Litigation Webinar Series

Enjoining Life Sciences Competition: A Review and Discussion

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Welcome

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Today's Topics

- Statutory Bases for Injunctions
- Preliminary Injunctions
- Permanent Injunctions

Life Sciences Competition

- Direct competitors
- Generic drug manufacturers
  - Hatch-Waxman Act
- Biosimilar manufacturers
  - BPCIA

Patent Act – Injunction Remedy

35 U.S.C. § 283

The several courts having jurisdiction of cases under this title 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.

- Basis for granting both preliminary and permanent injunctive relief.

Hatch-Waxman Act – Injunction Remedy

35 U.S.C. § 271(e)

(2) It shall be an act of infringement to submit— (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

. . .

(4) For an act of infringement described in paragraph (2)—

. . .

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product.

Hatch-Waxman Act – Injunction Remedy

35 U.S.C. § 271(e)

(2) It shall be an act of infringement to submit— (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

. . .

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.

Hatch-Waxman Act – Injunction Remedy

Special Considerations

- Preliminary Injunctions
  - Timing in view of 30-month stay.
  - Injunctions pending appeal.
- Permanent Injunctions
  - Scope: §271(e)(4)(B); § 283
  - When to make your case – at trial?

BPCIA – Injunction Remedy

35 U.S.C. § 271(e)

(2) It shall be an act of infringement to submit—

(C)

(i) with respect to a patent that is identified in the list of patents described in section 351(*l*)(3) of the Public Health Service Act (including as provided under section 351(*l*)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(*l*)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(*l*)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

BPCIA – Injunction Remedy

35 U.S.C. § 271(e)

(4) For an act of infringement described in paragraph (2)—

. . .

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product

. . .

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(*l*)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

BPCIA – Injunction Remedy

Special Considerations

- Preliminary Injunctions
  - Timing and 180-day notice of commercial marketing requirement.
  - Possible impact of not complying with the disclosure requirement of § 262(*l*)(2)(A).
  - Injunction pending appeal.
- Permanent Injunctions
  - Scope / As of Right: §271(e)(4)(D).

Amgen v. Sandoz

- SCOTUS does not decide whether violation of § 262(*l*)(2)(A) or any other BPCIA provision can be considered in deciding preliminary injunction motion.

In holding that § 262(*l*)(9)(C) represents the exclusive remedy for an applicant's failure to provide its application and manufacturing information, **we express no view on whether a district court could take into account an applicant's violation of § 262(l)(2)(A) (or any other BPCIA procedural requirement) in deciding whether to grant a preliminary injunction under 35 U.S.C. § 271(e)(4)(B) or § 283 against marketing the biosimilar**. *See Winter v. Natural Resources Defense Council, Inc.,* 555 U.S. 7, 20, 129 S. Ct. 365, 172 L.Ed.2d 249 (2008) (court should consider "balance of equities" in deciding whether to grant a preliminary injunction).

Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664, 1675 (2017)

Preliminary Injunctions

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Preliminary Injunctions

Purpose

At the stage of the preliminary injunction, before the issues of fact and law have been fully explored and finally resolved, "[t]he purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held."

Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1344-45 (Fed. Cir. 2008) (quoting *Univ. of Tex. v. Camenisch*, 451 U.S. 390 (1981)).

Preliminary Injunctions

Four Factor Test

- Likelihood of success on the merits;
- Likelihood of irreparable harm to patent owner in the absence of an injunction;
- Balance of equities favors the patent owner over the alleged infringer; and
- An injunction is in the public interest.

See, e.g., *Takeda Pharms. U.S.A. v. West-Ward Corp.*, 785 F.3d 625, 629 (Fed. Cir. 2015).

Preliminary Injunctions

How does "likelihood of success on the merits" work?

"The correct standard is not whether a substantial question has been raised, but whether the patentee is likely to succeed on the merits, upon application of the standards of proof that will prevail at trial. The question is not whether the patent is vulnerable; the question is who is likely to prevail in the end, considered with equitable factors that relate to whether the status quo should or should not be preserved while the trial is ongoing. The presentation of sufficient evidence to show the likelihood of prevailing on the merits is quite different from the presentation of substantial evidence to show vulnerability."

"No other court has held that when the attacker has presented a 'substantial question' on its side of the dispute—that is, more than a scintilla but less than a preponderance of evidence in support of its side—no injunction *pendente lite* is available."

Abbott Labs., 544 F.3d at 1364 (2008).

Preliminary Injunctions

How does “likelihood of success on the merits” work?

The district court also erred in failing to appreciate that to avoid a preliminary injunction, LTC needed only to offer proof that the ′929 patent was vulnerable, as opposed to clear and convincing evidence of its invalidity. As the patentee, Celsis bears the burden of proving that “in light of the presumptions and burdens that will inhere at trial on the merits,” the ′929 patent will withstand LTC's challenges to its validity. *See Amazon.com, Inc. v. Barnesandnoble.com, Inc.,* 239 F.3d 1343, 1350 (Fed.Cir.2001). Thus, if LTC raises a substantial question as to the ′929 patent's validity, the preliminary injunction should not issue.

Celsis In Vitro, Inc. v. CellzDirect, Inc., 664 F.3d 922, 931-32 (Fed. Cir. 2012) (Gajarsa, J., dissenting).

Preliminary Injunctions

How does “likelihood of success on the merits” work?

To establish a likelihood of success on the merits, a patentee must show that it will likely prove infringement of the asserted claims and that its infringement claim will likely withstand the alleged infringer's challenges to patent validity and enforceability. *Sciele Pharma, Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1259 (Fed. Cir. 2012) (citing *Amazon.com*, 239 F.3d at 1350). A preliminary injunction should not issue if the accused infringer “raises a substantial question concerning either infringement or validity.” *Amazon.com*, 239 F.3d at 1350.

Mylan Institutional LLC v. Aurobindo Pharma Ltd., 857 F.3d 858, 866 (Fed. Cir. 2017).

Preliminary Injunctions

Irreparable Harm

"As its name implies, the irreparable harm inquiry seeks to measure harms that no damages payment, however great, could address."

Celsis In Vitro, Inc. v. CellzDirect, Inc., 664 F.3d 922, 930 (Fed. Cir. 2012).

"Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm."

Aria Diagnostics, Inc. v. Sequenom, Inc., 726 F.3d 1296, 1304 (Fed. Cir. 2013) (quoting *Celsis in Vitro, Inc. v. CellzDirect, Inc.,* 664 F.3d 922, 930 (Fed. Cir. 2012)).

"Even where other competitors are in the market and price erosion is occurring, that does not negate the loss of market share and revenue from more competition during the litigation."

Abbott Labs., 544 F.3d at 1361-62.

Preliminary Injunctions

Irreparable Harm – Causal Nexus to Infringement

"To show irreparable harm, it is necessary to show that the infringement caused harm in the first place. Sales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons other than the patented feature. If the patented feature does not drive the demand for the product, sales would be lost even if the offending feature were absent from the accused product. Thus, a likelihood of irreparable harm cannot be shown if sales would be lost regardless of the infringing conduct."

Apple, Inc. v. Samsung Elecs. Co., 678 F.3d 1314, 1324 (Fed. Cir. 2012).

Preliminary Injunctions

Balance of Hardships

"[T]he fact that a patentee has licensed others under its patents does not mean that unlicensed infringement must also be permitted while the patents are litigated."

Abbott Labs., 544 F.3d at 1362.

Preliminary Injunctions

Balance of Hardships

"A record showing that the infringer will be put out of business is a factor, but does not control the balance of hardships factor. This court can easily imagine a situation where the loser on either side may have to close its doors. At this point, however, this court has seen no comparison of difficulties or losses Ariosa might experience weighed against the harms Sequenom might suffer without protection of its legal exclusive rights. For example, the district court made no findings on the harm that would accrue to Sequenom's R&D and investment in the technology, undermining work and money spent developing, validating, and commercializing any covered product."

Aria Diagnostics, Inc. v. Sequenom, Inc., 726 F.3d 1296, 1304 (Fed. Cir. 2013) (internal citations omitted).

Preliminary Injunctions

Public Interest

"The district court appreciated that the public interest includes consideration of whether, by shifting market benefits to the infringer while litigation is pending for patents that are likely to withstand the attack, the incentive for discovery and development of new products is adversely affected. The statutory period of exclusivity reflects the congressional balance of interests, and warrants weight in considering the public interest."

Abbott Labs., 544 F.3d at 1362.

Preliminary Injunctions

Public Interest

"[I]nvestment in drug research and development must be encouraged and protected by the exclusionary rights conveyed in valid patents. That incentive would be adversely affected by taking market benefits away from the patentee and giving them to the accused infringer in this case. *See id.* Though LTC argues that it sells products for drug research and development such that the public interest would disfavor enjoining LTC, both LTC and Celsis sell the same products and are in direct competition. In other words, the public can obtain the products from Celsis. The record shows that the district court has considered and properly addressed the public's interest in obtaining an adequate supply of pooled multi-cryopreserved hepatocyte products."

Celsis In Vitro, Inc. v. CellzDirect, Inc., 664 F.3d 922, 931-32 (Fed. Cir. 2012) (internal citation omitted).

Preliminary Injunction

Appellate Review – When to Appeal?

28 U.S.C. § 1292(a)(1) and (c)(1)

(a) Except as provided in subsections (c) and (d) of this section, the courts of appeals shall have jurisdiction of appeals from:

(1) Interlocutory orders of the district courts of the United States, the United States District Court for the District of the Canal Zone, the District Court of Guam, and the District Court of the Virgin Islands, or of the judges thereof, granting, continuing, modifying, refusing or dissolving injunctions, or refusing to dissolve or modify injunctions, except where a direct review may be had in the Supreme Court;

(c) The United States Court of Appeals for the Federal Circuit shall have exclusive jurisdiction--

(1) of an appeal from an interlocutory order or decree described in subsection (a) or (b) of this section in any case over which the court would have jurisdiction of an appeal under section 1295 of this title;

Preliminary Injunction

Appellate Review – Abuse of Discretion Standard

"It is well settled that the granting of a temporary injunction, pending final hearing, is within the sound discretion of the trial court; and that, upon appeal, an order granting such an injunction will not be disturbed unless contrary to some rule of equity, or the result of improvident exercise of judicial discretion."

"Abuse of discretion is established 'by showing that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings.'"

Abbott Labs., 544 F.3d at 1345.

Preparing for a Preliminary Injunction

Think Trial

- Claim Construction
- Infringement
- Validity
- The Market
  - Know your business
  - Price erosion
  - Reputation
  - Customer goodwill

Preparing for a Preliminary Injunction

Presenting Your Arguments

- Experts
- Declarants
- Case Law
- Hearing

Preparing for a Preliminary Injunction

What if I need discovery?

- Typically, Rule 26(f) conference must occur before discovery.
- But, as noted in the FRCP 26(d) advisory committee notes (1993), discovery can occur earlier by local rule, order, or stipulation, which "will be appropriate in some cases, **such as those involving requests for preliminary injunctions** or motions challenging personal jurisdiction."

Permanent Injunctions

FISH.

Permanent Injunctions Pre-*eBay*

"Following the jury verdict, the District Court denied MercExchange's motion for permanent injunctive relief. *275 F. Supp. 2d 695 (2003)*. The Court of Appeals for the Federal Circuit reversed, applying its '***general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances***.' *401 F.3d 1323, 1339 (2005)*. We granted certiorari to determine the appropriateness of this general rule."

eBay v. MercExchange, 547 U.S. 388, 391 (2006).

Patent Act – Exclusive Right

35 U.S.C. § 261

"patents shall have the attributes of personal property"

35 U.S.C. § 154(a)(1)

"the right to exclude others from making, using, offering for sale, or selling the invention"

Right to Exclude vs. Remedy

"According to the Court of Appeals, this statutory right to exclude alone justifies its general rule in favor of permanent injunctive relief. . . . But the creation of a right is distinct from the provision of remedies for violations of that right."

eBay v. MercExchange, 547 U.S. 388, 392 (2006).

Permanent Injunctions Post-*eBay*

Four Factor Test

- Plaintiff has suffered an irreparable injury;
- Remedies at law ($) are inadequate to compensate;
- Balance of hardships between plaintiff and defendant warrant an equitable remedy; and
- Public interest not disserved by a permanent injunction.

eBay v. MercExchange, 547 U.S. 388, 391 (2006).

Will a Court *Really* Permanently Enjoin a Drug?

Amgen, Inc. v. Sanofi, 2017 WL 4413412 (Fed. Cir. Oct. 5, 2017).

- Case between two competitors, each with a product on the market.
- District Court granted a permanent injunction after weighing the *eBay* factors.
- Federal Circuit stayed injunction pending appeal.
- Federal Circuit vacates district court's judgment, including the award of permanent injunction.
- Federal Circuit finds fault with district court's injunction analysis.

District Court's Focus: Competition

"[C]ourts (presumably struggling to balance the absence of a presumption of irreparable harm with a patentee's right to exclude) have frequently focused upon the nature of the competition between a plaintiff and a defendant in the relevant market in the context of evaluating irreparable harm and the adequacy of money damages. Courts awarding permanent injunctions typically do so under circumstances in which the plaintiff practices its invention and is a direct market competitor. Plaintiffs also frequently succeed when their patented technology is at the core of their business, and/or where the market for the patented technology is volatile or still developing."

- Irreparable harm favors plaintiffs.
- Inadequacy of remedies at law favors plaintiffs.
- Balance of hardships is neutral.

Public Interest

"The public generally is better served by having a choice of available treatments. Therefore, the court finds itself between a rock and a hard place, i.e., being a patent holder and a verdict winner should be a meaningful factor in the balancing test, but taking an independently developed, helpful drug off the market does not benefit the public. '[T]he touchstone of the public interest factor is whether an injunction, both in scope and effect, strikes a workable balance between protecting the patentee's rights and protecting the public from the injunction's adverse effects.' The court concludes that the public interest of having a choice of drugs should prevail. **This factor weighs in favor of defendants**."

Will a Court *Really* Permanently Enjoin a Drug?

Amgen, Inc. v. Sanofi, 2017 WL 4413412, at *9 (Fed. Cir. Oct. 5, 2017).

- *eBay* violated because permanent injunction can only be issued if court concludes the injunction would not disserve the public interest.
- Here, the court found that it would disserve the public interest, but granted injunctive relief anyway.

> "If a plaintiff fails to show 'that the public interest would not be disserved by a permanent injunction,' then the district court may not issue an injunction."

Will a Court *Really* Permanently Enjoin a Drug?

Amgen, Inc. v. Sanofi, 2017 WL 4413412, at *10 (Fed. Cir. Oct. 5, 2017).

- District court erred in analysis of public interest factor by concluding that the public interest of having a choice of drug should prevail over a verdict in favor of the patentee.

  "But eliminating a choice of drugs is not, by itself, sufficient to disserve the public interest. Under such an approach, courts could never enjoin a drug because doing so would always reduce a choice of drugs. That, of course, is not the law."

  "Just as a patent owner does not automatically receive an injunction merely by proving infringement, an accused infringer cannot escape an injunction merely by producing infringing drugs. Accordingly, a reduction in choice of drugs cannot be the sole reason for a district court to deny an injunction.

Will a Court *Really* Permanently Enjoin a Drug?

WBIP, LLC v. Kohler Co., 829 F.3d 1317, 1343 (Fed. Cir. 2016)

"The district court's decision [denying an injunction] is based on its reasoning that having more manufacturers of a lifesaving good in the market is better for the public interest. But this reasoning is true in nearly every situation involving such goods, such that, if it alone is sufficient, it would create a categorical rule denying permanent injunctions for life-saving goods, such as many patented pharmaceutical products. As the Supreme Court has warned, categorical rules regarding permanent injunctions are disfavored. And Congress has expressly indicated that injunctions may be granted in cases involving lifesaving goods, such as pharmaceutical drugs. *See* 35 U.S.C. § 271(e)(4)(B)."

Federal Circuit Dicta: *Apple v. Samsung*

"Apple does not seek to enjoin the sale of lifesaving drugs, but to prevent Samsung from profiting from the unauthorized use of infringing features in its cellphones and tablets."

- Federal Circuit statement in assessing public interest factor.
- Reversed denial of permanent injunction.

Precedent for Enjoining Innovator Drug?

- *Amgen v. Roche*, 581 F. Supp. 2d 160 (D. Mass. 2008)
  - Roche developed version of EPO with a longer half-life and less frequent dosing.
  - Roche's product *had not yet launched.*
  - Overview of *eBay:*
    - Look at equity practice – consider the "difficulty of protecting a right to *exclude* through monetary remedies that allow an infringer to *use* an invention against the patentee's wishes."
    - Not very consistent with activity of patent trolls.
  - *eBay*'s application (at that time):
    - Injunctions issued in all but 2 of 26 post-*eBay* cases involving *direct competitors.*
    - In one, the damages award contemplated a going forward royalty.

Precedent for Enjoining Innovator Drug?

- *Amgen v. Roche*, 581 F. Supp. 2d 160 (D. Mass. 2008)
  - First 3 *eBay* factors favor injunction: Roche's entry into market would cause "immense, immeasurable, irreparable harm, with the balance of hardships falling on Amgen."
  - Public Interest not disserved by *maintaining status quo.*
    - Court's main focus:
      - Patient Health: Would there be patients for whom EPOGEN does not work?
      - Medicare savings: Beneficial impact of a competitive product on Medicare?
      - Interest in robust patent system and the economic incentives it creates.

"[T]he public interest would not be disserved by an injunction because there is **no solid evidence that patients or the public coffers will suffer significant harm if the status quo is maintained**. In this case, the public's interest in a robust patent system that maintains incentives for pharmaceutical innovation outweighs the highly speculative, de minimis benefits that might occur as the result of a denial of an injunction.

Precedent for Enjoining Innovator Drug?

- *Amgen v. Roche* appeal: "We do not disturb the court's injunction." 580 F.3d 1340, 1386 (Fed. Cir. 2009).

- Ultimately, the parties entered a settlement that kept Roche's drug off the market until mid-2014 (last asserted patent expired 2015).

Enjoining a Marketed Drug

Sanofi-Aventis Deutschland v. Glenmark, 821 F. Supp. 2d 681 (D.N.J. 2011).

- Brand had market exclusivity for Tarka ACE inhibitor.
- Before trial, Plaintiffs moved for a preliminary injunction.
- Court denied the preliminary injunction.
- Defendant launched.
- Jury verdict for Plaintiffs.

Irreparable Harm / Inadequate Remedies

"Plaintiffs argue that as a result of Defendants' infringing generic Tarka product Plaintiffs have suffered irreparable injuries, such as loss of sales, loss of market share, price erosion, and loss of customer goodwill. ***Plaintiffs and Defendants are direct competitors in the Tarka market, and prior to Defendants' launch, Plaintiffs had 100% of the Tarka market; now every sale made by Defendants is a sale lost by Plaintiffs***. Plaintiffs have lost at least two-thirds of its market share, and expects its market share to decrease further as generic products usually obtain about 90% of the market."

at 694

Irreparable Harm / Inadequate Remedies

"Plaintiffs and Defendants are two ***head-to-head competitors*** in the Tarka marketplace; every sale of Defendants' generic Tarka is a lost sale by Plaintiffs. As discussed above, Plaintiffs have suffered ***a loss of market share, harm to reputation, and price erosion***, all of which are facts that tend to establish the inadequacy of a legal remedy."

at 694

Balance of Hardships

"The fact this Court did not enjoin Defendants from launching their generic product only means that Defendants were not in violation of any court order; it does not negate the fact that in deciding to launch, without a final ruling on the validity of the '244 patent, Defendants undertook a calculated business risk. ***Any harms Defendants may suffer as a result of an injunction 'were almost entirely preventable and were the result of its own calculated risk to launch its product pre-judgment***.' *Sanofi-Synthelabo v. Apotex, 470 F.3d 1368, 1383 (Fed. Cir. 2006)*."

at 695

Public Interest

" ***'[S]elling a lower priced product does not justify infringing a patent***,' and although the Hatch-Waxman Act encourages making lower cost generic drugs available to the public, ***'it does not do so by entirely eliminating the exclusionary rights conveyed by pharmaceutical patents***. Nor does the statutory framework encourage or excuse infringement of valid pharmaceutical patents.' *Pfizer, Inc. v. Teva Pharms. USA, Inc., 429 F.3d 1364, 1382 (Fed. Cir. 2005)"*

at 696

Defeating a Motion for Permanent Injunction

Johnson & Johnson v. Ciba Vision, 712 F. Supp. 2d 1285 (M.D. Fla. 2010)

- Case between two competitors, each with a product on the market.
- J&J found to infringe.
- J&J's product: Acuvue Oasys contact lenses.
- District Court denies CIBA's motion for a permanent injunction.
  - Licensing
  - Public interest

District Court on CIBA's Licensing

"Looking at ***CIBA's licensing behavior*** and the specific facts of this case, the Court, as it did at the preliminary injunction stage (*see* Doc. 49 at 15), finds compelling that ***CIBA has been willing to share the Nicolson patents with so many of its competitors (again, including J&J itself)***. This conduct, taken in its totality, is inconsistent with CIBA's assertion that only enforcement of its right to exclude J&J from using the Nicolson patents will redress the harm that CIBA will suffer in the future on account of J&J's infringement."

at 1289

Public Interest

CIBA's Arguments:

- Public interest in enforcement of patent laws.
- Injunction would only cause some inconvenience to Oasys wearers.
- Overwhelming majority of Oasys wearers could be refit into other lenses.
- No negative effect on public health.

Public Interest

J&J's Arguments:

- Oasys best selling lens in the market.
- Oasys is the most comfortable lens, which is the determining factor about whether a patient will be able to wear a lens.
- Oasys is more effective than competitor lenses.
- Refitting is inconvenient and, not always successful, and could take multiple doctor visits at ~$100.

District Court on Public Interest

"This evidence convinces the Court that millions of innocent contact lens wearers will suffer real adverse consequences if sale of ACUVUE(R)OASYS is enjoined. ***These are not just issues of comfort or cosmetics***, as CIBA argues, but rather deal with the more substantive ***concerns of proper vision and eye care. There will also be significant disruption, confusion and cost*** (estimated to be in the hundreds of millions of dollars) caused by ACUVUE(R)OASYS patients being abruptly told that the contact lens for which they have been fitted and with which they are satisfied, is no longer available."

at 1292

District Court on Public Interest

"Choosing a new lens will ***at minimum require refitting and the new lens may not prove as efficacious as the ACUVUE(R)OASYS lens***. Moreover, patients may have to be refitted more than once until an appropriate lens is found. ***An undefined number will not be able to be refitted appropriately at all***. CIBA's answer that 'they can just wear glasses' is no answer, in this Court's view."

at 1292

District Court on Public Interest

"The preponderance of the evidence convinces the Court that ***an injunction will create consequential medical, practical and economic issues*** for large numbers of ACUVUE(R)OASYS users. The deleterious effects of the injunction on the general public would simply be too great to permit."

at 1292

Permanent Injunctions

- Burden of proof.
- Timing / presentation of evidence.
- Procedure
- Factor-specific considerations.

Considerations for a Permanent Injunction

Irreparable Harm / Inadequacy of Monetary Damages

- Market
  - Direct competitors.
  - Two-player vs. Multi-player.
  - Effect on market share.
- Price erosion
- Loss of goodwill and reputation.
- Loss of customers and business opportunities.
- Patentee's willingness to license.

Considerations for a Permanent Injunction

Public Interest

- Having additional choices or lower prices not sufficient.
- Interchangeability between products and availability of alternatives.
- Differences in efficacy between products.
- Differences in safety between products.
- Potential for use in different populations.
- Potential for patient disruptions.
- Tailor to minimize disruption.

Questions?

Thank you!

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