December 15, 2016

Litigation Webinar Series

Minimizing Willful Infringement Post-Halo

John Johnson
Principal, New York

Brian Coggio
Of Counsel, New York

Mike Sobolev
Associate, Silicon Valley

Overview

- Litigation Series
  - Key Developments & Trends
- Housekeeping
  - CLE Contact: Jane Lundberg
    - lundberg@fr.com
  - Questions
  - Materials: fishlitigationblog.com/webinars
- #fishwebinar

Disclaimer

The purpose of this presentation is to provide educational and informational content and is not intended to provide legal services or advice. The opinions, views and other statements expressed by the presenter are solely those of the presenter and do not necessarily represent those of Fish & Richardson P.C.

June 23, 2016

Litigation Webinar Series

Enhanced Damages in Patent Cases After *Halo v. Pulse*

Craig Countryman
Principal
Southern California

Today’s Outline

- *Halo* sneak peek
- What’s the Big Deal?
- Willfulness Development Over the Past 20 years
- *Halo*—How Did it Change Existing Law?
- Confusion and Open Questions after *Halo*
- Practical Implications
- Implications Hatch Waxman/General Pharma

Halo Electronics, Inc. v. Pulse Electronics, Inc.

- Decided June 13, 2016
- Unanimous
- Breyer concurrence (joined by Kennedy and Alito)
- *Seagate* test for willfulness is "unduly rigid, and it impermissibly encumbers the statutory grant of discretion to district courts."

(Slip Opinion) OCTOBER TERM, 2015 1

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

HALO ELECTRONICS, INC. *v.* PULSE ELECTRONICS, INC., ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 14–1513. Argued February 23, 2016—Decided June 13, 2016*

Section 284 of the Patent Act provides that, in a case of infringement, courts "may increase the damages up to three times the amount found or assessed." 35 U. S. C. §284. The Federal Circuit has adopted a two-part test for determining whether damages may be increased pursuant to §284. First, a patent owner 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." *In re Seagate Technology, LLC*, 497 F. 3d 1360, 1371. Second, the patentee must demonstrate, also by clear and convincing evidence, that the risk of infringement "was either known or so obvious that it should have been known to the accused infringer." *Ibid.* Under Federal Circuit precedent, an award of enhanced damages is subject to trifurcated appellate review. The first step of *Seagate*—objective recklessness—is reviewed *de novo*; the second—subjective knowledge—for substantial evidence; and the ultimate decision—whether to award enhanced damages—for abuse of discretion.

In each of these cases, petitioners were denied enhanced damages under the *Seagate* framework.

Held: The *Seagate* test is not consistent with §284. Pp. 7–15.

(a) The pertinent language of §284 contains no explicit limit or condition on when enhanced damages are appropriate, and this Court has emphasized that the "word 'may' clearly connotes discretion." *Martin* v. *Franklin Capital Corp.*, 546 U. S. 132, 136. At the same time, however, "[d]iscretion is not whim." *Id.*, at 139. Although there

*Together with No. 14–1520, *Stryker Corp. et al.* v. *Zimmer, Inc., et al.*, also on certiorari to the same court.

Halo Electronics, Inc. v. Pulse Electronics, Inc.

- Evidentiary standard lowered from "clear and convincing evidence" to "preponderance of the evidence"
- Appellate standard of review increased from "de novo" to "abuse of discretion"

(Slip Opinion) OCTOBER TERM, 2015 1

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

HALO ELECTRONICS, INC. *v.* PULSE ELECTRONICS, INC., ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 14–1513. Argued February 23, 2016—Decided June 13, 2016*

Section 284 of the Patent Act provides that, in a case of infringement, courts "may increase the damages up to three times the amount found or assessed." 35 U. S. C. §284. The Federal Circuit has adopted a two-part test for determining whether damages may be increased pursuant to §284. First, a patent owner 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." *In re Seagate Technology, LLC*, 497 F. 3d 1360, 1371. Second, the patentee must demonstrate, also by clear and convincing evidence, that the risk of infringement "was either known or so obvious that it should have been known to the accused infringer." *Ibid.* Under Federal Circuit precedent, an award of enhanced damages is subject to trifurcated appellate review. The first step of *Seagate*—objective recklessness—is reviewed *de novo*; the second—subjective knowledge—for substantial evidence; and the ultimate decision—whether to award enhanced damages—for abuse of discretion.

In each of these cases, petitioners were denied enhanced damages under the *Seagate* framework.

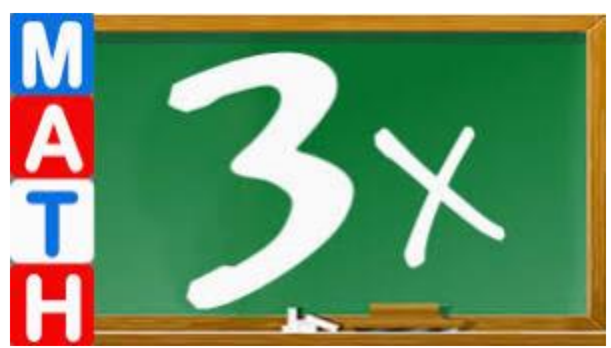
Held: The *Seagate* test is not consistent with §284. Pp. 7–15.

(a) The pertinent language of §284 contains no explicit limit or condition on when enhanced damages are appropriate, and this Court has emphasized that the "word 'may' clearly connotes discretion." *Martin* v. *Franklin Capital Corp.*, 546 U. S. 132, 136. At the same time, however, "[d]iscretion is not whim." *Id.*, at 139. Although there

*Together with No. 14–1520, *Stryker Corp. et al.* v. *Zimmer, Inc., et al.*, also on certiorari to the same court.

What's the Big Deal?

Can Possibly Mean Enhanced Damages & Attorneys' Fees



What's the Big Deal?

Enhanced Damages Up to Three Times

- The Patent Act (35 U.S.C § 284) gives district courts statutory authority to enhance damages:

  "[T]he court may increase the damages up to three times the amount found or assessed."

- At the discretion of the district court judge

- "Up to three times"

What's the Big Deal?

Attorney Fees in Exceptional Cases

- The Patent Act (35 U.S.C. § 285) gives a court statutory authority to award attorney fees:

  "The court in exceptional cases may award reasonable attorney fees to the prevailing party."

- Willful infringement is a basis for exceptionality

- At the discretion of the district court judge

What's the Big Deal?

Potential Jury Impact

- Evidence of willful infringement can be damaging to the Defendant's image
- Can predispose the jury against the Defendant

Some History…

Federal Circuit Develops Willful Infringement Jurisprudence

- 1982 – CAFC formed, in part to combat disrespect for patent rights
- 1983 – *Underwater Devices* (affirmative duty of care/seek and obtain opinion)
- 1986 – *Kloster Speedsteel* (adverse-inference rule)
- 2004 – *Knorr-Bremse* (adverse-inference rule thrown out)
- 2007 – *Seagate* (two-prong objective-subjective test)
- 2012 – *Bard* (judge decides objective prong of test)
- 2016 – Supreme Court in *Halo* (rejects two-prong objective-subjective test)

The *Halo* Swing

Pro
Patent Owner

Pro
Accused Infringer

The *Halo* Swing

Pro
Patent Owner

Pro
Accused Infringer

1983

Underwater

The *Halo* Swing

Pro
Patent Owner

Pro
Accused Infringer

1986
Kloster

1983
Underwater

The *Halo* Swing

Pro
Patent Owner

Pro
Accused Infringer

1986
Kloster

1983
Underwater

2007
Seagate

The *Halo* Swing

Pro
Patent Owner

1986
Kloster

1983
Underwater

2007
Seagate

2012
Bard

Pro
Accused Infringer

The *Halo* Swing

Pro
Patent Owner

Pro
Accused Infringer

1986
Kloster

1983
Underwater

2016
Halo

2007
Seagate

2012
Bard

?

The *Halo* Swing - *Seagate*

Pro
Patent Owner

1986
Kloster

1983
Underwater

2007
Seagate

Pro
Accused Infringer

Some History… *Seagate*

Seagate (2007)

- Federal Circuit creates a new two-prong test for willful infringement (objective and subjective recklessness)

Some History… *Seagate*

Seagate (2007) – Objective Prong

- "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."
- Threshold inquiry - don't go on to subjective prong unless objective prong is met
- Evaluate possible claim construction, non-infringement or invalidity defenses that could be made on behalf of someone in Defendant's position – if reasonable argue no objective recklessness

Some History… *Seagate*

Seagate (2007) – Subjective Prong

- "[T]he 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."

- Subjective factors
  - Defendant's actual mental state
  - Knowledge of patent and product
  - Copying
  - Emails, e.g., "I don't care about this patent"
  - Investigation and response to notice
  - Concealment

The *Halo* Swing — *Bard*

Pro
Patent Owner

Pro
Accused Infringer

1986
Kloster

1983
Underwater

2007
Seagate

2012
Bard

Some History… Federal Circuit Goes Further

Bard (2012)

- Objective prong is a question of law for the judge
- Easier to get rid of willfulness pre-trial (e.g., summary judgment) with a reasonable defense
- Jury may not see potentially damaging evidence (copying, concealment of infringement, ignoring notice)

The *Halo* Swing – Supreme Court Speaks

?

Pro
Patent Owner

1986
Kloster

1983
Underwater

2016
Halo

2007
Seagate

2012
Bard

Pro
Accused Infringer

The Supreme Court Speaks: the Concern

Halo (2016)

- Seagate test for willfulness is "unduly rigid, and it impermissibly encumbers the statutory grant of discretion to district courts."

- Seagate's objective recklessness requirement "excludes from discretionary punishment many of the most culpable offenders, such as the 'wanton and malicious pirate' who intentionally infringes another's patent—with no doubts about its validity or any notion of a defense—for no purpose other than to steal the patentee's business." 136 S. Ct. at 1932

The Supreme Court Speaks: the Concern

Halo (2016)

- “Under [*Seagate*], someone who plunders a patent—infringing it without any reason to suppose his conduct is arguably defensible—can nevertheless escape any comeuppance under § 284 solely on the strength of his **attorney's ingenuity**.” 136 S. Ct. at 1933

- Culpability for torts “generally measured against the knowledge of the actor at the time of the challenged conduct”

The Supreme Court Speaks: the Solution

Halo (2016)

- Get rid of *Seagate*'s objective prong

- Subjective recklessness may still be relevant

  "The subjective willfulness of a patent infringer, intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless." 136 S. Ct. at 1933.

The Supreme Court Speaks: the Solution

Halo (2016)

- Look at whether defendant's conduct was "egregious"

> "Section 284 gives district courts the discretion to award enhanced damages against those guilty of patent infringement. In applying this discretion, district courts are to be guided by the sound legal principles developed over nearly two centuries of application and interpretation of the Patent Act. Those principles channel the exercise of discretion, limiting the award of enhanced damages to **egregious** cases of misconduct beyond typical infringement." 136 S. Ct. at 1935.

The Supreme Court Speaks – Other Issues

Halo (2016)

- Use "preponderance" of evidence instead of "clear and convincing"
- Appellate review – "abuse of discretion" rather than "*de novo*" review
- Enhanced damages not automatic – "courts should continue to take into account the particular circumstances of each case in deciding whether to award damages, and in what amount"

Halo – Concurring Opinion

Breyer Attempts to Soften the Swing

- Willfulness cannot be based on “evidence [that] shows that the infringer knew about the patent and nothing more”
- Failure to obtain advice of counsel still may not be used to show willfulness (see Section 298 of Patent Act)
- Enhanced damages should have “careful application, to ensure that they only target cases of egregious misconduct”

Open Questions and Confusion

Legal Framework Before/After *Halo*

- *Seagate & Bard*
  - C&C Evidence Objective Prong *(Seagate)* – *de novo*
  - C&C Evidence Subjective Prong (*Seagate*) – substantial evidence
  - Enhanced Damages (*Read*) – abuse of discretion

- *Halo*
  - Enhanced damages only to be awarded for egregious misconduct
  - Preponderance of evidence for enhanced damages
  - No three step appellate review; "abuse of discretion" for enhanced damages
  - Subjective willfulness may warrant enhanced damages

Open Questions and Confusion

Willfulness in *Halo*

- Awards of enhanced damages under the Patent Act over the past 180 years establish that they are not to be meted out in a typical infringement case, but are instead designed as a "punitive" or "vindictive" sanction for egregious infringement behavior. The sort of conduct warranting enhanced damages has been variously described in our cases as **willful**, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate." 136 S. Ct. at 1932

- The subjective **willfulness** of a patent infringer, intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless." *Id.* at 1933

- Consistent with nearly two centuries of enhanced damages under patent law, however, such punishment should generally be reserved for egregious cases typified by **willful** misconduct." *Id.* at 1934

Open Questions and Confusion

So What's the Test After *Halo*?

- "[A]part from its emphatic abrogation of *Seagate's* willfulness test, *Halo* itself offered little by way of a concrete standard to assume the mantle." *Simplivity Corp. v. Springpath, Inc.*, No. CV 4:15-13345-TSH, 2016 WL 5388951, at *17 (D. Mass. July 15, 2016)
- Standard for enhanced damages is "egregious" misconduct, at the discretion of the court. But what is egregious misconduct?
- Test for willful infringement?
- Willful infringement still an issue to be determined apart from enhanced damages? Judge or jury?
- What is the relationship between willfulness and enhanced damages? Do they overlap?

Open Questions – Jury or Judge?

Who Decides Willful Infringement?

- *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1341 n.13 (Fed. Cir. 2016)
  - "there is a right to a jury trial on the willfulness question"
  - "Our case law is clear that in the absence of the Court overturning our established precedent that precedent remains in effect"
- *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, No. 14-CV-02061-H-BGS, 2016 WL 4377096, at *8 (S.D. Cal. Aug. 17, 2016) (Rejecting the argument that "a separate factual finding of willfulness by a jury no longer exists under the [*Halo*] standard.")
- Yes willfulness is still a separate issue from enhanced damages and is decided by the jury. But what is the test?

Open Questions – Willfulness

What Is the Test for Willfulness?

- 12 willfulness cases reaching the jury post-*Halo*
- Studied jury instructions
- Federal Circuit Bar Association (FCBA) issued a post-*Halo* model willfulness jury instruction
- Presented to juries as a combination of guidance from *Halo* and *Seagate* subjective prong

Jury Instructions Post-*Halo*

Plaintiff Friendly (CH2O v Meras, CDCA)

11 In addition, to prove that either one or both of Meras and Houweling's "willfully"
12 infringed the '470 patent, CH_2O must persuade you that it is more likely than not
13 that either one or both of Meras and Houweling's acted in a manner that was
14 wanton, malicious, in bad-faith, deliberate, consciously wrongful or flagrant. In
15 determining whether the alleged infringement (if any) by either or both Meras and
16 Houweling's was willful, you may consider all relevant facts.

Jury Instructions Post-*Halo*

Defendant Friendly (Finisar v Nistica, NDCA)

7 To prove willful infringement, Finisar must persuade you by a preponderance of the
8 evidence that Nistica acted in bad faith, deliberately, or with reckless disregard of claim 24 of the
9 '599 patent. You must base your verdict on Nistica's knowledge and actions at the time the
10 infringement happened. Infringement alone is not enough to prove willfulness and mere
11 knowledge of the '599 patent at the time of infringement is not enough to prove willfulness.
12 You should consider all of the circumstances including Nistica's motive or intent in
13 developing the accused products, whether Nistica knew or should have known that its conduct
14 was unreasonably risky and whether Nistica had a reasonable belief at the time of the alleged
15 infringement that its products did not infringe the '599 patent.

Jury Instructions Post-*Halo*

Neutral (Polara v Campbell, CDCA)

8 To prove willful infringement, Polara must prove by a preponderance of
9 the evidence that Campbell's infringement of the '476 Patent was egregious,
10 measured against Campbell's knowledge at the time of the infringement.
11 Egregious conduct could also be described as willful, wanton, malicious, bad-
12 faith, deliberate, consciously wrongful, flagrant, or characteristic of a pirate.
13
14 In determining whether Campbell acted egregiously, you must consider
15 the totality of circumstances surrounding the infringement of the '476 Patent,
16 including, but not limited to, the following factors:
17
18 (1) whether Campbell acted in a manner consistent with the standards
19 of commerce for its industry;
20
21 (2) whether Campbell intentionally copied the technology from Polara
22 covered by the '476 Patent;

Jury Instructions Post-*Halo*

Neutral (Polara v Campbell, CDCA)

24 (3) whether or not Campbell made a good faith effort to avoid
25 infringing the patent, for example by taking remedial action upon learning of
26 the '476 Patent such as ceasing infringing activity or attempting to design
27 around the patent;

1 (4) whether Campbell reasonably believed that it had a substantial
2 defense to infringement and reasonably believed that the defense would be
3 successful if litigated. Because this determination turns on Campbell's actual
4 knowledge, Campbell cannot rely on a defense to infringement that was not
5 known to Campbell at the time it engaged in the infringing conduct; and
6
7 (5) although there is no obligation to obtain an opinion of counsel,
8 whether Campbell relied on a legal opinion that was well-supported and
9 believable and that advised Campbell (1) that the product did not infringe
10 Polara's patent or (2) that the patent was invalid or unenforceable.

Open Questions – Enhanced Damages

What is the Test for Enhanced Damages?

- §284 makes it clear enhanced damages are awarded at the discretion of the district court (the judge)
- Halo makes clear that judges should exercise their discretion based on whether the accused infringer's conduct was **egregious**
- What is egregious?

Open Questions-Enhanced Damages

What is Egregious Conduct?

- "Awards of enhanced damages under the Patent Act over the past 180 years establish that they are not to be meted out in a typical infringement case, but are instead designed as a "punitive" or "vindictive" sanction for egregious infringement behavior. The sort of conduct warranting enhanced damages has been variously described in our cases as willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate." 136 S. Ct. at 1932.
- District courts enjoy discretion in deciding whether to award enhanced damages, and in what amount. But through nearly two centuries of discretionary awards and review by appellate tribunals, "the channel of discretion ha[s] narrowed," so that such damages are generally reserved for egregious cases of culpable behavior. *Id.*
- District courts should exercise discretion to enhance damages in "egregious cases typified by willful misconduct." *Id.*

Open Questions – Enhanced Damages

What is Egregious Behavior?

- The Read factors (*Read Corp. v. Portec, Inc.*, 970 F.2d 816, 827 (Fed. Cir. 1992)):

  (1) whether the infringer deliberately copied 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

  (9) Whether defendant attempted to conceal its misconduct

Open Questions – Enhanced Damages

What is Egregious Behavior?

- In practice, courts analyze the *Read* factors for determining egregiousness and ultimately enhanced damages
- Also in practice, some of the *Read* factors are relevant for the jury's consideration of willfulness (as we have seen from various post-*Halo* jury instructions)

Statistics Post-*Halo*

How Often is Willfulness Found Post-*Halo*?

	Bard - Halo	**Post-Halo**
Jury Finding Willfulness	45%	80%

- ~ 35% increase in willful infringement findings
- But JMOL and appeals not completed in post-*Halo* cases
- Yet standard of review is more deferential now
- Caveat - small sample size

Statistics Post-*Halo*

How Often Are Damages Enhanced Post-Halo?

- 10 courts considered enhancement post-Halo
- 5 courts enhanced
  - 2 trebled damages
  - 2 doubled damages
  - 1 enhanced by 66%
- 5 courts did not enhance
- 50 – 50

Minimizing Risk Post-*Halo*

Potential Impact of *Halo*

- Willfulness is easier to prove under *Halo's* lower evidentiary standard and without *Seagate's* objective prong
- Willfulness will reach the jury more often
- Willfulness will not be set-aside post-trial by the judge on JMOL as often
- Willfulness will be harder to overturn on appeal under the new more deferential appellate review standard
- Plaintiffs will use willfulness as leverage

Minimizing Risk Post-*Halo*

Totality of the Circumstances

- Who are you? What kind of resources?
- Who is the patent owner?
  - Competitor v. NPE
- How did you become aware?
  - Design phase/company clearance
  - Cease & desist with specificity v. form letter
  - Your response and when

Minimizing Risk Post-*Halo*

Some Suggestions

- Assess internal company policy
  - If none, consider one
- Show behaved in good-faith
- Perform internal investigations
  - IP Department, Engineering, Other
- Document investigations (e.g., claim charts)
- Be prompt
- Respond substantively to cease & desists
- Designate an internal patent clearance person

Minimizing Risk Post-*Halo*

Some Suggestions

- Consider external investigations, especially for high-risk circumstances
- Consider privilege issues to minimize waiver
- Review internal document retention policy
- Provide in-house training
  - Minimize the patent enthusiast
- Maintain independent development evidence
- Follow the policy

Minimizing Risk Post-*Halo*

Opinions of Counsel

- No obligation, but could help on both willfulness and enhancement
  - Some Post-Halo jury instructions reference opinions
  - *Read*: “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”
- If a jury instruction states that Defendant was not obligated, but an opinion was procured, may lean the jury towards Defendant
- If inducement could be an issue, then another reason (non-infringement)

Minimizing Risk Post-*Halo*

Opinions of Counsel – *Post-Halo Examples*

- *LoggerHead Tools, LLC v. Sears Holdings Corp.*, No. 12-CV-9033, 2016 WL 5112017, at *4 (N.D. Ill. Sept. 20, 2016) (summary judgment of no willful infringement because the accused infringer had consulted with patent counsel during design process and had a non-infringement opinion)

- *Trustees of Boston Univ. v. Everlight Elecs. Co.*, No. 12-11935-PBS, 2016 WL 3976617, at *4 (D. Mass. July 22, 2016) (although jury found willful infringement under *Seagate*, denying enhanced damages in part because accused infringer obtained two non-infringement opinions of counsel)

- *Georgetown Rail Equip. Co. v. Holland L.P.*, No. 6:13-CV-366, 2016 WL 3346084, at *21 (E.D. Tex. June 16, 2016) (enhancing damages in part because of failure to investigate)

Hatch-Waxman/General Pharma Practice

Willful Infringement and Attorney Fees In Hatch-Waxman Actions

- In typical patent infringement actions, an opinion of counsel may help negate allegations of willful infringement and attorney fees. In Hatch-Waxman actions, an "opinion letter," typically the paragraph IV certification and related notice letter, can cause the opposite result

- The seminal case awarding attorney fees to the plaintiff patentee in a Hatch Waxman action is *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal, Inc.,* 21 F. Supp. 2d 366 (S.D.N.Y. 1998), *aff'd,* 231 F.3d 1339 (Fed. Cir. 2000)

- There, attorney fees were awarded by the district court due to a baseless paragraph IV certification and the court held that this conduct constituted "willful infringement." The court dismissed Danbury's argument that the ANDA filing was an "artificial" act of infringement and could not therefore support a finding of willful infringement

- The Federal Circuit affirmed the award on the broader basis that the action was an "exceptional case" under 35 U.S.C. § 285. It stated:

    - "The joint operation of §§ 271(e) and 285 require the [ANDA filer] to display care and regard for the strict standards of the Hatch-Waxman Act when challenging validity. . . . The Hatch-Waxman Act thus imposes a duty of care on an ANDA certifier. Thus, a case initiated by [an ANDA] filing, like any other form of infringement litigation may become exceptional if the ANDA filer makes baseless certifications." 231 F.3d at 1347.

Willful Infringement and Attorney Fees In Hatch-Waxman Actions

- The Hatch Waxman Act, 35 U.S.C. § 271(e)(4), states that a court may award of attorney fees under section 285 as one possible remedy relating to an ANDA filing.

- In *Takeda Chemical Industries, Ltd. v. Mylan Laboratories, Inc.*, 549 F.3d 1381 (Fed Cir. 2008), the Federal Circuit affirmed an award of $16,800,000 in fees and expenses where the two ANDA filers submitted baseless paragraph IV certifications. Attorney fees were awarded under section 271(e)(4), and expert witness fees were awarded under the court's inherent powers.

- Unlike the district court decision in *Yananouchi,* the award was not based on "willful infringement."

Willful Infringement and Attorney Fees In Hatch-Waxman Actions

- In *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004), the Federal Circuit reversed a finding of willfulness based on an ANDA filing, holding that “the mere fact that a company has filed an ANDA. . . cannot support a finding of willful infringement for purposes of awarding attorney’s fees pursuant to 35 U.S.C. § 271(e)(4).” *Id. at 1350-51.* But attorney fees can be awarded in “exceptional cases” under section 285.

- Numerous district court decisions have dismissed allegations of willful infringement in Hatch-Waxman actions in view of *Glaxo. See, e.g., Nycomed U.S. Inc. v. Glenmark Generics Ltd.*, 2010 WL 1257803, *4-*5 (S.D.N.Y. 2010); *Sepracor Inc. v. Dey, L.P.*, 2008 WL 4377570, *3 (D. Del. 2008); *Allergan, Inc. v. Alcon, Inc.*, 2005 WL 3971927 (D. Del. 2005).

Willful Infringement and Attorney Fees In Hatch-Waxman Actions

- Some courts, however, have noted that "*Glaxo* does not stand for the proposition that there can be no willful infringement in an ANDA case. Rather a finding of willful infringement cannot be based ***solely*** in the fact that an ANDA application was filed." *Wyeth v. Anchen Pharmaceuticals,* 2006 WL 6103249, *2 (S.D. Cal. 2006) (emphasis added). Thus, many courts have allowed allegations of willful infringement to stand and permitted discovery on the issue. *See, e.g., Wyeth v. Teva Pharmaceuticals USA, Inc.,* Civ. A. No. 03-1293 (D.N.J. Aug. 5, 2004).

- Regardless, a bogus "opinion" presented in the paragraph IV certification and notice letter can give use to attorney fees in a Hatch Waxman case, even where allegations of willful infringement are dismissed. *See Janseen, L.P. v. Barr Labs., Inc.,* 2008 WL 323558 (D.N.J. 2008); *Aventis Pharm. Deutschland GmBH v. Lupin Ltd.,* 409 F. Supp. 2d 722 (E.D. Va. 2006).

Willful Infringement And Attorney Fees In Hatch-Waxman Actions

- Moreover, even if willful infringement is not found, a frivolous paragraph IV certification and notice letter can give rise to a finding that the case was exceptional under section 285. *See Novartis Pharmaceuticals Corp. v. Roxane Laboratories, Inc.,* 2009 WL 1140440 (D.N.J. 2009).

* * *

- In conclusion, an allegation of willful infringement in a Hatch-Waxman action may be met with a motion to dismiss. Therefore, the complaint should not rely *solely* on such allegations to support any award of attorney fees, but also include broader language under sections 285, 271(e)(4), and even refer to the inherent power of the court.

Questions?

Thank you!

John Johnson
Principal, New York
212-641 2202
jjohnson@fr.com

Brian Coggio
Of Counsel, New York
212-641-2336
coggio@fr.com

Mike Sobolev
Associate, Silicon Valley
650-839-5044
sobolev@fr.com

Please send your NY CLE forms or questions about the webinar to marketing at lundberg@fr.com.

A replay of the webinar will be available for viewing at
http://www.fr.com/events/webinar-minimizing-willful-infringement-post-halo/

© Copyright 2016 Fish & Richardson P.C. These materials may be considered advertising for legal services under the laws and rules of professional conduct of the jurisdictions in which we practice. The material contained in this presentation has been gathered by the lawyers at Fish & Richardson P.C. for informational purposes only, is not intended to be legal advice and does not establish an attorney-client relationship. Legal advice of any nature should be sought from legal counsel. Unsolicited e-mails and information sent to Fish & Richardson P.C. will not be considered confidential and do not create an attorney-client relationship with Fish & Richardson P.C. or any of our attorneys. Furthermore, these communications and materials may be disclosed to others and may not receive a response. If you are not already a client of Fish & Richardson P.C., do not include any confidential information in this message. For more information about Fish & Richardson P.C. and our practices, please visit www.fr.com.

#1 Patent Litigation Firm *(Corporate Counsel, 2004–2016)*

APPENDIX

Some Post-*Halo* Cases

Juries Hearing and Finding Willful Infringement

- *Polara Engineering, Inc. v Campbell Company,* in the Central District of California (June 30, 2016)
- *Dominion Resources, Inc. v. Alstom Grid, Inc.*, in the Eastern District of Pennsylvania (July 1, 2016)
- *CH2O, Inc. v. Meras Engineering, Inc.*, in the Central District of California (September 6, 2016)
- *Cellular Communications Equipment v. Apple, Inc.*, in the Eastern District of Texas (September 14, 2016)

Some Post-*Halo* Cases

Juries Hearing and Finding Willful Infringement

- *Core Wireless Licensing S.a.r.l. v. LG Electronics, Inc.*, in the Eastern District of Texas (September 16, 2016)
- *Johnstech Intl v JF Tech Behad*, in the Northern District of California (September 27, 2016)
- *Barry v. Medtronic, Inc.,* in the Eastern District of Texas (November 11, 2016)
- *Arthrex, Inc. v. Smith & Nephew, Inc.*, in the Eastern District of Texas (December 9, 2016)