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### Patent Infringement Litigation: Obtaining TROs, Injunctions and Other Preliminary Relief

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Today's faculty features:

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# Patent Infringement Litigation: Obtaining TROs, Injunctions and other Preliminary Relief

Anthony J. Fitzpatrick May 24, 2012

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### Determining the type of relief to seek:

- Temporary Restraining Order (TRO)
- Preliminary Injunction
- Alternatives:
  - Expedited discovery
  - Early trial on the merits
  - A very focused injunction, e.g. enjoining the defendant from using a particular component or process

### Temporary Restraining Orders:

- Fed. R. Civ. P. 65(b)
- Ex parte:
  - Movant must show that there will be immediate irreparable harm before adverse party can be heard.
  - Movant's attorney must certify as to efforts made to give notice, or reasons why notice should not be required.

### Temporary Restraining Orders:

- Cannot be issued for more than 14 days.
- Rule 65(b)(3): "If the [TRO] is issued without notice, the motion for a preliminary injunction must be set for hearing at the earliest possible time."

#### <u>Duane</u>Morris

### **Preliminary Injunction**

• Fed. R. Civ. P. 65(a)

#### **Know Your Venue:**

- Local Rules
- Standing Orders
- Know your judge:
  - Many judges may be reluctant to make a significant decision on the merits of a patent case on a truncated record and on an expedited basis.
  - Consider a venue that has a lot of patent cases, and hence where the judges may be more comfortable with patent disputes.

### <u>Duane</u>Morris

### When to seek a TRO?

Extreme emergency

### When to seek a Preliminary Injunction?

- Preliminary injunction:
  - At the outset of litigation
  - During litigation e.g. a "launch at risk" during Hatch-Waxman litigation
  - After trial:
    - Cephalon v. Mylan (D. Del. 2011) the District Court held that patents-in-suit were obvious, yet granted an injunction pending appeal

### Why seek preliminary relief?

- Irreparable harm to the patentee
- Strategic advantages:
  - The patentee can take time to prepare its filing, and then impose a compressed schedule on the accused infringer
  - Put pressure on the accused infringer to settle
- Convey to the Court that the case is important and time-sensitive

#### What are the odds of success?

- Docket Navigator® search conducted May 21, 2012, regarding motions for preliminary injunction:
  - Denied = 185
  - Granted = 113
  - Ruling deferred = 19
  - Denied without prejudice = 16
  - Denied in part, granted in part = 11

### What if you lose?

- File an immediate appeal!
- 28 U.S.C. § 1292:
  - Injunction decisions granting, denying, modifying, dissolving, etc. – are automatically reviewable by the Federal Circuit.
- The Federal Circuit is not afraid to make decisions regarding preliminary injunctions – see e.g. Apple v. Samsung Electronics (Fed. Cir. May 14, 2012)

### <u>Duane</u> Morris

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### Patent Infringement Litigation: Obtaining TROs, Injunctions and other Preliminary Relief

Preliminary Injunctions in Patent Litigation

Melanie R. Rupert
May 24, 2012

### **Topics for Discussion**



- Standards for preliminary injunctions in patent litigation
  - Likelihood of success on the merits
  - Irreparable harm
  - Balance of hardships
  - Public interest
- Preliminary injunctions for biosimilars (BPCIA)

# **Authority to Issue Preliminary Injunctions**



- Under 35 U.S.C. § 283, federal district courts "may 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 purpose of a preliminary injunction is to "protect the status quo . . . to prevent irreparable harm during the pendency of a lawsuit ultimately to preserve the court's ability to render a meaningful judgment on the merits"

In re Microsoft Corp. Antitrust Litig., 333 F.3d 517, 525 (4th Cir. 2003)

# Elements Required for a Preliminary Injunction



- ▶ Patentee has burden to establish right for preliminary injunction in light of four factors:
  - Whether the patentee is <u>likely to succeed on the</u> <u>merits</u> at trial;
  - Whether the patentee is likely to suffer <u>irreparable</u>
     <u>harm</u> in the absence of preliminary relief;
  - Whether the <u>balance of hardships</u> tips in the patentee's favor; and
  - Whether the injunction is in the <u>public interest</u>

See, e.g., Celsis In Vitro, Inc. v. CellzDirect, Inc., 664 F.3d 922, 926 (Fed. Cir. 2012)

# Elements Required for a Preliminary Injunction



- ▶ "Likelihood of success on the merits" requires that the court consider the strength of the parties' substantive positions
  - Findings are preliminary do not bind court at trial on the merits
  - Raises complex issues regarding burdens of proof
- Irreparable harm," "balance of hardships," and "public interest" are equitable factors that generally do not turn on the merits of the case, but rather the effects of an injunction on the parties and the public
- Contrary to earlier Federal Circuit precedent, there is now <u>no</u> <u>presumption of irreparable harm</u>, even if a patentee shows a strong likelihood of success on the merits

Robert Bosch LLC v. Pylon Mfg. Corp., 659 F.3d 1142, 1149 (Fed. Cir. 2011)

# Elements Required for a Preliminary Injunction



The Federal Circuit has held that a court determining whether to grant a preliminary injunction must consider and balance each of the four factors – and that failure to do so is an abuse of discretion

Procter & Gamble Co. v. Kraft Foods Global, Inc., 549 F.3d 842, 847 (Fed. Cir. 2008); see also Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 21-22 (2008)

 At a minimum, a patentee must establish both likelihood of success and irreparable harm to obtain a preliminary injunction

Altana Pharma AG v. Teva Pharms. USA, Inc., 566 F.3d 999, 1005 (Fed. Cir. 2009)

 A court denying a preliminary injunction for failure to demonstrate likelihood of success or irreparable harm need not consider the other factors

See Reebok Int'l Ltd. v. J. Baker, Inc., 32 F.3d 1552, 1556 (Fed. Cir. 1994)

#### **Likelihood of Success on the Merits**



▶ A patentee must "demonstrate that it will likely prove infringement of one or more claims of the patents-in-suit, and that at least one of those same allegedly infringed claims will also likely withstand the validity challenges presented by the accused infringer"

AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1050 (Fed. Cir. 2010)

- Requires two-step analysis which mirrors trial on the merits
  - First, claims are construed
  - Second, infringement and validity/enforceability defenses are assessed

See Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1339 (Fed. Cir. 2003)

#### **Likelihood of Success on the Merits**



While the burdens of proof in the preliminary injunction "track" onto those for a trial on the merits, they are not necessarily identical

See Titan Tire Corp. v. Case New Holland, 566 F.3d 1372, 1376-77 (Fed. Cir. 2009)

- Relevant question at the preliminary injunction stage is whether the patentee is "likely to succeed" with respect to proving infringement and overcoming validity and enforceability defenses
- Interplay between the "likely to succeed" standard and the accused infringer's ultimate burden to prove invalidity at trial by "clear and convincing evidence" remains a disputed issue



- ▶ Two conflicting schools of thought:
  - If the accused infringer articulates a credible validity defense that the patentee cannot show "lacks substantial merit," the patentee cannot establish a likelihood of success on validity

- or -

 If, at the preliminary stage, the accused infringer cannot provide clear and convincing evidence of invalidity (or something close to it), the patentee is likely to succeed on validity at trial



- Some Federal Circuit panels require the <u>patentee</u> to show that validity defenses are not credible
  - Preliminary injunction will not issue if accused infringer raises a "substantial question" regarding validity that the patentee cannot show lacks "substantial merit"
  - The issue at the preliminary injunction stage is not "invalidity" of the patents-in-suit, but merely "vulnerability" to an invalidity defense

See, e.g., Amazon.com v. Barnesandnoble.com, 239 F.3d 1343, 1350-51, 1359 (Fed. Cir. 2001)

➤ This is a significant departure from the standard at trial, where the <u>accused infringer</u> has the burden to prove invalidity by clear and convincing evidence



- Other Federal Circuit panels argue that the "substantial question" standard is an artifact of Federal Circuit precedent and departs from the Supreme Court's "likelihood of success" standard
  - While the patentee has the burden to demonstrate a likelihood of success on the merits, the burden of proving invalidity rests on the accused infringer at every stage in litigation
  - If, at the preliminary stage, the accused infringer has not set forth strong evidence of invalidity, the patentee is likely to succeed on overcoming invalidity defenses at trial
  - Merely requiring a showing of "vulnerability" to invalidity challenges is inconsistent with these burdens

See, e.g., Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1363-64, 1368 (Fed. Cir. 2008); see also Celsis In Vitro, 664 F.3d at 926, 928



▶ In 2009, one Federal Circuit panel attempted to craft a comprehensive burden-shifting scheme to address this issue – but it did not take hold

See Titan Tire, 566 F.3d at 1379-80; cf. Kimberly-Clark, 660 F.3d 1293, 1299 (Fed. Cir. 2011) (Newman, joined by O'Malley & Reyna, JJ., dissenting)

▶ Both the Federal Circuit *en banc* and the Supreme Court refused to hear a recent split decision on this issue

See, e.g., Kimberly-Clark Worldwide, Inc. v. First Quality Baby Prods., LLC, 431 Fed. App'x 884 (Fed. Cir. 2011), reh'g en banc denied, 660 F.3d 1293 (Fed. Cir. 2011), cert. denied, 132 S. Ct. 1143 (2012)

 Split decisions have continued this year, and this issue may remain panel-dependent for years to come

See Celsis In Vitro, 664 F.3d at 934-35 (Gajarsa, J., dissenting)

### Irreparable Harm



- ▶ The irreparable harm analysis is fact-specific, and cannot be conducted mechanically
  - Patentee's right to exclude is relevant to irreparable harm, but alone, it cannot be dispositive
    - See Robert Bosch, 659 F.3d at 1149
  - Federal Circuit has defined irreparable harm as "harm that could not be sufficiently compensated by money damages or avoided by a later decision on the merits" – but has also stated that "the mere possibility of future monetary damages does not defeat a motion for preliminary injunction"
    - Compare Canon, Inc. v. GCC Int'l, Ltd., 263 Fed. App'x 57, 62 (Fed. Cir. 2008) with Celsis In Vitro, 664 F.3d at 930
- In practice, a finding of likelihood of success on the merits may influence a court's finding on irreparable harm

## Irreparable Harm: Impact of Likelihood of Success



King v. Corepharma (Contract)	King v. Sandoz (Patent)
King exhibited a "high likelihood of success" of breach of contract	Sandoz " <i>raised a substantial question</i> " of noninfringement and invalidity based on anticipation and obviousness
"King argues that it is being irreparably harmed by the presence of generic competition in the pharmaceutical marketplace because it will <i>lose market share and suffer price erosion The Court is persuaded by King's irreparable harm arguments</i> in this case, especially given that Corepharma is the third entrant into the marketplace."	"In cases where the presumption [of] irreparable harm is not available (either because there was no strong showing of likelihood on the merits or the case was decided post-Winter), courts have routinely decided that market share and price erosion do not amount to irreparable harm."

King Pharms., Inc. v. Corepharma, LLC, No. 10-1878, 2010 WL 1850200 (D.N.J. May 17, 2010)

King Pharms., Inc. v. Sandoz, Inc., No. 08-5974, 2010 WL 1957640 (D.N.J. May 17, 2010)

## Irreparable Harm: Impact of Likelihood of Success



#### King v. Corepharma (Contract)

# "[King's expert] credibly testified that third party payors . . . will move King's patented product off of their formularies in the presence of generic competitors . . . . [King's expert] further testified that it would be impossible to predict the future price of Skelaxin, and thus any damages later awarded to King would be imprecise."

#### King v. Sandoz (Patent)

"[King's expert] gives no reason why these damages are more difficult to estimate or calculate than in any other patent case. . . . '[N]either the difficulty of calculating losses in market share, nor speculation that such losses might occur, amount to proof . . . justifying the extraordinary relief of an injunction prior to trial."

King Pharms., Inc. v. Corepharma, LLC, No. 10-1878, 2010 WL 1850200 (D.N.J. May 17, 2010)

King Pharms., Inc. v. Sandoz, Inc., No. 08-5974, 2010 WL 1957640 (D.N.J. May 17, 2010)

### **Irreparable Harm: Direct Competitors**



- Where the patentee directly competes with the accused infringer, a preliminary injunction is possible, but not guaranteed
  - Courts have differed over whether potential loss of sales, price erosion, and loss of market share amounts to irreparable harm, or harms that should only be compensated

Compare Celsis In Vitro, 664 F.3d at 930 with Abbott Labs. v. Andrx Pharms., Inc., 452 F.3d 1331, 1347-48 (Fed. Cir. 2006)

 While head-to-head competition in a two-supplier market generally supports finding irreparable harm at the permanent injunction stage, it is unclear whether that holds at the preliminary injunction stage

Compare Abbott Labs., 544 F.3d at 1361-62 with King Pharms., 2010 WL 1957640, at \*5

### **Irreparable Harm: NPEs**



- A non-practicing entity ("NPE") is patentee that has not attempted to practice its invention or otherwise commercialize its invention (e.g., by exclusive licensing)
- As an NPE cannot have facts like lost sales and lost market share, NPE status significantly weighs against a finding of irreparable harm – but it is not dispositive

See, e.g., High Tech Medical Instrumentation, Inc. v. New Image Indus., Inc., 49 F.3d 1551, 1556 (Fed. Cir. 1995)

 Courts have generally rejected loss of an NPE's opportunity to license or commercialize patented technology as grounds for irreparable harm

See, e.g., Paice LLC v. Toyota Motor Corp., 504 F.3d 1293, 1302-03 (Fed. Cir. 2007); z4 Techs., Inc. v. Microsoft Corp., 434 F. Supp. 2d 437, 440 (E.D. Tex. 2006)

# Irreparable Harm: Future and Indirect Competitors



Where a patentee is years away from marketing a competing product (e.g., an unapproved drug that is still in clinical trials), courts may disregard allegations of future lost sales and market share as too speculative to support a finding of irreparable harm

Novo Nordisk A/S v. Pfizer, No. 06-5819, 2006 WL 3714312 at \*5 (S.D.N.Y. Dec. 14, 2006); see also Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 21-22 (2008)

In some circumstances, a patentee may assert irreparable harm based on lost sales of unpatented products, if such losses are causally related to infringing activities

See, e.g., Broadcom Corp. v. Qualcomm Inc., 543 F.3d 683, 701-03 (Fed. Cir. 2008)

In any case, the alleged irreparable harm must have a causal nexus with the alleged infringing activities

See Apple Inc. v. Samsung Elecs. Co., Ltd., No. 2012-1105, at 16-18 (Fed. Cir. May 14, 2012) (slip op.)

### **Balance of Hardships**



- Requires the court to balance the hardship towards the accused infringer caused by grant of a preliminary injunction against the hardship towards the patentee caused by a denial of injunction
- Analysis of hardship to the patentee overlaps significantly with the irreparable harm inquiry
- Alleged hardship to the accused infringer may be discounted if stemming from a "calculated risk" to develop an infringing product (e.g., an infringing generic drug product)

See Celsis In Vitro, 664 F.3d at 931; Everett Labs., Inc. v. Breckenridge Pharms., Inc., 573 F. Supp. 2d 855, 870 (D.N.J. 2008)

If injunction turns out to be wrongfully granted, reasonably quantifiable harms to accused infringer proximately caused by the injunction may be compensated under a bond posted under Rule 65(c), Fed. R. Civ. P.

#### **Public Interest**



- Findings on the public interest factor frequently track whether there is a likelihood of success on the merits
  - *E.g.*, in the Hatch-Waxman context, courts granting injunctions have focused on the public interest in enforcing valid pharmaceutical patents, while courts denying injunctions have focused on the public interest in the availability of cheap generic drugs

Compare Pfizer, Inc. v. Teva Pharms. USA, Inc., 429 F.3d 1364, 1382 (Fed. Cir. 2005) with CollaGenex Pharms., Inc. v. Ivax Corp., 375 F. Supp. 2d 120, 140-41 (E.D.N.Y. 2005)

- Generally, courts find little public interest in granting an NPE's request for preliminary injunction
- ➤ The public interest factor carries more weight when an injunction would result in removal of a key medical product from the market that has distinct benefits from other available products

See, e.g., Bard Peripheral Vascular, Inc. v. W.L. Gore & Assoc., Inc., No. 03-0597, 2009 WL 920300 at \*9 (D. Ariz. Mar. 31, 2009), aff'd, 670 F.3d 1171 (Fed. Cir. 2012)

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## Preliminary Injunctions Under the BPCIA



- ➤ The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") provides an abbreviated pathway for biosimilars based on regulatory data previously submitted for reference product
- The BPCIA contains provisions governing patent litigation relating to the biosimilar product, including preliminary injunctions
  - Notice of intent to market: Abbreviated biologic applicant must provide at least 180 days notice of intention to market, regardless of existence of patents
  - Reference product sponsor can seek preliminary injunction after receiving notice and before marketing until court decides infringement, validity, and enforceability
  - Requires the parties to "reasonably cooperate" in expediting discovery in connection with the preliminary injunction motion

42 U.S.C. § 262(I)(8)

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### **Preliminary Injunctions Under the BPCIA**



- The BPCIA does not set forth the relevant standards for issuing preliminary injunctions — but there is currently no indication that the analysis will differ from preliminary injunction analysis generally
- Patents eligible for consideration in preliminary injunction analysis
  - Patents-in-suit in the pending litigation
  - Patents in the original lists exchanged by the parties, but not included in the final lists
  - Newly issued or exclusively licensed patents

42 U.S.C. § 262(I)(8)(B)



### **Thank You**

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### PRÉLIMINARY INJUNCTIONS AFTER *EBAY*

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

### Issue:

Considered the appropriateness of the "general rule" applied by the Federal Circuit "that courts will issue permanent injunctions against patent infringement absent exceptional circumstances."

### Rationale:

No justification for departing from the well-established principles of equity that require application of the four-factor test.

# eBay Inc. v. MercExchange, L.L.C. 547 U.S. 388 (2006), cont'd

### Holding:

We hold only that the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards.

# Question Raised by *eBay --* Did the presumption of irreparable harm still apply in the context of preliminary injunctions?

- Ortho McNeil Pharmaceuticals, Inc. v. Barr Labs, 2009
   U.S. Dist. LEXIS 62721 (D.N.J. July 21, 2009):
  - "Although, as this Court discussed at the preliminary injunction hearing, the Court is of the view that the presumption of irreparable harm, *Pfizer, Inc. v. Teva Pharms.USA, Inc., 429 F.3d 1364, 1381 (Fed. Cir. 2005*), **did not survive the Supreme Court's decision in** *Ebay,* resolving this legal question is unnecessary for deciding the instant motion."
- Eisai Co. v Teva Pharms., 2008 U.S. Dist LEXIS 33747
   (D.N.J. Mar. 28, 2008)
  - Declining to read *eBay* to prohibit a presumption of irreparable harm and applying the presumption.

### The Eisai Court's Reasoning

"[T]he Federal Circuit has since referenced eBay in an appeal from the grant of a preliminary injunction to a pharmaceutical company that had established a likelihood of success on the merits and thereafter received a presumption of irreparable harm from the district court. Abbott Laboratories v. Andrx Pharms, Inc., 452 F.3d 1331, 1347 (Fed. Cir. 2006). In Abbott, the Federal Circuit acknowledged eBay in a different part of the opinion, but then, after reversing the district court's decision on likelihood of success, explained that because of that failure to demonstrate likelihood of success, the patentee was "no longer entitled to a presumption of irreparable harm." *Id. at 1348.* Presumably, if the Federal Circuit had read eBay as broadly as Teva reads it, then the Abbott court would have noted at such a juncture that a presumption of irreparable harm no longer exists, period."

Eisai Co. v Teva Pharms., 2008 U.S. Dist LEXIS 33747, \*31 (D.N.J. Mar. 28, 2008)

### No Presumption of Irreparable Harm

Robert Bosch LLC v. Pylon Mfg. Corp., 659 F.3d 1142, 1149 (Fed. Cir. 2011)

Bosch concerned a permanent injunction, but addressed the presumption of irreparable harm generally.

The Supreme Court, however, did not expressly address the presumption of irreparable harm, and our subsequent cases have not definitively clarified whether that presumption remains intact. Seé <u>Broadcom Corp. v. Qualcomm Inc., 543</u> F.3d 683, 702 (Fed.Cir.2008) ("It remains an open question whether there remains a rebuttable presumption of irreparable harm following *eBay.*" (internal quotation marks and citation 1149\*1149 omitted)). Our statements on this topic have led one district court judge to conclude that "the presumption of irreparable harm is at best on life support." Red Bend Ltd. v. Google, Inc., 2011 WL 1288503, at \*18 (D.Mass. Mar.31, 2011) (citations omitted). We take this opportunity to put the question to rest and confirm that eBay jettisoned the presumption of irreparable harm as it applies to determining the appropriateness of injunctive relief.

### Sample Decisions Where Irreparable Harm Found

- Abbott Laboratories v. Sandoz, 544 F.3d 1341 (Fed. Cir. 2008)
  - District Court stated that Abbott was entitled to a presumption of irreparable harm, but then discussed evidence of irreparable harm. *Abbott Labs. V. Sandoz*, 500 F.Supp.2d 807, 842-843 (N.D. III. 2007).
  - Federal Circuit ignored the presumption. 544 F.3d at 1362-1363. It instead discussed evidence of market share and revenue loss and pointed to precedent supporting price erosion and loss of market position as evidence of irreparable harm.
- AstraZeneca v. Apotex, 633 F.3d 1042 (Fed. Cir. 2010)
  - No discussion of the presumption of irreparable harm
  - Types of harm considered included:
    - Change in circumstances from settlement agreement with thirdparty Teva. No evidence to establish what the two player market would have been.
    - Loss of goodwill
    - Layoffs

### Sample Decisions Where Irreparable Harm Found

- Celsis in Vitro, Inc. v. Cellzdirect, Inc., Fed. Cir. Jan. 9, 2012
  - Affirming grant of preliminary injunction
  - Types of harm considered included:
    - Price erosion
    - Damage to ongoing customer relationships
    - Loss of customer goodwill (when effort made to restore original price)
    - Loss of business opportunities

### Sample Decisions Where No Irreparable Harm

- Altana Pharma v. Teva Pharms, 566 F.3d 999 (Fed. Cir. 2009)
  - Federal Circuit affirmed denial of preliminary injunction.
  - Found no error in district court's finding of no irreparable harm.
  - Types of harm argued by Altana included:
    - Price erosion
    - Loss of market share
    - Lost profits
    - Lost research opportunities
    - Possible layoffs

# Apple Inc. v. Samsung Electronics Co. Fed. Cir. May 14, 2012.

- District Court (N.D. Cal.) denied Apple's motion for a preliminary injunction.
- Federal Circuit affirmed the denial with respect to three of the four patents at issue.
  - Apple argued erosion of design and brand distinctiveness, resulting in loss of goodwill, and lost sales.
  - District Court found that Apple failed to establish a nexus between the alleged harm and the alleged infringing conduct.
  - Federal Circuit agreed that the district court was correct to require a nexus. "Sales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons other than the patented feature."
  - Delay

# Apple Inc. v. Samsung Electronics Co. Fed. Cir. May 14, 2012, cont'd

With respect to the fourth patent at issue on that PI motion, a design patent, the district court concluded that Apple had shown that it was likely to suffer irreparable harm. Factors considered included:

- Relative market share of the two parties
- Absence of other competitors in the relevant market
- "that design mattered more to customers in making tablet purchases, which helped Apple establish the requisite nexus."
- "The fact that Apple had claimed all views of the patented device and the fact that it was prompt in asserting its patent rights were also properly accorded weight by the court."

Given the deferential standard of review, the Federal Circuit did not find an abuse of discretion here.

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