amend his complaint to satisfy the Iqbal standards").

[198] *See generally* Jason Rantanen, *Slaying the Troll: Litigation As an Effective Strategy Against Patent Threats*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 159 (2006).

[199] *See supra* Section IV.B.2.

is even truer for large corporations. Further, large corporations are less likely to be plaintiffs. This is because their products usually involve a large number of patented technologies, many of which are possibly held by their competitors.[200] Therefore, it makes more business sense for large corporations to cross-license their patents with their competitors rather than file lawsuits against each other.

4. Different levels of impact on pharmaceutical and information technology industries

It has been reported that patent troll lawsuits have affected various industry sectors disproportionately.[201] Therefore, it will not be surprising that different industries will be affected by the heightened pleading standard to different extent. Patents in pharmaceuticals and biotechnology pose significantly different issues, in the context of infringement actions, from those posed by information technology patents. Pharmaceutical patents often attract a relatively small number of infringement claims as the patented drugs can be precisely described by their distinct molecular structures.[202] By contrast, an information technology company may have a patent with a large number of claims or multiple patents that are "stacked" together to cover a product, which is much more commonly targeted by patent troll suits.[203]

The heightened pleading standard will impact the pharmaceutical industry and information technology industry differently in at least three aspects. First, due to the different nature of inventions described above, pharmaceutical and biotechnology patents tend to have far fewer claims than patents on information technology.[204] Therefore, the requirement to assert specific patent claims in the complaint is less imperative in a litigation involving pharmaceutical or biotechnology patents than that involving information technology patents. Second, while a certain drug is usually covered by one patent with a few claims, an electronic device or software may be covered by several patents with hundreds of claims.[205] Therefore, a requirement to identify the specific products and specific aspects of the products that are allegedly infringing is of much more significance to the information technology industry. Consequently, requiring the plaintiff to assert the specific patent claims and the specific infringing products would affect the information industry much more than the pharmaceutical industry.

Finally, in the pharmaceutical or biotechnology industry, a patent holder is usu-

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[200] *See generally* Herbert Hovenkamp et. al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1720 (2003).

[201] Thomas H. Kramer, *Proposed Legislative Solutions to the Non-Practicing Entity Patent Assertion Problem: The Risks for Biotechnology and Pharmaceuticals*, 39 DEL J. CORP. L. 467, 477-78 (2014).

[202] *Id.* at 490.

[203] *Id.* at 477-78 and 490.

[204] *Id.* at 490.

[205] *See id.*

ally unable to obtain information about its competitor's potentially infringing manufacturing processes without discovery, rendering some patent holders with legitimate infringement claims unable to provide the required specificity under the heightened pleading standard.[206] On the other hand, reverse engineering in the information technology industry is a common practice used to find out how a product or process allegedly infringes a patent claim. Therefore, requiring the patentee to assert how the accused product or process infringes the asserted claims in the complaint will impose much more difficulty for the pharmaceutical or biotechnology industry.

The heightened pleading standard's possible bigger impact on the information technology industry than on the pharmaceutical industry is expected and desirable. As discussed above, the information technology industry is much more frequently targeted by frivolous behaviors of patent trolls than the pharmaceutical industry. Therefore, it would be a good result if the heightened pleading standard would be able to significantly reduce patent trolls' frivolous claims against the information industry and leave the pharmaceutical industry largely intact. To the extent that the heightened pleading standard could in some cases make it hard for a pharmaceutical company to bring meritorious suits because it is impractical to obtain information regarding how its claims are infringed, district judges can exercise their discretion to permit limited discovery at the motion-to-dismiss stage as permitted by the *Twombly/Iqbal* standard.[207]

VII. Conclusion

With the recent abrogation of Rule 84 and Form 18, the law of patent infringement is pleading at the corner of another turn. It will take courts several years to hash out what exactly the heightened pleading standard under *Twombly* and *Iqbal* requires, but district courts have been experimenting with this issue already. As this article argues in the last section, the changes to come will likely be more effective in reducing nuisance-value infringement claims, and the new standard will likely serve the purpose of promoting innovations and businesses better than the old standard.

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[206] *See* Paul R. Gugliuzza, *Patent Litigation Reform: The Courts, Congress, and the Federal Rules of Civil Procedure*, 95 B.U. L. REV. 279, 301 (2015); H.R. Rep. No. 113-279, at 105-06 (2013); Hearing on Small Businesses and Patent Abuse Before the S. Comm. on the Judiciary, 113th Cong. (Dec. 17, 2013) (remarks of Steve Bossone, Vice President, Intellectual Property, Alnylam Pharms.), *available at* http://www.judiciary.senate.gov/download/testimony-of-bossone-pdf&download=1, *archived at* http://perma.cc/8JLF-SYKR.

[207] *See* Gugliuzza, *supra* note 206, at 301.

Innovative Contracting for Better Material Transfers

Karen E. Sandrik*

Empirical studies find that contrary to expected outcomes, it is not patents that most often impede research. Instead, it is access to tangible research inputs that is more likely to cause the delay or abandonment of promising research. Difficulty in the negotiation and execution of material transfer agreements (MTAs), the contractual agreements governing the transfer of materials, research tools, and data, is the cause. This Article addresses a new trend in MTA practice that is both exciting and problematic.

In the past, MTAs largely functioned as a recording mechanism to track who had what materials and to set expectations in the case of a laboratory accident or infringement lawsuit involving the transferred material. Now, however, some industry parties are using MTAs to gain more than just a record of the transfer and basic representations and warranties. Industry parties are using MTAs to develop

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and build relationships. This, in turn, is leading to more shared innovative activity, a key factor in moving scientific fields forward. Yet this progress towards more shared innovative activity is not without cost. Most notably, this modern MTA practice is increasing transaction costs and the likelihood of bargaining breakdowns because not everyone is using MTAs in this way. In order to facilitate access to materials, tools, and data while also furthering shared innovative activity, non-industry parties, most notably, academic institutions, should join the modern MTA regime. Lawyers have an opportunity to improve the material transfer process through innovative contracting practices. This Article provides suggestions on how to accomplish this by overcoming contested terms and using a modern MTA to give access to materials and help develop collaborative relationships.

Introduction

Shared innovative activity is the key to the progression of science.[1] In today's sophisticated world, it is rare for an isolated researcher to discover or invent something new. Instead, new discoveries, products, and inventions require a team of researchers spanning academic institutions, research laboratories, and industry to come together to share researchers' expertise, laboratory space and equipment, materials, and general know-how and expenses. The future of science is this togetherness. How best to support the foundation of shared innovative activity through access to tangible research inputs is the subject of this article.

The foundation of shared innovative activity is access—access to one another's materials, research tools, and data. Access is more problematic for researchers than are patents.[2] If a biotechnology company develops a promising oral enzyme inhibitor for the treatment of patients with a broad range of blood cancers, it will need the financial backing and expertise of a larger pharmaceutical company to move forward in development of the inhibitor and in clinical trials to bring the promising new discovery to the public.[3] Before partnering with the biotech company, an inter-

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1 This understanding of science and innovation is apparent in statements made by individuals such as Dr. Michael Caligiuri, director of the Ohio State University Comprehensive Cancer Center and CEO of the Arthur G. James Cancer Hospital and Richard J. Solove Research Institute. He recently explained that "[t]here is no routine cancer, and today it takes the collective minds across disciplines, institutions and industry to move the field forward." *The Ohio State University and University of Michigan Partner with Industry to Bring Oral Cancer-Fighting Patch to Patients*, THE OHIO STATE UNIVERSITY COMPREHENSIVE CANCER CENTER (June 5, 2014), http://cancer.osu.edu/news-and-media/news/ohio-state-and-university-of-michigan-partner-to-bring-oral-cancer-fighting-patch-to-patients.

2 *See* Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 1060 HOUS. L. REV. 1059, 1061-62 (2008) (explaining that "[m]ore significant to researchers than patents . . . have been practical restrictions on access to materials and data, such as requirements for institutional assent to the terms of materials transfer agreements (MTAs)."). *See also* John P. Walsh, Charlene Cho & Wesley M. Cohen, *Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research*, 36 RES. POL'Y 1184, 1190 (2007) (same).

3 *See, e.g.*, *Infinity and AbbVie Announce Global Strategic Collaboration to Develop and Commer-*

ested pharmaceutical company will require access to the oral enzyme inhibitor, a type of "material," and its accompanying data so that the pharmaceutical company may determine the inhibitor's efficacy potential as well its compatibility with the pharmaceutical company's particular knowledge and expertise in the field of pharmacology.

The biotech and pharmaceutical companies will sign some form of a material transfer agreement ("MTA") to grant the pharmaceutical company access to the material and sometimes its accompanying data.[4] Internal policies at the majority of academic institutions, industry partners, and federal agencies require an executed MTA before a transfer. This is so even when there is no plan for further shared innovative activity.

For example, when the University of North Carolina (UNC) or the U.S. Centers for Disease Control and Prevention (CDC) needs tissue samples containing the MERS-CoV (MERS) virus in order to begin testing and learning about the virus,[5] they only want immediate access. UNC and the CDC each have their own research laboratories, scientists, and general know-how to conduct their own analysis, at least at this initial stage. Even though there is no repeated interaction desired with the transferor, both UNC and the CDC must still negotiate and execute a MTA to get access to these crucial samples.[6] With the MERS samples, MTAs were negotiated and executed by the UNC, the CDC, and at least 40 others from around the world. The majority of these MERS samples came from an academic institution in the Netherlands, a laboratory in the United Kingdom, and from Saudi Arabia.[7]

These two examples demonstrate that MTAs are used worldwide in both the collaborative partnership between biotechnology and pharmaceutical companies and the one-time interaction between the transferor and transferees of the MERS samples. And all across the world, the negotiation and execution of MTAs, as they did with the MERS-CoV outbreak, cause delays of research. Parties consistently state

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cialize Duvelisib (IPI-145) In Oncology, INFINITY PHARMACEUTICALS, INC. (Sep. 3, 2014), http://phx.corporate-ir.net/phoenix.zhtml?c=121941&p=irol-newsArticle&ID=1963180.

4 Industry parties quite frequently use other terms such as licenses and collaborative agreements.

5 Jim Wappes, *WHO Raises its MERS-CoV Counts to 55 Cases, 31 Deaths*, CTR. FOR INFECTIOUS DISEASE RESEARCH AND POLICY (June 7, 2013), http://www.cidrap.umn.edu/news-perspective/2013/06/who-raises-its-mers-cov-count-55-cases-31-deaths.

6 *See, e.g.*, Robert Coos, *Saudis to Send Animal Samples to US in MERS-COV Probe*, CTR. FOR INFECTIOUS DISEASE RESEARCH AND POLICY (May 24, 2013), http://www.cidrap.umn.edu/news-perspective/2013/05/saudis-send-animal-samples-us-mers-cov-probe; Christian Nordqvist, *MERS-CoV Death Toll Rises to 31*, MEDICAL NEWS TODAY (Jun. 8, 2013, 12:00 PM), http://www.medicalnewstoday.com/articles/261671.php.

7 *See* Coos *supra* note 6; *See also* Laurie Garrett, *Why a Saudi Virus is Spreading Alarm*, COUNCIL ON FOREIGN RELATIONS (May 29, 2013), http://www.cfr.org/public-health-threats-and-pandemics/why-saudi-virus-spreading-alarm/p30799.

that "MTAs are a pain in the neck,"[8] so why do lawyers and technology transfer offices insist on the execution of MTAs prior to transfer?

To begin with, it is important to note that unlike with patents where the "burden of inertia" is on the patent holder to detect infringement and enforce its rights, the party in need of materials, tools, or data must bear the cost of finding the needed input and obtaining access.[9] In other words, one in need of a research input does not have the option to "take now, pay later."[10] Two more reasons that MTAs are so heavily used is because there is substantial risk and uncertainty in these types of transfer.[11]

Risk exists, for example, in the form of everything from patent, tort, and contract litigation to laboratory accidents and the simple but perilous handling of contaminated tissue samples.[12] Uncertainty exists when there is a sharing and developing of proprietary information. Development of this information often takes millions of dollars and many years to discover and develop. The sharing of that information necessarily involves inherently volatile collaborative relationships. Risk and uncertainty are mitigated, at least in part, and planned for, as much as is possible, if the expectations of the parties are discussed, planned, and recorded so that all may review the written contract if the transfer does not go as planned.

Even though the built-in confidential nature of MTAs makes empirical research hard to conduct, especially in industry practice, it is believed that hundreds of thousands of MTAs are signed every year globally, with academic institutions in the United States alone spending millions annually to manage their MTA practice.[13]

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8 Ian M. MacKay, *Questions about MERS, MTAs, and Mistakes*, VIROLOGY DOWN UNDER BLOG (May 26, 2013), http://virologydownunder.blogspot.com/2013/08/questions-about-mers-mtas-and-mistakes.html.

9 *See* Eisenberg, *supra* note 2, at 1062.

10 Under a "take now, pay later" rule, interested users or takers of a particular entitlement can unilaterally act, so as long as they pay the officially determined price for that entitlement. Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293, 1302 (1996).

11 Similar to others writing about contracts in the field of science and technology, when using the terms "risk" and/or "uncertainty" I am adopting H. Knight's usage. *See generally* Frank H. Knight, UNCERTAINTY AND PROFIT (1921) (differentiating "risk" from "uncertainty" as a quantity that can be measured).

12 Even simple skin coverage, particularly of sensitive areas of the body such as the eye, ear, and nose, can be difficult. As of December 2014, 335 relief workers died while fighting against transmission of the Ebola virus infections in West Africa. *US Army Adopts and Deploys Provodine® from Microdermis to Fight Ebola*, LIFE SCI. W'KLY. (Dec. 1, 2014, 12:19 PM), http://venturebeat.com/2014/12/01/us-army-adopts-and-deploys-provodine-from-microdermis-to-fight-ebola/. This number is likely to dramatically decrease in the future after a MTA recently allowed the U.S. Army Medical Research Institute of Infectious Diseases to test Provodine® to determine its antiseptic protection even of sensitive body parts after exposure to Ebola virus particles. *Id.*

13 *See Benefits of MTAShare*, VAND. UNIV., CTR. FOR TECH. TRANSFER & COMMERCIALIZATION, http://cttc.co/cttc/content/inventors/mtashare/benefits-mtashare (last visited Apr. 3, 2016) (click on

This is significant because MTAs rarely generate money and often cause delays to research due to the lengthy negotiations and outright denial of—or lack of response to—material transfer requests. This Article identifies reasons for delays in negotiations as well as the high numbers of denials or failed negotiations.[14] MTAs are, at least compared to other licensing instruments in the technology transfer world, uncomplicated documents. Yet, it often takes lawyers and MTA specialists months to negotiate and execute one MTA. In the case of the so-called "Harvard oncomouse," it took four years of negotiations to permit noncommercial researchers to use the oncomice without cost.[15]

The previously proposed solutions to the increased transaction costs and bargaining breakdowns of MTAs often involve some sort of a standardized MTA. I argue here that the missing piece is not the goldilocks standardized form. This is because a new form will not solve the previously unidentified problem that is discussed here. In short, while some parties believe they are negotiating with the same objective in mind—a transferred material, tool, or data—this, in fact, is not true. The delays in execution and failed negotiations occur because MTAs serve more than one function, yet lawyers and licensing specialists have largely missed this important detail. This lack of understanding leads to misunderstandings and complaints that the other side "just doesn't get it."[16]

When parties are employing a MTA for a one-time interaction, like with the MERS example above, they are using what I will call herein a "traditional" MTA. Traditional MTAs have been in practice for decades and are the favored type of MTA of academic institutions.

Oftentimes, when academic institutions negotiate with an industry partner, however, there is tension among the transfer specialists and lawyers because the industry partner does not want a one-time interaction. Instead, the industry partner only wants to take on the transaction costs to transfer the material, tool, or data when it will lead to potential shared innovative activity. In essence, the industry partner is using the MTA to help build a collaborative relationship. I will call this use of a MTA a "modern" MTA. Whether in industry contracting practice it is called a MTA in title or not, and this varies widely, and whether or not the industry party even

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MTAShare video on "Key Benefits of MTAShare").

14 There is also evidence that MTA requests are so numerous and taxing on resources that academic institutions and faculty members are simply ignoring them. Wendy D. Streitz & Alan B. Bennett, *Material Transfer Agreements: A University Perspective*, 133 PLANT PHYSIOLOGY 1, 1 (2003), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC523866/.

15 *See* Fiona Murray, *The Oncomouse That Roared, Hybrid Exchange Strategies as a Source of Distinction at the Boundary of Overlapping Institutions*, 116 AM. J. SOC. 2, 367 (2010), *available at* http://fmurray.scripts.mit.edu/docs/Murray_AJS_2010_653599.pdf.

16 This is a remark that one industry MTA specialist made in frustration when discussing MTA negotiations with academic institutions.

consciously recognizes the difference, a modern MTA serves a different function than a traditional MTA.

The modern MTA helps parties build relationships and plan for uncertainty by combining firm terms with clear obligations and soft contract terms, such as "good faith," "commercially reasonable efforts," or "diligent efforts," with terms that are non-remedial or unenforceable terms because they are too vague, indefinite, or speculative.[17] The combination of these varied terms allows parties to respond cooperatively to risk and uncertainty by creating, in most instances, formal boundary lines and some sort of accompanying mechanism that helps the parties flesh out more details of the agreement at a later point.

The modern MTA is a type of contract that is leading to shared innovative activity where not just materials are shared, but also scientists, laboratories, proprietary information, and marketing plans. After extensive research, including interviews with academic and industry parties, I find that the modern MTA is in use almost exclusively by industry parties.[18] Lawyers and licensing specialists at academic institutions where there is a desire to build relationships and bring upstream research into the downstream process need to recognize and employ modern MTAs. The modern MTA is not a new form to take the place of the traditional MTA; rather, it is a different way of contracting that achieves a different goal. This Article provides guidance to academic institutions and others currently using a traditional MTA who want to embrace a more innovative and modern MTA practice that fosters collaboration.

Part I of this Article traces the development of academic science and identifies the key features of the traditional MTA most often used by academic and government scientific institutions. Part II discusses industry science and identifies the key features of the modern MTA. Part III.A argues that there are still situations that the

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[17] This occurs where no promise or obligation is made or incurred. Ronald J. Gilson, Charles F. Sabel, and Robert E. Scott, in a series of articles on "contracting for innovation," call this process "braiding." *See generally* Ronald J. Gilson et al, *Braiding: The Interaction of Formal and Informal Contracting in Theory, Practice, and Doctrine*, 110 COLUM. L. REV. 1377 (2010). I have added non-remedial clauses, because in my research, I found those terms are more common than legally unenforceable terms.

[18] Although I have done my best to include a representative sample of MTAs from a broad range of technological fields and varied institutions, there are noteworthy limitations to my research and sample size. MTAs often include a confidentiality requirement, making it difficult as a researcher to gain access to the full text and surrounding context of the agreement. I have done my best to overcome this access hurdle by conducting in-person and telephone interviews with multiple technology transfer specialists at academic institutions and in-house counsel and outside counsel responsible for drafting MTAs for industry parties. Even with these interviews, however, I was most successful in speaking with and gaining access to MTAs where academic institutions and biotechnology companies had partnered with publicly traded pharmaceutical companies. This success was largely based upon the fact that federal securities laws require publicly traded companies to make disclosures that frequently capture these agreements. As such, there is the potential for an industry-based bias present in this Article, one that I hope to overcome in future projects.

traditional MTA should be used in, but that particular contested terms leading to lengthy negotiations need addressing. This Part offers pragmatic work-around solutions for these contested terms. Part III.B argues for the adoption of the modern MTA when a one-time transaction is not desired. This Part identifies potential enforcement problems with the modern MTA and offers solutions to lawyers and contracting specialists in technology transfer offices.

I. The Development of the "Traditional" MTA

The commercialization of science continues to evolve. In the twentieth century, commercial scientists generally focused on applied science while noncommercial scientists focused on basic science. The noncommercial scientists, employed at universities, teaching hospitals, and research laboratories, were thought of as "pure scientists," leaving the commercialization of their basic science discoveries to industry. This broad classification of noncommercial and commercial scientists still exists today, although the classification has been rebranded in part and the separation is now quite blurred. Today, basic science, the understanding of science, is generally termed "upstream" research or the upstream process. Conversely, applied science, the use of science, is often referred to as "downstream" research and development or the downstream process.

Just like with basic science, upstream research is focused on scientific discovery with the end goal of better understanding the subject matter at study.[19] Take Dr. Mary-Claire King, for example. Dr. King, at the time a faculty member at UC-Berkeley, received financial support from the National Cancer Institute (NIC) to study hereditary breast cancer.[20] She was not focused on creating a new therapy or diagnostic screening process at that point, but instead on making a discovery that might help her and others better understand hereditary breast cancer. Dr. King was focused on upstream research. Ultimately, it was Dr. King and her laboratory that proved there is a single genetic mutation, breast cancer susceptibility gene 1 (BRCA1), located on chromosome 17, which is responsible for inherited breast and ovarian cancers.[21]

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[19] *See* Meir Perez Pugatch et al., *Taking Stock: How Global Biotechnology Benefits from Intellectual Property Rights*, PUGATCH CONSILIUM (June 2012), https://www.bio.org/sites/default/files/Pugatch%20Consilium%20-%20Taking%20Stock%20Final%20Report%20(2).pdf (defining upstream process as "[t]he range of research and development activities which relate to the pre-market and development stages of a product or technology"); Ed Levy et al., *Patent Pools and Genomics: Navigating a Course to Open Science*, 16 B.U. J. SCI. & TECH. L. 75, 76 (2010) (explaining that although an imprecise term, upstream research is the type "intended to yield information or knowledge.").

[20] *See Enhancing Breast and Ovarian Cancer Care: The Discovery of BRCA1 and BRCA2*, NATIONAL CANCER INSTITUTE, (Mar. 2014), http://www.cancer.gov/aboutnci/servingpeople/cancer-research-progress/discovery/brca.

[21] After Dr. King's discovery, Dr. Mark Skolnick, again with funding from NIC, was the first to clone the gene and pinpoint its exact location. *See* Laurie McHale, *Putting the Puzzle Together*, U.

The opposite of upstream research is downstream research. This is where scientists, most often industry scientists, are focused on developing the upstream science discoveries into a product or process to bring to the market.[22] After Dr. King's increased understanding and isolation of BRCA1, the next step was for scientists in the downstream process to create a diagnostic screening process for BRCA1. After the discovery of BRCA1, and shortly thereafter BRCA2, Myriad Genetics won this race after collaborating with over 444 outside scientists in its endeavor to find the most effective diagnostic test for BRAC1 and BRAC2.[23]

This once clear demarcation between noncommercial scientists focusing on upstream research and commercial scientists on downstream research is not so clear anymore. Moreover, the "distinction" between upstream and downstream research, like with basic and applied science, is largely dynamic.[24] Academic institutions are seeking to turn their upstream research into downstream development that may lead to "blockbuster" patents, and industry scientists are doing more research work in the upstream process.[25]

For example, in 2007, New York University received approximately $650 million in royalties for an autoimmune-disease-treating pharmaceutical developed by two researchers.[26] The total royalties generated are estimated at $1 billion.[27] Similarly, Northwestern University received around $700 million in royalties for a pharmaceutical treatment for seizures developed by a chemistry professor.[28] The success stories of NYU and Northwestern, among others, have motivated academic institutions to protect faculty output though patent law and contract law and then to ag-

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WASH. (Nov. 6, 1996), https://www.washington.edu/alumni/columns/sept96/king1.html.

22 *See* Pugatch et al., *supra* note 19 (defining downstream process as "the range of activities that relate to the market and post-market phases (including commercialization) of a new product or technology . . ."); Levy et al., *supra* note 19, at 76 (describing downstream research as "research that can directly form the basis of a product.").

23 *See* Mark C. Capone, *Setting the Record Straight: Comments on Recent Media Reports Regarding BRCA1/2 Patents,* Myriad Genetics (Apr. 23, 2010), https://www.myriad.com/lib/speaker-portal/Setting%20the%20Record%20Straight.pdf.

24 *See generally* DONALD E. STOKES, PASTEUR'S QUADRANT: BASIC SCIENCE AND TECHNOLOGICAL INNOVATION (1997) (challenging the linear model of the relationship between basic and applied science).

25 *See, e.g.*, Ronald I. Eisenstein & David S. Resnick, *Blockbuster Patents Enrich University Coffers, but can also Affect Future Patenting and Research Decisions,* NATURE (2001), http://www.nature.com/bioent/2003/030101/full/nbt0901-881.html.

26 *See* Karen W. Arenson, *Manhattan Drug Research Benefits University*, N.Y. TIMES, May 8, 2007, *available at* http://www.nytimes.com/2007/05/08/nyregion/08mbrfs-drug.html?_r=0.

27 Richard Perez-Pena, *Patenting Their Discoveries Does Not Pay Off for Most Universities, a Study Says*, N.Y. TIMES, Nov. 20, 2013, at A18, *available at* www.nytimes.com/2013/11/21/education/patenting-their-discoveries-does-not-pay-off-for-most-universities-a-study-says.html.

28 *See* Jon Van, *Drug Find Worth $700 Million*, CHI. TRIBUNE (Mar. 10, 2008), http://articles.chicagotribune.com/2008-03-10/business/0803090219_1_gaba-richard-silverman-*drug*-companies (explaining that Dr. Silverman's discovery is the "chemist's version of a Power-Ball ticket").

gressively license and enforce the patented technology. This means that academic institutions in many instances are indistinguishable from their industry counterparts.[29]

On the other end, industry is not only funding more research, in particular university research,[30] industry partners are themselves entering upstream efforts. This means that industry parties are focusing more on the upstream process much like academic institutions are finding themselves in the downstream process. For example, it is widely known that pharmaceutical companies play a vital role in proving or disproving medical hypotheses that noncommercial scientists put forth, but pharmaceutical and biotech companies similarly play a complementary role in the discovery of new compounds.[31] It is the discovery of these compounds in the upstream process that after much testing leads to new (downstream) pharmaceutical products.

This blurred line between upstream and downstream research and noncommercial and commercial science has many advantages. The growth of academic science into downstream research and development, for example, has lead to groundbreaking innovation. From penicillin production, to Plexiglas and the Polio and Hepatitis B vaccines, warfarin and insulin to antigens and saccharin—academic science has undeniably changed the world.[32] This innovation has also led to another positive change—a substantial amount of money poured back into science departments and research laboratories.[33]

Furthermore, there is an increased understanding that "today, it takes the collective minds across disciplines, institutions and industry to move [a] field forward."[34]

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29 *See, e.g.*, Peter Lee, *Patents and the University*, 63 DUKE L.J 1, 5 (2013) (stating that "academic science has become more aggressive, and universities have begun behaving more like typical commercial entities"); *see also* Mark Lemley, *Are Universities Patent Trolls?* 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 611 (2008) (describing push to maximize licensing revenues as strong trend among universities today).

30 Justin Biddle, *Bringing the Marketplace into Science: On the Neoliberal Defense of the Commercialization of Scientific Research*, 274 SCI. IN THE CONTEXT OF APPLICATION 245, 246 (2010) (explaining that "the boundaries between business, on the one hand, and government and university research, on the other, are becoming ever more blurry").

31 *See* JOHN L. LAMATTINA, DRUG TRUTHS: DISPELLING THE MYTHS ABOUT PHARMA R&D 4 (2009) (tracing "[t]he principle of lowering LDL cholesterol" and explaining that this movement forward in understanding the relationship between heart disease and cholesterol was supported by discoveries of various compounds by a microbiologist working at the Sankyo company in Tokyo and a team of Merck chemists).

32 *See University Inventions that Changed the World*, IPADVOCATE.ORG (Nov. 10, 2009), http://www.ipadvocate.org/pdfs/Uni%20Inventions%20Changed%20the%20World.pdf.

33 Many of the grants that fund this research and development require the academic institutions to direct revenues back into research and development efforts. *See also* Alan Dove, *When Science Rides the MTA*, 110 J. CLINICAL INVESTIGATION 425, 425 (2002), *available at* www.jci.org/articles/view/16546/pdf (reflecting that "the commercialization of academic science, particularly biomedical research, has provided a significant source of new funding and sped medical advances from the laboratory to the clinic.").

34 *Ohio-Based Venture Therapeutics Named Industry Partner*, OHIO STATE UNIV., (June 5, 2014),

Shared innovative activity can help expedite the understanding of a field, leading to new discoveries and development of targeted therapies and diagnostic tests.[35] Commentators like Henry Etzkowitz, a leading international scholar responsible for the "Entrepreneurial University" and "Triple Helix" concepts linking university research with industry and government research,[36] furthers this line of reasoning by defending what he calls the "assisted linear model of science and innovation policy."[37] He finds that there is more effective translation of scientific results into downstream marketable products when there is a close nexus between academic institutions, federal agencies, and industry parties.[38] It is also better understood now that "shared innovative activity tends to characterize the early phase of establishment of an industry."[39]

The term "shared innovative activity" is noteworthy. It is a type of collaborative activity, one that requires repeated interactions in order to share innovation responsibility. This is the kind of collaboration that is needed between academic institutions, federal agencies, and industry to continue establishing new fields and deepen understanding of existing ones. Shared innovative activity is also needed to smooth the transition from upstream research to downstream development, especially as academic institutions continue to explore (and at times struggle) with downstream research and development. Yet shared innovative activity is not easy. Shared innovative activity involves detailed research and collaboration agreements that seek to outline expectations of parties and to provide direction in the midst of risk and uncertainty. These agreements can take months, sometimes years, to negotiate and execute. During that negotiation between lawyers, scientists may struggle to gain access to the building blocks they need for a particular project. Among other consequences, long negotiations may lead to the loss of a grant or the window of time for a particular research project closing.

The building blocks of innovation are materials. Scientists must have physical materials, research tools and data, such as plasmids, cell lines, a high-powered microscope, etc., for experimentation. Furthermore, just as the need for shared innovation activity is seemingly on the rise because of the high level of sophistication within current science and technology, the price of materials, research tools, and data is also on the rise. Receiving access to materials, research tools, and data, wheth-

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http://cancer.osu.edu/news-and-media/news/ohio-state-and-university-of-michigan-partner-to-bring-oral-cancer-fighting-patch-to-patients.

35 *See id.* ("This type of collaboration, involving multiple university partners with strong industry support, is increasingly essential to expedite the discovery, development and delivery of more targeted cancer therapies.").

36 *See Human Sciences and Technologies Advanced Research Institute—About Us*, STANFORD UNIVERSITY, http://hstar.stanford.edu/3helix_about_us (last visited Jan. 24, 2015).

37 Biddle, *supra* note 30, at 246.

38 *See id.* (explaining that Etzkowitz's "line of reasoning . . . is echoed by many within university administration.").

39 Katherine J. Strandburg, *User Innovator Community Norms: At the Boundary Between Academic and Industry Research*, 77 FORDHAM L. REV. 2237, 2245 (2009) (internal citations omitted).

er that access is linked to a bigger collaboration or not, in practice requires an executed MTA. As the line between upstream and downstream research blurs and academic institutions more frequently seek to protect their intellectual property rights, access to materials, research tools, and data has become more restricted.[40]

The MTA went from a relatively rare occurrence to an everyday practice in academic institutions' technology transfer offices. It is estimated that large academic institutions each execute thousands of MTAs annually, spending over $100,000 in MTA management costs.[41] Smaller academic institutions report executing hundreds of MTAs annually,[42] with the collective academy spending millions each year for simple management of MTAs.[43]

The traditional MTA comes in various forms today but at the core is a unifying set of terms that lead to a one-time interaction between the parties. The set of terms concern liability, warranties, and use of the transferred material. This is largely due to standardization efforts of the Association for University of Technology Managers ("AUTM"). The AUTM assembled a special interest group that discussed MTAs with the National Institutes of Health ("NIH").[44] An internal committee of this project produced the Uniform Biological Materials Transfer Agreement ("UBMTA"), and although there are hundreds of signatories, a recent AUTM MTA survey found that the UBMTA is not in widespread use.[45] Instead, academic institutions and government agencies are using their own variations of the UBMTA.[46] Some commentators think that the delays surrounding MTAs are because of their sheer complexity and volume and because the "goldilocks" standard MTA has not yet been developed. This has resulted in calls for more standardization.

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40 *See* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 294 (2003) (explaining "[a]n important consequence of this shift has been an increase in restrictions on the transfer of research tools, even those that are not patented"). For a discussion on the potential erosion of public sector values as a result of academic science becoming more like that of industry science, see John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L. J. 101, 110-11 (2001).

41 *See* Bentley, *supra* note 13, at *5.

42 *See, e.g., MTAs*, EMORY U. OFFICE OF TECHNOLOGY TRANSFER (2015), http://ott.emory.edu/about/statistics/mta.html (illustrating steady growth of executed MTAs from 2005-2013, with approximately 700 in 2013).

43 *See* Bentley, *supra* note 13, at *5. It is also likely that these numbers are greatly underestimated as many technology transfer offices and industry specialists do not track or report their respective MTA numbers and practices. *See* Philip Mirowski, *Livin' with the MTA*, 46 MINERVA 317, 323-24 (2008).

44 NATIONAL INSTS. OF HEALTH, UNIFORM BIOLOGICAL MATERIALS TRANSFER AGREEMENT (1995), *available at* http://www.autm.net/Content/NavigationMenu/Members/UBMTA/default.htm (search "Uniform Biological Materials Transfer Agreement").

45 ASS'N OF UNIV. TECH. MANAGERS, AUTM 2011 MATERIAL TRANSFER AGREEMENT SURVEY REPORT (2011), *available at* http://www.autm.net/AUTMMain/media/Resources/Documents/MTASURVEYFINAL.pdf.

46 *See* Rai & Eisenburg, *supra* note 40, at 306.

This next Part will briefly trace the historical roots of the MTA, identify the form and function of the traditional MTA today, and discuss the recent calls for standardization efforts in more detail. Ultimately, I argue that another standardized MTA is not what the market needs. Instead, parties need to better identify whether their transfer requires a traditional MTA or whether the transfer requires a modern version of the MTA, one that plans for repeated interactions between the parties.

A. The Rise of Academic Science

The long-standing rhetoric surrounding universities is that they are secluded high above the world in ivory towers, divorced from the reality of the world and the market.[47] In academic science terms, the suggestion is that universities are more concerned about upstream research than how that research is applied or utilized in the downstream process. The recent downstream success of academic institutions like Columbia and NYU demonstrates this this is no longer true (if it ever was).

Notably, however, organized discussions about MTAs did not occur until the early 1990s. It was then that a special interest group was put together by the AUTM to think about standardization of MTAs for the first time. Conversely, there are oft-repeated stories about how materials were once shared informally, with no written agreement, between noncommercial and commercial scientists.[48] What caused this dramatic change in how materials are shared?

One reason for the sudden appearance of MTAs is increased financial support and patenting in academic science. After World War II there was a rush to support academic science.[49] The time period of 1950-1975 saw rapid increases in federal expenditures for research and development, and, concomitantly, higher numbers of patents issued to universities.[50] Federal expenditures supporting research and devel-

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47 *See* Lee, *supra* note 29, at 7-8; Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373, 1374 (2006) ("Universities have a reputation for being isolated ivory towers"); C.L. Max Nikias, Exec. Vice President and Provost, Univ. S. Cal., Beyond the Ivory Towers: On Tomorrow's American Research University, Thirty-First Annual Earl V. Pullias Lecture (Jan. 22, 2009), *available at* http://www.president.usc.edu/speeches/beyond-the-ivory-towers-on-tomorrows-american-research-university/ ("We face increasing cynicism about the academy. Elite research universities have been criticized as being too divorced from the concerns of ordinary women and men, too insular, too wealthy, too inefficient, too expensive, too naïve about the realities of life beyond the ivory tower."). *See also* Steven Shapin, *The Ivory Tower: The History of a Figure of Speech and Its Cultural Uses,* 45 BRIT. J. HIST. SCI. 1, 1-27 (Mar. 2012), *available at* http://www.fas.harvard.edu/~hsdept/bios/docs/shapin_Ivory_Tower_BJHS.pdf (providing the historical origin of the phrase "ivory tower" and how it has changed over the years).

48 *See, e.g.*, LaMattina, *supra* note 31, at 44 (former Pfizer researcher explaining that "[m]any years ago, MTAs were unheard of").

49 *See* ELIZABETH POPP BERMAN, CREATING THE MARKET UNIVERSITY: HOW ACADEMIC SCIENCE BECAME AN ECONOMIC ENGINE 19 (2012) ("University research was a modest, small-scale endeavor until the Manhattan Project demonstrated the power of science and, in the process, transformed the way it was organized.").

50 *See id.* at 35-36.

opment made up 55% of all university research spending in 1953 and 73% in 1966.[51] In actual dollars, universities received approximately $273 million in 1953, accounting for 5.3% of total national research and development expenditures.[52] This percentage rose to 7.9% in 1965 and to 10% in 1970.[53]

In the 1950s and 1960s there were roughly fewer than 100 patents issued per year to universities, yet in 1972 there were over 200 patents awarded to universities.[54] By 1975, that number was at 300.[55] This means that between the mid-1960s and mid-1970s the number of issued academic patents tripled.[56] During the mid-1970s there were pushes from private industry and federal agencies to support research and the collaboration between academic science and industry science.[57] This caused new tension. I argue more collaboration and shared innovative activity is a worthwhile goal, but that we must work to decrease tension that occurs when combining industry and academic science.

One of the reasons for this tension when combining academia and industry in the 1970s is the same reason there is tension today: there are inconsistent missions. There is an inconsistent mission in industry versus academia and to make matters more complicated, there is also an inconsistent mission in academia itself.

As identified and described by technology transfer specialists, there are multiple missions in academic science such as the preservation and dissemination of ideas and the generation and output of new discoveries.[58] At times, these missions seem to conflict, making it difficult to maintain consistency in the ultimate objective(s) of academic institutions.[59] Moreover, the mission of an academic institution may not also be the same as those of its faculty. Ultimately, the rewarding nature of the patent system—disclosure of an invention in a particular way resulting in the grant of twenty years of exclusive rights to the invention—seems largely incongruent with ensuring that the public has equal and affordable access to output. Interviews I have conducted, as well as those by other commentators, confirm that "[c]ompanies [continue to] complain that universities do not understand business and suffer from a

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51 *Id.* at 37.
52 *Id.*
53 *Id.*
54 *Id.* at 100.
55 *Id.*
56 *See id.* at 95 (explaining that "the number of patents issued to universities roughly tripled between the mid-1960s and the mid-1970s.").
57 *Id.*
58 *See* Council on Gov't Relations, *Material Transfers in Academia: 20 Questions and Answers* (Sept. 2003), http://www.ucop.edu/research-policy-analysis-coordination/_files/Materials_Transfer_in_Academia.pdf.
59 *Id.*

cultural schizophrenia about whether they are businesses or academic institutions."[60]

Compare the at-time competing missions of academic institutions to that of industry: profit maximization. Although industry scientists may work in laboratories that collaborate with large numbers of academic scientists, their end goal of producing a successful product or process makes for a different work environment than that of an academic institution. Academic scientists operate under a somewhat open environment with research results being published and presented, whereas industry scientists are much more likely to keep their research and the results secret until at least the patenting process is well on its way.[61] As one patent scholar and former academic scientist notes, "it is more difficult to stabilize and enforce norms of sharing in a community consisting of both academic and industry scientists than in a more homogenous academic research community."[62]

Stabilizing and enforcing norms in a heterogeneous science community was made more difficult when Senator Bayh in 1980 "managed to squeak" the University and Small Business Patent Procedures Act through Congress.[63] Commonly referred to as the Bayh-Dole Act, the Act has profoundly impacted academic science.[64] The Bayh-Dole Act affirmed that universities are allowed to patent any resulting inventions if several conditions are met.[65] These conditions include the university's disclosure to the federal government of an invention "within a reasonable time,"[66] as well as informing the federal government of any intent to obtain a patent[67] and providing updates when requested to do so.[68] Also, "the university must retain title," "share licensing proceeds with the inventors," and "the balance of licensing income must be used to support 'scientific research or education.'"[69] With this new legislation, among other things, Congress aimed to encourage collaboration between non-profit entities, including academic institutions, and industry.[70] Yet with increased funding and academic and industry patenting, there is more secrecy and competition.[71] When academic and industry scientists come together to share or

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60 Mirowski, *supra* note 43, at 328 (internal citations omitted).

61 *See* Strandburg, *supra* note 39, at 2260 (suggesting that "the social benefits of research tool sharing are less clear when industry scientists are involved since they are more likely to keep their research results secret").

62 *See id.*

63 Ritchie de Larena, *supra* note 47, at 1375 n.5.

64 *See* BERMAN, *supra* note 49, at 113-115 (discussing factors leading to the explosion of academic patenting and naming one of the critical three as the passing of the Bayh-Dole Act).

65 *See* Ritchie de Larena, *supra* note 47, at 1375.

66 35 U.S.C. § 202(c)(1) (2000).

67 35 U.S.C. § 202(c)(3).

68 Ritchie de Larena, *supra* note 47, at 1375.

69 *Id.* (citations omitted).

70 *Id.*

71 Secrecy must be maintained until at least a patent application is filed. This is truer under today's patent system than ever before. As of March 16, 2013, we are now under a first-to-file regime, as opposed to a first-to-invent system, making secrecy until the patent application is filed key. *See*

transfer technology, including materials, research tools, and data, the clash of internal academic goals and industry goals is apparent.[72]

Moreover, the tension between university research and industry research is not new, but the norm is shifting so that universities in particular disciplines are more consistently competing with industry partners. This means that academic and industry scientists may be engaged in similar research and development efforts. As a former president of Duke remarked, "universities should do all that is reasonably possible to earn returns on inventions, and should not be timid in making prudent business arrangements to assure the largest fair return."[73]

This cultural change is another reason why there was a sudden increase in the use of MTAs.[74] Virtually every transfer is accompanied by a transfer agreement. On average, a technology transfer office sees two or more MTA requests, whether outgoing or incoming, per day, with at least "annual compounded growth rates of incoming MTAs of somewhere between 6% and 15%, with no end in sight."[75]

With the aim of protecting discoveries in industry, academic science, and government science, every material is a piece in the puzzle that could be the last one needed to create that blockbuster patented technology. Conversely, due to the value of patentable technology (and therefore liability in a patent infringement suit), as well as the increasing volatility and sophistication of technology (for example, tissue samples from animals and humans infected with MERS or Ebola or tools to build the latest nuclear weapons), every material has much more liability attached to it. This increases the risk of transfer and the level of attention paid to the agreements that accompany these high-risk transfers.

America Invents Act, Pub. L. No. 112-29 (2011).

72 *See* John E. Tyler III, *Advancing University Innovation: More Must Be Expected—More Must Be Done*, 10 MINN J.L. SCI. & TECH. 143, 158 (2009).

73 Lee, *supra* note 29, at 39 (citing Terry Sanford, *The University and Technology: New Paths and New Perspectives*, 1 in THE LAW OF BUSINESS AND LICENSING: LICENSING IN THE 1980S 1, 1-67 (Robert Goldscheider and Tom Arnold eds., 1989)).

74 *See* Richard Li-Dar Wang, *Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-Through Royalties*, 10 YALE J.L. & TECH. 251, 253 (2008) (explaining that "[t]he prospect of having to apply for patents is causing an increasing number of researchers to keep their excellent ideas secret at least until the patent application is filed.").

75 Mirowski, *supra* note 43, at 325 (Mirowski believes that these numbers "are almost certainly underestimates").

B. The Traditional MTA and the Efforts to Standardize

In the past 30 years there have been repeated calls for and attempts made to standardize MTAs. Among others, the NIH, AUTM, former Science Commons (currently a part of the Creative Commons), a non-profit plasmid bank at addgene.com, the Scripps Research Institution, and individual universities like Vanderbilt have answered calls for standardization with their respective MTAs or systems for streamlining the process.[76] Although there are standardized MTAs available for use, a 2011 AUTM MTA Report shows that the noncommercial entities that made the most vocal calls for a standardized option, that is, universities, teaching hospitals, and non-profit research laboratories, are nevertheless not routinely using the standardized options.[77]

Despite this nonuse, at least part of the academic institution intellectual property community would like to see another standardized option; in particular, one that is designed for industry-to-academic institution exchange. Yet efforts to draft a standardized industry-to-academic institution MTA continuously are "impeded by the varying positions among companies."[78] Perhaps an opportunity exists for a scholar, one not tied to a particular technology transfer office or to an industry partner, to draft an unbiased standardized agreement for use in the industry-to-academic institution transfers. But why would a standardized agreement work any better now than it has in the past, especially when the easier transfers from academic-to-academic institutions are not executed using the currently available standardized options?

Industry counsel and technology transfer counsel know the risks of transfers. They know how to draft MTAs. The lack of standardized options is not the problem. Instead, there is a disconnect regarding the mission of the MTA that is similar to the disconnect in the sometimes dueling missions of academia. This lack of synergy is causing much of the delay in executing MTAs.

Lawyers and licensing specialists are not starting with the same outcome in mind. Does the MTA need to simply serve as a record of the transfer of a material and outline of respective liabilities? Or is the MTA a stepping-stone towards a larger collaboration involving repeated interactions?

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76 *See infra* Part I.B and accompanying notes.

77 *See supra* note 45, at 11(finding that for academic-to-academic transfers, only a minority of institutions used standardized agreements made available by the National Institutes of Health"). *See also* Rai & Eisenberg, *supra* note 40, at 305-06 (explaining that the UBMTA has enjoyed "limited success" and that academic institutions "substitute . . . their own form agreement[s] for the UBMTA").

78 *See* Rai & Eisenberg, *supra* note 40, at 305-06 (discussing one industry-to-academic institution initiative that is "classified according to the degree of exclusivity needed by the provider company relevant to a particular material" and that "[l]ower-risk exchanges could then be standardized, and higher risk exchanges could occur according to agreed-upon general principles, with latitude to negotiate.").

MTAs vary widely between academic institutions and industry partners. Yet the basic term sheet is largely similar—identifying the parties subject to the agreement, the material, the length of time the material is needed, and the recipient's intended use of the material, etc. This front-page similarity leads to the failed identification of the two different functions and corresponding types of MTA: the traditional MTA and the modern MTA. The traditional MTA is currently in high use in technology transfer offices. After the Bayh-Dole Act was passed in 1980 and as biomedicine continued to thrive, scientists became increasingly vocal in the 1990s that the progress of their research was slowed down because of lengthy MTA negotiations.

An empirical study published in 2002 found that over 47% of academic geneticists who had asked "other faculty for additional information, data, or materials regarding *published* research reported that at least one of their requests had been denied in the preceding three years."[79] This is a significant increase from the previously reported number in the mid-1990s, which was just over 34%.[80] The authors of the study explain the cause may be that the "material transfer agreements have become so complex and so demanding that they inhibit sharing."[81] Other studies show the delays and forced abandonment of projects resulting from prolonged or failed MTA negotiations.

For example, in studying MTAs the Science Commons reported different numbers than the 2011 AUTM MTA Report. According to the Science Commons, in the academic-to-academic context, studies show estimated delays of transfer range over 1 month for 11% to 16% of MTA requests "to estimates that there are routine delays of over 6 months for 20% of requests and over 2 months for 42% of requests."[82] In industry-to-academic transfers, "most observers believe the situation is worse."[83] The Science Commons does not give time estimates for industry-to-academic transfers, but cites the lack of any standardized agreement as a reason why delays are worse. The Science Commons then gives estimates that in the industry-to-academic transfers the denial rates are almost twice that of the academic-to-academic requests (33% compared to 18%).[84]

The 2011 AUTM MTA Report finds that in the academic-to-academic MTAs, 92% are completed in 3 months or less, while in the industry-to-academic MTA requests, 79% are completed in 3 months or less.[85] In terms of failed negotiations,

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79 Eric G. Campbell et al., *Data Withholding in Academic Genetics: Data From a National Survey*, 287 JAMA 473, 473 (2002), *available at* http://www.ncbi.nlm.nih.gov/pubmed/11798369 (emphasis added).

80 *Id.* at 478.

81 *Id.* at 479.

82 *Empirical Data About Materials Transfer Problems*, SCIENCE COMMONS, sciencecommons.org/projects/licensing/empirical-data-about-materials-transfer (last visited Apr. 12, 2016).

83 *Id.*

84 *Id.*

85 *Supra* note 45, at 19.

transfer technology specialists from UC-Davis have estimated that in the year 2007, 10-25% of incoming materials from industry were never executed.[86] The UC-Davis team did not report how long the successfully negotiated transfers took to negotiate and execute.

Certainly while the numbers vary from study to study, it is nevertheless clear that the negotiation process of MTAs, especially when it is between industry and academic institutions, takes a period of time that may be detrimental to specific research projects due to grant timelines and the general racing pace of research and technology. Studies further show that outright denials of requests even for published research are increasing, as is the "abandonment of 'promising research projects' because materials are not received."[87]

Academic institutions argue that the MTAs causing these transfer delays or denials are agreements that call for a indemnification of laboratory accidents or patent infringement lawsuits resulting from use of the transferred material, cash payment, a reach-through royalty on the sales of any developed product, a reach-through equity share of any company developed from technology developed using the transfer materials, a grant-back provision allowing the transferor an option to license any technology arising through the use of the materials, a provision prohibiting the sharing of the materials with other universities or private firms, and even pre-publication editorial review of any research results.[88] These contested terms are discussed with suggested workaround solutions in Part III.

One of the reasons why these terms are frequently contested is that the traditional MTA does not contain many of these more controversial terms. So when they are in the modern MTA, which is seeking to build a relationship, these terms seem out of place and inappropriate. The reason why these terms are not in the traditional MTA is perhaps due most recently to the National Institutes of Health (NIH). As a response to the increasingly vocal complaints of the complexity and volume of MTAs, the NIH and universities collaborated in 1995 to develop a standard material transfer agreement for the transfer of biological materials (for example, plasmids, compounds, antibodies, and peptides). This standard agreement, the "Uniform Biological Material Transfer Agreement," or UBMTA, has over 500 universities and colleges that are signatories.[89]

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[86] *See* ALAN B. BENNETT ET AL., INTELL. PROP. MGMT. IN HEALTH AND AGRIC. INNOVATION: A HANDBOOK OF BEST PRACTICES 697 (A Krattiger et al. eds., 2007), *available at* www.ipHandbook.org.

[87] *Supra* note 82.

[88] Rai & Eisenberg, *supra* note 40, at 294-95. *See also supra* note 58 (explaining that MTAs have problematic terms that "restrict academic freedom," "assert excessive rights of ownership," and "ask for inappropriate indemnification by the university.").

[89] *Master UBMTA Agreements* Signatories, ASS'N OF UNIV. TECH. MANAGERS, http://www.autm.net/resources-surveys/material-transfer-agreements/uniform-biological-material-transfer-agreement/master-ubmta-agreement-signatories/ (last visited Apr. 4, 2016).

The UBMTA is the most widely recognized pre-negotiated, standardized MTA. However, as noted above, the UBMTA has failed to garner use by many academic institutions and non-profits. That said, it is representative of what I am calling here the "traditional MTA." The terms and conditions of the UBMTA are simple and short. Most notably, ownership of the material stays with the Provider.[90] If the Recipient of the material creates any substances or products that contain or incorporate the material that results in a modification of the material, the Recipient retains that ownership. The UBMTA directs the parties to clear ownership status of the material with these two clauses.

The "use" clause of the UMBTA states that the Recipient of the materials agrees to only use the transferred material "for teaching and academic research purposes" and only in the Recipient Scientist's lab.[91] The Recipient also may not transfer the material to anyone else without written permission, and if the Recipient wants to use the material in clinical trials or for other diagnostic purposes involving human subjects, the Recipient has to get prior written consent of the Provider.[92] Following the clauses regarding the ownership, use, and further transfer of the material, the UBMTA contains a standard warranty disclaimer. And finally, it contains a liability clause under which the Recipient assumes all liability for damages arising "from its use, storage or disposal of the Material" and requires the Recipient to acknowledge the transfer of the material in an attribution clause in all publications using the material.[93]

The UBMTA is completely pre-negotiated, with signatories only needing to execute the 2-page UBMTA implementing letter when they want to transfer materials. The UBMTA Implementing Letter serves to record materials or tools transferred between universities, and the only place where the terms might vary is if there is a "transmittal fee" for the materials.[94] This is not mandatory, but if the parties choose to include one then the Recipient can "reimburse the Provider for preparation and distribution costs."[95] The opening paragraph of the 2-page implementing letter states:

> The purpose of this letter is to provide a record of the biological material transfer, to memorialize the agreement between the PROVIDER SCIENTIST . . . and the RECIPIENT SCIENTIST . . . to abide by all terms and conditions of the Uniform Biological Material Transfer Agreement ("UBMTA") March 8, 1995, and to certify that the recipient . . . organization has accepted and signed an unmodified copy of the UBMTA. The recipient organization's Authorized Official also will sign this letter if the recipient scientist is not authorized to certify on behalf of the recipient organization. The recipient scientist (and the Authorized

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90 *Id.*
91 *Id.*
92 *Id.*
93 *Id.*
94 Uniform Biological Materials Transfer Agreement (UBMTA), ASS'N OF UNIV. TECH. MANAGERS, *http://www.autm.net/autm-info/about-tech-transfer/about-technology-transfer/technology-transfer-resources/ubmta/* (last visited Apr. 4, 2016) (click "Download UBMTA Implementing Letter").
95 *Id.*

> Official of Recipient, if necessary) should sign both copies of this letter and return one signed copy to the provider. The provider scientist will forward the material to the recipient scientist upon receipt of the signed copy from the recipient organization.[96]

This agreement contemplates that the parties are going to transfer the material, that the parties will conform to their promises, and that the parties will not use this agreement for any further interaction. There is no reach-through agreement, no licensing options, and no shared responsibilities for publication or patent applications. Also, if a modification of the material transferred does occur and needs a different ownership term, for example, the UBMTA simply instructs the two parties that they may negotiate for that outside of the UBMTA.[97] The only standard set by the UBMTA regarding future collaboration is that if the Recipient wants to use or license the material or modification for commercial purposes, the Recipient must "negotiate in good faith" with the Provider for this separate right.[98] This does not so much contemplate collaboration, but the expectation that the Recipient will ask permission from the Provider for commercial use rights.

There are many situations that might occur outside the proper scope of the UBMTA. For example, if the material transfer is requested for a research project that has any ties to a third party, and many do, the UBMTA is generally inappropriate because the UBMTA was pre-negotiated without the third party's involvement. The 2011 AUTM MTA Report found that out of 83 survey respondents reporting on academic-to-academic transfers (understood to be the least difficult kind of transfer), "only 31 percent reported frequently receiving the uniform biological material transfer agreement as the proposed agreement."[99] Conversely, 61% reported frequently using their own agreement.[100]

The NIH itself provides other standardized options for academic-to-academic transfers, as well as transfers involving industry partners. The NIH also published guidelines in 1999 to aid biomedical transfers between NIH-funded parties and others.[101] And although those that receive funding from the NIH are strongly encouraged to use the NIH forms, the MTA Report showed that only 15% of survey respondents frequently use the NIH Simple Letter Agreement.[102] The NIH describes its Simple Letter of Agreement (SLA) as one that may be "[u]sed to transfer vectors, plasmids, compounds, antibodies, peptides, etc."[103] This means that the SLA covers many of the same materials that the UBMTA does. As with the UBMTA, the

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96 *Id.*

97 *See id.*

98 *Id.*

99 *Supra* note 45, at 11.

100 *Id.* at 16.

101 *See Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Resources: Final Notice*, 64 Fed. Reg. 72090 (Dec. 23, 1999).

102 *Id.*

103 *Material Transfer Agreements*, TECH. TRANSFER CTR. OF THE NAT'L CANCER INST., https://ttc.nci.nih.gov/forms/mta.php (last visited Sept. 1, 2014).

SLA has specific representations that the Recipient makes when using this agreement, such as that the material transferred "will be used for teaching or not-for-profit research purposes only," that the material "will not be further distributed to others without the Provider's written consent," and that the Recipient "agrees to acknowledge the source of the material in any publications reporting use of it."[104]

The SLA also expressly disclaims on the Provider's behalf that any representations or warranties come with the Material, and states that the "Recipient assumes all liability for claims for damages against it by third parties which may arise from the use, storage or disposal of the material except that, to the extent permitted by law, the Provider shall be liable to the Recipient when the damage is caused by the gross negligence or willful misconduct of the Provider."[105] This is substantially similar to the clauses in the UBMTA. But the NIH also provides templates to use for the transfer of human materials, the Human Materials – Material Transfer Agreement (HM-MTA), and for transfers of organisms such as mice and flies, the Material Transfer Agreement for the Transfer of Organisms (MTA-TO).[106] Both the HM-MTA and the MTA-TO are used exclusively for the transfer of materials between academic institutions or non-profit organizations.

As stated above, despite the ready availability of standardized MTAs, academic institutions frequently use their own agreements. This is likely for several reasons, but mainly because the underlying grant that supported the creation of the material to be transferred has strings attached to future transfers. And certainly, if the grant is from an industry partner, there will be transfer restrictions regardless of its use, whether it is for upstream or downstream transfer. The academic institutions' standardized MTAs also do not support further downstream use or collaboration.

Consequently, the pre-negotiated, noncommercial-only and static nature of the standardized UBMTA, SLA, HM-MTA, and MTA-TO makes them unsuitable for many requests. That is not to say that these agreements do not have their use. When materials need to be exchanged quickly, like with the MERS example above, these standardized options set easy bright lines for parties to follow and are suitable for transfers between academic institutions.

Perhaps one of the best examples of a standard one-time interaction with a near automatic MTA is WiCell, "the global leader in the banking, cytogenetic testing and distribution of stem cell lines."[107] WiCell is a subsidiary of WARF, the Wisconsin

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[104] *See id.* (click "Simple Letter of Agreement (SLA)").

[105] *Id.*

[106] *See id.* (click "Human Materials - Material Transfer Agreement (HM-MTA)" or "Material Transfer Agreement for the Transfer of Organisms (MTA-TO)").

[107] WICELL, http://www.wicell.org (last visited Jan. 24, 2015) .

Alumni Research Foundation, and was selected by the NIH to host the National Stem Cell Bank.[108]

If a researcher wants a particular type of stem cell line, she merely has to point and click on a website to put the stem cell line into her online shopping basket. The researcher then goes through checkout, which requires registration and an accompanying MTA depending on the line selected. If one is from the Wisconsin International Stem Cell Bank, which is operated by WiCell, a simple MTA is required upfront.[109] The MTA used is the SLA, and represents the traditional MTA at its best. Researchers are not going to collaborate with WiCell. Researchers just want access to the stem cell lines housed with WiCell. The only catch is that it is only a near-automatic system if the request from WiCell is for noncommercial purposes. If there is any potential for downstream use, this takes the request out of the standardized form and opens up more tailored negotiations.

As for academic institutions specifically, while university technology office staff understands that "academic investigators often find MTAs burdensome," they are steadfast in asserting that MTAs must be used to help protect their institution's interests.[110] Technology transfer specialists opine that "[t]his protection is important to the university, investigators and laboratory personnel, and seeking this protection is driving the increased number of MTAs."[111] Research also shows that it is academic institutions that are driving the increased numbers of MTA requests.[112]

C. Mechanics of the Traditional MTA

The following discussion will highlight specific MTA practices at academic institutions across the nation. These practices will be compared to the UBMTA to fully understand what academic institutions often include that the UBMTA does not. As stated above, even though an overwhelming number of academic institutions are signatories of the UBMTA, they more often use their own version of the traditional MTA. Take for example, the Technology Transfer System of the University of California ("UC"), which has existed in some capacity for over 40 years and is quite expansive. The UC Technology Transfer System is made up of, and responsibility is shared, by the UC's Office of the President, 10 UC campus technology offices, and the Lawrence Berkeley National Laboratory.[113] Like the missions of universities

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[108] *See id.*

[109] *Request for iPS Wisconsin Materials,* WICELL, (2006), http://www.wicell.org/media/WiCellAgreements/WiCell-iPS-MTA.pdf.

[110] James Henderson, *Commentary: Counterpoint: MTAs as a Practical Necessity*, 22 NATURE BIOTECHNOLOGY 722, 722 (2007), *available at* www.nature.com/nbt/journal/v25/n7/full/nbt0707-722.html.

[111] *Id.*

[112] Mirowski, *supra* note 43, at 325-26 ("It is one thing to blame the rise in MTAs upon rapacious corporations and their crafty legal departments, but it is quite another to acknowledge that the university sector has been doing more and more of this to itself.").

[113] *Ideas, Inventions, Impact, Technology Commercialization Report*, U. OF CA. (2013), *available at*

back in the 1930s and 1940s, the UC focuses on the public's access to any resulting innovation, stating that "[o]ne significant aspect of the University of California's public service mission is to ensure that the results of its research are made available for public use and benefit."[114]

Unlike many other academic institutions, the UC Technology Transfer Program publishes annual Technology Commercialization Reports, with the 2013 Report detailing the number of inventor disclosures (1,727), new license agreements executed (427), and new companies launched (71).[115] The 2013 Report also shows that in 2013, the UC filed 1,832 patent applications, was issued 395 U.S. patents, and had 2,328 active licenses.[116] And, finally, the 2013 Report shows that its royalty and fee income was $106 million.[117]

The UC Technology Transfer Program has many personnel that are focused on MTAs. In the UC-Davis Office alone, for example, there are two staff members who are "Senior MTA Analyst[s]," two more that are "MTA Analyst[s]" and an "MTA and Intellectual Property Analyst."[118] There is one more spot listed on the website for a MTA Analyst that is "In Recruitment."[119] This is in addition to each science-heavy college, such as the College of Biological Sciences and College of Engineering, having its own designated Intellectual Property Officer.[120]

The practice of the UC system is that before "proprietary or valuable material changes hands," a MTA should be executed between the sponsor and receiving party.[121] Each technology transfer office is tasked to help its respective faculty members and researchers negotiate and execute these agreements.[122] There is a standard procedure in place at each individual UC technology transfer office. This procedure is not consistent as to the precise intake forms from campus to campus, although generally it is consistent in that the faculty member, depending on whether it is an outgoing material transfer or an incoming material transfer, fills out a transfer form and submits it to the office for its review.

In the first part of the UC MTA information gathering forms, the UC campus-specific forms look very similar to the UBMTA. The main purpose of these intake

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http://www.ucop.edu/innovation-alliances-services/_files/ott/genresources/documents/IASRptFY13.pdf.

114 *Supra* note 58.

115 *Supra* note 113, at 3.

116 *Id.* at 19-22.

117 *Id.*

118 *Innovation Access,* UC-DAVIS, OFFICE OF RESEARCH, http://research.ucdavis.edu/contact-us/innovationaccess/ (last visited Sept. 1, 2014) (directory showing MTA Specialist positions).

119 *Id.*

120 *Id.*

121 *See, e.g., Research Materials,* UC-IRVINE, OFFICE OF TECH. ALLIANCES, ota.uci.edu/industry-resources/research-materials.html (last visited Apr. 3, 2016).

122 *Id.*

forms is to gather the proper recordation information. These forms also ask whether derivatives or modifications of the material will be made and inquire about the extent of possible third party interaction with the material.[123] This includes whether third party material will be added to the incoming material, whether there is third party funding for this material, and what interest there is by the principal investigator at this outside organization, if any. Unlike the previously discussed standardized options, these forms allow for upfront understanding of potential third-party ties to the particular material.

From these intake forms, the respective UC technology transfer office has the basic information and likely just needs to add a few provisions. In the UC-Irvine MTA Agreement covering outgoing biological materials, presumably used when the receiving institution is not an implementing member of the UBMTA or when there is a third party interest at stake and so the UBMTA form is not an option, the UC-Irvine Agreement states that the following conditions must be agreed to prior to the transfer of the materials:

> [T]he Biological Materials will be used only in scientific research;
>
> [T]he Biological Materials will be used with caution and prudence in any experimental work and that the Biological Materials will not be used on any human subjects;
>
> Recipient Institution will bear all risk to Recipient Investigator and to others resulting from use of the Biological Materials;
>
> Recipient Institution will defend, indemnify and hold harmless The Regents for all claims, losses and expenses resulting from your use of the Biological Materials;
>
> Recipient Investigator and Institution will not allow the Biological Materials to be transferred to any other party or use them for commercial purposes without the express written consent of The Regents;
>
> Recipient Investigator and Institution will not allow the Biological Materials to be transferred to any other party or use them for commercial purposes without the express written consent of The Regents;
>
> The University of California will be acknowledged in any publications resulting from your work with the Biological Materials and the UCI Investigator will be given credit in such publications, as scientifically appropriate; and
>
> Recipient Investigator will inform the UCI Investigator of experimental results obtained from using the Biological Materials.[124]

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[123] UC-Irvine specifically asks "Do you plan to use third party materials that were brought into UCI in your research with the Material(s)?" and "Do you have a financial interest in the outside institution (income, consulting, gift, stock ownership or management position)?" *Id.*

[124] *Outgoing Material Transfer*, UC-IRVINE OFFICE OF TECH. ALLIANCES, http://ota.uci.edu/industry-resources/outgoing-material-transfer.html (last visited Apr. 4, 2016).

Like the UBMTA and NIH forms, the UC-Irvine standardized MTA adds in the typical disclaimer of express and implied warranties, and, further, a sentence adding that "The Regents makes no representation and provides no warranty that the use of the material will not infringe any patent or other proprietary right."[125] The remainder of the UC-Irvine standardized MTA agreement is a clause stating that there is no license is granted or implied in the MTA.[126]

Overall, the UC system wants more protection than the UBMTA and NIH forms give it in regards to indemnification and rights to the results of research conducted using the transferred material. This UC-Irvine MTA wants the Recipient to not only take responsibility for its own use of the material, but also to completely "defend, indemnify and hold harmless" the UC.[127] It is noteworthy that although academic institutions complain that industry partners want too much in terms of indemnification, as will be discussed in the next section, the UC system makes this same request of others.

The UC-Irvine MTA also goes beyond the UBMTA and the NIH forms when it states that the Recipient "will inform" the UC scientist of its research results using the material. The Recipient's research must be academic in nature, but there is no reciprocal clause stating that the UC-Irvine must use the Recipient's research results for noncommercial purposes. So instead of the right to potentially have access to or use of any research or resulting substance or product that is made using the material through a reach-through royalty or option right, the UC system wants to obtain the research results and use them how it seems fit.

The UC-Irvine MTA may be interpreted as sending mixed signals and exemplary of the dueling missions within academia. The UC system focuses on making its research available for the public use and benefit, yet it also it puts restrictions on others using its materials. As the UC system's annual technology commercialization reports demonstrate, the UC system does want to make use of the patent system, bring products to the market, and create new companies that will then subsequently compete with the UC on the market.

A significantly smaller public institution than that of the UC, but one that nevertheless has a very active technology transfer practice is Georgia Technology Institute ("Georgia Tech"). At Georgia Tech, the Georgia Tech Research Corporation (GTRC), set up as a state-chartered 501(c)(3) not-for-profit corporation, serves as the governing body that protects and manages all intellectual property created at Georgia Tech.[128] The GTRC is just one of approximately 100 separate entities connected to state institutions that either completely own or perhaps just license intel-

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[125] *Id.*
[126] *Id.*
[127] *Id.*
[128] *About GTRC*, GA. TECH RESEARCH CORP., www.gtrc.gatech.edu/about-us/ (last visited Apr. 3, 2016).

lectual property of those respective state institutions.[129] The GTRC does a variety of business and contracting activities for Georgia Tech, but it is the Office of Industry Engagement within the GTRC that "is responsible for the protection, licensing, and management of Georgia Tech's intellectual property portfolio."[130]

In 2012, the Office of Industry Engagement reported that it spent $730 million on research expenditures, had 407 invention disclosures filed, received 79 new U.S. patents, executed 89 new licenses and/or license options (bringing the total active licenses to 620), and facilitated the formation of 12 new startups.[131] Despite its different organizational structure from the UC system, Georgia Tech employs a similar process to be followed by faculty or researchers who want to send or receive materials to support research. There is an Outgoing Material Transfer initiation form and an Incoming Material Transfer initiation form.[132]

The questions on the Incoming Initiation Form focus on third-party involvement, asking "[w]ill the Material be used with any materials you have received or will receive from any other institution, corporation, or business entity" and "[w]ill the Material be used in collaboration with any non-GIT parties?"[133] The Georgia Tech Incoming form does get a bit more detailed, however, specifically wanting to know if the Material being received by the Georgia Tech researcher is human embryonic stem cells or recombinant DNA, both biological materials that are infamously covered by university patents.[134] It also asks whether the Provider requires a MTA, and, if not, the Principal Investigator is able to skip a number of questions and ultimately provide very little detail to the Georgia Tech Office of Industry Engagement.[135]

The Outgoing Initiation Form asks whether the Material being sent from Georgia Tech is "associated with an invention already disclosed to the Office of Innovation and Translational Research."[136] The Outgoing Form also asks the third party

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[129] *Id.* Georgia Tech further explains that "[t]hese foundations are organized primarily to permit their host universities to operate research programs by minimizing the impact of restrictive state contracting and financial procedures." *Id.*

[130] *Related Offices*, GA. TECH RESEARCH CORP., www.gtrc.gatech.edu/related-offices (last visited June 28, 2015).

[131] *Economic Impact Data*, GA. TECH RESEARCH CORP., industry.gatech.edu/about/impact/ (last visited June 28, 2015).

[132] *Id.*

[133] Incoming Material Transfer Initiation Form, GA. TECH RESEARCH CORP., http://industry.gatech.edu/researchers/forms/ (last visited Apr. 4, 2016) (click "Incoming Material Transfer initiation form).

[134] *Id.*

[135] *Id.*

[136] Outgoing Material Transfer Initiation Form, GA. TECH RESEARCH CORP., http://industry.gatech.edu/researchers/forms/ (last visited Apr. 4, 2016) (click "Outgoing Material Transfer initiation form").

question, adding, "Are there other reasons why you believe an MTA is necessary?"[137]

Georgia Tech puts in writing that MTAs are only legally enforceable at Georgia Tech if particular people execute the MTA.[138] This is likely in response to a practice early on where MTAs were "more often than not . . . summarily signed by the researcher in question, without any oversight concerning their provisions."[139] Unlike the UC system, at least UC-Irvine, Georgia Tech does not make its template MTA publicly available.

Private institutions also manage and execute hundreds of MTAs per year. Most private institutions, such as Emory[140] and Columbia,[141] handle them similarly to the UC system and perhaps like Georgia Tech, at least as much as the intake and outtake forms show. Dartmouth is slightly different in that it publicly posts its standardized agreements prior to the transfer, not just its intake or outtake forms.[142]

Dartmouth has three separate Outgoing MTAs: MTA to Nonprofit Institutions, to Industry, and to Industry with a Fee. The MTA with Nonprofit Institutions looks similar to the UBMTA and covers biological materials. Ownership stays with Dartmouth, Dartmouth gives no warranties, and the Recipient must hold Dartmouth "harmless from any loss, claim, damage or liability, which may arise from Recipient's use, storage and disposal."[143] This is similar to the UC-Irvine MTA, but it is narrower. The scope of the UC-Irvine MTA indemnification clause is "for all claims, losses and expenses resulting from [the] use of the Biological Materials," whereas the Dartmouth MTA with Nonprofit Institutions is limited to the Recipient's use, storage, and disposal of the transferred material. Note that this still goes beyond the UBMTA that just requires the Recipient to assume all liability for damages arising from "use, storage or disposal of the Material."[144]

The Outgoing MTA to Industry and to Industry with Fee also covers "Biological Material" and both have the same warranty disclaimer.[145] The other provisions are much more carefully, and perhaps warily, drafted. The MTAs state that the Bio-

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[137] *Id.*

[138] *Material Transfer Agreements*, GA. TECH. SCH. OF LIT., MEDIA, AND COMM., http://lmc.gatech.edu/~hpritchard/3404/MTA2.swf (last visited Apr. 4, 2016).

[139] Mirowski, *supra* note 43, at 321.

[140] *See Office of Technology Transfer, Research Administration, MTAs,* EMORY UNIV., http://ott.emory.edu/about/statistics/mta.html (last visited Apr. 4, 2016).

[141] *See Technology Ventures, Forms + Agreements*, COLUM. UNIV., techventures.columbia.edu/inventors/forms-agreements (last visited June 28, 2015) (using the common Incoming and Outgoing forms to help expedite the information sharing process and get the MTA drafted and executed quickly).

[142] *See Technology Transfer Office, Material Transfer Agreements*, DARTMOUTH COLL., www.dartmouth.edu/~tto/mtas.html (last visited Apr. 4, 2016).

[143] *Id.*

[144] *See supra* note 94.

[145] *See supra* note 142.

logical Material is "not to be given or made available to any other person (other than those scientists working in collaboration with you), firm, or corporation, but [is] to remain under your immediate and direct control."[146] The next paragraph explains that the Biological Material, or any part of it, is not to be used "in or for the production of products for sale, unless XYZ also agrees that prior to any commercialization of any products or processes derived from or with the use of the Biological Material, XYZ will provide appropriate compensation to Dartmouth in accordance with license or other agreement negotiated in good faith between Dartmouth and XYZ."[147]

The MTAs also make clear that Dartmouth is to retain and/or obtain specific rights, namely, that sharing the Biological Material with "XYZ" does not prohibit Dartmouth from sharing the Biological Material with any other commercial or non-commercial entities. Moreover, that XYZ agrees that if it publishes any results of its research that it must appropriately acknowledge Dartmouth's contribution, "as scientifically appropriate."[148] The MTA for Industry with Fee is substantially identical to a transfer without any fee, but has a one-time payment fee ("the Biological Material is provided to you for a one-time license free of $5000 for internal research and /or evaluation purposes only").[149]

Overall, the Dartmouth forms are not as far-reaching as the UC-Irvine MTA with its indemnification or requirement that it be informed of research results, although it contains more projections and restrictions than the UBMTA. These forms are also more detailed with respect to what Dartmouth can do with the material; namely, that it can continue to share it with others for commercial or academic research. But like the UBMTA, NIH forms, and UC-Irvine MTAs, these MTA forms set up the expectation that the material will be transferred and the parties will stick to the agreement and not interact again. There is no talk of future agreements or future expectations of potentially working together. This is the essence of the "traditional" MTA: a one-time transfer of materials with no ties going forward.

Lastly, another private university is emerging as a particular leader in the MTA field. Vanderbilt recently launched "MTAShare," an automated and scale-able system that both processes and manages Vanderbilt-specific MTAs.[150] MTAShare uses the standardized UBMTA and the NIH Implementing Letter, and also has a recordation system to help Vanderbilt track its many outgoing and incoming MTAs.

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146 *Id.*
147 *Id.*
148 *Id.*
149 *Id.*
150 *See Benefits of MTAShare*, VAND. UNIV., CTR. FOR TECH. TRANSFER & COMMERCIALIZATION, http://cttc.co/cttc/content/inventors/mtashare/benefits-mtashare (last visited Apr. 3, 2016).

With MTAShare, Vanderbilt believes that the MTA transaction time will be reduced, resulting in saved money and less researcher frustration.[151]

This particular system may help in tracking and managing MTA requests, but it is limited in its adaptability and widespread use. The largest impediment is that the UBMTA, the NIH standardized forms, and the similar MTAs of individual academic institutions all assume that the point of the MTA is simply to record a transfer and outline which party has responsibility if something goes wrong with the transfer. These largely standardized MTAs are static contract mechanisms that assume the same underlying purpose.

As shown in the next section, however, there is another purpose of the MTA that underlies many industry MTAs. The modern function of a MTA is more often tailored to support the beginning of a collaborative relationship. This does not mean that every MTA leads to a further collaboration, but there appears to be an expectation that the MTA is not just for recordation purposes, but rather to set the stage for shared innovative activity.

II. The Emergence of the "Modern" MTA

The above section explains that academic institutions experience longer delays and more failed negotiations when the other party is an industry party. In academia, the response to the increasing MTA requests and delays in negotiating MTAs is to standardize. The thought is that standardization will decrease transaction costs, thereby increasing the flow of materials, tools, and data between scientists.

Industry is not taking this approach to increased MTA requests. Instead of standardization, many industry companies are creating more diverse MTAs. This is particularly true in the biotech and pharmaceutical industry. This industry appears to consistently tailor each MTA to the material and its unique potential for collaborative efforts. Accordingly, these MTAs do not look like the UBMTA or the university templates discussed above, although certainly some of the same clauses are contained within. What is in the modern MTA that is not in the traditional MTA are forward-looking terms that set up the parties for further interactions leading towards shared innovative activity.

When the MTA is between an industry party and a federal agency, the industry partner's aim is to move quickly from a MTA to a CRADA. A CRADA, a Cooperative Research and Development Agreement, allows federal agencies and nongovernment parties to conduct collaborative research together.[152] In a CRADA, each

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[151] *Id.*

[152] *How and When to Use a CRADA*, NAT'L INSTS. OF HEALTH, http://www.nimh.nih.gov/labs-at-nimh/collaborations-and-partnerships/cooperative-and-development-research-agreements/how-and-when-to-use-a-crada.shtml (last visited Apr. 3, 2016).

party must make an intellectual contribution.[153] Furthermore, a CRADA allows a federal agency to receive direct funding from private industry in exchange for the private industry being given access to the federal agency's "personnel, facilities, equipment, and expertise to perform the collaborative research."[154] While there are formal steps that a research-oriented federal agency and nongovernmental party must take when moving from the MTA to the CRADA letter of intent proposing a CRADA and finally to an actual CRADA, the CRADA itself has can vary significantly. Each agency tailors the CRADA to meet the parties desired scope and depth of research and collaboration.[155]

If a federal agency is not involved and instead it is just two or more industry parties coming together, there are not the formal steps as seen with the CRADA. The contractual agreements from the beginning of the companies' relationships look more like a licensing agreement that sets the boundaries of the working relationship allowing for joint exploration. Accordingly, a MTA may be contained within a collaboration agreement, or it may be the first official step that is then amended, expanded or simply terminated to make way for the next contractual agreement.

Overall, the MTA is no longer a simple recording device in industry like the traditional MTA is in academia. It is a stepping-stone. The next Part will explore why industry science is moving in this direction. Understanding the scope and objective of industry science, just like with academic science, will better inform relevant actors and commentators why industry partners are shaping the MTAs they way they are right now.

Accordingly, Part A will focus on the increased scope of private industry. Part B will discuss and analyze recent creative "MTA" contracts in industry science, which are not always called MTAs but do involve the transfer or sharing of materials, tools, or data. Once transfer specialists understand the difference between the traditional MTA and modern MTA, they will be better equipped to lead their companies and academic institutions into the future of science: shared innovative activity that succeeds because of interfirm research and collaboration.

A. Increased Scope of Industry Science

Scientists working in the "discovery" phase are not limited the way noncommercial scientists working in a non-profit laboratory are.[156] There are many for-profit companies, ranging from the small biotechnology firm to the publicly traded pharmaceutical giant that houses thousands of commercial scientists engaged in the

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[153] *Id.*

[154] LAMATTINA, *supra* note 31, at 45.

[155] *Id.*

[156] LAMATTINA, *supra* note 31, at 23 (describing the "discovery" phase as one that at pharmaceutical companies includes "early experimentation . . . focused on inventing a compound that has the credentials to justify its worthiness for clinical studies").

discovery phase of research. The amount of commercial scientists working on the upstream phase of research has, like with academic scientists working on the downstream phase of research and development, recently increased.[157]

One way to access this trend is to look at the increase in biotechnology and gene sequence patents. In 1990, fewer than 1,000 biotechnology patents issued. By 1998, the number of biotechnology patents had skyrocketed to 5,977 patents.[158] The number of biotechnology patents declined over the next few years, yet the PTO granted 4,324 in 2004.[159] This number continued to decline slightly, with just under 4,000 biotechnology patents granted by the PTO in 2009.[160]

The numbers worldwide similarly track this rapid increase in biotechnology patents. In 1977, measured by PCT applications, there were just 12 biotechnology patents filed globally.[161] By 2009, this number had increased by over 77,000%, reaching 9,339 patents filed globally in the field of biotechnology.[162] The number of biobioscience patents issued in the U.S. has continued to steadily increase every year since 2009.[163]

The trend of more upstream patents, especially in areas like bioscience, is not likely to change, although there is an ongoing debate about the impact that upstream patents might have on the rate of innovation in fields like biotechnology research.[164] The most notable projection of a decline in this area regards funds from the NIH and from risk capital investment.[165] These trends as to increased upstream patents and potentially less funding are indicators that we can expect more competition among scientists for grants and funding from the government and from within the market itself.

Increased competition due to limited resources and the high valuation of blockbuster patents likely means that we will continue to see a growth in the volume of MTAs. Moreover, as more upstream materials and tools are patented, there will be higher amounts of risk, liability, and perceived value when sharing these patented materials and tools. And with academic institutions competing for downstream

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157 *See* Wang, *supra* note 74, at 253 (explaining that "breakthroughs in biotechnology and prosperous development in the biotechnology industry" have led to "a large increase in the number of patents granted.").

158 *Id.* at 255 (citing David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 TEX. L. REV. 1677, 1687–1731 (2007)).

159 *Id.*

160 Pugatch et al., *supra* note 19.

161 *Id.* at 29.

162 *Id.*

163 George Goodno, *National Bioscience Report Shows Industry Robust with Strong Prospects for Growth*, BIOTECHNOLOGY INNOVATION ORG. (June 24, 2014), https://www.bio.org/media/press-release/national-bioscience-report-shows-industry-robust-strong-prospects-growth.

164 *See id.*

165 *Id.*

products and processes, industry partners will similarly be even more cautions when sharing materials because those materials might find their way into back into direct competition with the sharing industry company. This may be in the form of the receiver of a material licensing a product containing the material to a competitor, or the receiver herself may use the material as a foundation to compete in the market.

There is another reason why we will continue to see an increase in MTAs. It is commonly understood that interfirm collaboration is how companies are able to stay abreast of rapid, technology change. Sharing or transferring of materials figures into this interfirm collaboration picture in an important way, since companies do not want to merely borrow or lend materials to other experts in a related or directly analogous field. Companies want to form relationships and ultimately have those experts help them move their particular technology and science forward. In many instances, industry partners are using MTAs as an opportunity to identify and establish working relationships that can lead to further downstream shared innovative activity.

I argue the convergence of academic science, government science, and industry science, along with the more sophisticated fields requiring interfirm collaboration to move forward, are why we are already starting to see a new responsive trend in industry MTAs. As the next Part will illustrate, the direction of MTAs in industry practice is not so much toward new terms, but how lawyers use the MTA. It is not used to set expectations for a one-time interaction like the traditional MTA, but, rather to set up and control repeated interactions like we expect to see in CRADAs or licensing agreements. Accordingly, the function, although not necessarily the form, of many industry MTAs is significantly different than the traditional MTA used in many non-profits and in the majority of academic institutions.

B. A Modern MTA

Industry MTA specialists are taking into account more factors than ever before when setting the parameters of allowed behavior for a recipient of transferred material. These factors are causing tension, however, when industry negotiates with academia. As one industry MTA specialist remarked to me, academics "just don't get" the factors that go into negotiating and ultimately drafting a MTA. This lack of synergy is even apparent in the literature on how industry scientists describe the value and use of MTAs compared to academic scientists. MTAs are used for more than the physical transfer materials, tools, or data to another party, but also to allow controlled access to materials, tools, or data to help scientists gather information on whether or not they want to work together.

Take, for example, John LaMattina, a 30-year chemist at Pfizer and current director of Zafgen Inc. and Ligand Pharmaceuticals, Inc. When describing a particular project at Pfizer, LaMattina explains that MTAs must "be in place before collabora-

tions occur in order to protect the rights of all involved."[166] He makes this statement when detailing a project that started with a conversation at a conference between a scientist in Pfizer's immune suppression group and a researcher at the NIH.

After this initial conversation, LaMattina states that "the first thing" Pfizer needed was "access" to the particular enzyme that the researcher at the NIH was studying in his lab.[167] Pfizer needed access to evaluate the potential synergy between the researcher at NIH and at Pfizer. This is why the parties quickly drafted and executed a MTA. The MTA carved the pathway to shared innovative activity. Shortly after Pfizer received access to biological materials necessary to further their understanding of the NIH enzyme, the parties confirmed they wanted not just to share materials but also knowledge and personnel.

Because the NIH is a federal agency, the next step in this collaboration was a CRADA. As explained above, the CRADA is a detailed, collaborative agreement between a federal agency and another nongovernmental party(s) under which each makes an intellectual contribution to a joint project. In any given CRADA, there are several layers of contracting, often quite creative and innovative with some enforceable terms and unenforceable terms, to set the expectations and endgame if something goes wrong with the research or the parties during the collaboration.

Examples of enforceable terms are clauses containing third-party infringement warranties and indemnification in the case of a third-party infringement lawsuit. Examples of legally unenforceable terms are those allowing but not requiring the other party to purchase a product (there is no promise made obliging oneself) or those that suggest the parties will use best efforts to produce "something" but how and what they produce is left open for future planning (there is not yet anything to buy or sell).[168] Although those particular terms in modern MTAs are unenforceable in a court of law, they explain and memorialize to the respective parties that there is a shared goal for more interaction. In other words, the modern MTA sets the expectation that these parties are sharing materials in the hopes that it will prove advantageous given each respective party's expertise and know-how to work together.[169]

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[166] LAMATTINA, *supra* note 31, at 44.

[167] *Id.*

[168] *See* Ronald J. Gilson et al, *Contracting for Innovation: Vertical Disintegration and Interfirm Collaboration*, 109 COLUM. L. REV. 431, 460, 465 (2009) (explaining similar unenforceable terms in John Deere supply and collaboration agreements and an Apple-SCI supply and collaboration agreement) (hereinafter *Contracting for Innovation*).

[169] The modern MTA then contains both enforceable and unenforceable terms, creating a "braided" contract. *See* Ronald J. Gilson et al, *Braiding: The Interaction of Formal and Informal Contracting in Theory, Practice, and Doctrine*, 110 COLUM. L. REV. 1377 (2010) (hereinafter *Braiding*). This "contracting for innovation" will be discussed in the next section. *See Contracting for Innovation*, *supra* note 168 at 431, 432 (term used by Gilson, Sabel, and Scott to describe unique contracting practices used by parties to help develop relationships and trust in field of science and technology).

The MTA between Pfizer and NIH opened the door to the CRADA. A researcher and scientist conversed about their respective projects, realized there was a potential link, and signed an agreement giving access to proprietary (and in some cases patented) materials with the expectation of learning more about each other. The MTA between Pfizer and the NIH facilitated shared innovative activity in this interaction.

A similar interaction involving industry and a federal agency is demonstrated in a 2012 CRADA between Newlink Genetics Corporation and the National Cancer Institute ("NCI") (an Institute of the NIH).[170] The CRADA between these two parties covers the clinical development program of 1-methyl-D-tryptophan ("1MT") to see its effect on various cancerous tumors. But like with Pfizer and the NIH, the CRADA was not the starting point of this collaboration.

In 2007, NewLink and NCI executed a CRADA Letter of Intent to permit preclinical and clinical development of 1MT. In this Letter of Intent, the parties outlined their potential project and its scope. But before the Letter of Intent could be put together, the parties had to learn enough information from one another to evaluate the potential of this project. This initial learning and sharing process that sets the stage is accomplished by a MTA. MTAs also continue to provide access to "Investigational Agent[s]" from NCI to NCI Extramural Investigators" to support the CRADA.[171]

NewLink disclosed a "typical" MTA in its 10-Q disclosure in Appendix C of its NCI-NewLink agreements. So although NewLink did not disclose the particular MTA in this situation, we can still see how NewLink's MTAs differ from the traditional MTA. The NewLink MTA has two clauses that help place the "Research Material" within the bigger "Research Project."[172] This allows NewLink to very clearly define and consequently limit the use of the Research Material. But NewLink also recognizes that there are aspects of the Research Project that are not yet defined, which means that the use of Research Material within that bigger whole might still provide NewLink and the receiver of the Research Material with something unexpected.

In the case where the Research Material leads to something bigger, perhaps a patent disclosure that "claim[s] the use and/or the composition" of the Research Material, NewLink uses normative terms to set the parties' expectations. For example, the parties will enter into a licensing agreement "on terms to be negotiated in good faith by the Collaborator[s] and Institution," the "Institution agrees not to offer

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[170] On file with author.

[171] *Cooperative Research and Development Agreement for Extramural-PHS Clinical Research*, SEC. AND EXCH. COMM'N, http://www.sec.gov/Archives/edgar/data/1126234/000112623412000024/nlnk-20120331xex106.htm (last visited Jan. 27, 2015).

[172] *Id.* at 97.

to license [the Invention] on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator," and "Institution agrees to file and prosecute patent application(s) diligently and in a timely manner." All of this is premised on an action that the parties do not have to take if they do not want to; and, hence we see an unenforceable clause within a broader (and enforceable) contractual agreement.

When both parties are from industry, there is more fluidity in the agreements and stages of shared innovative activity. In the Sangamo Biosciences, Inc. ("Sangamo") and Sigma-Aldrich Co. LLC ("Sigma") License Agreement, as of September 2, 2014, there are six amendments to the original agreement dating back to July 10, 2007.[173] In 2007, Sigma gained access, or as the parties stated, "a certain license to use Sangamo's proprietary zinc finger protein [ZFP] technology." The sixth amendment is meant to "provide Sigma with greater flexibility."[174] Like with several of the terms above, it is not clear how to measure or enforce this particular term.

Nevertheless, it memorializes the flexibility and fluidity of the licensing agreement based on Sigma's access to Sangamo's ZFP technology. It also demonstrates that the parties have mutually agreed to amend the legally governing contracts when needed instead of attempting to figure everything out in one contract upfront—and before the parties have any real idea of the scope of likely success of the collaboration. With the first agreement, providing mutual access to one another's materials, research tools, and/or data, a relationship is formed. Down the line, and with forward-looking and normative terms, this relationship has evolved into sharing know-how, decision-making, and profits.

Another Sangamo license agreement, this time with an international industry partner, Shire AG, again models the modern MTA. This particular agreement is termed a "collaboration and license agreement" and provides Shire AG access to Sangamo's ZFP technology similar to the access it gave to Sigma back in 2007, but it is more than a transfer or access to materials and data related to Sangamo's ZFP technology.

In this particular agreement between Sangamo and the Swiss company, the parties are using the license agreement to set the broad expectations for future shared innovative activity. In the parties' words, their "desire [is] to engage in a collaborative research program to identify products and processes employing Sangamo's zinc finger DNA-binding technology for treating certain diseases caused by particular monogenic defects, which can be advanced into human clinical trials and following

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[173] *See* License Agreement between Sangamo Biosciences, Inc. and Sigma-Aldrich Co. (on file with author).

[174] Attached to this agreement is another amended license agreement between Sigma and a buyer that is simply correcting one definitional term in an earlier agreement whereby Sigma sold cell lines that it created under the original license agreement with Sangamo.

regulatory approval, commercialized."[175] Shire is given complete discretion to commercialize any Shire ZF Product it develops in this agreement, and it will do so using "Commercially Reasonable Efforts."[176]

Just like with a traditional MTA, there are the commonplace disclaimers of any warranties and with the ownership of the original technology staying with the supplier (in this case Sangamo), but there is also use of language like "reasonably," "good faith," and "diligent."[177] There is the floor of the agreement—Sangamo owns everything and claims no knowledge of infringement and no acceptance of any responsibility of what Shire does—and there is the ceiling of the agreement—where Shire is allowed to basically do anything it wants (within the law of course) with technology it develops in this collaborative relationship. There is also a licensing fee floor, in this case, $13 million, with a flexible ceiling based on percentages of products sold. In-between the floor and the ceiling the parties will work together guided by a joint steering committee ("JSC") that can solve problems as they arise.

One last example of a modern MTA is the "Co-Development and Collaborative Agreement" between two between Aveo Pharmaceuticals, Inc. ("Aveo") and Biodesix, Inc. ("Biodesix").[178] On August 17, 2009, the parties entered into a "Mutual Confidentiality Agreement," likely where the parties got together to discuss possible collaboration.[179] The next (at least publicly available) agreement is a MTA that was effective starting April 5, 2011, and that was amended three times after 2011 (April 1, 2013, May 21, 2013, and April 4, 2014).[180]

Aveo agreed to supply to Biodesik with Ficlatuzumab, a "potent hepatocyte growth factor (HGF) inhibitory antibody that binds to the HGF ligand with high affinity and specificity to inhibit HGF/c-Met biological activities."[181] In addition, Aveo agreed to supply to Biodesik clinical specimens (including "samples, tissues, fluid, and other biological and pharmaceutical materials generated or obtained in connection with this Agreement or the MTA") so that Biodesik could further develop and commercialize Ficlatuzumab.[182] Like with Sangamo and Sigma, Aveo and Biodesik continued to amend the MTA to reflect the growing and changing interfirm collaboration.

Overall, the modern MTA is not static. It is dynamic and opens the door for shared innovative activity. It does not matter whether it is the NIH or a subsidiary of

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[175] *Supra* note 173.
[176] *Id.*
[177] *See id.*
[178] *See* Co-Development and Collaboration Agreement between Aveo Pharmaceuticals, Inc. and Biodesix, Inc. (on file with author).
[179] *Id.*
[180] *Id.*
[181] *Our Product Candidates, Ficlatuzumab*, AVEO ONCOLOGY, http://www.aveooncology.com/our-product-candidates/ficlatuzumab/ (last visited Jan. 27, 2015).
[182] *See supra* note 178.

it like the NIC, an international not-profit cooperation,[183] an American non-profit foundation,[184] or another industry partner,[185] and it does not matter what the parties call the particular agreement(s); tracing the steps leading to the in-depth research collaboration is substantially similar. And most importantly, here, the MTA or "License Agreement" that gives access to materials opens the door after an initial conversation in which scientists learn that they want to explore opportunities of shared innovative activity that can more efficiently move a field forward than working on their own. The drafter of MTAs must understand what kind of collaboration is desired: a one-time interaction between the parties where a quick transfer of material is to take place and nothing more, or a transfer where the aim is to gain access to a material or tool in order to evaluate whether more in-depth collaboration between the parties is desirable.

Given this information, it makes sense that industry partners are not taking time to respond to many requests for materials from academic institutions. It is billed as just that—a one-time, arm's-length interaction with little lead-in conversation. Industry partners would rather respond to a request where there is more interest and attention to getting to know one another.

Of course, not every interaction must or necessarily should be one that will result in repeated interactions. That said, I do assume here that society should want to encourage this type of interaction, as both noncommercial and commercial scientists at academic institutions, research laboratories, and companies realize that in order to stay competitive and to make a difference in a highly sophisticated and fast-moving technological world, collaboration among specialists is needed. The following section addresses how to bridge the gap between the traditional MTA used heavily by academic institutions and the modern MTA used heavily by pharmaceutical and biotech companies. There is a time and place for both, but identification and communication of research goals must be communicated between scientists and then between lawyers in order to avoid long delays or simple failures to negotiate and execute a license.

III. Bridging the Gap and Moving Forward

The difference between the traditional and modern view of MTAs is perhaps most recognizable in how scientists based in industry, academia and even government frame their use of, and complaints about, the material transfer process. LaMattina remarks that the first formal step in possible collaboration between Pfizer

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[183] *See, e.g.*, Collaborative Research and Development Agreement between the Swiss not-for-profit and 4-Antibody AG, a private pharmaceutical company based in Europe that was recently acquired by Agenus Inc., a Lexington, Massachusetts-based biotechnology company (on file with author).

[184] *See, e.g.*, Research Agreement between Anacor Pharmaceuticals, a biopharmaceutical company based out of Palo Alto, California and the Bill and Melinda Gates Foundation, a Washington charitable trust and tax-exempt private foundation (on file with author).

[185] *See, e.g.*, *supra* note 178.

and HIH researchers was to get access to NIH's of-interest enzyme, and that a MTA gave this access while also protecting "the rights of all involved."[186] In reference to how industry and academia interact and negotiate MTAs, lawyers and MTA specialists at biotech firms seemed frustrated with their interactions with academic institutions. They voiced complaints that the academic institution did not understand the big picture.

Academics seem to share a similar sentiment about industry scientists and lawyers. When talking to and reading the work of academia transfer specialists, they have consistent complaints about academia-industry MTAs. The most voiced and documented complaint is the amount of time it takes to negotiate MTAs with industry partners, especially when compared to the time it takes to negotiate and execute MTAs with fellow academic institutions. Academic institutions want a quick interaction that allows them to continue working on their own with their specific research projects and grants.

But why in particular does it take more time to negotiate a MTA when the other party is an industry partner as opposed to another institution? This gets to the second consistent complaint of academic transfer specialists: industry asks for too much in MTAs. Industry wants to begin a collaborative relationship with a MTA, and largely, academic institutions do not.

This divergence is seen in a report prepared by the Office of Research and Development at the U.S. Environmental Protection Agency in response to President Obama's 2011 Memorandum on "Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Business ("EPA Report")." The EPA Report sheds light on how government agencies view "collaborative partnerships." Although in many ways government agencies are unique in their research and each agency works a bit differently, I found in my research that academic institutions are quite similar to government agencies such as the NIH in contracting practices and views of MTAs.

Remember that a CRADA "is the main vehicle" for partnerships with the government that aims at the creation of commercial activity and growth of the economy.[187] This is in contrast to a "Materials CRADA." The EPA Report states that a Materials CRADA "is used when there is a minimal amount of collaborative research and an exchange of research materials." And, lastly, "[w]hen an exchange of research materials is desired with no collaboration, [this] is when a Materials Transfer Agreement (MTA) is used."[188]

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[186] *See* LAMATTINA, *supra* note 31, at 44.

[187] Presidential Memorandum – Accelerating Technology Transfer and Commercialization of Federal Research in Support of High-Growth Business, U.S. ENV'T. PROT. AGENCY (Oct. 28, 2011), *available at* http://www.nist.gov/tpo/publications/upload/EPA-Tech-Transfer-Plan.pdf.

[188] *Id.*

This chestnut gets to the heart of the disconnect between the traditional MTA and the modern MTA: the function of the traditional MTA is to simply exchange materials with no collaboration while the function of the modern MTA is to open the door to future collaboration. Now that the different functions of the MTA are known, lawyers have an opportunity to bridge the gap for their respective clients and ensure that legal process is not holding up scientific innovation. Instead, legal process should actively help foster more opportunities for shared innovative activity.

Lawyers must quickly determine what type of MTA is most desirable. Furthermore, they must be able to get past particular problematic terms in industry-to-academic transfers. There are three such terms that academic institutions complain of most frequently when contracting with an industry partner. Each of these three terms will be discussed below with suggestions for how to overcome this current gap between the traditional MTA and modern MTA. This discussion offers simple but effective ways that the traditional MTA can be updated so that when a one-time interaction is desired by a requesting party, the party can clearly communicate this expectation while also giving the other party the protection and potential options it feels it needs in order to not only make it worth its time, but also advantageous to effectuate the transfer.

A. One-time Interactions: Contracting Around Contested Terms

The first term causing delays in transfers is indemnification, the second is ownership, and the third discussed here is publication. There are some transfer specialists that point to the simple, but important fact that academic institutions implicitly understand the constraints and goals of other academic institutions. This is why in part the academic-to-academic transfers appear to be easier than industry-to-academic transfers. There is a commonality of core missions. Many academic institutions and faculty members share the fundamental understanding that their research is first and foremost noncommercial in nature, as well as that there are limitations to what the administration at their respective institutions will and will not support.[189]

Yet there are concerns that as grants become more competitive among principal investigators, anti-collaborative behavior will be encouraged. Conversations with scientists and scholars indicate that this is a legitimate concern, and, further, that it may already be taking place. All the more reason that the MTA literature must continue to progress in academia so that there will be better lawyering that furthers the mission to foster shared innovative activity for the greater public good.

[189] *See* Bennett et al., *supra* note 86, at 703 (stating that the "[s]haring of materials between university scientists is generally less problematic than transfers between industry and academia, primarily because the cultures and motivations of each institution involved in the exchange are similar").

Focusing here on academic-to-industry transfers, there are several reasons that these transfers are "much more complex" and "much more prone to failure."[190] As detailed above, the core mission of academic institutions is generally to support the pursuit of knowledge and dissemination of such knowledge to the public. This may be contrasted with an industry partner's goal of maximizing its profit, which is achieved by quickly bringing a product or process to the market. The starting points are not the same, causing misunderstandings in upstream negotiations. Beyond the contrasting missions of academic and industry parties, another reason is because the industry partner often wants too much from an academic institution, or at least too much from an academic institution's perspective.[191]

This is particularly hard to understand for industry parties as some academic institutions are aggressively licensing their technology and in some cases acting like a so-called patent troll.[192] As a consequence of this recent shift in academic institutions towards protecting and enforcing intellectual property rights, industry partners may view academic institutions as competition. Instead of playing a supporting role as noncommercial scientists focused in basic science that generate developments that will in turn be passed to industry partners through publication, presentation, or explicit long-term partnerships, academic science has evolved such that academic institutions are a key player in markets. Faculty are encouraged to disclose their ideas and discoveries to their respective technology transfer office so that the technology transfer office can help protect and develop these ideas into a marketable downstream product or process. On one hand this evolution may help decease the gap in missions between academic institutions and industry players, creating more synergy between the two and making research and development agreements easier to come by, yet it is also confusing to industry parties. Overall, however, academic institutions remain largely different than their industry counterparts. This is because the core mission and structure of the university remains the same despite the interest in capturing the downstream market.

The first contested term discussed here—liability and/or indemnification—reflects this difference. Parties, and not just those involved in technology transfer

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[190] *See id.*

[191] *See Redeploying Bayh-Dole*, *infra* note 196, at 914 (explaining that "[o]verly aggressive industry demands regarding access to research results, failure to properly address conflicts of interest, and unnecessarily strict prohibitions on timeliness of publication or sharing of information can all interfere with proper academic priorities").

[192] *See* Lemley, *supra* note 29; *see also* Nick DeSantis, *Judge Adds $366-Million to Patent-Lawsuit Award for Mellon*, THE CHRONICLE OF HIGHER EDUC. (Apr. 1, 2014), *http://chronicle.com/blogs/ticker/jp/judge-adds-366-million-to-patent-lawsuit-award-for-carnegie-mellon-u* (discussing reward amount for Carnegie Mellon in a patent infringement suit where Carnegie Mellon did not make, nor use, the infringed technology). Recent university practices also show that "there is little indication that universities are particularly effective or enlightened stewards of technology." Lee, *supra* note 29, at 80 (further explaining that "in cases involving human embryonic stem cells, cotransformation, and genes related to breast cancer, universities have exhibited many of the same rent-seeking, self-interested tendencies as commercial entities.").

negotiations, do not like to accept liability for others' actions or the duty to indemnify another party. In academic science it is common for the recipient of the material, as evidenced by the UBMTA, to take responsibility for "its use, storage or disposal of the Material."[193]

Standardized university-specific forms also include an indemnification clause. For example, the UC-Irvine MTA states that the "Recipient Institution will defend, indemnify and hold harmless The Regents for all claims, losses and expenses resulting from your use of the Biological Materials."[194] From these traditional MTAs, one learns that transferors want the recipient of the material to take responsibility for their own actions and use of the transferred material, as well as to take on the risk that if anything goes wrong (for example, the use of the material infringes upon another's patent or a laboratory accident occurs), the recipient will defend and hold the transferor harmless. However these standardized intake MTA forms are misleading in some cases. Although it is common to include a liability clause, an indemnification is often a deal-breaker for academic institutions. This is so even though academic institutions include the clause in their own MTAs.[195]

The indemnification clause is problematic for academic institutions for two reasons. First, there are many states that prohibit their state institutions from indemnifying other parties. This includes states such as Alabama, Georgia, Kentucky, and New York.[196] Second, even when state law does not expressly prohibit taking on the risk to indemnify another party, the academic institutions' own internal policies prohibit the practice. Academic institutions are risk averse.[197] Academic institutions will not take on the risk of a patent infringement claim, and as we have seen repeatedly in the last decade, such claims can easily cost millions of dollars to defend.

However, technology transfer offices must understand a particular reason that industry partners fight so hard to shift risk to academic institutions when transferring materials, tools, or data. If the industry partner is working with a public institution, then that public institution, as an arm of the government, may claim the protection of sovereign immunity.[198] This means that if the public institution infringes

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193 *See* UBMTA, *supra* note 44.

194 Univ. Cal. Irvine, *supra* note 124.

195 The practice of universities demanding that others indemnify them sometimes goes even further. John Tyler of the Kaufmann Foundation explains that "[a]n extreme, but not unheard of . . . behavior is for a university to demand that its licensee indemnify the university if the research results it is licensing infringe or if the university actually lacks the right to license it." This type of aggressive licensing is overreaching behavior on the university's behalf that "inhibits commercialization and utilization and undermines the [Bayh-Dole] Act's purposes." John E. Tyler III, *Redeploying Bayh-Dole: Beyond Merely Doing Good to Optimize the Potential in Results of Taxpayer-Funded Research*, 38 J. TECHNOL. TRANSF. 911, 925 (2013) (hereinafter "*Redeploying Bayh-Dole*").

196 *See* Bennett et al., *supra* note 86, at 702.

197 *See id.* at 704 (explaining that universities are most concerned in transfer agreements with "the fundamental mission of the institution and their low tolerance for financial or legal risk").

198 *Redeploying Bayh-Dole*, *supra* note 196, at 926.

another's rights, and assuming the government or institution did not expressly accept risk in some way, sovereign immunity may mean that the aggrieved party must seek other avenues to recoup some of the lost value of its patented or otherwise protected technology.[199] In short, the aggrieved party will look to the licensors or contributors to the university's infringing technology, especially the university's industry partners that may have deep pockets.

When transferring technology and sharing materials, tools, and data, academic institutions have the opportunity to use innovative contracting to manage expectations and set up a mechanism to help maintain these expectations in the face of uncertainty and risk. If industry partners are demanding the academic institution to indemnify and defend it in the case of a third party suit, and the academic institution will not do so, the parties may achieve a compromise using warranty and representation clauses.

The academic institution can take on some risk by making reasonably informed decisions about how the material will be used and what type of due diligence has been performed about the research project that the material or tool will be used to support. By representing to the industry partner that the principal investigator has worked with the technology transfer office (and most likely a registered patent attorney), and that to the best of its knowledge the university's use of the transferred material will not infringe a third party's rights, an industry partner may be satisfied despite the lack of a traditional indemnity clause.

The university can also contractually warrant to keep the industry partner apprised of any potential third party violations, even if it appears, at least at first, to involve the entire project (as opposed to the use of the tool). This will help industry partners know that an academic institution understands the risk involved and that it will take measures to keep the industry party apprised of any potential problems with the shared material. This very simple yet potentially effective workaround to the traditional indemnification clause can refocus the conversation when academic institutions and industry parties stalemate during an indemnification negotiation, allowing them to move past the oft-contested term and spread the risk and uncertainty of infringement and lab accidents.

The second term that causes delays is the ownership of resulting innovations, and really the royalty possibilities, if the academic institution brings a product to market or sells the product to another. The rights to any intellectual property developed in part or whole from transferred material is arguably the hardest to negotiate. The reason is money, or at least the opportunity for money. And if money is not possible, a second best option is access to any developed know-how or technology

[199] *See id.* (explaining that a consequence of a university claiming the protections of sovereign immunity "could force a victim of university infringement to pursue the best available alternative—the party to whom the university licensed its innovation.").

created using the shared material. Both parties, whether industry or academic, understand the value of cash flow in research and development is often just as important as avoiding existing patents while conducting research and development. Money and access to technology can lead to better innovation, and, again, more opportunities for royalties from downstream research and development.

Wanting to make money after letting another scientist borrow something valuable is not a bad objective. After all, it likely cost the transferring party time and money to create the material that was transferred. That said, royalty and access clauses might quickly become non-collaborative terms of a MTA when the transferring party overreaches.

One often overlooked impact of fundamental differences in mission and structure of academic institutions compared to industry parties is that academic institutions may not be able to give ownership rights or access to fruits of research in a way that industry most desires and is accustomed to receiving when dealing with another industry party. This is not because of restrictions that the academic institution put on itself, but rather governmental restraints.

Most notably, academic institutions are often private and public non-profit universities that have obtained tax-exempt status under Internal Revenue Code ("IRC") section 501(c)(3).[200] In addition, some universities have received U.S. federal tax-free status on bonds issued to build or improve research facilities.[201] This tax-free status means that the vast majority of universities and teaching hospitals are subject to particular regulations of activities. The relevant IRC rules that attach to the tax-exempt status and legally restrain university activity deal with the licensing of inventions and the acceptance of money for sponsored research.[202] This does not mean that universities will lose their tax-exempt status if they license their inventions or receive money for sponsored research activities, assuming that they are indeed set up and in fact operating for "educational" purposes to "carr[y] on scientific research in the public interest."[203]

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200 *See Redeploying Bayh-Dole*, *supra* note 196, at 914 (explaining that "industry often fails to appreciate that U.S. universities must comply with a regimen of laws and regulations relating to their status as either governmental bodies or public charities under section 501(c)(3) of the Internal Revenue Code"). *See also supra* note 197, at 701-02; Sean O'Connor et al, *Legal Context of University Intellectual Property and Technology Transfer*, prepared for *The Committee on Management of University Intellectual Property: Lessons from a Generation of Experience, Research, and Dialogue*, National Research Council, The National Academies, September 20, 2010, at 74 (hereinafter *Legal Context of University IP and Tech Transfer*). Even though these academic institutions may not pay federal taxes, they may pay unrelated business income taxes (UBI). *Id.*

201 *See supra* note 197, at 701.

202 *Legal Context of University IP and Tech Transfer*, *supra* note 200, at 74. For a thorough treatment of tax-exempt universities, see Peter D. Blumberg, *From "Publish or Perish" to "Profit or Perish: Revenues from Technology Transfer and the 501(c)(3) Tax Exemption*, 145 U. PA. L. REV. 89, 115 (1996).

203 IRS Reg. 1.501(c)(3)-1(d)(5)(v) (2014), 26 C.F.R. 1.501(c)(3)-1(d)(5)(v)("The fact that any organ-

Academic institutions subject to these regulations bear the burden to prove that their primary purpose is "scientific research in the public interest," and although the regulations do not precisely define what is or is not "scientific" there is a helpful court construction of the term.[204] The Court of Claims, precursor to the Federal Circuit, defined "scientific" research quite broadly.[205] If the research meets one of the following criteria, then it is likely deemed "scientific" for purposes of the IRS regulations:

> (1) involved the use of observation or experimentation to formulate or verify facts or natural laws; (2) could only have been performed by an individual with advanced scientific or technical expertise; (3) added to knowledge within a particular scientific field; (4) involved the application of mathematical reasoning; or (5) was an attempt to systematize or classify a body of scientific knowledge by collecting information and presenting it in a useful form.[206]

Academic institutions then have a relatively easy time retaining their tax-exempt status when they conduct research. The research is carried out by faculty members and graduate students who have a high degree of scientific expertise, and the research is done to either aid students in learning, is ultimately published, and often is linked to the community with hopes to positively impact the economic climate or surrounding industry. This said, the IRS is aware of recent changes in academic science. In 2008, the IRS sent approximately 400 compliance questionnaires to colleges and universities that focused on, among other things, how academic institutions reported revenues and expenses from their activities that generated unrelated business income during the tax year ending in 2006.[207]

An academic institution may lose its tax-exempt status if it is not careful when managing its intellectual property portfolio. This impacts the way that academic institutions interact with industry partners, which industry partners often do not fully understand because they are not subject to these specific IRS Regulations. This is an area that good lawyering can help improve. A 501(c)(3) scientific organization will not keep its status "if an organization (1) retains (directly or indirectly) the ownership or control of more than an insubstantial portion of the patents, copyrights, pro-

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ization (including a college, university, or hospital) carries on research which is not in furtherance of an exempt purpose described in section 501(c)(3) will not preclude such organization from meeting the requirements of section 501(c)(3) so long as the organization meets the organizational test and is not operated for the primary purpose of carrying on such research.").

204 *Legal Context of University IP and Tech Transfer*, *supra* note 200, at 75-76.

205 IIT Research Inst. v. United States, 9 Cl. Ct. 13 (1985).

206 *Legal Context of University IP and Tech Transfer*, *supra* note 201, at 75-76. The Court of Claims' construction of what is scientific research for purposes of IRC rules is buttressed by the IRS regulations. These regulations provide a bit of guidance in regards to what does not constitute scientific research: for example, "the ordinary testing or inspection of materials or products or the designing or construction of equipment, buildings, etc." IRS Reg. 1.501(c)(3)-1(d)(5)(ii), 26 C.F.R. 1.501(c)(3)-1(d)(5)(ii).

207 *See Statement on the IRS Compliance Questionnaire for Colleges and Universities*, AGB/NACUBO (Dec. 17, 2009), *available at* http://www.nacubo.org/Documents/BusinessPolicyAreas/AGB_NACUBO_IRS_Compliance.pdf.

cesses, or formulae resulting from its research *and* (2) does not make such intellectual property available to the public."[208]

The IRS Regulations are clear that granting exclusive licenses is disfavored and such licenses are only to be given when an exclusive license is "the only practicable manner" that allows for the intellectual property or know-how to benefit the public.[209] Otherwise, the intellectual property or know-how should be made available to the public on a nondiscriminatory basis, presumably in the form of nonexclusive licenses or by placing it in the public domain. Accordingly, when industry partners and academic institutions are negotiating the transfer of materials, research tools, or data, academic institutions have restrictions on what they can and cannot offer to incentivize the industry partner to make the transfer. Exclusive licensing opportunities are rare for industry partners and they need to understand that a refusal by an academic institution to grant one is not based just on economical considerations but also on compliance with federal law. Demanding an exclusive license to use any resulting intellectual property from the use of the industry material, tool, or data is a deal breaker for academic institutions.

This is further buttressed by NIH Guidelines that counsel parties not to exclusively license research tools, reflecting a concern that access to tools is a key component to innovation. Only if an exclusive license cannot be avoided does NIH find that an exclusive license may be an acceptable if "the licensor retains rights to make the research tool widely available to researchers through unrestricted sale, or the licensor retains rights to make the research tool widely available." [210] Other options should be explored before walking away from the negotiation table but again, industry counsel must understand that academic institutions are not as free to easily consider some of the more common ownership licensing options. Most notably, three that are often in play during MTA negotiations are reach-through royalties, grant-backs or a first right of refusal option, and field-of-use restrictions. Each comes with its own set of complications.

Reach-through royalties are controversial at best, and at worse, run afoul of the patent misuse doctrine and antitrust laws. A reach-through royalty is when parties agree that one has the right to "reach through" the unknown nature of future technology and capture the right to royalties of a successful commercialization of the previously unknown technology.[211] Take a research tool, for example, that an industry partner shares with an academic institution. Suppose the industry partner completes the transfer with no transfer fee because it was too hard to determine the value of the research tool to the academic institution (or, also as likely, the academic institution does not have sufficient funding for acquiring the use of research tools).

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[208] 26 C.F.R. 1.501(c)(3)-1(d)(5)(iv).

[209] *See* IRS Reg. 1.501(c)(3)-1(d)(5)(iv)(b), 26 C.F.R. 1.501(c)(3)-1(d)(5)(iv)(b).

[210] *Supra* note 101, at 72095.

[211] *See* Alfred C. Server et al, *Reach-Through Rights and the Patentability, Enforcement, and Licensing of Patents on Drug Discovery Tools*, 1 HASTINGS SCI. & TECH. L.J. 21, 22 (2009).

Instead, the transferring industry partner obtains the right to capture some portion of any valuable intellectual property the academic institution creates with the use of the transferred research tool. This is a classic use of a reach-through clause in a MTA. It allows the transferring party to claim some of the profits of the later developed invention or new process.

For research tools in particular, commentators have voiced concerns that reach-through royalties stifle downstream innovation[212] and may contribute to a growing anticommons.[213] Moreover, some commentators have voiced concern that reach-through royalties are contributing to the decline in the sharing ethos.[214] Yet proponents of reach-through royalties argue that they allow for more creative ways to ensure that the right incentives are in place to encourage and facilitate research and development (most notably in expensive innovation industries such as pharmaceuticals).[215] They also point to small biotechnology companies that market their research tools which arguably helps others in their research and development.[216] For these small firms, the licensing of these research tools is their main source of income.[217]

Reach-through royalties were such a concern, especially with the transfer of research tools and the drama of the Harvard oncomouse, that the NIH specifically prohibited this licensing practice in its 1999 guidelines. The NIH Guidelines responded to a commentator that advocated for the use of reach-through rights for those recipients who cannot afford to buy or license tools to nevertheless still obtain access in return for giving up some percentage of profits from a possible later developed product or process.[218] The NIH responded that despite this seemingly persuasive reasoning, the NIH "finds that such practices contribute not only to specific restriction of access to subsequent tools arising out of the NIH-funded work, but also to the general proliferation of multiple ties and competing interests that is the source of the current access problems."[219] In even stronger language, the NIH stated that it "does not support the coupling of procurement with intellectual property

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[212] *See id.* at 23 (explaining that "tool users, among others, argue that the excessive protection of research methods and tools, particular reach-through protections, stifles downstream drug development efforts to the detriment to the public").

[213] *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 699 (1998).

[214] *See* Kimberlee A. Stafford, *Reach-Through Royalties in Biomedical Research Tool Patent Licensing: Implications of NIH Guidelines on Small Biotechnology Firms*, 9 LEWIS & CLARK L. REV. 699, 700 (2005). *See also* Strandburg, *supra* note 39, at 2259 (explaining that "[b]esides sometimes failing to receive materials requested from industry suppliers, academic scientists complained of requests for onerous terms of transfer, such as reach-through royalties").

[215] *See id.*

[216] *See id.*

[217] *See id.*

[218] *See supra* note 101, at 72091.

[219] *Id.*

rights and restrictions and expects Recipients to ensure that NIH-funded tools are not restricted as a result of such agreements."[220]

The NIH Guidelines are applicable to those that receive NIH funding, including non-profits, universities, and private companies.[221] One particular reason why reach-through royalties are still an issue more than ten years since the guidelines were published is because it is large companies that often have the research tools that academic institutions want to use. Those large companies are not often recipients of NIH funding, unlike several of their much smaller competitors. These companies have the money and tools and can name their terms. Technology transfer specialists have reported that in their experience, transfers from industry to academic institutions (even as large as the UC) are often low priority.[222]

So if industry is less likely than ever to share materials, tools, and data with academic institutions because they view academic institutions as competitors, albeit competitors who cannot afford to pay for the materials upfront, what can be done to help move the transfer process along? Academic institutions have to give industry partners a reason to let them use their materials or tools. Most academic institutions cannot pay for the use of these tools upfront, hence the need, at least in part, for reach-through royalties partners.

Although reach-through royalties do have a negative reputation and a lot of fear surrounds them because of downstream access to technology, innovative contracting offers the ability to creatively contract around the problematic aspect of reach-through royalties. Instead of completely banning reach-through royalties, like the NIH recommends, academic institutions should embrace the negotiation power the possibility of reach-through royalties gives them. Certainly academic institutions must do so with caution to ensure that a reach-through royalty clause does not restrict further research. If an industry partner demands not only future royalties of any resulting technology created with the transferred tool, but also some sort of power over how the tool or created technology is used, this can stifle downstream opportunities with third parties. This is when academic institutions and industry transfers will fail.[223]

One way for academic institutions to successfully use reach-through royalties as a bargaining tool, one that will not impact the way that academic institutions bring their products or processes to market, is to allow some form of reach-through on value but not use of the technology. In this manner, reach-through royalties should be limited to royalties on future technology. This should likely be a flat or tiered percentage of the sales with an aim towards capping the total royalties at an amount

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220 *Id.*

221 *Id.*

222 *See supra* note 14, at 2.

223 *See id* (citing "the need to avoid creating conflicting legal obligations with third parties" as a top concern of universities when negotiating technology transfer with industry partners).

the parties agree to upfront. This allows industry to regain the value of their shared material or tool that the academic institution could not or would not pay upfront, while allowing unfettered sharing and/or transferring of the altered material or tool.

Another way industry can partner with academia successfully when transferring materials, tools, or data is by acquiring a "grantback" right to use the invention that comes out of the academic institution using the transferred material. And if not a grantback, then perhaps an "option" to be the first party to negotiate for the right to license the technology would work effectively. It is in the industry party's best interest to ensure that it gets a grantback right to use any of the created technology, or at least the first option to negotiate a license to use the technology. This enables the industry party the chance to recoup any money it spent to create the materials or tool that was transferred, as well as bring the academic institution's new invention to the public. Technology transfer offices find this much less controversial than reach-through royalties, and "in many cases" they find themselves in a better position to make this sort of concession.[224]

One note of caution here is that a grantback or option to be the first negotiator is only an attractive substitute for reach-through royalties if the original grantback is not an exclusive right to use. In essence, the industry transferor is negotiating for the right to use the technology in its practices but not for the power to prevent others from also using the academic institution's technology, including the academic institution itself. If the academic institution is going to take on a responsibility for no upfront consideration, it needs to make sure it is not hamstringing itself down the road. The goal is to quickly and efficiently get the academic institution's faculty output disseminated to the public, and this is most often done by making the technology widely available to other noncommercial and commercial scientists.

Another way that academic institutions can help encourage industry partners to execute technology transfers is to ensure that the academic institution does not act as a direct competitor and/or help another direct competitor of the industry partner. This may be achieved by using a field-of-use restriction clause. This clause will restrict the academic institution's right to use the material for a particular type of research, mainly noncommercial research. This clause has the potential to further principal investigators' work that is still at the upstream research process, but it is best used cautiously at academic institutions when they are contemplating downstream research and application. This is because a field-of-use restriction may prevent the academic institution from disseminating the resulting invention to the public if it will be doing so for money either by selling the resulting product or process itself or licensing others to do so. In contrast, field-of-use restriction clauses can

[224] *See supra* note 197, at 702 (discussing that in three technology office specialists' experience, "the recipient, in many cases, may be able to grant a first right or an option to negotiate a non-exclusive or exclusive commercial license to such inventions").

more liberally be utilized to gain access to materials, tools, or data when the recipient of the material is still conducting upstream research.

Yet there are negatives to field-of-use restrictions and use restrictions more generally. These all hinge on the fact that ownership stays with the provider of the material and, consequently, the provider restricts the recipient's use of the material in its upstream or downstream research. In essence, the provider narrows the ways that the recipient is allowed to use the transferred material. This is especially so when the materials or tools are in the biomedical field.

For example, when WARF collected human embryo donations, the consent forms contained promises to the donors regarding the subsequent use of the embryo cells (for example, "that cells would not be combined 'with a nonhuman embryo,' that could prevent 'important research'").[225] From these donations, and after a Wisconsin-Madison scientist and his team developed long-lasting primate embryonic stem cells, WARF obtained three broad patents on human embryonic stem cells and cell lines (hESCs).[226] WARF then transferred hESCs lines to requesting academic institutions with executed MTAs (and, at least originally, $5,000). A controversial use restriction within the MTAs was that researchers were barred from sharing hESCs "with others" and that researchers had to show annual research plans for use of the hESCs.[227]

To many researchers these use restrictions were contrary to the very purpose of academic science—to promote scientific progress and dissemination of new knowledge and products to the public.[228] But these use restrictions were designed at least in part due to the promises WARF made to the donors. This contract-within-a-contract or "nested contract" problem is common in academic research, demonstrating the need to carefully draft the original consent forms when collecting materials and data. A use restriction such as sharing with others is non-collaborative and should be avoided by limiting early promises to donors and elsewhere. Reassurances of ethical scientific experiments may be necessary but the scope of use of materials is often changed or altered upon advancement in a scientific field. Keeping broad language in original consent forms will help enable adaptability in further use of the collected materials.

Ultimately, with the right combination of pressure through "criticism by academic scientists and representatives of government institutions that provide significant funding of health-related research," in addition to "co-opting activity," "most notably, by the [NIH's] choosing WARF's subsidiary WiCell to be the host of the

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[225] John M. Golden, *WARF's Stem Cell Patents and Tensions Between Public and Private Sector Approaches to Research*, 38 J.L. MED. & ETHICS 314, 319 (2010).
[226] *Id.* at 315.
[227] *Id.* at 319.
[228] *Id.*

National Stem Cell Bank," WARF liberalized its use-authorization practices.[229] This also arguably shows that WARF had more ability to contract around its original promises to donors, perhaps by including a more narrow field-of-use restriction instead of a general use restriction.

The final most often contested term in industry-to-academic transfers involves publication rights. Academic scientists are concerned about rights to publish and present results and conclusions of the research conducted with the use of shared materials, tools, or data. This is so not only because of the pressure to "publish or perish" in academia, or necessarily to maintain tax-exempt status, but also because it is the culture in academia to share knowledge with other scientists and the public through publication or presentation. If another academic institution or industry partner attempts to control the dissemination of research results or conclusions through a publication restriction in a MTA, it may lead to a failed negotiation. Although many academic institutions are willing to send the provider of a material a copy of a manuscript or notes of a presentation and give the provider 30 to 60 or so days to approve it, that is all an academic institution will routinely agree to when negotiating a material transfer.[230]

Publication restrictions also come in the form of attribution to the provider. Both the UBMTA and the NIH SLA require proper attribution be given to the source of any material used.[231] No co-author attribution is warranted unless there is a more in-depth collaboration beyond merely sharing materials. There are some surprising stories of providers demanding co-authorship, but those are few and far between and should promptly be denied as unethical and overreaching. Research shows that while this is of primary concern to academic scientists, it is often easily negotiable once the provider is reassured that it will have a chance to review any paper prior to publication.[232] Like with indemnification and ownership, academic institutions can take calculated risks here by ensuring that the industry's period to review or file a patent is limited and does not extend to control over the actual results of tests or ultimate publication.

B. Fostering Shared Innovative Activity: A Modern MTA

The difficult part about the use of the modern MTA is not about particular terms like with the traditional MTA, although similar stalemates can occur, but rather the high level of uncertainty inherent in embarking on a collaborative journey to create "something." If just one party undertakes the journey, information costs, opportunism, and hold-up risks are decreased. Innovation and the progress of science moves faster, however, when there is a collaborative and iterative process of multiple parties combining their different skills and resources together. This means that parties

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[229] *Id.* at 318.
[230] *See supra* note 197, at 697.
[231] *See supra* Part I.B.
[232] *See supra* note 45.

will need to share highly proprietary and valuable information, as well as personnel and resources, in an environment that is not only uncertain but ripe for opportunism and hold-up.[233]

How can we best support and thereby encourage collaboration while also decreasing opportunities to exploit information and resources or hold up innovation for purposes of personal gain? Recently, Ronald J. Gilson, Charles F. Sabel, and Robert E. Scott have argued that parties are at least partially self-governing themselves by intertwining governance mechanisms that are enforceable in contract law with those that are not enforceable, most often for want of definiteness.[234] This process is termed "braiding," and the contract that contains these braided mechanisms a "contract for innovation."[235]

The Sangamo Biosciences and Shire AG Collaboration and License Agreement discussed above is an example of a braided contract for innovation. In the original agreement, Shire AG was given access to Sangamo's zinc finger DNA-binding technology. The parties came together not for Shire AG to interact just once with Sangamo, but rather for the parties to determine if a further collaboration might produce a viable product using the zinc finger DNA-binding technology. With terms such as "reasonably," "good faith," and "diligent," the parties are able to use these soft terms and thereby allow for subsequent adjustments as needed.[236]

Furthermore, the parties are not bound to purchase or sell in the broad sense of that language from one another, although perhaps it is more accurate to say that the parties are not obligated to develop a product together. The parties *may* develop therapeutic or diagnostic products, yet there is no obligation on the parties beyond making a good faith effort to come up with some product containing the zinc finger technology. With this great level of uncertainty and high level of liability and expense, unexpected events will happen.

A modern MTA, which grants access to needed or desired materials, tools, or data, and additionally opens the door for meaningful shared innovative activity, helps parties respond together to the inevitability of changed circumstances. When more tests are needed, a particular compound is found to be ineffective, clinical trial

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233 *See Contracting for Innovation*, *supra* note 168, at 451 (explaining that "problems of opportunism and the risk of hold-up. . . seem endemic in . . . interactive collaborative relationships").

234 *Braiding*, *supra* note 169, at 1377.

235 *Id.* Gilson, Sabel, and Scott explain that they "call the legal instrument that facilitates the interfirm collaboration a contract for innovation." *Id.* at 1383.

236 *See Contracting for Innovation*, *supra* note 168, at 433-43. The authors explain that using these terms by themselves is insufficient to constrain opportunism because of the moral hazard that one party has "the discretion to adjust performance as conditions change [and] always choos[e] the best alternative for himself." *Id* at 454. While I agree that this is problematic, I think these terms can effectively be used when there is an enforcement mechanism such as a joint steering committee where a more clear definition of required behavior may be decided cooperatively.

results are disappointing, etc., they have a decision-making partnership to work through the extra expense and uncertainty.

The biggest downside to a modern MTA is what happens if a breach occurs that the parties cannot resolve internally. A court or arbitration panel will have a difficult time assessing damages in light of the fact that the parties started the relationship, and likely the contract still reflects, that the parties will work together to create "something" in "good faith." That said, parties, like Sangamo and Shire, are putting in place mechanisms that decrease the likelihood of needing a judge to determine liability. Sangamo and Shire, like many other parties, included a formal process that they will go through before seeking the help of any court or arbitration panel. It is called a Joint Steering Committee (JSC). JSCs are common in biotech and pharmaceutical contracts.

Although JSCs are tailored for the specific project and parties, their function and purpose is to construct a decision-making process that will be used when there is disagreement between the contracting parties. JSCs are generally comprised of employees from each contracting party that are designated to serve, and out of that the employees together select a chairperson. The JSC is tasked with finding a resolution for any problem that is not easily solved in the laboratory, and if the JSC cannot reach a consensus, then the decision will go to the top executives of the company. It is rare for the JSC to fail to work out the problems. Moreover, it is viewed as a failure and embarrassment if the JSC has to go to the next level of the decision-making process. Overall, the JSC is a great mechanism to help parties solve issues that arise in a modern MTA or other innovative contract where flexible terms are intentionally selected to encourage collaboration and quick changes.

This is particularly true given the problem of enforcing these braided contracts. The particular question that arises is what happens if the JSC fails to reach an agreement on a disputed matter, such as whether to identify a new compound to test when a previous compound fails to meet expectations in testing, and if the CEOs or last level of decision makers also fail to reach a consensus? How does a court or arbitration panel decide something that the parties could not?

Gilson, Sabel, and Scott argue that some courts are already correctly enforcing these contracts by using "low-powered formal enforcement."[237] In contract law terms, low-powered sanctions are not expectation damages. Instead, low-powered sanctions are more akin to reliance or restitution damages. The authors believe the braiding mechanism contained within innovative contracts will work if "[t]he courts are only deploying low-powered incentives; that is, courts sanction only cheating of the parties' mutual commitment to iterative collaboration, but do not attempt to reg-

[237] *See Braiding*, *supra* note 169, at 1415-16. The authors explain that expectation damages, the general remedy in contract law, are not possible when there is a breached agreement. The expectation was to create something new, and a court will not order the parties to continue working together to create that something that was unidentifiable by the parties themselves. *Id.* at 1425-27.

ulate the course or the outcome of the collaboration."[238] In this way, they argue the law should only catch and sanction, as the authors say, "red-faced" violations.[239] Yet these violations of shared innovative activity, where one party simply learns from and then takes from the co-party without working together to create something new, will only have to pay for the non-breaching party's reliance damages, or perhaps disgorge any unjust enrichment that it received from the non-breaching party. This is an undeveloped area of innovative contracting in the shadow of patent law. In many MTAs, parties are contracting in the shadow of patent law, and where patent law has high-powered sanctions in the form of enhanced damages for willful infringement.

We must continue to push forward how parties contracting in the shadow of patent law and using innovative contracting may obtain the protection of higher-powered sanctions, those that will more seriously deter "red-faced" violators. Of course, and as occurs with modern MTAs, sometimes after access is given and an iterative collaborative relationship is established, it turns out not to be a desirable collaboration. Contract law and patent law must be sensitive to the needs of the parties and allow research and collaboration agreements to fail without imposing a sanction that will crowd out or deter future collaborations. I aim to explore in future research how contract law and patent law can best support shared innovation collaboration in the shadow of contract law, one that the modern MTA leads parties to develop.

Conclusion

In this Article, I have identified why MTAs continue to cause delays and frustration despite the fairly simple drafting and language needed: many lawyers and MTA specialists believe that there is just one function and purpose of MTAs when there is actually more than one. A traditional MTA is best used for a quick, one-time transfer of materials when no collaboration or further interaction is desired. A modern MTA is best used when there is a desire for repeated interaction in the form of shared innovative activity. I have argued that parties must recognize the different uses of MTAs. Moreover, I have argued that in order to continue moving forward, science and technology needs collaboration between researchers from across a broad variety of institutions and industries. Using the modern MTA to help develop collaborative relationships has the potential to bring together these diverse researchers, scientists, institutions, and industries.

This Article has also identified that there is still a time and place for a traditional MTA, but even the traditional MTA needs better innovative contracting. The contested terms of indemnification, ownership, and publication rights are slowing the negotiation process and in some cases causing negotiation efforts to fail completely.

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[238] *Id.* at 1427.
[239] *Id.* at 1417.

This hurts innovation and is contrary to the shared goal of bringing new products and technology to the market. I have identified work-around solutions that can make an immediate impact in reducing negotiation time and therefore increasing efficiency in the MTA process.

The "UNLIMITLESS": On How to Remedy the Inadequacies of a Language-Based System for Patent Claims

Amir H. Khoury*

Introduction

Over the past three decades, it has become self-evident that patents are complex legal constructs that are expensive to obtain and even more so to protect through litigation. These problems plague the patent system not only in the United States but around the world as well. This persistent and pressing reality is largely owed to the structure of patents and especially the patent claims section therein. In this regard,

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the most important section of any patent application and patent registration is the patent claims section. That section, which defines what is claimed by the inventor, is essentially the legal "fence" that the inventor erects in order to protect his invention.[1] These patent claims utilize language; it is the tool by which patent claims are constructed and communicated. Enter the dissonance between the need for precise "fences" and the limits of linguistic expression. Indeed, while language is rich, it is not limitless, and it is far from exact. As the title of this work suggests, words are, in and of themselves, "unlimitless" in their ability to create clear-cut patent claims. Furthermore, given that various parties interact with the words in patent claims, e.g. applicant, examiner, courts, and other parties, it is no wonder that the substance of these legal "fences" is in many cases a subject of contention.

In this paper I describe the inherent limits of language and words to express exact elements objectively. I identify this limitation as the source of the problems that plague the patent system. In a nutshell, my contention is that a language-based patent claims system does not, and by definition cannot, create clear boundaries between inventions and cannot ensure that "fences" around patents are rendered impregnable. As such, patent registration, enforcement and litigation relating thereto remain complex and costly, and their outcomes are in many cases cast in doubt. Thus, while the patent system attempts to ensure protection for inventions in the private domain vis-à-vis the public domain, the "fences" between those domains, due to the linguistic inadequacies, are no more than suggestive.

In this paper I propose shifting to another, more refined model; one that is a compilation of language and other tools such as visual depiction, predetermined jargon and preset classifications. I explain how this model can be formulated and put into practice, and why it will greatly improve patent prosecution and enforcement.

This paper is comprised of three chapters. In the first chapter, I shed light on the reality pertaining to the staggering costs of the prosecution and litigation of patents. In the second chapter, I explain why a language-based patent claims system is not sustainable, and why indeed it constitutes the core of the problem that plagues the patent system nowadays. In the third and last chapter of the work, I survey current solutions that courts have formulated in order to alleviate problems relating to patent claims and explain why such solutions are insufficient. I then propose a new model for dealing with patent claims, which could make patent registration and litigation a much cheaper endeavor.

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[1] The fence metaphor is widely used in literature. *See, e.g.*, ALAN L. DURHAM, PATENT LAW ESSENTIALS: A CONCISE GUIDE 92 (2013) ("The function of patent claims is to identify the subject matter covered by the patent. If patent infringement can be compared to trespassing, the claims serve as the boundary markers that define what is, or is not, an encroachment on the inventor's exclusive territory.").

I. The Grim Reality of Patent Prosecution and Litigation

In its essence, a patent is a contract between the state and an inventor whereby if the inventor shares his knowledge with the world, the world (i.e., the state) shall reward him (or her) with a right over his invention for a limited period of time. But this "contract" is not limited to those parties (i.e. the inventor and the state) and its impact extends to others that are not formal parties to said contact. These 'external' parties include the users (consumers) of the technology as well as the competitors in the field. Notwithstanding their formal status, both of these "silent" parties (users and consumers) have an interest in getting access to the technology with minimum costs attached. Thus, the patent contract is one that has repercussions beyond the formal two parties referred to therein (the inventor and the state). This multiparty involvement in the process renders the patent contract a very complex endeavor that involves a delicate social balance. While in the classic two-party contract the parties are at liberty to draw the terms of the agreement and to assign to each other certain rights or obligations, in the case of the patent contract, the state performs a dual function. That is to say, the state not only functions in a technical capacity, that is of registering the invention, but more so it also acts as an entity whose task is to establish the borderline between the private domain of the inventor and the public domain of the external parties. Thus, patents involve an ongoing tug-of-war between the inventor who is seeking to maximize returns by expanding his control or monopoly over the technology and between the external "silent" parties who have a vested interest in ensuring access to the invention for themselves. And in between these polarized interests of rewarding the inventor and of ensuring access to technology, exists the never-ending endeavor to maintain the primary purpose of patent law, which is to promote the progress of science and innovation.[2]

These competing interests and the endeavor to reconcile them within the conventional patent claims construct are what create an expensive patent system. Indeed, the cost of patents in prosecution and litigation is not a cliché that practitioners and academics use. The empirical data leaves no room for doubt as to the staggering costs of the patent system as far as inventors and/or patent owners are concerned. A 2013 survey by the American Intellectual Property Law Association, regarding the average litigation costs for patent infringement suits, proves this beyond doubt.[3] Specifically, that survey found that the costs of patent litigation for claims in patents that were valued at under $1 million are over $800,000.[4] Furthermore, according to that survey, the average costs for patent litigation involving patents which were valued in the range of $1 million to $25 million rose to $2.5 mil-

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2 This rationale is spelled out in the Constitution of the United States of America. U.S. Const. art. 1, §8, cl. 8 ("To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.").

3 *See*, Intellectual Property Insurance Corporation, *AIPLA 2013 Report of the Economic Survey*, http://www.patentinsurance.com/custdocs/2013aipla%20survey.pdf.

4 *Id.*

lion.[5] The survey found that the average legal costs for patent litigation in patents valued in excess of $25 million were over $5 million.[6] It is important to note that the survey focused on the actual cost of fighting over the patent i.e., both as a defendant and as a plaintiff. However, the survey excluded the damages that a defendant would have to bear if he was not able to repel the case. What is striking is that patent litigation is almost twice as costly as the already too-expensive litigation pertaining to trademarks, copyright and trade secrets.[7] The cumulative sum of these costs is almost unimaginable. In this regard, the Techdirt podcast reports that "patent litigation cost US business about a trillion dollars in a quarter century".[8]

This bleak reality is part of the patent landscape that seems to be considered a given. Jim Kerstetter eloquently sums up this grim reality by remarking:

> "Welcome to the patent legal industry, a high-priced, high-stakes but ultimately indispensable part of doing business in high tech or any other industry that relies on innovation. Even the staunchest defenders of the current patent system agree the litigation can be onerous and sometimes the patents that get rewarded don't make a whole lot of sense, but they argue that the anarchic alternative would be even worse".[9]

I beg to differ, with the prognosis. In my view, this reality is not the only possible outcome; a better patent system can and should be achieved. This research will hopefully contribute to this endeavor.[10]

Given this state of affairs, the rational, *albeit* undesirable, thing to do is to settle out of court. In principle a settlement can be a very good thing in that it allows the parties to reach an amicable resolution without expending costs and time in the process. Notwithstanding this rationale, a settlement that is not induced by a freedom of choice but rather imposed by the circumstances of a party is very problematic to say the least. Indeed, it causes financially weaker parties to capitulate before an opponent on the unleveled playing field on which they find themselves. In this regard Kerstetter observes, "For small companies, however, simply fighting a patent suit

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5 *Id.*

6 *Id.*

7 For the full and detailed numbers in the survey see American Intellectual Property Law Association *Id.* For a broad review *see* World Intellectual Property Organization, *IP Litigation Costs*, WIPO MAG., (Feb. 2010), http://www.wipo.int/export/sites/www/wipomagazine/en/pdf/2010/wipo_pub_121_2010_01.pdf

8 Glyn Moody, Patent Litigation Cost US Business About A Trillion Dollars In A Quarter Century, Outweighing Benefits, TECHDIRT, https://www.techdirt.com/articles/20140416/04183626928/patent-litigation-cost-us-business-about-trillion-dollars-quarter-century-outweighing-benefits.shtml

9 Jim Kerstetter, How much is that patent lawsuit going to cost you?, CNET, http://www.cnet.com/news/how-much-is-that-patent-lawsuit-going-to-cost-you/

10 The debate over the state of patent law in the U.S. and the need for rethinking some lingering issues including reform thereof is evident in the literature and in legal recourse. *See, e.g.*, Andrew Baluch, *Patent Reform 2015: A Comprehensive Guide to Current Patent Reform Developments in Congress, the Executive Branch, the Courts and the States* (Jan. 23, 2015 ed.), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2414306

can be financially ruinous. That's why many are willing to settle, even if they believe they did nothing wrong."[11] Kestetter accepts that this "seems unfair, but often heading into the courtroom is a roll of the dice."[12] This is another component of the grim reality of the conventional patent system.

To my mind, this reality is unacceptable. It is unacceptable simply due to the fact that, by design, patents were supposed to be a tool for sharing knowledge and were never about excessive control which sometimes seems to amount to 'hoarding' (for lack of a better term) science.[13] Patents were conceived of a true yearning to share knowledge. They were intended to be an inclusive incentive-driven system, not an exclusive cost-barricade type construct, as they have become.[14]

II. The Inadequacies of Language-Based Patent Claims

The most important section of any patent application and patent registration is the patent claims section. This section, which defines what is claimed by the inventor, is essentially the legal "fence" that the inventor erects in order to protect his invention. These patent claims utilize language; it is the tool by which patent claims are constructed and communicated. Enter the dissonance between the need for precise "fences" and the limits of linguistic expression. Indeed, the reality is that while language is rich, it is not limitless, and it is far from exact. In this regard, as the title of this research suggests, words are in and of themselves "unlimitless" in their ability to create clear-cut patent claims. Furthermore, given that various parties interact with the words in patent claims, e.g. applicant, examiner, courts, and other parties, it is no wonder that the substance of these legal "fences" is in many cases a contentious subject.

a. The Claim as the 'Source Code' of Patents

An invention is protected through the claims section in the patent. The claims section is separate from the specification (description) section, which describes in

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11 Kerstetter, *supra* note 9.

12 *Id.* (Regarding the inherent problem of the system, Kerstetter quotes Christopher Marlett, CEO of MDB Capital Group, an investment banking firm that focuses on intellectual property: "What happens in that courtroom is that it's a very technical presentation to a jury that has no technical background, . . . In a lot of these cases, the juries say this is above my head, and the judgment goes to the lawyer they like the most. That introduces great risk into the equation." Kerstetter then states: "If these claims were decided by a panel of technical experts, the fight would be worth it. But a jury of your peers, who aren't exactly your technical peers? Maybe that's something to be avoided.").

13 Consider patent trolls the most vivid reflection of the ugly side of the patent system.

14 Andrew Grosvenor, Why 'Patent Trolling' by High-Tech Companies is Stifling Competition & Innovation – And What we Should Do About It, (2011), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1923989("The purpose of the patent system is to encourage innovation and to reward inventors by protecting the fruits of their labor. Abuse of this sanctioned monopoly is helping to consolidate the tech marketplace to the few large companies that are winning the patent 'arms race.'").

great detail how to create or build the relevant invention. In this regard, while the specification section is, in essence, the "builder's manual" of the invention, the patent claims section is where the inventor and/or patent owner stipulates that certain elements in the invention belong to them and cannot be infringed upon by others. The claim or claims in that section are intended to precisely set out the parameters of the invention. In this regard these claims are effectively the legal "fence" around the patented invention. They define the scope of the private domain that is the invention. Tun-Jen Chiang and Lawrence Solum define this important distinction between the claims and the specification: "[T]he claim and the specification both describe the invention, but they serve different roles. For legal purposes, it is the claim that defines patent scope."[15] Peter Manell observed: "The construction of patent claims plays a critical role in nearly every patent case. It is central to the evaluation of infringement and validity, and can affect or determine the outcome of other significant issues such as unenforceability, enablement, and remedies."[16] It is worth noting that ever since the United States Supreme Court's 1892 decision in *Topliff*, U.S. courts have recognized the patent application as the most difficult legal instruments that can be drafted.[17] Furthermore, Chiang and Solum explain that "claim scope equals patent scope, which makes claims very important. It is equally axiomatic that claim scope is defined by the text of the claim."[18] As such, the claims section is the most crucial section of the patent since it separates the private domain from the public domain, thus allowing users and competitors to operate within the latter while prohibiting them from operating within the former. But as clearly alluded to above, constructing a "fence" is not a technical issue. It has clear ramifications for the technological landscape, since what is enclosed within the "fence" is effectively off-limits to the world. Hence, the immense responsibility bestowed on the Patent Office of accepting or rejecting patent claims and on the courts for interpreting said patent claims. These are great responsibilities given their far-reaching impact on all parties involved. The weight of words is crucial in patent claims. Ac-

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15 Tun-Jen Chiang & Lawrence B. Solum, *The Interpretation-Construction Distinction in Patent Law*, 123 YALE L.J., 530,540 (2013).

16 Peter S. Menell, et al., *Patent Claim Construction: A Modern Synthesis and Structured Framework*, 25 BERKELEY TECH. L.J., 711, 714 (2010).

17 Topliff v. Topliff, 145 U.S. 156, 171 (1892) ("The specification and claims of a patent, particularly if the invention be at all complicated, constitute one of the most difficult legal instruments to draw with accuracy . . . "). *See also*, Sperry v. Florida, 373 U.S. 379, 383 (1963); Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.2d 855, 856-57 (1988) ("This appeal again illustrates one of the many difficult dichotomies that lurk in the lacunae of patent law. On one side rests the very important, statutorily-created necessity of employing the clearest possible wording in preparing the specification and claims of a patent, one of the most difficult legal instruments to draw with accuracy.' On the other lies the equally important, judicially-created necessity of determining infringement without the risk of injustice that may result from a blindered focus on words alone."); Gene Quinn, *Patent Drafting: Not as Easy as You Think*, IPWATCHDOG, http://www.ipwatchdog.com/2014/05/17/patent-drafting-not-as-easy-as-you-think/id=49638/ (explaining that this view has remained consistent over the years).

18 Chiang, *supra* note 16, at 540.

cording to Silverman "how a court interprets a single word in a patent claim could determine whether it concludes that patent infringement does or does not exist."[19]

Generally, there are basic rules or steps that apply when attempting to construct a patent claim. First and foremost the claim needs to be bound by the claim language that is the meaning of the terms and words as understood by those of ordinary skill in the art.[20] Second, the courts will resort to the wording of the specification as it reflects on the claims.[21] Third, the courts will resort to the prosecution history of the invention since this reflects the intended scope of rights that the inventor sought when filing to patent his invention.[22] Furthermore, the courts may also turn, as a last resort, to the extrinsic meaning of the language of the claim (e.g. use of dictionaries, treatises, and encyclopedias).[23] This 'hierarchy' (so to speak) is crucial in providing additional proof that the wording of patent claims remains an enigma in that its interpretation is, in many cases, context-dependent and is never truly defined as a "fence" needs to be. Shawn Kolitch suggests that there should be more dominant use of the preamble of the claim in trying to define its scope.[24] I shall revisit the scope issue in the third and final chapter of this paper.

Therein lies the quandary; that while patent claims are decisive in determining the scope and strength of a patent, they are basically a language-based test and as such are not capable of pinpointing its intended accuracy. In the next chapter I shall show why this language-based system is inherently an unsuitable building material for what is supposed to be: a clearly defined and stable legal "fence". To continue the metaphor, while cement is a crucial element in erecting a strong fence, it is not sufficient in and of itself to create that fence. So it is with patent claims; that is to say: a language-based system is not enough.

b. Are Patent Claims the Only Problem?

From the outset, I should like to point out that the assertion that language-based patent claims are the source of the problem in patents is not accepted by all. In this regard, I would refer to the work by Chiang and Solum, who contend that while "ambiguity of claim language is generally considered to be the most important problem in patent law today . . . . This diagnosis is fundamentally wrong." In their view, with which I respectfully disagree, "[C]laims are not often ambiguous, and

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19 Arnold B. Silverman, *Watch What You Say—Appellate Court Clarifies Standards for Interpreting Technical Patent Claim Language*, TMS, http://www.tms.org/pubs/journals/JOM/matters/matters-0604.html.

20 Shawn Kolitch, *Patent Claim Construction: The Neglected Preamble*, 8(1) INTELLECTUAL PROPERTY NEWSLETTER, http://www.khpatent.com/files/9492SJK_Patent_Claim_Construction.pdf.

21 *Id.*

22 *Id.*

23 *Id. See also*, Ruoyu Roy Wang, *Texas Digital Systems v. Telegenix, Inc.: Toward A More Formalistic Patent Claim Construction Model*, 19 BERKELEY TECH. L.J. 153 (2004) (on the use of dictionaries).

24 *Id.*

linguistic ambiguity is not a major cause of the uncertainty in patent law today."[25] In their view the problem of patents is not linguistic ambiguity but rather that "uncertainty in claim application most typically arises because judges have core policy disagreements about the underlying goals of claim construction."[26] Thus, Chiang and Solum reject the proposition that underlies this work, namely that the problem with patent claims is not the language or words therein but the fact that there is no clear common policy amongst judges when constructing patent claims.[27] In this regard they argue that the root cause of difficulty in analyzing patent claims is not "linguistic indeterminacy".[28] In their view uncertainty as to patent claim interpretation "arises because judges disagree about whether to follow the linguistic meaning as a matter of normative policy."[29]

As stated above, I find myself in disagreement with Chiang and Solum's proposition. I do concede, however, that there are other problems that plague the patent system. Still, I hold fast to the view that the language-based construct of patent claims holds the lion's share of the reason why the patent system is broken.[30] While there is no doubt that a policy difference exists amongst judges in various jurisdictions, had there been clearer patent claims these policy issues would not have had a foot in the door to begin with. Had the patent claim construct been clearer to begin with, there would not have been any need, indeed any merit, for judges to weigh in with their respective policy views. Simply stated, unambiguous patent claims draw clear "fences" that lead to clear-cut decisions devoid of any policy-related intervention by judges. Thus, the policy issue, while factually correct, is merely a symptom of the ailment that is an incoherent patent system at large, with the claims being a manifestation, or even a catalyst, therein. Indeed, while attempting to limit the discussion to the issue at hand, I should like to add that the lack of a coherent and unified patent system is and will continue to preserve the complex, costly, unclear, unstable system in which our innovators, and indeed all of us, find ourselves mixed-up in. I have in the past alluded to and examined some of these issues.[31] Without opening a lengthy discussion on these issues, I will mention some of them that will need to be fixed or addressed with the conventional patent system. These, much like patent construction, remain a stumbling block in the path to a vibrant and seamless patent system.

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25 Chiang, *supra* note 16, at 530.

26 *Id.*

27 *Id.* at 534.

28 *Id.*

29 *Id.*

30 The 'Broken System' narrative has resonated for the past two decades in the U.S. and elsewhere. See, e.g., ADAM B. JAFFE & JOSH LERNER, Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and what to Do About it, (2004).

31 *See, e.g.*, Amir H. Khoury, *The End of the National Patent Office*, 52 IDEA 199 (2012).(discussing the lack of unification in the patent system).

My first assertion about the problems that plague the patent system at large is the lack of unification.[32] In a nutshell, just as there is one technology, so too there should be one single international patent office.[33] In this context my assertion is that the "traditional" or conventional mode of operation of the National Patent Office is no longer compatible with the way in which innovations are being registered, patented, protected and enforced around the world.[34] In my view, the reduced relevance of the National Patent Office has been a direct byproduct of the cross-border nature of innovation, the world-encompassing threshold of patent registration (i.e. the international novelty requirement), and the international structure of patent protection.[35] Indeed, given the nature of patents and the centralized international patent system that is already in place, the role of the National Patent Office has become largely overshadowed by an international patent system comprising well-defined legal and administrative structures such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS); the Patent Cooperation Treaty (PCT)) as well as a 'Patent Prosecution Highway' consturc.[36]

My second assertion regarding the patent system is that the patent term of one-term-fits-all does a disservice to the promotion of technology and to the preservation of the incentive mechanism that drives it forward.[37] My view continues to be that while the scope of patent rights (patent breadth), is a crucial element in preserving the incentive to innovate, it is not sufficient to create the real balance that needs to be struck between different market players.[38] In my view the patent term (patent length) is the missing piece in the puzzle.[39] Indeed, only a synthesis between both length and breadth can ensure a real balance between patent rights and access to technology.[40] There is a need to discontinue the use of a single patent term for all types of patents since the 'Commercial Capacity' of innovations is itself differential.[41] For this purpose, I have proposed a differential patent term in which duration is contingent on the type of innovation and its underlying technology.[42]

The third element which, I think, reflects badly on the patent system at large is the inability to make room for real and pressing social interests that need to be factored in to the patent system when making determinations pertaining to compulsory

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32 *See id.*
33 *Id.* at 202.
34 *Id.*.
35 *Id.*
36 *Id.* at 199 (". . . the National Patent Office is now on its way to becoming a mere relic of a territorially-oriented framework—an anachronism that must be changed to promote useful science and innovation around the world.")
37 Amir H. Khoury. *Differential Patent Terms and the Commercial Capacity of Innovation*, 18 TEX. INTELL. PROP. L.J. 373 (2010).
38 *Id.* at 374.
39 *Id.* at 374-76.
40 *Id.*
41 *Id.*
42 *Id.*

licensing, etc. This is especially evident and acute when it comes to access to medicines.[43]

All of the three abovementioned elements depict weaknesses that are inherent in the conventional patent system at large. I will refrain from addressing these issues further, and remain focused here on the issue at hand. I have made note of these issues here in order to highlight the extent of deviation of the conventional patent system from its original intent, namely; to harness knowledge and to provide an incentive for innovation. Indeed, the overriding theme of those preceding research projects, and of this current project, is that all barriers to knowledge and to sharing of knowledge should be removed in a manner that increases the chances of technological innovation, renders the system less costly, more attainable and accessible by all and for the collective benefit of society.

c. The Limits of Language in Patent Claims

The first thing that is striking about patent claims is the attempt to express technology in words. Indeed, to erect a "fence" that is supposed to be solid and well defined by using words. Evidently, this is virtually impossible! This is because words are not limitless. Their ability to convey exact ideas are limited by linguistic constraints as well as personal connotations.[44] Language is a tool to express ideas but these ideas involve at least two parties. The speaker (or writer) who has an idea which he wishes to convey by using certain words; and the receiver (or reader) of said words who will engage in his own interpretation of the same. As such language is not a binary code or GPS system that denotes an exact reference to a number or position in space. Rather words are sounds that are expressed by one and received by another. Thus, the chance of misunderstanding, misinterpreting or miss construing an idea is far greater in the case of words. So while patents attempt to establish clear lines of division between that which is private and that which is public, those building blocks with which they attempt to do that are simply not suited for the task. Words cannot create a clear line of separation between public and private domains. In fact the amount of effort that has been exerted in crafting the word-claim structure shows that this is virtually impossible. Consider, for example, Robert Faber's analysis and compilation of the various terms that are commonly used in constructing patent claims.[45] Furthermore, Chiang and Solum recognize the academic discussion regarding the inherent problems of patent claims; they explain that "It is generally regarded as very important that patent scope be entirely independent of the policy judgment of individual judgesFalse Yet despite these routine pronounce-

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[43] Amir H. Khoury, *The 'Public Health' of the Conventional International Patent Regime & the Ethics of 'Ethicals'*, 26 CARDOZO ARTS & ENT. L.J., 25, 26 (2008).

[44] Svetlana Sheremetyeva, *Natural Language Analysis of Patent Claims* (2003), *available at,* http://dl.acm.org/citation.cfm?id=1119311.

[45] ROBERT C. FABER, LANDIS ON MECHANICS OF PATENT CLAIM DRAFTING (5th ed. 2008).

ments by courts that they are rigidly adhering to claim text, it still seems that claim scope is wildly unpredictable."[46]

The awareness of the inherent weakness of words to convey clear-cut ideas is not new. Over the years philosophers, linguists, and courts have had to struggle with this reality. Justice Frankfurter, in the context of interpreting statutes, remarked that words are "symbols of meaning" that "seldom attain more than approximate precision."[47] This applies in the case of patent claims as well. The following examples highlight some specific mechanisms for dealing with this difficulty in the context of patents.

i. Use of Open-Ended Terms

Use of open ended terms is prevalent in patent claims. Consider the terms 'consisting' and 'comprising'. While these words, linguistically speaking, are seen as synonymous, the same does not apply in the patent context. In patent claims, those two words are deemed to have different meanings. While the former is held to denote a very broad and open claim, with possibly unspecified elements, the latter is deemed to be narrower in scope and containing the materials specified therein. Both terms allow for interpretation and, in some cases, the inclusion of additional elements that are otherwise not mentioned therein.

ii. Use of Constructive Ambiguity

In the case of constructed ambiguity, patent claims can be used to expand the technological envelope that surrounds the patent. The prominent term in this regard would be the term **"preferably"**. In this case it is possible to understand from the patent term that the component is optional but not essential. Effectively this means that additional components could be used. This obviously leaves the patent owner protected even if a competitor introduces a new component.

iii. Use of False-Positive Terms

False-Positive terms, such as "may", "might" etc., can be used in patent claims. Such terms not only carry the possibility of occurrence but also the lack thereof. Thus, such a claim would cover both incidents. Again, it is noticeable that the use of such terms would invite not only much interpretation but also can induce a lack of clarity as to the scope of incidents that are covered by the patent.

The linguistic challenge that is posed by the patent claims also manifests itself on the chronological level. The interpretation that should be given to a certain term

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[46] Chiang, *supra* note 16, at 540.

[47] Felix Frankfurter, *Some Reflections on the Reading of Statutes*, 47 COLUM.L. REV. 527, 528 (1947).

is affected by time. Mark Lemley observes that, "In order to construe the claims of a patent, the court must fix the meaning of the claim terms as of a particular point in time."[48] In his view: "Both the knowledge of the PHOSITA in a particular field and the meaning of particular terms to that PHOSITA will frequently change over time."[49] But he too is aware of the chronological element when he ponders the question: "But at which point in time shall we fix the meaning of the claims?"[50] Still, the issue is much deeper; indeed it appears that the court's interpretation of claim terms is contingent on time as well as the legal issues that are in contention (e.g. novelty or non-obviousness; enablement or written description).[51] This, coupled with ambiguity and the self-interest of the inventor, as well as other parties, leads to a problematic concoction whereby the "fences" (i.e. the patent claim) are seen through the eyes of the beholder.

Another manifestation of the weakness of language is reflected in the ever-growing length of patent applications. Dennis Crouch alerts us to the reality that U.S. patents are increasing in size and complexity.[52] Thus, not only has the length of the specification increased over time, but the number of patent claims has also been on the rise.[53] These findings are yet another indication of the complex nature of patents, and the rising costs associated with the prosecution and litigation of the same. This serves as an additional indication of the direct correlation between the inadequacy of words *per-se* and the complexity of patents. Logic dictates, and the facts show that, where words fail to provide clear-cut protection more words are needed to fortify the claims from all possible avenues of interpretation; it is a cascade effect of sorts. When the building blocks of the legal "fence" are not adequate more blocks are needed to strengthen the "fence" in order to render it impregnable. These attempts are also destined to fail or at least to encounter challenges. Justice Frankfurter observes that, "If individual words are inexact symbols, with shifting variables,

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48 Mark A. Lemley, *The Changing Meaning of Patent Claim Terms*, 104 MICH. L. REV., 101, 102 (2005).

49 *Id.* (the term PHOSITA denotes a "person having ordinary skill in the art.").

50 *Id.*

51 *Id.* at 103. (Lemley observes that "It is a fundamental principle of patent law that the time as of which we determine the meaning of claim terms varies depending on what legal rule is at issue. Where the question is one of novelty or nonobviousness - whether the invention is truly new - the courts compare the patented invention to the prior art as both were understood at the time of the invention. Where the question is one of enablement or written description - whether the inventor understood and described the invention in sufficient detail - courts evaluate the adequacy of the disclosure based on the meaning of the claims at the time the patent application was filed. Where the question involves the meaning of a special patent claim element called a means-plus-function claim, courts evaluate the scope of that claim element at the time the patent issues. And where the question involves alleged infringement of the patent, courts evaluate infringement in at least some circumstances based on the meaning of the claim at the time of infringement.").

52 DENNIS D. CROUCH, THE RISING SIZE AND COMPLEXITY OF THE PATENT DOCUMENT, UNIV. OF MO. SCH. OF LAW LEGAL STUDIES RESEARCH PAPER NO. 2008-04 (2008), *available at*, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1095810.

53 *Id*; *see also* John R. Allison & Mark A. Lemley, *The Growing Complexity of the United States Patent System*, 88 B.U.L Rev., 77, 97 (2002).

their configuration can hardly achieve invariant meaning or assured definiteness."[54] Furthermore, in *Autogiro Co. of Am v. United States,* the court went on to observe that, "the very nature of words. . . make[s] a clear and unambiguous claim a rare occurrence." [55]

I should like to state that while I do not condone such use on the macro-policy level, I understand it completely. It is, after all, a logical tendency of those who are engaged in writing such claims; in their endeavor to expand their (private) domain and to cover their territory lest it be invaded by other contenders or competitors and to make room for judicial discretion that keeps the invention within the scope of patent protection.[56] While this is logical, its ramifications are clear: the inclusive nature of patent language is intended to create a closed domain in knowledge. Herein lies the dichotomy; using words in an inclusive manner in order to create an exclusive domain.

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It is important to note that the ambiguity of the text and the way in which to interpret patent claims has had far-reaching effects and has become part of a debate within the Federal Circuit.[57] Craig Nard identifies two schools of thought on how patent claims need to be interpreted: "hypertextualism" and "pragmatic textualism."[58] Nard notes that hypertextualism remains the predominant interpretive approach to claim interpretation.[59] In his view, "[T]his overly formalistic and acontextual approach is misguided and self-contradictory. It proclaims to read claim language as a person of ordinary skill in the art would but, at the same time, eschews the use of extrinsic evidence, thus distancing itself from the very industry its ultimate interpretation will most directly affect."[60] Nard favors "pragmatic textualism", because it is "consistent with the patent code and contemporary legal and hermeneutic philosophy."[61] In his view, "The pragmatic textualist judge not only understands the importance of textual fidelity, but he also embraces technologic context and is sensitive to process considerations such as institutional compe-

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54 Felix Frankfurter, *supra* note 48 at 528.

55 384 F.2d 391, 396 (1967).

56 William Redin Woodward, *Definiteness and Particularity in Patent Claims*, 46 MICH. L. REV., 755, 755 (1948) ("[T]he habit of using out-of-the-way verbiage may lead the practitioner by force of habit to pass over a simple term like "sleeping car" in favor of a more elaborate phrase like "a communal vehicle for the dormitory accommodation of nocturnal viators ").

57 *See generally*, Stephanie Ann Yonker, *Post-Phillips Claim Construction: Questions Unresolved*, 47 IDEA 301 (2007) (surveying Federal Circuit jurisprudence on claim construction). *See also*, Ehab M. Samuel, *Phillips v. AWH Corp., Inc.: A Baffling Claim Construction Methodology*, 16 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 519 (2006) (discussing the Phillips v. AWH Corp., Inc. distinctions on the "specification-based approach" v. the "claim-based approach").

58 Craig Allen Nard, *A Theory of Claim Interpretation*, 14 HARV. J.L. & TECH 2, 82, (2002).

59 *Id.*

60 *Id.*

61 *Id.*

tence."[62] This separation within U.S. courts reflects the reality that words in and of themselves fail to clearly draw the parameters of the legal "fence" that is the patent claim. Golden confirms the existence of this division within the court.[63] Golden also acknowledges various steps that have been undertaken with the purpose of bringing "greater predictability and rationality to claim construction".[64] The most notable of these, according to Golden, is the creation of the United States Court of Appeals for the Federal Circuit in 1982, which acts as an appellate court with exclusive jurisdiction over appeals in cases that arise under federal patent law. Golden also refers to the 1996 the Supreme Court opinion in *Markman v. Westview Instruments, Inc.*, which affirmed the Federal Circuit's holding that claim construction is a task for judges rather than juries.[65] But despite both of these steps, Golden concludes that "claim construction jurisprudence continues to bear hallmarks of unpredictability."[66] He explains that "reversal rates of district court claim constructions stand at roughly 34%," and that Federal Circuit judges do not apply similar claim construction methodologies.[67] This also proves that the problems with the patent claim system are not contingent on the court's membership or on the fact that juries were involved; the problems are much more deeply rooted, and effectively relate to the fact that patent claims in their linguistic construct fail, by definition, to attain clarity. It is worth noting that even the *Phillips* case did not do much by way of sidestepping these challenges. In *Phillips,* the court ruled that intrinsic evidence, such as claims and prosecution history, are very important for claim interpretation.[68] In that respect the court stated that the "context in which a term is used in the asserted claim can be highly instructive."[69] But the court also maintained that extrinsic evidence, such as use of dictionaries, can be useful in shedding light on the meaning of a claim term.[70] Evidently, the courts have not fashioned a clear-cut set of tools that can be utilized when constructing patent claims. This problem does not lie in the court's lack of ability to decide, but rather in the fact that words have a limited power to act as clear building blocks for constructing the "fence" that is the patent claim. As the title of this work suggests, words are "unlimitless" in their impact. Hence, a new fresh approach is needed, one in which words, whether intrinsic or extrinsic, are not the only factor to be considered.

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62 *Id.*

63 John M. Golden, *Construing Patent Claims According to Their "Interpretive Community": A Call for an Attorney-Plus-Artisan Perspective*, 21 HARV. J.L.& TECH. 321, 324-25 (2008).

64 *Id.* at 323

65 *Id.* at 323-2.

66 *Id.* at 324.

67 *Id.* 324-25.

68 Phillips v. AWH Corp. (Phillips II), 415 F.3d 1303, 1321 (Fed. Cir. 2005) (en banc).

69 *Id.* at 1314.

70 *Id.* at 1318.

III. Conceptions of a New Model for Patents

In trying to resolve this crisis in the language-based patent system, the courts have resorted to a few measures. While these measures have not been effective in resolving the inherent weaknesses, they do reflect the extent of the problem.

The first of these measures, which has been undertaken by courts, pertains to prior judicial definitions of terms, or expressions appearing in claims. That is to say, courts have resorted to looking at how prior courts have interpreted a given term. This practice is logical and warranted, yet it does not resolve the problem at its core. That is because all of the parties engaged in a given patent related proceeding (i.e. conflict) cannot predict, (know in advance), what a court will decide to do; that is to say, will a court place its ruling on prior judicial definitions or will the court go it alone in interpreting the wording of a patent claim? Also, the parties in these cases are likely to find themselves involved in a secondary tussle over the nature of the judicial sources on which the court will have to base its interpretation. Evidently, this is a paradox, or at least a bottomless pit, which leads to the same problem to begin with: Who has the authority to provide an interpretation for a given word? And what is the authoritative interpretation? [71]

The second type of measure that courts have utilized is the attempt to formulate general rules for the interpretation of claims, is the basic rule of interpretation stipulates according to which: terms need to be construed literally, barring any Patent Office proceedings or by prior art, or by judicial determination to the contrary. In simpler terms, the idea behind this rule is that a patentee is bound by the language and terms of his claim. Unfortunately, this rule, despite its best intentions, is at best circular. That is to say, it does not prescribe who should determine the patentee's actual intent? It also, does not specify at what point in time did that intent culminate? Furthermore, this rule itself is not applied in the same manner by all courts. Indeed, it has been shown, time and again, that these rules can vary from one court to another.[72]

The third of these measures is the development of specific doctrines, which reflect the general dissatisfaction with the limits of patent claims and the problems, referred to as "friction blocks," that they entail. The most prominent of these doctrines is the Doctrine of Equivalents, which allows courts to expand the scope of patent rights granted by the Patent Office.[73] But this comes with a cost and is viewed

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[71] This complexity is similar to that found in private international law over issues of forum as well as the applicable substantive law.

[72] *See supra* Chapter 2.

[73] *See* Michael J. Meurer & Craig Allen Nard, *Invention, Refinement and Patent Claim Scope: A New Perspective on the Doctrine of Equivalents*, 93 GEO. L.J. 1947, 1948 (2005).

by some as unsuitable and even contrary to the patent claim rationale (i.e. the notice function) of clearly defining the scope of the private domain.[74]

As I have already stated, these measures are also insufficient to remedy the existing challenges of relying solely on words within patent claims. Therefore, the initial problem (that is the inherent weakness of a langue-based patent system) persists: The ability to describe technology with words in not limitless. Words are "unlimitless", they are limited in what they can do. Thus, the "fences," which are initially intended to be built with words are nothing more than smokescreens. Bluntly speaking, nothing is truly defined in the patent field; most of it is open to interpretation and as such patent claims, despite the best intentions, are ultimately one of the main reasons that the patent system is broken; the other three primary reasons have been briefly discussed above.[75]

As we have seen thus far, a language-based patent claim system is part of this problem. Therefore, the patent system is in dire need of more stability. It is worth noting that the idea of seeking stability in patents is already finding root in the conventional patent system. Consider, for example, the principle whereby parties to a patent dispute are not at liberty to argue for more than one meaning to a patent claim that will apply to both validity and infringement. Similarly, the courts give a single meaning to a patent claim in any given case. This idea of singularity reflects the need to construe a clear borderline between the private domain, which is the patent claim and the public domain, which is beyond its coverage.

Thus, what I aim to do in this chapter is to give rise to this approach of singularity. My intent is to advance a clearer, more transparent, and less costly patent system by dealing head-on with the main problem as I see it: the inadequacy of a language-based patent claim/s system. Indeed, in order to fix the patent system, one needs to fix the reasons that caused it to be broken in the first place. This chapter is devoted to that end. In my view, my research project here blends well with previous research projects that have addressed methods that are intended to simplify the patent claims system.[76] For example, Svetlana Sheremetyeva has considered methods

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[74] See *id.* at 1947, 1951. ("The friction theory suffers from three main weaknesses. First, the theory is implausible on empirical grounds. The frictions that supposedly block proper claim breadth, [such as limits of language, mistake, and unforeseeability,] are missing from the leading cases. Second, there is not a convincing answer to the question of why the doctrine of equivalents, rather than some other doctrinal approach, should be used to overcome the frictions. The frictions can be overcome, or at least mitigated, for example, by astutely amending claims during prosecution; . . . through a reissue proceeding after the patent issues; or through artful claim drafting as an initial matter. Third, proponents of a far-reaching DOE fail to pay adequate attention to the notice function of patent claims and are insufficiently sensitive to patent law's delicate incentive dynamic.").

[75] *See supra* Part 2.2.

[76] *See* Svetlana Sheremetyeva , *Automatic Text Simplification for Handling Intellectual Property (The Case of Multiple Patent Claims)*, PROCEEDINGS OF THE WORKSHOP ON AUTOMATIC TEXT SIMPLIFICATION: METHODS AND APPLICATIONS IN THE MULTILINGUAL SOCIETY 41 (Constantin Orasan, Petya Osenova & Cristina Vertan eds., 2014), http://www.aclweb.org/anthology/W14-5605;,

aimed at facilitating the cognitive process of understanding the innovation that is described within patent claims.[77] In that research Sheremetyeva has proposed two levels of simplification: the macro-level and the micro-level.[78] Her proposed macro-level simplification relates to the visualization of the hierarchy of multiple claims.[79] The micro-level simplification, on the other hand, includes visualizing the claim terminology, simplifying the sentences structure of claims (shorter sentences), and building a graph depicting the interrelationship amongst the invention's elements.[80] In her view, with which I agree, achieving such simplification "could increase the overall productivity of human users and machines in processing patent applications."[81] The solution that I suggest is based on similar principles, but is different in its application. In a nutshell, my view is: Patent claims need to be shorter in length, more exact in coverage, and based on mathematical and/or scientific considerations rather than word connotations. Specifically, I would suggest the following elements to be introduced:

a. Visual Aided Claims (VAC)

I think that there needs to be broader use of claim drawings, visual aids to substantiate the text in the claims. Granted, drawings in patent applications are not compulsory and have presently no real legal weight in determining the actual scope of the patented invention. Presently, drawings are used to assist in understanding the invention and especially the specification. But given that the claims are intended to reflect the elements within the specification claimed by the inventor, it follows that attempting to visualize patent claims, by inserting drawings therein, and by making drawing an integral part thereof, is only logical. This does not undermine the patent claims section. In fact, there is no real rationale as to why patent claims need to be in writing. The main aim of patent claims, as I understand it, is to ensure that what is claimed is indeed valid and can withstand a challenge to the contrary. This, in many cases, could be attained by merging the linguistic with the visual. In fact, this merger is likely to reduce linguistic ambiguity and clarify many claims in every given invention.[82] Indeed, I believe that while the patent claims are the legal

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JOE BLOG, SIMPLIFICATION OF PATENT CLAIM SENTENCES FOR THEIR MULTILINGUAL PARAPHRASING AND SUMMARIZATION, http://webcache.googleusercontent.com/search?q=cache:HV2ywgSKyd4J:www.taln.upf.edu/system/files/biblio_files/Bouayad-Agha%2520et%2520al.%2520-%25202009%2520%2520Simplification%2520of%2520Patent%2520Claim%2520Sentences%2520for%2520their.pdf+&cd=1&hl=en&ct=clnk&gl=us;, Nadjet Bouayad-Agha et. al, *Simplification of Patent Claim Sentences for Their Paraphrasing and Summarization* (2009), http://www.aaai.org/ocs/index.php/FLAIRS/2009/paper/viewFile/101/306.

77 Sheremetyeva, *supra* note 77, at 41.

78 *Id.*

79 *Id.*

80 *Id.*

81 *Id.*

82 Bernadette Marshall, *Good Patent Drawings Make a Better Patent Application*, NB GRAPHICS & ASSOCIATES, INC. (2009), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1477386 ("[N]arrative language, discussion and descriptions must be clear and unambiguous." But, in her view, "Imagery is just as critical but is regularly included somewhat as an afterthought." She em-

"fence", they remain contingent on the other elements. It is a symbiotic relationship; the claims should not be out-side the limits of the invention as detailed in the specification section. As such, I support the view that is well articulated by Arnold Silverman: "[I]t is important to employ in the claims technical terms, the meanings of which are clear. One also may employ the specification and, where appropriate, the drawings to make sure that the technical disclosure is clear." [83] In this regard, Christopher Cotropia emphasizes the interconnectivity between the speciation and the claims; he sees the specification as a low-cost source of information for interpreting patent claims.[84] In his view: "The information in the specification is already tailored to and in context with the claim under interpretation. In addition, the specification provides invention-specific information in a low-cost fashion and includes information that caters to an interpreter's familiarity and ease with understanding 'things'".[85]

The correlation between the quality of a patent and the quality of the drawing therein has already been alluded to. Bernadette Marshall contends that: "'[A] picture speaks a thousand words.' That ancient adage certainly holds true in the case of patent drawings. An invention can often be more easily explained through drawings than in reams of description. Accurate, clear drawings strengthen and enhance patent applications, helping overloaded patent examiners to understand inventions faster."[86] But Marshall also states that the drawings not only benefit the patent system on the technical level, (i.e. the patent specification) they also, and in my opinion more importantly, benefit the patent system on the legal level.[87] Here Marshall explains that, "Simple, clear and precise images also help to instruct judges in cases of patent infringement, often clarifying the patent owners' claims and clinching the decision in their favor."[88] Thus, by making room for drawings in patent claims, the entire process of patent construction would be rendered simpler and more precise. In this regard, patent drawings can reflect the interaction between the patent and prior art. The drawings can more precisely, and I would say, more easily, illuminate this connection by adding specific views in order to "illustrate a problem the invention solves, a particular advantage it offers or a need it fulfills."[89]

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phasizes "patent drawings are an integral part of the process and should be considered with the same care as the rest of the patent application.")

83 Arnold B. Silverman, *Watch What You Say—Appellate Court Clarifies Standards for Interpreting Technical Patent Claim Language*, THE MINERALS, METALS & MATERIALS SOC'Y (Apr. 2006), http://www.tms.org/pubs/journals/JOM/matters/matters-0604.html.

84 Christopher A. Cotropia, *Patent Claim Interpretation and nformation Costs*, 9 LEWIS & CLARK L. REV. 57, 59 (2005).

85 *Id.*

86 Bernadette Marshall, *Better Drawings Make a Better Patent*, WIPO MAG., 20 (Apr. 2010), http://www.wipo.int/wipo_magazine/en/2010/02/article_0008.html

87 *Id.*

88 *Id.* at 21.

89 *Id.* ("Prior art can be used to show contrast or to differentiate a new invention from an older one or, for a new invention consisting of an improvement to an existing one, the drawings can show the

I also agree with Marshalls auxiliary remarks whereby clear drawings and (effectively, as a direct result) unambitious patent claims can act as a deterrent to potential infringers, who would otherwise lurk in murky waters. What is more such a clear patent claims construct would also guide other infringers, who might otherwise have stepped into the private domain based on a faulty assessment as to the scope of the patent.[90] In all, the drawings, once formally added into the patent claim system as I submit here, will relieve the patent claims from much of their inherent ambiguity. It is a win-win situation for the inventors, patent examiners, judges, and even competitors acting in good faith. It is justified both in the micro and in the macro-levels of patent policy. Here one might also entertain an idea that visually supported patent claims would also facilitate more effective and less costly computer aided patent searches. Where computers, (just as humans) might not be able to analyze and effectively compare complex language-based claims, they might more easily find similar drawings depicting identical or similar technology. While the final determination as to similarity might be on the individual (examiners, judges etc.), still the initial task of surveying and mapping would be more effectively and speedily achieved using a computer aided program that is geared to identifying "similar" drawings, that themselves constitute or at least are strongly indicative of the 'intention' of the language in a given patent claim.

In order to render this suggestion operable, there will need to be a unification of the drawing requirements in all countries, regions, as well as within the PCT. It is clear that while this is not an easy endeavor it is one that is needed and that is attainable given that the basic drawing requirements are similar in most jurisdictions. Indeed, even now there is already some harmony amongst national patent laws over the form of drawings. In many jurisdictions the respective patent offices requires clear drawing, in black and white with solid black lines on white paper. In those jurisdictions the main difference, as it stands, is the size of the paper.[91]

I should clarify here, that my proposal applies equally to utility patents as well as to design patents, where patent drawings are already widely used and in some cases constitute a requirement for filing.[92] In both cases, drawing should be allowed and even encouraged due to the benefits that can be derived from them.[93] With that

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improved portion with enough of the old invention to demonstrate the connection.")

90 *Id.* at 20 ("Drawings can also work to the advantage of patent holders in negotiating damages or a settlement. Even more important, meticulously prepared drawings that make the patent understandable and unambiguous may mean potential infringers will think twice about copying. The earlier infringement is deterred the better it is for patent owners.").

91 The USPTO allows letter size paper or A4 (with constant margins). 37 C.F.R. § 1.84(f), (g). However, the PCT only accepts size A4. WIPO, PCT r. 11.5, *available at* http://www.wipo.int/pct/en/texts/rules/r11.htm.

92 Marshall, *supra* note 87 at 21 ("According to USPTO guidelines, 'the drawing disclosure is the most important element of the application,' and the drawings in design patent applications 'constitute the entire visual disclosure of the claim.' In well-executed drawings 'nothing regarding the design sought to be patented is left to conjecture.").

93 *Id.* ("Placing an invention in its intended environment can make it more easily understandable, and

being said, the drawings should not be a compulsory part of all patent claims given that in some cases they might not be needed or might even be irrelevant, for example in the case of an active ingredient in a chemical product. Thus, the system needs to make room for drawings in all relevant types of patents, but not to make it a requirement for all patents, because in some cases the patent does not require this.

And on an end note, in this discussion pertaining to drawings, I see no conceptual problem with expanding these visual aids to encompass an audio visual claim system, namely, a short film (animated or otherwise) regarding the working of the invention. Such a system would be of relevance to both the specification decision and to the claims section. In a nutshell, in a world where visual communication has become so dominant, accessible, and developed, there is no reason to keep a language based patent system that is effectively stuck in the nineteenth century!

b. Harmonized Jargon

Another tool that needs to be employed towards creating a more exact patent claim system pertains to the use of a harmonized jargon manual where terms used in patent applications are based on the same exact definitions therein. What I am referring to here is not a jargon of legalistic wording, such already exists; rather my proposal relates to technical words and their meaning and connotation.[94] This, I believe, will assist all concerned in avoiding misunderstandings and sidestepping disagreements. Typically, said disagreements arise in relation to what the patent attorney (or inventor) meant to say and, more importantly, what the patent registrar granted based on the wording of the claim. The jargon can become the patent system's "friend" and ally rather than its burden.[95] Such a jargon-manual would be a rolling project, meaning that it can start with a few basic terms and over time include more terms. The main benefit of a jargon manual would be that all who are engaged in the drafting or interpretation of patent claims would adhere to the meaning therein, thus rendering the terms more harmonized and predictable in their meaning or scope. What is more, as technology progresses, so too new terms will need to be defined as well. In order to lower transition costs, the jargon would only apply to new applications and patents, such that within two decades of its introduction all existing patents will be subject to it. Ideally, this project should be delegated to qualified patent attorneys, each in his or her scientific fields of expertise. It would be, metaphorically speaking, the rock on which all claims would be erected; a far-cry from the ambiguity, and sporadic nature, of the terminology now being used. In

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the drawings themselves can be arranged in such a way that it helps readers to better understand the invention. Plan or elevated views, perspective views, isometric projections, sectional views and exploded views can be used as well.").

94 See, e.g.,Arnold B. Silverman & George K. Stacey, Understanding "Patentese"—A Patent Glossary, http://www.tms.org/pubs/journals/jom/matters/matters-9609.html (an example patent glossary).

95 Woodward, *supra* note 57 at 755 ("[P]rofessional jargon, if properly used, may aid rather than detract from certainty of interpretation and can save a great deal of expensive effort on the part of those most concerned.").

this regard, Lee Petherbridge highlights the existence of the problem of ambiguity by observing: "Perhaps the most obvious way to achieve interpretive flexibility is to seek vagueness when claiming and describing an invention. The use of vague claims increases flexibility because vagueness can enable various arguments to be advanced when seeking the meaning of terms that appear claim terms . . . ".[96] It is worth noting that the *Texas Digital Systems, Inc. v. Telegenix, Inc.*,[97] ruling reflects this tendency to also resort to a formalistic approach of interpretation. In that ruling the court reaffirmed the presumption of the ordinary meaning of a claim and explicitly elevated the dictionaries' role in claim construction.[98] My proposal regarding the establishment of an agreed upon jargon or, if you will, a comprehensive world dictionary, would be a further step toward an external, objective, and consistent interpretation of claims and terms therein.

c. Classification of Claims

Another tool that is intended to create an easier method of communication for patent claims is classification. Every claim would further be classified in a number code that reverts to the Strasbourg Agreement or a classification type that is similar thereto. In my view, the cheapest system for attaining a viable Patent Claim Classification (PCC) would be by resorting to and expanding on the already existing classifications of patents as set by the *Strasbourg Agreement Concerning the International Patent Classification*[99] of 1971, and as amended in 1979 (IPC). This agreement, to which 62 countries are now parties, is used by the patent offices of more than 100 countries as well as four regional offices and the secretariat of the World Intellectual Property Organization (WIPO) under the Patent Cooperation Treaty.[100] The *Strasburg Agreement* (IPC) has proved its worth in the retrieval of patent documents when searching for *prior art.* It is widely used by patent-issuing authorities; potential inventors; research and development units; and others concerned with the application or development of technology. The international classification is dependable because it is continuously revised.[101] This classification applies to various documents relating to patents for invention including published

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96 Lee Petherbridge, *Sympoosium: on the Development of Patent*, 43 LOY. L.A. L. REV. 893, 902 (2010).

97 308 F.3d 1193 (Fed. Cir. 2002); *See also,* Jennifer R. *Johnson, Out of Context: Texas Digital, the Indefiniteness of Language, and the Search for Ordinary Meaning*, 44 IDEA 521, 532 (2004).

98 *See* Ruoyu Roy Wang, *Texas Digital Systems v. Telegenix, Inc.: Toward A More Formalistic Patent Claim Construction Model*, 19 BERKELEY TECH. L.J. 153 (2004).

99 Strasbourg Agreement Concerning the International Patent Classification, Mar. 24 1971, 26 U.S.T. 1793, 1160 U.N.T.S. 483.

100 *See Summary of the Strasbourg Agreement Concerning the International Patent* Classification (1971), WIPO, http://www.wipo.int/treaties/en/classification/strasbourg/summary_strasbourg.html., (the *Patent Cooperation Treaty* established a system for attaining multiple registrations of patents around the world by using WIPO International Bureau).

101 *Id.* (the current 9th Edition entered into force on January 1, 2009; the revision is conducted by a Committee of Experts in which all member states are represented).

patent applications, inventors' certificates; utility models and utility certificates. It is open to all countries that are member of the *Paris Convention*.[102] As such, this system of classification facilitates "an effective search tool for the retrieval of patent documents by intellectual property offices and other users, in order to establish the novelty and evaluate the inventive step or non-obviousness (including the assessment of technical advance and useful results or utility) of technical disclosures in patent applications".[103] Furthermore, the *Strasbourg Agreement* can be utilized in order to achieve other goals, namely to facilitate access to the technological and legal information contained therein.[104] The IPC is sufficiently detailed so as to allow for a precise classification of all patentable subject matter. The IPC provides for a detailed hierarchal structure of classification. The highest part of that hierarchy is comprised of 8 broad sections. Each section is designated by one of the capital letters A through H. Each section carries a title that provides a broad description of the relevant section, namely. A: Human Necessities; B: Performing Operations and Transporting; C: Chemistry and Metallurgy; D: Textiles; Paper; E: Fixed Constructions; F: Mechanical Engineering, Lighting, Heating, Weapons, and Blasting; G: Physics; H: Electricity.[105] Each section is subdivided into classes which are the second hierarchical level of this system of classification. Each class symbol consists of the section symbol followed by a two-digit number. The class title gives an indication of the content of the class.[106] Each class, in turn, comprises one or more subclasses which are the third hierarchical level in this method of classification. The subclass title indicates as precisely as possible the content of the subclass.[107] Each

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[102] *Id. See also* Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S.305. English and French are the working languages of that agreement. Strasbourg Agreement Concerning the International Patent Classification art 3(1), Mar. 24 1971, 26 U.S.T. 1793, 1160 U.N.T.S. 483. Pursuant to Article 3(2) of the Strasbourg Agreement, official texts of the Classification may be established in other languages.

[103] WIPO, *International Patent Classification (Version* 2015), *Guide*, 1, WIPO, http://www.wipo.int/export/sites/www/classifications/ipc/en/guide/guide_ipc.pdf. (The text of the first edition of the Classification was established pursuant to the provisions of the European Convention on the International Classification of Patents for Invention of 1954. Following the signing of the Strasbourg Agreement, the International (European) Classification of Patents for Invention, which had been published on September 1, 1968, was as of March 24, 1971, considered and referred to as the first edition of the Classification. Guide to the IPC (2015).).

[104] Its other aims are intended to include the creation of a basis for selective dissemination of information to all users of patent information; investigating state-of-the-art technology in given fields; the preparation of industrial property statistics which in turn permit the assessment of technological development in various areas. *Id.* at 1. Between 1974-2005, the IPC has been periodically revised in order to improve the system and to take account of technical development. *Id.* at 2-3. Following the conclusion of its reform in 2005, the IPC was divided into core and advanced levels. *Id.* at 2. Specifically the core level is updated once every three years and the advanced level is continually revised. *Id.*

[105] *Id.* at 4. Each section title is followed by a summary of the titles of its main subdivisions; within sections, informative headings may form subsections, which are titles without classification symbols (e.g. Section A (Human Necessities) contains the following subsections: Agriculture; Foodstuffs; Tobacco; Personal or Domestic Articles; Health; Amusement. *Id.*

[106] E.g. H01 Basic,Electric Elements.

[107] E.g. H01S Devices Using Stimulated Emission; *see supra* note 105 at 5. Most subclasses have an

subclass is broken down into subdivisions referred to as "groups," which are either main groups (i.e., the fourth hierarchical level of classification) or subgroups.[108] The subclasses are further divided into subgroups. In all, the IPC creates approximately 70,000 subdivisions.[109] As such, the IPC provides an internationally uniform classification of patent documents and functions as an effective search tool for the retrieval of patent documents by intellectual property offices.

My proposal is to extend the patent classification further into each patent claim. I believe that the IPC's meticulous system of classification can be utilized, as a basis for classifying patent claims. For this purpose, the same body of experts that are entrusted with the task of classifying patents can now be delegated the task of further classifying patent term types.[110]

My proposed system of classification would also need to address two more challenges: the possibility for multiple classifications of a single patent claim and the prospect of changes in the field of innovation. In my opinion the first challenge can be tackled by opting for a system that would be contingent on the *dominant technology* that exists within the invention. As for the second challenge, I would propose a mechanism for the periodical review of the *technology*. Thus, any change in the field of technology of a certain innovation can be immediately translated into the new classification for the patent's duration.

To sum up, the use of the existing IPC would entail fewer costs and can be more easily introduced into the respective national laws of countries. The IPC's well-established structure; within the international patent regulative framework make it the cheapest and most accessible method for classifying technology for my proposed model. But above all, my proposed system of classification would allow inventors to state a clear classification for each patent claim thus clarifying the intent with respect to the said claim, and rendering the patent claims a stronger "fence" in the face of those seeking to infringe the invention. Such a clearly marked fence around the invention can prevent the trespass by others who might otherwise act using the pretense of vague patent claim language. A good and viable system of classification would thus be a win-win for all, except for premeditated infringement; wherein said (classified) claims would act as a more effective deterrent. This patent

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index which is merely an informative summary giving a broad survey of the content of the subclass. *Id.* The electronic version of the IPC allows users to view the content of a subclass also by order of complexity of the subject matter.

[108] *See supra* note 105 at 5. Each group symbol consists of the subclass symbol followed by two numbers separated by an oblique stroke e.g. H01S 3/00. *Id.*

[109] *See Summary of the Strasbourg Agreement Concerning the International Patent Classification* (1971), WIPO, http://www.wipo.int/treaties/en/classification/strasbourg/summary_strasbourg.html (The appropriate IPC symbols are indicated on patent documents (published patent applications and granted patents), of which over 2,000,000 are issued each year. The appropriate symbols are allotted by the national or regional industrial property office that publishes the patent document).

[110] Understandably, the determination of the respective patent terms for each class of patent claims may require consulting with experts who are familiar with the particular market at issue.

claim classification PCC would not only assist in patent searches and in finding prior art but would also, metaphorically speaking, place the invention or a specific claim in a more exact point in the innovative space; a sort of three-dimensional placement of the claim in the technological sphere. This classification is intended to bring all forms of scientific discovery into a clearer realm.

d. Condensing Claims

Another tool, which I suggest to employ, involves the way patent claims are worded. Specifically, my proposal here is to reduce every claim to one clear sentence where possible, so as to reduce the problem of defining, explaining or interpreting long sentences or photographs. The approach to wording patent claims needs to be primarily qualitative rather than overly quantitative. It is important to note that a one sentence rule formally exists where, at least in the case of USPTO, there is a requirement according to which each claim in a patent must be written as a single sentence, although sub-paragraphing is encouraged.[111] It is worth noting that this is not easy to apply. Indeed, patent attorneys have found ways in which to circumvent this rule by creating virtually unreadable patent claims.[112] In my view, this is unacceptable. Thus, shorter (and clearer) sentences and terms as described above are likely to further assist in alleviating the potential for complicated and long sentences under which much ambiguity can 'take flight'.

e. Modular Structure for Claims

Another method that should be employed, and which I believe can reduce the interpretation burden in patent claims is to invoke a modular structure for claims, that is, to divide any invention into three claim segments: the structural, the functional and the material. An inventor needs to place each of his claims into any one of the three segments. The first segment is focused on the structural, that is to say, elements that are used to build the structure of the patented invention. For example, in the context of a frying pan this would include matters such as the length of the handle, the size of the pan, its depth and other dimensions. Second, the functional part would describe what is claimed by way of its functionality. For example, assume that we are dealing with an invention of a solar-powered frying pan. In this case the structural segment in the patent claim section would deal with the size and dimensions of the pan. The structural segment would create an exclusion for the

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[111] *See, e.g.*, THE USPTO MANUAL OF PATENT EXAMINING PROCEDURE, SECTION 608/01(M) FORM OF CLAIMS (R-1), (9th ed. 2014). ("While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with 'I (or we) claim, 'The invention claimed is' (or the equivalent) . . . Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations . . . Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation.").

[112] D. C. Toedt, For faster, clearer patent applications, defy the USPTO's Single-Sentence Rule, ON CONTRACTS (Dec. 10,2007), http://www.oncontracts.com/multi-sentence-claims/.

dimensions of the pan, if it has one or two handles, or any other defining structural element that is claimed. In the functional section the inventor will claim the elements in his invention that allow the transformation of solar energy into heat, and thus to fry foods. And last, in the material section, the inventor can claim certain materials or types of materials that can be used to manufacture the pan (e.g. glass, porcelain, aluminum, steel etc.). In this way, and by looking at any invention as a three-tier construct, it is possible to at least have an indication, when constructing a given patent claim, as to its intended overall aim of coverage. This would ultimately compel inventors, and their patent agents, to be more precise in their claims and leave less room for linguistic ambiguity. In essence it would help create a stronger and more exact "fence". That would guard the inventor from the public domain, and would also protect the public domain from potential intrusion by the private domain. It is worth noting that this endeavor of erecting the "fence" correctly is intended to ensure that the inventor does not receive protection that is broader in scope than his contribution to the art. This was made evident in *EXXON/Fuel Oils*[113] where the Technical Board of the European Patents Office (EPO) stated: "[C]laims must be supported by the description, in other words it is the definition of the invention in the claims that needs support. . . [T]his requirement reflects the general legal principle that the extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art in order for it to be supported, or justified."[114] This view embodies the doctrine of "sufficiency".[115]

f. Auxiliary Tools

In addition to the four primary tools that constitute the core of my proposed model, there are additional auxiliary tools, which I believe, can also contribute to the success of the proposed model.

i. Applicant Record Indication

A more personalized tool to combat patent claim ambiguity is, where applicable, to subject any given claim to identical wording in other patents owned or registered by the same applicant. That is to say, patent owners would not be allowed to suggest alternate meanings to terms in patent claims that they have previously used. This binds an applicant and holds him to his own words; under this approach an applicant is deemed to aim for a specific meaning for every term or word that he uses. In this way applicants will need to think well before stating a certain word, phrase

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[113] See, Decision T409/91, *EXXON/Fuel Oils* 1994 O.J. E.P.O. 653.

[114] *Id.* at 659.

[115] For more on the doctrine of Sufficiency see Sivaramjani Thambisetty , The Evolution of Sufficiency in Common Law, London School of Economics and Political Science (2013), LSE Legal Studies Working Paper No. 6/2013; Robin Feldman , The Inventor's Contribution, 6 UCLA Journal of Law & Technology, (2005) ; Timothy R. Holbrook , Patents, Presumptions, and Public Notice, 86 Indiana Law Journal, 779, (2011).

or term in a specific context. This also allows for a certain stability in the text and maintains coherence across claims and even separate patent registrations.

ii. Patent Domain Dispute Procedure

Another way to preempt costly conflicts over patent claims and solve potential problems in this regard, would be to create a patent claim dispute settlement procedure. Such a procedure would be geared toward settling claim-related disputes before they mature into full-fledged problems. This is to try to preempt larger legal disputes down the road. It seems to me that *ad-hoc* arguments or disputes over specific claims need to be handled without delay and addressed from the outset. Just as with trademarks, a determination of non-distinctiveness needs to be resolved for patent claims. The faster such issues are set aside and dealt with amicably, the less potential for costly, complicated litigation down the road, when the parties are already deeply invested in the technology and in its use. It is worth noting that in the case of trademarks the WIPO Domain Name Dispute Settlement Process could act as a useful example to a professional dispute settlement. A professional impartial entity can deal with it in an efficient manner. The semi-privatization of patent claim disputes may also alleviate the workload of patent examiners and patent registrars.

iii. Progressive Fees

Finally, I would suggest setting progressive patent fees that are based on the level of complexity and length of the patent claims therein. This might create an incentive for inventors to work more diligently to produce shorter, more concise, and clearer patent claims. This approach is also logical in that it not only creates an incentive but also factors in the time that examiners will need to invest in order to examine the patent application and the claims therein. Granted, utilizing monetary incentives in this context may be a risky tool, since, some inventors will not be deterred by large sums of monetary fees if the patent that they seek is worth more to them. This would fit into the logic of efficient breach.[116] Indeed, it is hard from the beginning to foresee the impact of such progressive fees that cannot in and of themselves deter this practice of complicated and expansive language in patent claims. Yet, in addition to the other tools used here, the use of progressive fees could create a sufficient incentive towards the simplification of patent claims.

Summary

In this paper, I have argued that patent prosecution and litigation is far too expensive and complex. This is owed to various factors, predominantly the conven-

[116] See generally,Stephen Michael Waddams, Breach of Contract and the Concept of Wrongdoing, 12 S.C.L.R. , 1, (2000) (this doctrine has for over five decades been a point of contention between two schools of thought).

tional system of language-based patent claims. The power of words is not limitless, and when it comes to patent claims ambiguity has been and remains a substantial block in erecting the legal "fence" around innovation that comprises patent claims that are the building blocks of the patent system. In this research, I have proposed methods to render the patent system more exact and less costly. I have done this in chapter three where I have suggested ways in which to shift away from total reliance on a language-based system to a multitier system where words are only one competent of the patent claim. It is my belief that this proposed model can overcome the inadequacies of the language-based patent system and make up for the "unlimitless" power of words in patent claims.