

**CLOSING THE WILLFUL
INFRINGEMENT FLOODGATES:
THE EFFECTS OF *IN RE SEAGATE* BOTH
INSIDE AND OUTSIDE THE GENERIC
PHARMACEUTICAL LITIGATION ARENA**

By

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I. INTRODUCTION

Proper resolution of the dilemma of an accused infringer who must choose between the lawful assertion of the attorney-client privilege and avoidance of a willfulness finding if infringement is found, is of great importance not only to the parties but to the fundamental values sought to be preserved by the attorney-client privilege.²

In the above quote, the United States Court of Appeals for the Federal Circuit (Federal Circuit) characterized the competing interests involved where an accused patent infringer relies upon the advice of counsel defense to combat an allegation of willful infringement.

Compelled by the Federal Circuit to show “due care” to respect presumptively valid patent rights, an accused infringer had to secure an opinion from competent patent counsel on the issues of

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2. *Quantum Corp. v. Tandon Corp.*, 940 F.2d 642, 643 (Fed. Cir. 1991).

validity, infringement, or enforceability of the patent-in-issue. However, to effectively utilize this opinion in litigation, the accused infringer necessarily had to waive the attorney-client privilege and decline the protections afforded by the work product immunity doctrine in connection with that opinion. These draconian measures were taken to show the accused infringer's good faith reliance on the advice of counsel to avoid a finding of willfulness and resultant enhanced damages, as well as possible attorney fees in those willfulness cases which the court deemed exceptional under the Patent Act.

This judicially-crafted framework had its beginning shortly after the creation of the Federal Circuit. Aimed at remedying the missteps of "widespread disregard of patent rights,"³ the case law beginning with *Underwater Devices*,⁴ and evolving through *Kloster Speedsteel*,⁵ *Knorr-Bremse*,⁶ and *EchoStar*,⁷ created a structure prompted by laudable intentions, but saddled the parties with practical and costly challenges stemming from vitiating the attorney-client privilege and work product doctrine. However, this Federal Circuit structure became a Trojan horse of maladies, embroiling the parties in costly, discovery-intensive litigation even before the claims, the real heart of an infringement suit, were construed.

The Federal Circuit recognized corrective action was needed and that *In re Seagate* provided the platform to revise the willfulness standard and limit the privilege and immunity waivers associated with the advice of counsel defense.⁸ In a significant reversal, the patentee now has the burden of showing "objective recklessness" to establish willful infringement.⁹ The Federal Circuit further

3. *Knorr-Bremse Systeme Fuer Nutzfahreuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1343 (Fed. Cir. 2004) (en banc) (citing ADVISORY COMMITTEE ON INDUSTRIAL INNOVATION FINAL REPORT, DEP'T OF COMMERCE (1979)).

4. *Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380 (Fed. Cir. 1983).

5. *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565 (Fed. Cir. 1986).

6. *Knorr-Bremse*, 383 F.3d 1337.

7. *In re EchoStar Commc'ns Corp.*, 448 F.3d 1294 (Fed. Cir. 2006) (en banc).

8. *See In re Seagate Tech., LLC*, 497 F.3d 1360 (Fed. Cir. 2007) (en banc).

9. *See infra* notes 49-106 and accompanying text (discussing the evolution of case law pertaining to willful infringement).

raised the bar that a patentee must meet to show willfulness and significantly narrowed the scope of waiver that a defendant risks from relying on an opinion counsel to defeat a claim of willfulness.¹⁰

Seagate also sounds a potential death knell to pleading naked allegations of willful infringement in patent suits between brand-name and generic drug companies in a Hatch-Waxman dispute. The Hatch-Waxman procedures require a methodical, sequenced progression of analysis and activity surrounding the patentee's rights.¹¹ A generic company accused of willful infringement in this setting can point to the process itself, as well as other filings required within the process, *i.e.*, the notice letter, to show the absence of "objective recklessness."

And, *Seagate* may provide a district court with the authority to establish a bright line rule that willful infringement may not be alleged in ANDA litigation, subject to amending the complaint should discovery reveal disregard for the innovator company's patent. Indeed, the Federal Circuit invited the district courts to engage in this type of analysis when it stated, "[w]e leave it to future cases to further develop the application of this standard."¹²

This article begins with a scenario in the general counsel's office of a generic drug company navigating the ANDA process and transitions to a brief overview of relevant patent law principles to provide points of reference for the discussion of willful infringement and waiver of the attorney-client privilege and attorney work product immunity associated with the advice of counsel defense which follows. The evolution of the Federal Circuit's jurisprudence on the question of willful infringement and privilege waiver is examined.

Seagate is briefed with particular attention to the new "objective recklessness" standard and the attendant issues involving the attorney-client privilege and attorney work product immunity. With these principles established, discussion proceeds to the relevant portions of Hatch-Waxman and *Seagate's* impact in the

10. *See Seagate*, 497 F.3d 1360.

11. *See Drug Price Competition and Patent Term Restoration Act of 1984*, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended 21 U.S.C. § 355 (2006)).

12. *Seagate*, 497 F.3d at 1371.

ANDA setting, demonstrating that innovator plaintiffs will likely be unable to survive a generic company's motion to strike any "naked" allegation of willfulness, motion for judgment on the pleadings, motion to dismiss, or motion for summary judgment as to willful infringement given the higher standard of "objective recklessness" when applied to the ANDA process and its required filings.¹³

II. A HYPOTHETICAL EXAMPLE SHOWING THAT THE ANDA PROCESS, BY ITS STATUTORY CONSTRUCT, CONTEMPLATES THE ABSENCE OF "OBJECTIVE RECKLESSNESS" AND PUTS AN END TO NAKED ALLEGATIONS OF WILLFUL INFRINGEMENT BETWEEN INNOVATORS AND GENERIC PHARMACEUTICAL COMPANIES IN LIGHT OF *IN RE SEAGATE*

As counsel for a generic pharmaceutical company, your business model envisions identifying innovator drugs already approved by the Food and Drug Administration (FDA) which are being sold in the United States, developing the bioequivalent of that drug, and seeking entry into the market through the procedures commonly referred to as "Hatch-Waxman."¹⁴

In this instance, you have already reviewed the "Orange Book"¹⁵

13. *See, e.g.,* *Aventis Pharma Deutschland GMBH v. Cobalt Pharms., Inc.*, 355 F. Supp. 2d 586, 592 (D. Mass. 2005) (granting defendant's motion for judgment on the pleadings on plaintiff's willful infringement claim).

14. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at scattered sections of Titles 21, 35, and 42 of the United States Code) (commonly referred to as "the Hatch-Waxman Act").

15. Formally known as the Approved Drugs With Therapeutic Equivalence Evaluations, the compilation is commonly referred to as the "Orange Book"; *see also* 21 U.S.C. § 355(b)(1) (2006) (requiring NDA filers to submit "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug"); Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36,676 (June 18, 2003).

containing information on FDA approved drugs and identified the target. You retain outside patent counsel to review the patent covering the drug and to provide you with a written opinion discussing the validity, infringement, or enforceability of the patent. Upon review of outside counsel's opinion, you learn that two pieces of prior art, had they been before the patent examiner at the United States Patent and Trademark Office (USPTO), would have made this formulation obvious to one possessing ordinary skill in the art at the time of the underlying patent application.¹⁶ Consequently, there is a good faith basis to believe that the patent covering this drug is invalid. As such, you may lawfully seek entry into the market prior to the expiration of the innovator company's patent.

Accordingly, you counsel senior management that to gain FDA approval as a bioequivalent generic version of the innovator's drug, an abbreviated new drug application (ANDA)¹⁷ containing a "paragraph IV" certification is appropriate.¹⁸ In your paragraph IV certification, you certify that the patent covering the innovator drug is invalid, will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted, or is unenforceable."¹⁹

You are mindful your ANDA filing constitutes a statutory act of infringement and you potentially face having to defend a patent infringement lawsuit, which will often involve an allegation of willful infringement, given your clear awareness of the Orange Book patent.²⁰ As an incentive, though, your company, as the first generic ANDA-filer, stands to gain a 180-day exclusivity period as

16. See generally, *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007) (combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results).

17. See 21 U.S.C. § 355(j); see also 21 C.F.R. § 320.1(e) (1994) (defining bioequivalence as "the absence of significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study").

18. See 21 U.S.C. § 355(j)(A)(vii)(IV); see also *infra* notes 159-61 and accompanying text.

19. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

20. *Id.* § 271(e)(2)(A).

the only FDA-approved generic, which could lead to substantial financial successes outweighing the costs of the patent infringement defense.²¹

After you file with the FDA, you notify the innovator company of your filing by and through a Notice Letter.²² The Notice Letter must contain the detailed factual and legal basis for your claim of invalidity, non-infringement, or unenforceability.²³ The innovator company has 45-days to file a patent infringement lawsuit based upon the statutory act of infringement created by your ANDA filing.²⁴ Doing so will result in a 30-month stay of the FDA's approval of the ANDA, which will remain in effect until the suit is completed or the expiration of the time prescribed.²⁵ Alternatively, the 45 days can run, your ANDA is approved, and your company launches its product. At some point thereafter, the innovator company can nevertheless file a patent infringement lawsuit, with damages potentially available given your company's sales.

In either setting, the resulting lawsuit often includes allegations that the generic company willfully infringed the patent-at-issue, thereby forcing the generic to defend against those allegations, exposing the company to treble damages up to three times the amount of actual damages, allowing discovery on the related issues, and laying the groundwork for a potential claim of an exceptional case for purposes of securing an award of attorney fees.

Although rarely successful, pleading willful infringement often provided a strategic benefit because it forced a generic company to disclose the opinions on which it relied with regard to the validity, infringement, or enforceability of the brand-name company's patent. And, discovery was appropriate into these areas, involving not only document requests and interrogatories, but also depositions of counsel, and potential disqualification of law firms.

21. *See id.* §§ 355(j)(5)(B)(iv), (5)(D). These provisions govern the 180-day exclusivity period given to the first company to file an abbreviated new drug application with a paragraph IV certification.

22. *See id.* § 355(j)(2)(B).

23. *See id.*

24. *Id.*

25. 21 U.S.C. § 355(j)(5)(B)(iii).

In addition to “raising the bar” and making it more challenging to successfully plead and prove willfulness, the decision in *Seagate* heightens the importance of the notice letter a generic company issues to an innovator company as part of an ANDA filing. Among other requirements, this notice must include “a detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.”²⁶ The FDA regulations also require, for a patent alleged not to be infringed, an explanation of the theory of non-infringement.²⁷ Where the claim is that the patent is invalid or unenforceable, the regulation requires a full and detailed explanation of that assertion.²⁸

By providing the innovator company with this detailed factual and legal basis of the generic applicant’s opinion, it appears that in light of *Seagate*’s higher standard, the generic company is well-positioned to demonstrate the absence of “objective recklessness.” Indeed, the very ANDA approval process itself is mindful of the innovator’s presumptively valid patent rights, and requires a generic company to evaluate the innovator’s patent and certify a lack of infringement or invalidity, such that following those procedures ineluctably shows methodical consideration rather than “objective recklessness.”

Consequently, brand-name plaintiffs may be precluded from alleging willful infringement in their complaints due to the direct evidence in the form of a detailed factual and legal basis in the ANDA notice letter, already produced to the innovator prior to litigation, showing the absence of objective recklessness. This preclusion is, in fact, the result of a process designed to respect the presumptive rights of an innovator company’s patent(s).

Before considering the Federal Circuit’s willfulness case law, a brief introduction to fundamental patent law principles may be helpful to provide a basis to place *Seagate* and its application to generic and innovator pharmaceutical companies.

26. 21 C.F.R. § 314.95(c) (2003). The quoted language tracks the statute, with the potentially important exception that FDA has added the word “unenforceable.”

27. *Id.* § 314.95(c)(6)(i).

28. *Id.* § 314.95(c)(6)(ii).

III. GENERAL PATENT LAW PRINCIPLES: BACKGROUND FOR SEAGATE AND ANDA LITIGATION

Article I, Section 8, clause 8 of the United States Constitution vested power in Congress “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.”

Congress has from time to time used this power to enact various iterations of the patent statute, and today, the statute is found at Title 35 of the United States Code. By its terms, a patent confers the right to exclude others from making, using, selling, offering for sale, or importing into the United States the patented invention.²⁹ These rights become relevant when an individual engages in one of the five enumerated activities. Regardless of their intent, parties who engage in those acts without the permission of the patentee during the term of the patent can be liable for infringement.

The patentee may file a civil suit in federal court in order to enjoin infringers and obtain monetary remedies under federal question jurisdiction.³⁰ Although issued patents are presumed valid, accused infringers may, by clear and convincing evidence, show that the patent is invalid or unenforceable on a number of grounds.³¹ It is said in patent law that the claims define the invention; a patent claim is a single sentence definition of the exact scope of the intangible property right asserted by the inventor.³² The rights United States patents provide are effective only in the United States.³³

Literal patent infringement occurs if the accused composition or method includes every element exactly as recited in at least one of its claims.³⁴ Under this standard of absolute identity, if an accused product or process includes fewer elements or steps than were recited in the claims, there is no literal infringement. In some

29. 35 U.S.C. § 271(a) (2006).

30. *Id.* § 281; 28 U.S.C. § 1331 (2006).

31. 35 U.S.C. § 282.

32. *Id.* § 112.

33. *Dowagiac Mfg. Co. v. Minn. Moline Plow Co.*, 235 U.S. 641, 650 (1915).

34. John R. Allison & Mark A. Lemley, *The (Unnoticed) Demise of the Doctrine of Equivalents*, 59 STAN. L. REV. 955, 958-59 (2007).

instances, the scope of protection associated with a patent may be expanded beyond the literal wording of the claims under the doctrine of equivalents.³⁵ Under the doctrine of equivalents, an accused product that presents insubstantial differences from the claimed invention will be judged an equivalent and therefore an infringement.³⁶

The Patent Act sets forth the remedies a patentee may obtain upon a finding of infringement. These remedies include injunctions,³⁷ monetary damages,³⁸ and attorney fees.³⁹ The statute also allows for damages to be increased by up to three times the amount found.⁴⁰

Section 283 of the Patent Act allows courts to “grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.” The Patent Act also provides for the award of damages “adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer.”⁴¹

However, monetary recovery is limited to events occurring within six years prior to the filing of the complaint or counter claim for patent infringement.⁴² Damages can take the form of lost profits if the patentee can reasonably show that “but for” the infringement, he would have made the sales made by the infringer.⁴³ To do so, a patentee must normally show that (1) the patented product was in demand; (2) no acceptable noninfringing substitute was available; (3) the patentee or its licensees possessed the manufacturing and marketing capability to exploit the demand; and (4) the amount of profit the patentee would have made.⁴⁴

35. John M. Benassi et al., *Claim Construction and Proving Infringement: Impact of Phillips and Festo and Their Progeny*, 910 PLI/PAT 57, 91 (2007).

36. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997).

37. 35 U.S.C. § 283.

38. *Id.* § 284.

39. *Id.* § 285.

40. *Id.* § 284.

41. *Id.*

42. *Id.* § 286.

43. *See Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1551 (Fed. Cir. 1994).

44. *Panduit Corp. v. Stahl Bros. Fibre Works*, 575 F.2d 1152, 1158-59 (6th

The statute also provides that the award of damages to a prevailing patentee shall be no less than a reasonable royalty.⁴⁵ To determine this amount, the court engages in a legal fiction of a hypothetical licensing negotiation.⁴⁶

Section 287(a) of the Patent Act provides that patentees should affix the word “patent” or the abbreviation “pat.” on the product-in-issue, along with the number of the patent. If the patentee fails to mark in the specified manner, however, then damages can be limited only for acts occurring after the infringer receives actual notice of the infringement.⁴⁷

The Patent Act vests the trial court with the discretion to triple damages. Whether damages are determined by the court or the jury, “the court may increase the damages up to three times the amount found or assessed.”⁴⁸ Furthermore, “[b]ecause patent infringement is a strict liability offense, the nature of the offense is only relevant in determining whether enhanced damages are warranted.”⁴⁹

And, the Patent Act provides that “the court in exceptional cases may award reasonable attorney fees to the prevailing party.”⁵⁰ Where the prevailing party is the patent owner, the circumstances that make a case exceptional for the award of attorney fees generally align with those that would justify increased damages, namely, willful infringement.⁵¹

Cir. 1978).

45. 35 U.S.C. § 284.

46. *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp 1116, 1131-32 (S.D.N.Y. 1970).

47. *See* *Devices for Medicine, Inc. v. Boehl*, 822 F.2d 1062 (Fed. Cir. 1987).

48. 35 U.S.C. § 284.

49. *In re Seagate Tech., LLC*, 497 F.3d 1360, 1368 (Fed. Cir. 2007).

50. 35 U.S.C. § 285.

51. *Amsted Indus. Inc. v. Buckeye Steel Castings Co.*, 23 F.3d 374, 377 (Fed. Cir. 1994).

IV. WILLFUL INFRINGEMENT—FEDERAL CIRCUIT’S
JURISPRUDENCE

A. *The Totality of the Circumstances*

A finding of willfulness requires the fact finder to find by clear and convincing evidence “that the infringer acted in disregard of the patent.”⁵² “Willful infringement” is not just a means to enhance damages but also a statement that patent infringement, akin to other civil wrongs, is disfavored; “an intentional disregard of legal rights warrants deterrence.”⁵³

As the Federal Circuit has noted, the “[r]emedy for willful infringement is founded on 35 U.S.C. § 284,” which authorizes the trial judge to increase the damages up to three times the amount found or assessed, and 35 U.S.C. § 285, which empowers the trial judge to declare a case “exceptional” and award reasonable attorney fees to the prevailing party.⁵⁴ Indeed, the circumstances that make a case exceptional for the award of attorney fees generally align with those that would justify enhanced damages for willful infringement.⁵⁵

Although the statute does not specifically set forth the basis upon which damages may be enhanced, it is well-settled that where infringement has been specifically found by clear and convincing evidence to be “willful,” the court is authorized, but not required, to treble the damages.⁵⁶ Absent a statutory guide, the court has held that an award of enhanced damages requires a showing of willful infringement,⁵⁷ and this standard accords with Supreme Court precedent.⁵⁸

The determination of willfulness is made by assessing the

52. *Stickle v. Heublein, Inc.*, 716 F.2d 1550, 1565 (Fed. Cir. 1983).

53. *Knorr-Bremse Systeme Fuer Nutzfahreuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1342 (Fed. Cir. 2004).

54. *Id.*

55. *Amsted*, 23 F.3d at 376.

56. *Id.*

57. *See Jurgens v. CBK, Ltd.*, 80 F.3d 1566, 1570 (Fed. Cir. 1996).

58. *See Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 508 (1964) (enhanced damages were available for willful or bad faith infringement).

totality of the circumstances.⁵⁹

“Fundamental to the determination of willful infringement is the duty to act in accordance with law.”⁶⁰ In *Read Corp. v. Portec, Inc.*, the Federal Circuit explained that the most important consideration in willful infringement cases is the egregiousness of the defendant’s conduct based on all the facts and circumstances.⁶¹ At trial, there must be a finding of actual infringement, and then a separate finding by the fact finder of whether the defendant’s infringement was willful.⁶² In reaching its decision, the fact finder must consider the totality of circumstances, which includes the following factors:

- (1) whether the infringer deliberately copies the ideas or design of another;
- (2) whether the infringer, when he knew of the other’s patent protection, investigated the scope of the patent and formed a good faith belief that it was invalid or that it was not infringed;
- (3) the infringer’s behavior as a party to the litigation;
- (4) defendant’s size and financial condition;
- (5) closeness of the case;
- (6) duration of defendant’s misconduct;
- (7) remedial action by the defendant;
- (8) defendant’s motivation for harm; and
- (9) whether the defendant attempted to conceal its misconduct.⁶³

“‘Willfulness’ in infringement, as in life, is not an all-or-nothing trait, but one of degree. It recognizes that infringement may range from unknowing, or accidental, to deliberate, or reckless, disregard of a patentee’s legal rights.”⁶⁴ A finding of willfulness does not require an award of enhanced damages, it merely permits it.⁶⁵

59. *Rolls-Royce Ltd. v. GTE Valeron Corp.*, 800 F.2d 1101, 1110 (Fed. Cir. 1986).

60. *Knorr-Bremse Systeme Fuer Nutzfahreuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1343 (Fed. Cir. 2004).

61. *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826 (Fed. Cir. 1992).

62. *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1225 (Fed. Cir. 2006).

63. *Id.*

64. *Rite-Hite Corp. v. Kelley Co.*, 819 F.2d 1120, 1125-26 (Fed. Cir. 1987).

65. *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259 (Fed. Cir. 1999).

In *Underwater Devices, Inc. v. Morrison-Knudsen Company, Inc.*, the Federal Circuit may have been mindful of these principles and the mandate behind the court's very creation, which is to remedy the widespread disregard of patent rights that undermines the national innovation incentive.⁶⁶

B. Underwater Devices – “Due Care” to Obtain an Opinion of Counsel

In *Underwater Devices*, the patentee alleged willful infringement. The accused infringer defended by contending that it proceeded with the infringing activity in good faith based on reliance of its counsel.⁶⁷ Reviewing the district court's finding of willful infringement under the clearly erroneous standard, the Federal Circuit affirmed not only the finding, but also the trebling of the damages to the maximum authorized, as well as the award of attorney fees.⁶⁸

The court reasoned, “where, as here, a potential infringer has actual notice of another's patent rights, he has an affirmative duty to exercise due care to determine whether or not he is infringing.”⁶⁹ The court further reasoned that “[s]uch an affirmative duty includes, *inter alia*, the duty to seek and obtain competent legal advice from counsel *before* the initiation of any possible infringing activity.”⁷⁰

The accused infringer, who had actual notice of the patents-at-issue, did not evaluate the validity or infringement of the patents before beginning infringing activities.⁷¹ The accused infringer ordered the file histories “well after the infringement had begun,” and did not receive the opinion of its patent counsel until long after infringement had begun and after the complaint was filed.⁷²

And, the court flatly rejected the quality of counsel's patent

66. ADVISORY COMMITTEE ON INDUSTRIAL INNOVATION FINAL REPORT, DEP'T OF COMMERCE (1979).

67. *Underwater Devices, Inc. v. Morrison-Knudsen Company, Inc.*, 717 F.2d 1380, 1389 (Fed. Cir. 1983).

68. *Id.*

69. *Id.* at 1390.

70. *Id.* (emphasis in original).

71. *Id.*

72. *Id.*

opinions, consisting of several memoranda. Concerning the first memorandum, the court noted that “it was not legal advice upon which the appellate was justified in relying, since it was not based on an evaluation of the validity or infringement of the [patents].”⁷³ Indeed, the court went so far in denouncing counsel’s opinions that the court ultimately concluded the opinions demonstrated willfulness rather than good faith:

It contains only bald, conclusory and unsupported remarks regarding validity and infringement of the [] patents. Had it contained within its four corners a patent validity analysis, properly and explicitly predicated on a review of the file histories of the patents at issue, and an infringement analysis that, *inter alia*, compared and contrasted the potentially infringing method or apparatus with the patented inventions, the opinion may have contained sufficient internal indicia of creditability to remove any doubt that [accused infringer] received a competent opinion. What these memoranda clearly demonstrated was [accused infringer’s] willful disregard for the [] patents.⁷⁴

In further underscoring a patent’s presumption of validity, the court quoted the accused infringer’s counsel in the opinion, who, advised his client to “continue to refuse to even discuss the payment of a royalty.”⁷⁵ The attorney also advised that “[c]ourts, in recent years, have in patent infringement cases found the patents claimed to be infringed upon invalid in approximately 80% of the cases,” and that for this reason, the patentee would not risk filing suit.⁷⁶

Given these bad facts, the Federal Circuit was ostensibly reasonable and justified in sending a strong message to patent counsel and potential infringers alike to respect patent rights. Some may say that the Federal Circuit would have been remiss, on

73. *Underwater Devices*, 717 F.2d at 1390.

74. *Id.*

75. *Id.* at 1385.

76. *Id.*

these facts, if it neglected to hold that an accused infringer's duty of "due care," when having actual knowledge it may be infringing a particular patent, included "the duty to seek and obtain competent legal advice from counsel before the initiation of any possible infringing activity."⁷⁷

Noteworthy is that the Federal Circuit was created to unify the patent law by using one focused tribunal at a time "when widespread disregard of patent rights was undermining the national innovation incentive."⁷⁸ This mandate, coupled with the cavalier conduct of the accused infringer's counsel in *Underwater Devices*, prompted the Federal Circuit to create the "due care" standard to further buttress the presumptive validity of patents to deter potential infringers. All benevolent intentions aside, the implementation of *Underwater Devices* spawned unanticipated satellite litigation over the scope of privilege waiver stemming from disclosure of the accused patent counsel's written opinion. Therein lies a Hobson's choice.

C. *To Disclose or Not in Light of Underwater Devices?*

Under the Patent Act, a plaintiff may recover only actual damages accruing from the patent's issuance date.⁷⁹ On the one hand, willfulness focuses on the time when the infringer possessed knowledge of the patent and facts sufficient to establish an objectively high likelihood of infringement. On the other hand, actual damages focus on the conduct of the plaintiff, *i.e.*, when the plaintiff gave the defendant notice of the patent and its potential infringement. Thus, the Patent Act encourages patentees to place others on notice of infringement.

In light of *Underwater Devices*, the practice evolved along these lines: accused infringer receives a cease and desist letter from patentee; accused infringer either already had secured

77. *Id.* at 1389-90.

78. ADVISORY COMMITTEE ON INDUSTRIAL INNOVATION FINAL REPORT, DEP'T OF COMMERCE (1979).

79. There is an exception here: provisional rights under 35 U.S.C. §§ 122, 154(d)(1)(B), which provide ability to pursue damages corresponding to a reasonable royalty for infringement occurring subsequent to publication of the application and prior to issuance of a patent from the application.

infringement/validity opinion or promptly obtains such an opinion concerning infringement, validity, or the unenforceability of the patent-in-issue; the patent owner files suit, claiming willful infringement; the accused infringer asserts its good faith reliance on advice of counsel as a defense to willfulness, and produces the opinion, thereby waiving applicable privilege.⁸⁰

Generally, this legal opinion letter is protected from disclosure by the attorney-client privilege and the attorney work product doctrine.⁸¹ An attorney's opinion letter regarding a patent's validity, enforceability, or infringement normally embodies communications and "the attorney's mental impressions and beliefs, and reflects the attorney's opinion which is based on legal analysis and reasoning and involved the exercise of legal skills."⁸² Intentional waiver of the attorney client privilege occurs, as is often the case, where a party purposefully reveals protected information to those beyond the scope of the privilege.

The issue of privilege arose three years after *Underwater Devices*, in *Kloster Speedsteel, AB v. Crucible Inc.*⁸³ There, the Federal Circuit observed that the infringer "has not even asserted that it sought advice of counsel when notified of the allowed claims and [the patentee's] warning, or at any time before it began this litigation," and held that the infringer's "silence on the subject, in alleged reliance on the attorney-client privilege, would warrant the conclusion that it either obtained no advice or counsel or did so and was advised that its importation and sale of the accused products would be an infringement of valid U.S. patents."⁸⁴

Based upon the holdings and rationales in *Underwater Devices* and *Kloster Speedsteel*, the court in *Fromson v. Western Litho Plate & Supply Co.*⁸⁵ expanded upon the *Kloster* court's suggestion of the propriety of an "adverse inference." Confirming

80. Roderick R. McKelvie et al., *Nine Unanswered Questions After In re Seagate Technology, Inc.*, 20 No. 4 INTELL. PROP. & TECH. L.J. 14 (2008); see also F.R.E. 501.

81. *Am. Standard, Inc. v. Pfizer, Inc.*, 828 F.2d 734, 744 (Fed. Cir. 1987).

82. *Stix Prods. v. United Merchs. & Mfrs.*, 47 F.R.D. 334, 337 (S.D.N.Y. 1969).

83. *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565 (Fed. Cir. 1986)

84. *Id.* at 1580.

85. *Fromson v. W. Litho Plate & Supply Co.*, 853 F.2d 1568 (Fed. Cir. 1988).

that suggestion overtly, the Federal Circuit in *Fromson* established the general rule that “a court must be free to infer that either no opinion was obtained or, if an opinion were obtained, it was contrary to the infringer’s desire to initiate or continue its use of the patentee’s invention.”⁸⁶

Thus, as of 1988, the Federal Circuit continued to emphasize patent rights, and, in so doing, continued to set the stage for widespread waiver issues to be resolved by the district courts. This was so inasmuch as counsel and accused infringer had no meaningful alternative but to seek out and secure a patent opinion, voluntarily disclose it, and encounter the uncertainties related to the scope of privilege waiver. Or, counsel and the accused infringer could maintain the privilege only to endure an adverse inference, the possibility of trebled damages, and an award of attorney’s fees.

The Federal Circuit recognized the proverbial rock and hard place the accused infringer found itself: an adverse inference to be drawn because its invocation of privilege or failure to seek a detailed opinion of patent counsel in the first instance. Thus, the Federal Circuit recognized that this issue was ripe for consideration when it conducted an *en banc* review of cross appeals taken in *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana*.

D. The End of the Adverse Inference, but Waiver Remains Vexing

At trial in *Knorr-Bremse*, the accused infringers informed the court that it had consulted counsel concerning the patents at issue, but declined to produce any legal opinion or to disclose the evidence received, asserting the attorney-client privilege. Applying Federal Circuit precedent, the district judge found that “it is reasonable to conclude that such opinions were unfavorable.” The accused infringers were found liable for infringement and for willful infringement concerning air brakes.⁸⁷ No damages were awarded as no commercial sales had yet occurred. However, based on the finding of willful infringement, the court found that

86. *Id.* at 1572-73.

87. *Knorr-Bremse Systeme Fuer Nutzfahreuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1343 (Fed. Cir. 2004).

the case was “exceptional” and awarded the patentee partial attorney fees.⁸⁸

The accused infringer sought reversal of the finding of willful infringement, and argued that an adverse inference should not have been drawn from the withholding of an opinion of counsel concerning the patent issues.⁸⁹ After briefing and oral argument, the court took the case *en banc* to reconsider its precedent with respect to these aspects.⁹⁰ The court issued four questions and invited *amicus curiae*.⁹¹

Stating that “precedent to the contrary is overruled,” the Federal Circuit held that “no adverse inference that an opinion of counsel was or would have been unfavorable flows from an alleged infringer’s failure to obtain or produce an exculpatory opinion of counsel.”⁹² Thus, the court’s holding makes two points: there can be no adverse inference for declining to seek the opinion of counsel, and there can be no adverse inference from declining to disclose an opinion of counsel.

In its reasoning, the Federal Circuit referred to case law holding it improper to impose adverse inferences on invocation of the attorney-client privilege.⁹³ Perhaps of equal import, the Federal Circuit also recognized that “the issue has occasioned extensive satellite litigation, distorting the ‘conceptual underpinnings’ of *Underwater Devices* and *Kloster Speedsteel*.”⁹⁴

Those conceptual underpinnings focused on protecting patent rights and discouraging disregard for the law, but did not contemplate the extensive collateral issues involved in patent counsel’s opinion, the quality of the opinion, the timeliness of the opinion, how the opinion was communicated, the extent of the infringer’s reliance upon the opinion, waiver, the questions involved where more than one opinion existed, the scope of waiver, or the impact of the attorney work product doctrine.

88. *Id.*

89. *Id.*

90. *Id.*

91. *Knorr-Bremse Systeme Fuer Nutzfahreuge GmbH v. Dana Corp.*, 344 F.3d 1336 (Fed. Cir. 2003) (*en banc* order).

92. *Knorr-Bremse*, 383 F.3d at 1341.

93. *Id.* at 1345.

94. *Id.*

In light of the Federal Circuit's *en banc* review and consideration of the extensive *amicus curiae*, the court took affirmative steps to decrease the burden upon an accused infringer and respect the attorney-client privilege, thereby aligning the patent law in this area with broader civil law while simultaneously recognizing the presumptive validity of a patentee's rights. And, significantly, in the wake of *Knorr-Bremse*, an accused infringer with knowledge of another's patent still had a duty of "due care" concerning another's patent. In practice, to discharge that duty, accused infringers continued with regularity to seek and secure opinions from patent counsel and disclose those opinions in defending against willful infringement allegations, even though no adverse inference would be imposed for declining to do so.

Although the significance of the content of patent counsel's opinion was lessened in *Knorr-Bremse*, the dilemma of the broad scope of attorney-client and attorney work product waiver remained largely disjointed across the various circuits, leaving litigants with uncertainty and a dire need for a talisman to navigate the various rules across the various districts.

E. EchoStar—Can the Accused Infringer Withhold Anything?

Two years after *Knorr-Bremse*, EchoStar presented the Federal Circuit with the question of the extent to which a party waives its attorney client privilege and work product immunity when it asserts the advice of counsel defense in response to a claim of willful patent infringement.

The Federal Circuit in *In re EchoStar* held that the disclosure of any opinion waived privilege and work product as to all opinions given, whether before or after the complaint was filed and whether given by in-house or retained counsel.⁹⁵ Thus, only work product which was not communicated to the client remained protected from disclosure when an accused infringer relied on counsel's opinion to defend against willfulness.⁹⁶

TiVo sued Echostar for infringement and in response to the allegation of willful infringement, Echostar defended by relying on

95. *In re EchoStar*, 448 F.3d 1294 (Fed. Cir. 2006) (en banc).

96. *Id.* at 1297.

the opinion of in-house counsel.⁹⁷ After the lawsuit was filed, EchoStar sought out and secured an additional opinion on the patent at issue, but chose not to rely on it.⁹⁸ TiVo sought the production of all communications concerning both opinions, which the district court granted, allowing for redactions of information unrelated to infringement or information related to trial preparation.⁹⁹

The district court held that “by relying on advice of in-house counsel EchoStar waived its attorney client privilege and attorney work product immunity relating to advice of any counsel regarding infringement,” including retained counsel.¹⁰⁰ With regard to the scope of the waiver, the district court determined that the waiver “included communications made either before or after the filing of the complaint and any work product, whether or not the product was communicated to EchoStar.”¹⁰¹

Upon clarifying its order, the district court stated that the waiver of immunity extended to all work product of retained counsel whether or not communicated to EchoStar, reasoning that the documents sought could be relevant or lead to the discovery of admissible evidence because they might contain information that was conveyed to EchoStar, “even if the documents were not themselves conveyed to EchoStar.”¹⁰²

In response, EchoStar petitioned the Federal Circuit for a writ of mandamus, which was granted, and the court sat *en banc*. The court began its analysis of the attorney-client privilege waiver by noting “[t]he widely applied standard for determining the scope of a waiver of attorney-client privilege is that the waiver applies to all other communications relating to the same subject matter.”¹⁰³

Applying this rule to the case *sub judice*, the court concluded, “[t]hus, when EchoStar chose to rely on the advice of in-house counsel, it waived the attorney-client privilege with regard to any

97. *Id.*

98. *Id.*

99. *Id.*

100. *Id.*

101. *EchoStar*, 448 F.3d at 1297.

102. *Id.*

103. *Id.* at 1299 (citing *Fort James Corp., v. Solo Cup Co.*, 412 F.3d 1340, 1349 (Fed. Cir. 2005)).

attorney-client communications relating to the same subject matter, including communications with counsel other than in-house counsel, which would include communications with [retained counsel].”¹⁰⁴

Thus, by relying on in-house counsel’s analysis, EchoStar also waived its attorney client privilege concerning all communications about the patent at issue to any counsel, including retained counsel. Furthermore, that waiver extended from in-house counsel’s communications prior to the lawsuit to counsel retained after the lawsuit. *EchoStar* set an almost open-ended time frame for communications relevant to the subject of the waiver.

As the court noted:

[O]nce EchoStar chose to introduce the opinion, it opened to inspection all related advice sought and developed regarding EchoStar’s potential infringement Regardless of when the opinions or materials were transcribed or communicated to EchoStar, such information necessarily relates to the opinion being offered by [in-house counsel] and goes to show EchoStar’s state of mind with respect to willful infringement.¹⁰⁵

Clearly, having the two patent opinions, one from in-house and the other from retained counsel, could lead to disastrous results. However, *Echostar’s* facts presented the Federal Circuit with the opportunity to emphasize its view that waiver had to be broad to prevent gamesmanship, unfair advantage, or using “the attorney-client privilege as both a sword and a shield.” As the court observed, “[s]elective waiver of the privilege may lead to the inequitable result that the waiving party could waive its privilege for favorable advice while asserting its privilege on unfavorable advice.”¹⁰⁶

Turning next to the question of work product waiver, the Federal Circuit contrasted the protections found in the attorney client privilege and the attorney work product doctrine. “Unlike the

104. *Id.*

105. *Id.*

106. *Id.* at 1301.

attorney-client privilege, which protects all communications whether written or oral, work-product immunity protects documents and tangible things, such as memorandums, letters, and e-mails.”¹⁰⁷

Concerning waiver, the court noted that a waiver of work product is not as broad as a waiver of attorney-client privilege and extends only to factual or “non-opinion” work product concerning the same subject matter as the disclosed work product. And, the court emphasized that although the content of counsel’s work product opinion is relevant, the real significance is the accused infringer’s state of mind in light of counsel’s opinion, bearing on the question of willfulness:

Work product waiver extends only so far as to inform the court of the infringer’s state of mind. Counsel’s opinion is not important for its legal correctness. It is important to the inquiry whether it is ‘thorough enough, as combined with other factors, to instill a belief in the infringer that a court might reasonably hold the patent is invalid, not infringed, or unenforceable.’ It is what the alleged infringer knew or believed, and by contradistinction not what other items counsel may have prepared but did not communicate to the client that informs the court of an infringer’s willfulness.¹⁰⁸

Thus, *EchoStar* teaches that information unrelated to the defendant’s state of mind forms an outer limit to the reach of the work product immunity waiver. An additional limit inherent in the work product waiver concerns information that is not relayed to the client. If counsel’s work product is not communicated to the client, the waiver does not apply, understandably, because it provides little if any assistance to the court in determining whether the defendant knew he was infringing.

In the wake of *EchoStar*, an alleged infringer advancing an

107. *EchoStar*, 448 F.3d at 1301 (citing *Judicial Watch, Inc. v. Dep’t of Justice*, 432 F.3d 366 (D.C. Cir. 2005)).

108. *Id.* (quoting *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 944 (Fed. Cir. 1992)).

advice of counsel defense had to be prepared to disclose otherwise privileged communications and work product relating to the contents of the opinion, including “letters, memorandum, conversation, or the like between the attorney and his or her client, [as well as] any documents referencing a communication between attorney and client.”¹⁰⁹

A broad attorney client privilege waiver, coupled with a less broad but nevertheless penetrating work product waiver, limited only by work product not communicated to the accused infringer, literally opened in-house, retained, opinion, and trial counsel’s otherwise protected files to the scrutiny and leverage of the patentee. Because the breadth of that waiver was unknown, the accused infringer had to take a risk of exposing additional attorney-client privileged information in order to defend itself.

Intending to fix the wrongs of “widespread disregard of patent rights,” the jurisprudence beginning with *Underwater Devices*, and evolving through *Kloster Speedsteel*, *Knorr-Bremse*, and *EchoStar* created a framework prompted by laudable intentions, but wracked with practical and costly challenges, which all but vitiated the attorney-client privilege and work product doctrine. This framework embroiled parties in costly, discovery intensive litigation before the claims were construed, which is the crux of any patent litigation.

According to the case law, the burden was on the accused infringer to demonstrate “due care,” rather than on the patentee to show at least the absence of due care. A trial court was authorized under the case law to treble damages by applying a standard more in keeping with negligence (due care) than punitive damages (recklessness). Additionally, the accused infringer’s trial counsel’s files, as opposed to opinion counsel’s files, were available to the patentee on some undetermined, case-by-case basis. The Federal Circuit recognized that these issues required sweeping corrective action, and *Seagate* provided the case to do so.

109. *Id.* at 1304.

V. *IN RE SEAGATE—UNDERWATER DEVICES IS SUNK*A. *Willful Patent Infringement in the Southern District of New York*

In *Seagate*, Convolve and Massachusetts Institute of Technology filed suit against Seagate Technology and Compaq Computers alleging willful infringement of three patents, and subsequently amended their complaint to add a fourth count based upon a patent that issued after the initial complaint was filed.¹¹⁰

Prior to the lawsuit, Seagate requested and received legal opinions regarding the Convolve patents and pending application—which found claims of the patents to be either invalid or not infringed by Seagate’s technology, and that at least one patent was possibly unenforceable.¹¹¹ The opinions were prepared and tendered by counsel who acted separately and independently from Seagate’s trial counsel.¹¹²

As required by the district court’s scheduling order, Seagate gave notice of its intent to rely on the legal opinions asserting invalidity and noninfringement and subsequently disclosed all of its opinion counsel’s work product in addition to making the opinion counsel available for deposition.¹¹³ Not satisfied, however, Convolve moved to compel disclosure of communications and work product of *all* of Seagate’s attorneys, both in-house and trial counsel, a position countenanced by the Federal Circuit’s opinion in *EchoStar*.¹¹⁴

Although the legal opinions were from counsel independent of Seagate’s trial counsel, the district court, relying on *EchoStar*, ruled that the disclosure of the opinions waived the privilege for *all* communications with *any* counsel concerning the subject matter of the opinions and that this waiver extended from when Seagate first learned of the patents and lasted until the alleged

110. *In re Seagate Tech., LLC*, 497 F.3d 1360, 1366 (Fed. Cir. 2007).

111. *Id.*

112. *Id.* (“There is no dispute that Seagate’s opinion counsel operated separately and independently of trial counsel at all times.”).

113. *Id.*

114. *Id.*

infringement ceased.¹¹⁵

In other words, the court ruled that Seagate had broadly waived its attorney-client privilege as to the patents at issue, the protection of work product communicated to Seagate was waived, and the waiver extended to any of Seagate's counsel involved in the matter.¹¹⁶ The district court did provide for *in camera* review of information concerning trial counsel's litigation strategy, but opined that "any advice from trial counsel that undermined the reasonableness of relying on [opinion counsel's] opinions would warrant disclosure."¹¹⁷

In light of the district court's discovery order, Convolve, apparently recognizing the opportunity to gain an otherwise unavailable strategic advantage, sought production of trial counsel's opinions relating to infringement, invalidity, and enforceability of the patents at issue. Convolve also noticed depositions of Seagate's trial counsel.¹¹⁸ Seagate moved to stay the discovery order to seek certification of an interlocutory appeal, which the district court denied.¹¹⁹

In response, Seagate petitioned for a *writ of mandamus* with the Federal Circuit, seeking a stay of the district court's discovery orders.¹²⁰ Not only did the Federal Circuit stay the district court's discovery order, but the court also, *sua sponte*, initiated *en banc* review and directed briefing on the following three questions:

1. Should a party's assertion of the advice of counsel defense to a willful infringement extend waiver of the attorney-client privilege to communications with that party's trial counsel?
2. What is the effect of any such waiver on work product immunity?
3. Given the impact of the statutory duty of care standard announced in *Underwater Devices*, on the issue of waiver of attorney-client privilege, should

115. *Id.* at 1366-67.

116. *Seagate*, 497 F.3d at 1367.

117. *Id.*

118. *Id.*

119. *Id.*

120. *Id.*

this court reconsider the decision in *Underwater Devices* and the duty of care itself?¹²¹

Interestingly, the Federal Circuit declined to consider those portions of the district court's discovery orders which related to Seagate's in-house counsel, noting in a footnote that "[t]he questions presented for *en banc* review do not encompass this issue."¹²²

B. "Due Care" Becomes "Objective Recklessness"

Reviewing the district court's determination of the waiver of privilege for an abuse of discretion, and, because willful infringement and the scope of waiver accompanying the advice of counsel defense involved substantive patent law, the Federal Circuit applied its own jurisprudence in answering these questions, beginning with the appropriate standard by which to assess willfulness.

The court discussed the meaning of "willfulness" outside patent law, beginning with the meaning of the word as employed in the Copyright Act.¹²³ The court stated that for willful copyright infringement, other circuits have employed a recklessness standard in awarding enhanced damages.¹²⁴

The court then looked at how the Supreme Court addressed the meaning of willfulness in other areas of civil liability, specifically within the context of the Fair Credit Reporting Act.¹²⁵ Under that statute, a consumer is awarded actual damages for negligent violations of the law,¹²⁶ but can also recover punitive damages for willful violations.¹²⁷ In *Safeco*, the Supreme Court stated that "willful" includes reckless behavior,¹²⁸ and "this definition comports with the common law usage, 'which treated actions in

121. *Id.*

122. *Seagate*, 497 F.3d at 1367 n.2.

123. *Id.* at 1370.

124. *Id.*

125. *See Safeco Ins. Co. of Am. v. Burr*, 127 S. Ct. 2201 (2007).

126. 15 U.S.C. § 1681o(a) (2006).

127. *Id.* § 1681n(a)(2).

128. *Safeco*, 127 S. Ct. at 2209.

reckless disregard of the law as willful violations.”¹²⁹

Having referred to the Supreme Court to identify definitions and applications of “recklessness,” the court turned to the duty of care set forth in *Underwater Devices* and recognized that the standard for willfulness is more akin to negligence than reckless behavior, and, thus “fails to comport with the general understanding of willfulness in the civil context.”¹³⁰ Furthermore, the court stated:

the duty of care announced in *Underwater Devices* sets a lower threshold for willful infringement that is more akin to negligence . . . [and that] standard fails to comport with the general understanding of willfulness in the civil context [citations omitted], and it allows for punitive damages in a manner inconsistent with Supreme Court precedent.¹³¹

Characterizing willful infringement damages as a form of punitive damages, the Federal Circuit concluded that awarding enhanced damages for conduct that was merely negligent for failure to satisfy an affirmative duty of care is not consistent with the Supreme Court precedent regarding the award of punitive damages.¹³²

The court then addressed the holding in *Underwater Devices*, overruled it, and expressly required that “proof of willful infringement permitting enhanced damages requires at least a showing of objective recklessness.”¹³³ The court abandoned the affirmative duty of due care to seek opinion of counsel, but cited *Electro Med. Sys., S.A. v. Cooper Life Scis, Inc.*, 34 F.3d 1048, 1056 (Fed. Cir. 1994), which held that possession of a favorable legal opinion is not essential to avoid a finding of willful infringement; it is only one *important* factor to be considered.¹³⁴

129. *Seagate*, 497 F.3d at 1371.

130. *Id.* (citing *McLaughlin v. Richland Shoe Co.*, 486 U.S. 128, 133 (1988)).

131. *Id.* (citing *Safeco*, 127 S. Ct. at 2209)).

132. *Id.* (citing *Safeco*, 127 S. Ct. at 2209, 2213-15, 2216 n.20; *Smith v. Wade*, 461 U.S. 30, 39-49 (1983)).

133. *Id.*

134. *Id.*

So, the Federal Circuit replaced the lower “due care” with the higher standard of “objective recklessness.”

The court acknowledged that “reckless” is not a self-illuminating term and set forth two elements of proof.¹³⁵ The court explained that “to establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent.”¹³⁶

Second, the court noted that “if this threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer.”¹³⁷

Because there had been no record on the willfulness issue in the underlying district court case, the Federal Circuit did not apply the new willfulness standard, but instead, “left it to future cases to further develop.”

Thus, the Federal Circuit effectively shifted the burden from accused infringer to patentee: under the *Underwater Devices* standard, the accused infringer had the burden of proving due care, while under the new standard, the patentee must show that the accused infringer knew or should have known he was acting recklessly.

C. *Injunctive Relief as a Measure Of “Objective Recklessness?”*

The court also addressed the newly articulated standard for obtaining injunctive relief, as set forth by the Supreme Court in the *eBay* case.¹³⁸ The Federal Circuit stated that “in ordinary circumstances, willfulness will depend on an infringer’s prelitigation conduct.”¹³⁹ The court further suggested that the patentee’s remedy for reckless conduct by the accused infringer *post-filing* is a motion for a preliminary injunction.¹⁴⁰

135. *Seagate*, 497 F.3d at 1371.

136. *Id.*

137. *Id.*

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

139. *Seagate*, 497 F.3d at 1374.

140. *Id.*

The Federal Circuit inferred that a patentee who does not seek an injunction, or does not receive one, may have an uphill battle in proving that the accused infringer's conduct was reckless. By tying the recklessness inquiry to the standard for obtaining a preliminary injunction, the court suggested that a substantial question of invalidity, noninfringement, or unenforceability may likely be sufficient to avoid a finding of willfulness.

D. Privilege & Immunity Waivers—EchoStar is Curtailed, Somewhat

As previously discussed, *EchoStar* held that reliance on in-house counsel's advice to refute a charge of willfulness triggers waiver of the attorney-client privilege and work product protection for all communications on the same subject matters, as well as any documents memorializing attorney-client communications.¹⁴¹ The court noted the lack of uniformity in the district courts: some courts had held that the waiver extended to trial counsel while others had held the exact opposite; some courts had found a middle ground requiring disclosure of communications that are contrary to the legal opinion.¹⁴²

The Federal Circuit held that, generally, a party disclosing a legal opinion obtained from independent counsel does not waive the attorney-client privilege or work-product doctrine with respect to opinions of trial counsel.¹⁴³ "As a general proposition . . . asserting the advice of counsel defense and disclosing opinions of counsel do not constitute waiver of the attorney-client privilege for communications with trial counsel."¹⁴⁴ The court underscored "the significantly different functions of trial counsel and opinion counsel," and that these functions "advise against extending the waiver to trial counsel."¹⁴⁵ Also, the Federal Circuit noted that the

141. *In re EchoStar*, 448 F.3d 1294, 1299, 1302-03 (Fed. Cir. 2006).

142. *Seagate*, 497 F.3d at 1372.

143. *Id.* at 1373-74.

144. *Id.* at 1373.

145. *Id.* The court stated further that "defenses prepared [by litigation counsel] for a trial are not equivalent to the competent legal opinion of noninfringement or invalidity which qualify as 'due care' before undertaking any potentially infringer activity. *Id.* Because of the fundamental difference between these types of legal advice, this situation does not present the classic

Supreme Court has long recognized the need to protect trial counsel's thoughts.¹⁴⁶

Thus, the court's proclamation reconciles the lack of uniformity among the various district court interpretations by supplying a firmer rule that the reach of waiver does not extend to trial counsel. But, the court's opinion does allow for "unique circumstances" where waiver may be found.¹⁴⁷ This is not an "absolute rule" and "courts remain free to exercise their discretion in unique circumstances to extend waiver to trial counsel, such as if a party or counsel engages in chicanery."

The Federal Circuit held that the same rule applied to work product waiver, reasoning that, "as a general proposition, relying on opinion counsel's work product does not waive work product immunity with respect to trial counsel," absent "exceptional" circumstances.¹⁴⁸ Such unique or exceptional circumstances may be found when opinion counsel and trial counsel are collaborating in such a way that their distinctive functions blur.

For example, the role of opinion counsel as an objective resource is undermined when opinion counsel is advised by trial counsel as to how to craft the opinion. Although trial counsel and opinion counsel may work closely during various portions of the litigation, if the references cited and the arguments made are effectively chosen by trial counsel, an "exceptional" or "unique" circumstance may be found. Similar problems may arise when in-house counsel writes an opinion and participates in a collaborative effort with trial counsel.

In sum, *Seagate* overruled the long-standing "due care" requirement and announced the new two-part "objective recklessness" test. The burden shifted from the accused infringer to show "due care," to the patentee to show "objective recklessness." Seeking injunctive relief may be a predicate, or at least an indicator, of whether a case is appropriate for a finding of

'sword and shield' concerns typically mandating broad subject matter waiver. *Id.* Therefore, fairness counsels against disclosing trial counsel's communications on an entire subject matter in response to an accused infringer's reliance on opinion counsel's to refute a willfulness allegation." *Id.*

146. *Id.* (citing *Hickman v. Taylor*, 329 U.S. 495, 510-11 (1947)).

147. *Id.* at 1374-75.

148. *Seagate*, 497 F.3d at 1375.

willful infringement. Significantly, *Seagate* fenced off trial counsel concerning waiver. Procedurally speaking, the Federal Circuit granted *Seagate*'s petition for mandamus and directed the district court to "reconsider its discovery orders in light of this opinion."¹⁴⁹

VI. GENERAL IMPLICATIONS OF *SEAGATE*

The Federal Circuit's opinion may effectively end the use of standard language in pleadings to assert a charge of willful infringement in nearly all patent infringement cases. The "objective recklessness" requirement makes it more difficult to prove willful infringement and will likely mean that enhanced damages will not be awarded as often. While an accused infringer is not required to obtain a legal opinion to rebut willfulness, those opinions will still aid and be an invaluable if not crucial tool in defending a charge of willful infringement, particularly if the opinion is obtained before an infringement suit is filed. The risk of a broad waiver of attorney-client privilege after an accused infringer decides to rely on a legal opinion has also been reduced, further increasing the utility of legal opinions assessing validity, infringement, and enforceability of issued patents.

On remand from the Federal Circuit, the District Court for the Southern District of New York, applying the Federal Circuit's holding and analysis regarding the attorney-client privilege, denied *Convolve*'s motion for further discovery of defendant's in-house counsel's communications that were *not* disclosed to opinion counsel.¹⁵⁰ However, the court did state that *Convolve* may, in the future, make a specific showing that it was previously denied access to prelitigation communication of in-house counsel regarding the opinions.¹⁵¹

The district court put to rest *Convolve*'s argument that the "Federal Circuit's standard for willfulness retains an element of intent because willful infringement can still be demonstrated by a

149. *Id.* at 1376.

150. *Convolve, Inc. v. Compaq Computer Corp.*, No. 00 Civ. 5141, 2007 U.S. Dist. LEXIS 87286, at *14-15 (S.D.N.Y. Nov. 26, 2007).

151. *Id.*

showing of subjective bad faith.”¹⁵² The district court reiterated what the Federal Circuit clearly stated in *Seagate*—there is one standard for willful infringement, with two distinct hurdles: the first is to present clear and convincing evidence of an objectively high risk that the conduct constituted infringement, and the second is to show the defendant’s knowledge or constructive knowledge of the risk.¹⁵³

The district court clarified that with regard to discovery of in-house counsel communications with opinion counsel (before infringement or after a lawsuit was filed), it must first be determined whose opinion the defendant relied on in its defense—did it rely on in-house counsel or outside counsel or both?

Secondly, post-litigation communications do not affect the willfulness inquiry, which focuses on prelitigation conduct, and consequently, there is “no basis for taking discovery of in-house counsel’s communications after the litigation was commenced.”¹⁵⁴ With respect to outside opinion counsel, non-disclosed work product remained undiscoverable, although the District Court noted that information known by outside counsel would likely be conveyed to the plaintiffs through depositions of *Seagate*’s engineers.¹⁵⁵

VII. SEAGATE’S IMPACT ON ANDA LITIGATION

Seagate may have a particular impact in the context of pharmaceutical litigation under Hatch-Waxman. The Hatch-Waxman Act provides for FDA approval of generic drugs according to a statutory and regulatory procedure that is much faster and less expensive than the FDA-approval process that the original or innovator drug company followed before introducing its patented medication or method to the market.

As the Federal Circuit has noted, Hatch-Waxman attempts to balance the interest of the generic-drug manufacturers and the innovator companies whose pioneering drugs are subject to patent

152. *Id.* at *10-11.

153. *Id.* (citing *Seagate*, 497 F.3d at 1371).

154. *Id.* at *13 (citing *Seagate*, 497 F.3d at 1374).

155. *Id.* at *14.

protection.¹⁵⁶ A generic company enjoys a streamlined FDA-approval process for generic drugs while pioneer companies are rewarded for enduring the protracted FDA-NDA approval process by a patent term extension of up to five years of patent exclusivity.¹⁵⁷

Normally, one who uses a product or method protected by an existing patent is engaging in the use of the product and thus infringes. However, under Hatch-Waxman, generic companies may begin developing their drugs notwithstanding the pioneer company's patent protection.¹⁵⁸

Generic companies do not have to submit to the rigorous, expensive, and time-consuming drug safety and efficacy evaluation process necessary for the FDA to approve a new drug. The generic company need only file an ANDA that relies on the safety and efficacy of a drug previously approved by the FDA through the use of a NDA.¹⁵⁹

The Hatch-Waxman Act requires that the ANDA applicant file proof of bioequivalence and a certification.¹⁶⁰ In filing an ANDA,

156. For example, the Federal Circuit noted in *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.* that "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1327 (Fed. Cir. 2005).

157. 42 U.S.C. § 201 (2006); 35 U.S.C. § 156(a) (2006); *see also* *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990) (explaining the cited statutory provisions).

158. 35 U.S.C. § 271(e)(1) creates an exception to the law of infringement when the use of the invention is "reasonably related" to regulatory approval.

159. However, the 180-day exclusivity reward only applies to applications that contain a certification "described in subclause (IV) of paragraph 2(A)(vii)." In other words, exclusivity only applies to applications filed under 21 U.S.C. § 355(j)(2)(A)(vii), the provision listing the requirements for an "abbreviated application for a new drug." An application filed under Section 355(b)(2) is legally distinct, although a similar certification is required. Filing an application under Section 355(b)(2) does not give rise to an exclusivity period.

160. 21 U.S.C. § 355(j) (2006); *see also* 21 C.F.R. § 320.1(e) (1994) (defining bioequivalence as "the absence of significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study").

the applicant must make one of four certifications with regard to each patent listed in the “Approved Drug Products with Therapeutic Equivalence Evaluations,” known as the “Orange Book.” The Orange Book is published by the FDA in furtherance of the ANDA process for the generic company to review before seeking approval to manufacture, use, sell, or offer for sale FDA-approved drugs protected by the NDA applicant’s patent protection.

Upon filing an ANDA, a generic company determines which certification to make with regard to the pioneer company’s patent, including:

“(I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.”¹⁶¹

It is the final certification, the paragraph IV certification, that constitutes a statutory act of infringement.¹⁶² After such certification is made, the ANDA applicant must notify the patent owner and NDA holder of the certification and of the basis of its assertion that the patent is invalid or not infringed.¹⁶³ Notably, while the basis of the opinion is given to opposing counsel via the certification, the actual opinion is not usually disclosed. The patent owner has 45 days to file a patent infringement lawsuit against the ANDA filer to obtain a 30-month stay of the FDA’s approval of the ANDA.¹⁶⁴ All of this can and does occur even though the ANDA applicant has not yet engaged in truly commercial activities.

Once the brand-name company files its patent infringement suit, it often alleges that the generic company willfully infringed. Prior to the new standard announced in *Seagate*, the Federal Circuit held in *Glaxo Group Ltd. v. Apotex, Inc.* that the “mere fact that a

161. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

162. *Id.* § 271(e)(2)(A).

163. *Id.* § 355(j)(2)(B).

164. *Id.* § 355(j)(5)(B)(iii).

company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)."¹⁶⁵ That is, the "mere" filing of an ANDA does not, taken alone, constitute grounds for finding willful infringement.¹⁶⁶ Thus, it appears that district courts may entertain willfulness allegations as long as the allegation does not rest exclusively on the filing of an ANDA or Paragraph IV certification.

The *Glaxo* holding suggests that filing an ANDA, in conjunction with other activities, perhaps the other nine totality factors discussed,¹⁶⁷ may conceptually give rise to willfulness. Also in *Glaxo*, the ANDA application at issue was not filed pursuant to 21 U.S.C. § 355(j)(2)(A) and, as a result, did not include a paragraph IV certification.¹⁶⁸

The Federal Circuit was also careful to point out what its previous jurisprudence had held with regard to willful infringement in the ANDA setting. Namely, the Federal Circuit clarified its holding in the *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacol, Inc.* case, stating that "we did not agree that

165. *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1350-51 (Fed. Cir. 2004).

166. *Janssen, L.P. v. Barr Labs., Inc.*, No. 07-1515, 2008 U.S. Dist. LEXIS 7965, *10 n.1 (D.N.J., Feb. 4, 2008) ("The Court recognizes that, despite the clarity of the Federal Circuit's opinions in *Glaxo* [] and *Yamanouchi* [], plaintiffs in Hatch-Waxman Act cases repeatedly allege willful infringement based only on the filing of an ANDA and paragraph IV certification -- and district courts are repeatedly flooded with motions such as the one presented here. Faced with this recurring issue, the Court's Opinion now joins the litany of literature attempting to inform plaintiffs that the mere filing of an ANDA cannot give rise to a claim of willful infringement.") (citing *Forest Labs., Inc. v. Ivax Pharms., Inc.*, No. 03-891-JJF, 2007 U.S. Dist. LEXIS (D. Del., Mar. 15, 2007); *Aventis Pharma Deutschland GMBH v. Cbalt Pharm., Inc.*, 355 F. Supp. 2d 586 (D. Mass. 2005)).

167. See *supra* notes 56-60 and accompanying text.

168. *Glaxo*, 376 F.3d at 1344 ("In the current case, however, CA was approved under 21 U.S.C. § 357, a now-repealed provision of the Federal Food, Drug, and Cosmetic Act relating to antibiotics. Drug manufacturers who utilized Section 357 to obtain FDA approval are exempt from listing the patents related to their antibiotic in the Orange Book. Correspondingly, ANDA applicants attempting to market generics of such antibiotics are not required to file a certification under 21 U.S.C. § 355(j)(2)(A).").

the generic company had engaged in willful infringement, but rather determined that an award of attorney's fees was permitted because the generic had filed numerous baseless filings supporting its fruitless and meritless arguments, both in its case at trial and in its ANDA certification. Such unjustified litigation and misconduct has always justified a finding of an exceptional case."¹⁶⁹

This clarification may need further elaboration because, while the Federal Circuit stated in *Yamanouchi* that 35 U.S.C. § 271(e)(2) and (4) mean that filing of an ANDA is a basis for attorney fees under § 285, regardless of whether there is a commercial sale,¹⁷⁰ the Federal Circuit also stated that it "has recognized many varieties of misconduct that make a case exceptional for a fee award. Those forms of misconduct include willful infringement."¹⁷¹

The Federal Circuit's stance on willful infringement in the ANDA context seems to have flexibility, particularly because of the language employed: the "*mere*" filing of the ANDA and certification cannot constitute willful infringement.¹⁷²

That said, *Seagate* may place even more importance on the notice letter. When a generic company files an ANDA with a Paragraph IV certification, the generic is required to send the patent owner and NDA holder a "notice letter." This notice must include "a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed."¹⁷³ The FDA regulations also require, for a patent alleged not to be infringed, an explanation of the theory of

169. *Id.* at 1350; *see also* *Yamanouchi Pharms. Co., v. Danbury Pharmacal, Inc.*, 231 F.3d 1339 (Fed. Cir. 2000).

170. *Yamanouchi*, 231 F.3d at 1346 (citing 35 U.S.C. § 271(e)(2), (4)).

171. *Id.* at 1346-47 (citing *Avia Group Int'l., Inc. v. L.A. Gear Cal., Inc.*, 853 F.2d 1557, 1567 (Fed. Cir. 1988); *Rosemont, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1548 (Fed. Cir. 1984)).

172. *Wyeth v. Ranbaxy Labs. Ltd.*, 448 F. Supp. 2d 607, 612 (D.N.J. 2006) ("Based on the holdings of *Glaxo* and *Yamanouchi*, it is clear that the Federal Circuit has not foreclosed the possibility of an award of attorney fees under the "exceptional case" rubric in ANDA litigation."). This is permitted under 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285.

173. 21 C.F.R. § 314.95(c) (2003). The quoted language tracks the statute, with the potentially important exception that FDA has added the word "unenforceable."

non-infringement.¹⁷⁴ Where the claim is that the patent is invalid or unenforceable, the regulation requires a full and detailed explanation of that assertion.¹⁷⁵

In light of *Seagate's* holding, the notice letter which, of necessity, is sent prior to litigation, though after the technical act of infringement of submitting the ANDA, could well be sufficient to prove an absence of objective recklessness. And, in-house, opinion, or trial counsel should carefully consider the extent of the information contained in the notice letter, not only to satisfy the regulatory obligations, but also to potentially obviate the need to disclose the opinion of patent counsel. In other words, providing sufficiently detailed information in the notice letter may be sufficient to demonstrate the lack of objective recklessness, without resort to disclosure and waiver when defending against a willfulness allegation.

In any event, *Seagate*, when coupled with the statutory and regulatory requirements of Hatch-Waxman, indicates that innovator companies face an arduous challenge in surviving attacks on their naked willfulness pleadings. As one noted expert on generic pharmaceutical law stated:

For willfulness cases, the naked proposition of willfulness should be supported by specific facts. Courts should strike willfulness claims until such time that the complaint can be amended with such specific facts. Imposing a stricter pleading standard will simplify the discovery, avoid battles of attorney-client privilege, and move the case along so that the case can be adjudicated well before the 30-month stay expires. Discovery will be simplified because there will be less documentation tendered, less electronic discovery to sift through, less depositions, less motion practice, etc. Patentees asserting weak patents have every motive to unduly propagate and delay the litigation. If the defendant ultimately loses, then the issue of

174. *Id.* § 314.95(c)(6)(i).

175. *Id.* § 314.95(c)(6)(ii).

willfulness ripens and can be re-pled.¹⁷⁶

Put simply, generic drug companies are mandated by the statutes and regulations in Hatch-Waxman to follow specific, reasonable, lawful steps in challenging innovator patents prior to expiration. Methodically following those procedures, conceptually and in practice, is at odds with “objectively reckless” behavior. Consequently, the heightened standard for willfulness announced in *Seagate* stands to eviscerate the motions practice and attendant discovery normally associated with the advice of counsel defense.

And, for these reasons, *Seagate* provides the necessary precedent for district courts to establish a firm rule that willfulness allegations will be struck, *sua sponte*, with leave to amend should discovery unearth sufficient evidence of willfulness.

VIII. CONCLUSION

While the reality of *Seagate* is perhaps still setting in, it is clear that the decision, when considered against the backdrop of the cases that came before it, has not only raised the bar to prove an allegation of willful infringement, but also curtailed the scope of privilege and immunity waivers. Within the Hatch-Waxman regime, which requires generic pharmaceutical companies to adhere to the established statutory and regulatory framework when challenging the patent(s) of an innovative drug, proving “objectively reckless” behavior is likely an insurmountable hurdle—*Seagate* may end the flood of willful infringement allegations in the ANDA setting.

176. Shashank Upadhye, *Generic Pharmaceutical Patent and FDA Law* 631-32 (2008).