

Ability Of Licensees To Challenge Patent Validity In Federal Court System

MedImmune Inc. v. Genentech Inc., 549 US 118,
127 Sct 764, 81 USPQ2d 1225 (2007)

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1. What's at issue?

- *Lear v. Adkins* gives Licensee right to challenge validity
... Most of the time
- Licensee challenge option: Attack validity via Declaratory Judgment Act in Fed Court
- Federal jurisdiction limited under US. Const., Art. III to “cases” and “controversies”

MEDIMMUNE
ISSUE:

Can non-breaching Licensee start patent battle in Federal Court? Or does Fed Court violate U.S. Constitution by hearing such a case?

1. What's at issue?

The existing Fed. Cir. law provides a clear, definitive framework for analysis with an equally clear, definitive answer:

- Gen Probe rule: reasonable apprehension of suit
- Practical impact of Gen Probe: Breach required
- Crux of the MedImmune dispute: **There's no breach.**
- Apply Gen Probe: there is no "controversy" as required by Article III to support a DJ Action by a Licensee

Slam dunk win for Patent Owner, right?

1. What's at issue?

Venerable Old Reasonable Apprehension of Litigation Test according to Gen-Probe:

- (1) An explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and
- (2) Present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.

2. Constitutional Battleground

U.S. Constitution, Article III, Section 2

The judicial power shall extend to all **cases**, in law and equity, arising under this Constitution, the laws of the United States, and treaties made, or which shall be made, under their authority;--to all cases affecting ambassadors, other public ministers and consuls;--to all cases of admiralty and maritime jurisdiction;--to controversies to which the United States shall be a party;--to **controversies** between two or more states;--between a state and citizens of another state;--between citizens of different states;--between citizens of the same state claiming lands under grants of different states, and between a state, or the citizens thereof, and foreign states, citizens or subjects.

Cases and controversies

2. Constitutional Battleground

Constitutional Law impacts licensing a lot:

Brulotte and the Discoveries Clause

The Constitution by Art. I, § 8 authorizes Congress to secure "for limited times" to inventors "the exclusive right" to their **Writings and Discoveries**. Congress exercised that power by 35 U.S.C. § 154, which provides in part as follows:

"Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, for the term of seventeen years, of the right to exclude others from making, using, or selling the invention throughout the United States, referring to the specification for the particulars thereof. . . .

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2. Constitutional Battleground

Lear v. Adkins (and its progeny)

- **Separation of powers** (distinguishing Article I and Article III tribunals when applying *Lear* principles)
- **Hierarchy within the Constitution itself:**
Article III v. Discoveries clause (*Hemstreet* limiting *Lear*)

Article III policies prevail to settle litigation.

2. Constitutional Battleground

Aronson: federal preemption v. state contract law

- Erie v. Tompkins
- Federal powers v. state powers

2. Constitutional Battleground

MedImmune is the most direct clash between licensing law and the Constitution :

- Meaning of Constitution itself is altered as a consequence of this Supreme Court decision (more power for fed judiciary; more burdens, too)
- Patent license law happens to be the battlefield where this Art III battle was fought;
- Analogous to Gettysburg in Civil War

2. Constitutional Battleground

Article III battle explodes in MedImmune:

What kind of case or controversy satisfies Art III clause of Constitution?

Actual breach of a contract needed to trigger DJ jurisdiction?

If actual breach is not required, **what elements are needed** to support DJ jurisdiction and satisfy U.S. Const., Art III?

KEY!!!

What test will be controlling?

3. DJ Act and “new” test

Declaratory Judgment (DJ) Act,
28 USC §2201(a):

Authorizes federal courts to declare rights
when there is an “**actual controversy**”

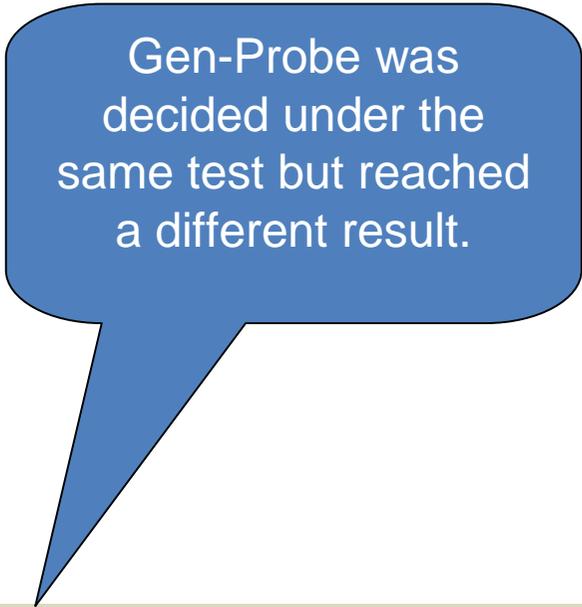
Constitutional per 1937 SCt decision

Is it still constitutional if construed to cover
non-breaches?

3. DJ Act and “new” test

Tests for establishing an “actual controversy” under the DJ Act:

- Definite and concrete
- Real and substantial
- Specific relief of conclusive character
- Not merely advice or hypothetical
- Adverse legal interests
- Sufficient immediacy and reality



Gen-Probe was decided under the same test but reached a different result.

Summary: substantial controversy between adverse parties of sufficient immediacy and reality to warrant relief. *Maryland Casualty* (1941).

3. DJ Act and “new” test

Totality of circumstances standard: substantial controversy between adverse parties of sufficient immediacy and reality to warrant relief. *Maryland Casualty* (1941).

Totality of Circumstances:

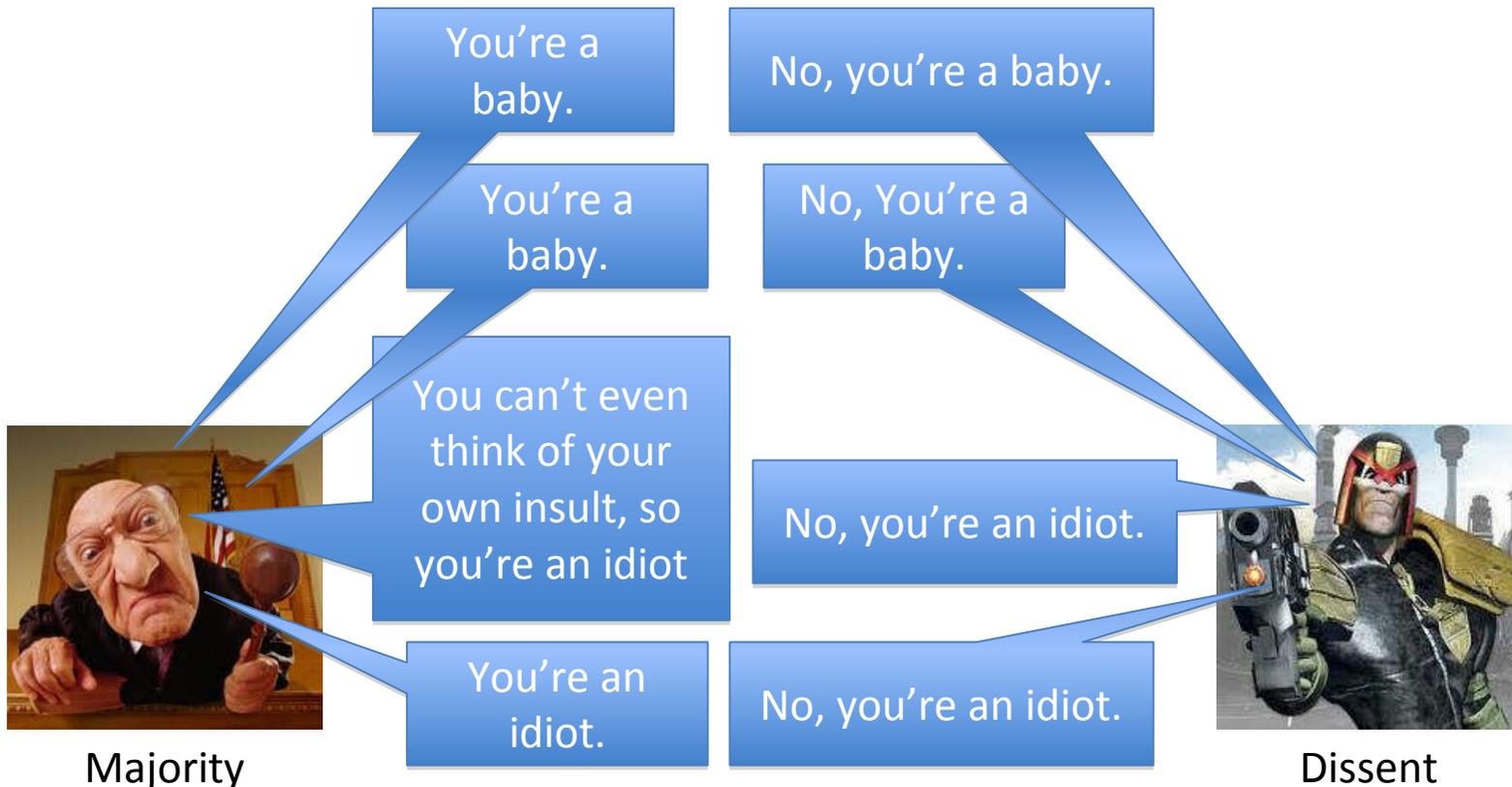
If A, B, C, D, and E are weighty enough, then F.

Bright line rule :

If A, B, D, and E in any amounts, then F.

3. DJ Act and new test

Footnote 7 confirms a pattern that shows that the Justices hotly debated the case and that the **majority and dissent vigorously disagree.**



3. DJ Act and new test

Dissent predicts *MedImmune* will unleash a parade of Article III monsters and contract demons.



4. Holding and applicable test

Held: License breach not required to support Article III jurisdiction

Adverse interests

Threat/coercion/affirmative act by Patentee

Immediacy of threat

Significance of the dispute

Winning fixes the problem

Old test
construed in a
new way

TEST: substantial controversy between adverse parties of sufficient immediacy and reality to warrant relief. *Maryland Casualty* (1941).

4. Holding and applicable test

- Gen Probe “reasonable apprehension of suit” test is retired without any fanfare
- Gen Probe gets almost no air time; insults Fed. Cir.
- Gutsy lawyering by Licensee, but huge \$\$\$ at stake

4. Holding and applicable test

Practical Impact:

MedImmune makes it **easier but not effortless** for a licensee to launch an Article III attack under DJ Act.

MedImmune impacts all areas of the law, not just patent license law

5. Supreme Court wanted this result with single-minded determination (8-1)

- Twists and contorts *Altvater* (S.Ct) so *Altvater* appears to be directly on point, but *Altvater* involved an actual breach
- *Willing* (S.Ct) held breach essential for DJ jurisdiction, but S.Ct disregarded as being pre-DJ Act

What is wrong with how S.Ct says enactment of the DJ Act impacts *Willing*?

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What is wrong with how S.Ct says enactment of the DJ Act impacts *Willing*?

In other words, enactment of DJ Act allows S.Ct to now construe U.S. CONSTITUTION differently! Backwards!!!

5. Pathetic Patentee Pleas Palpably for Palliated Panacea**

Patent owner gasps for life with pleas for fairness:

- Fairness: undermines the agreement
- Fairness: alters the deal
- DBK observation: Fairness is a key building block of a winning argument, but whole argument can't be "it's not fair"
- Cry-baby approach

** Patentee argues for outcome based on fairness and equity

6. MedImmunizations

1. *Alternative attacks*
2. *Repudiation v. Royalty obligation*
3. *License negotiations*
4. *Know how*
5. *Settlement Agreements*
6. *Covenants not to sue*
7. *Miscellaneous drafting strategies*

6. MedImmunizations: Attack strategies

What are exemplary ways that a Licensee can attack validity?

DJ attack (Article III)

Inter partes (or ex parte) reexamination (Article I)

Opposition

Inventorship/implied license/waiver etc.

Re-negotiate

Walker Process/Antitrust

Misuse (defense)????

7. MedImmunications: Repudiation v. Royalty Obligation

Repudiation (a.k.a. “Do I get my money back?”):

Does Licensee get a REFUND OF PAID ROYALTY after a successful attack?

Can Licensee stop paying royalty?

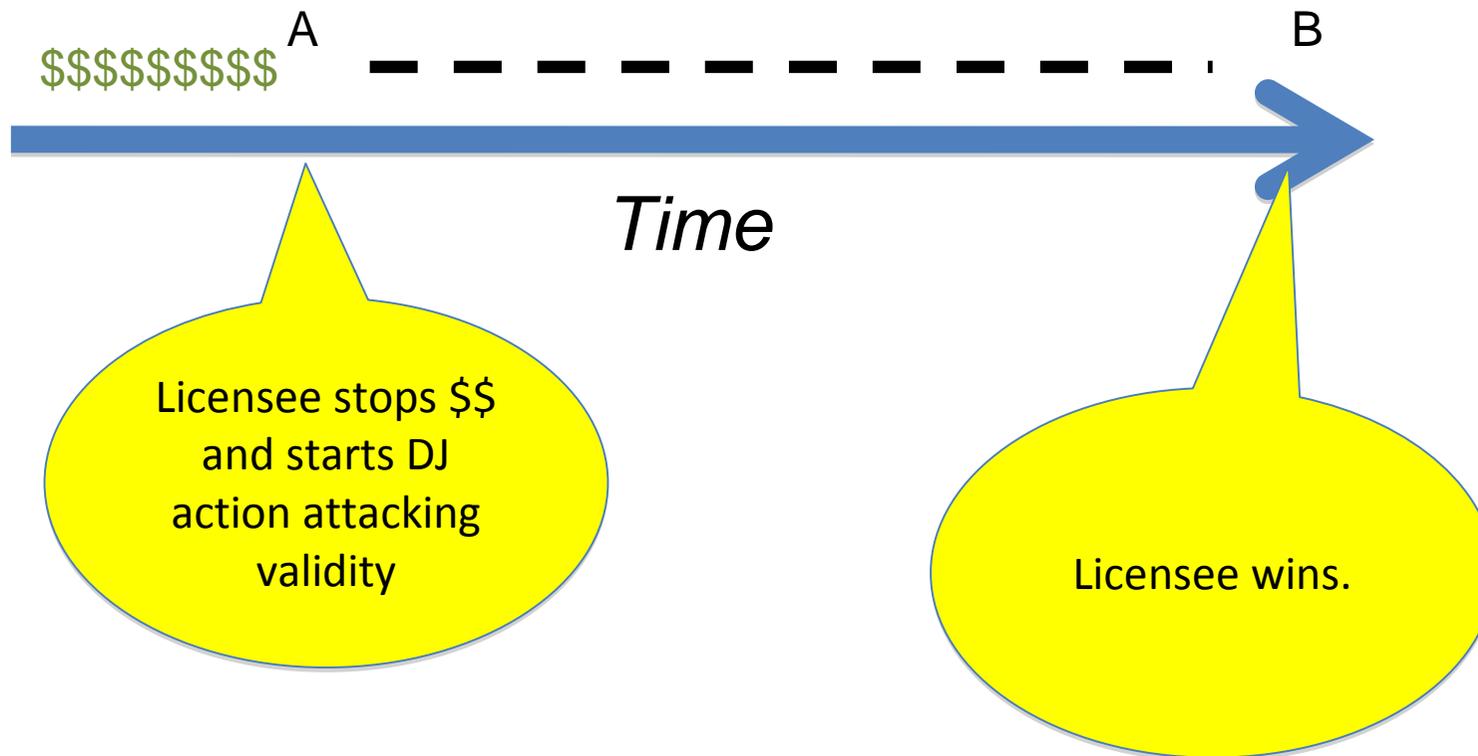
7. MedImmunications: Repudiation v. Royalty Obligation

Repudiation v. Royalty obligation



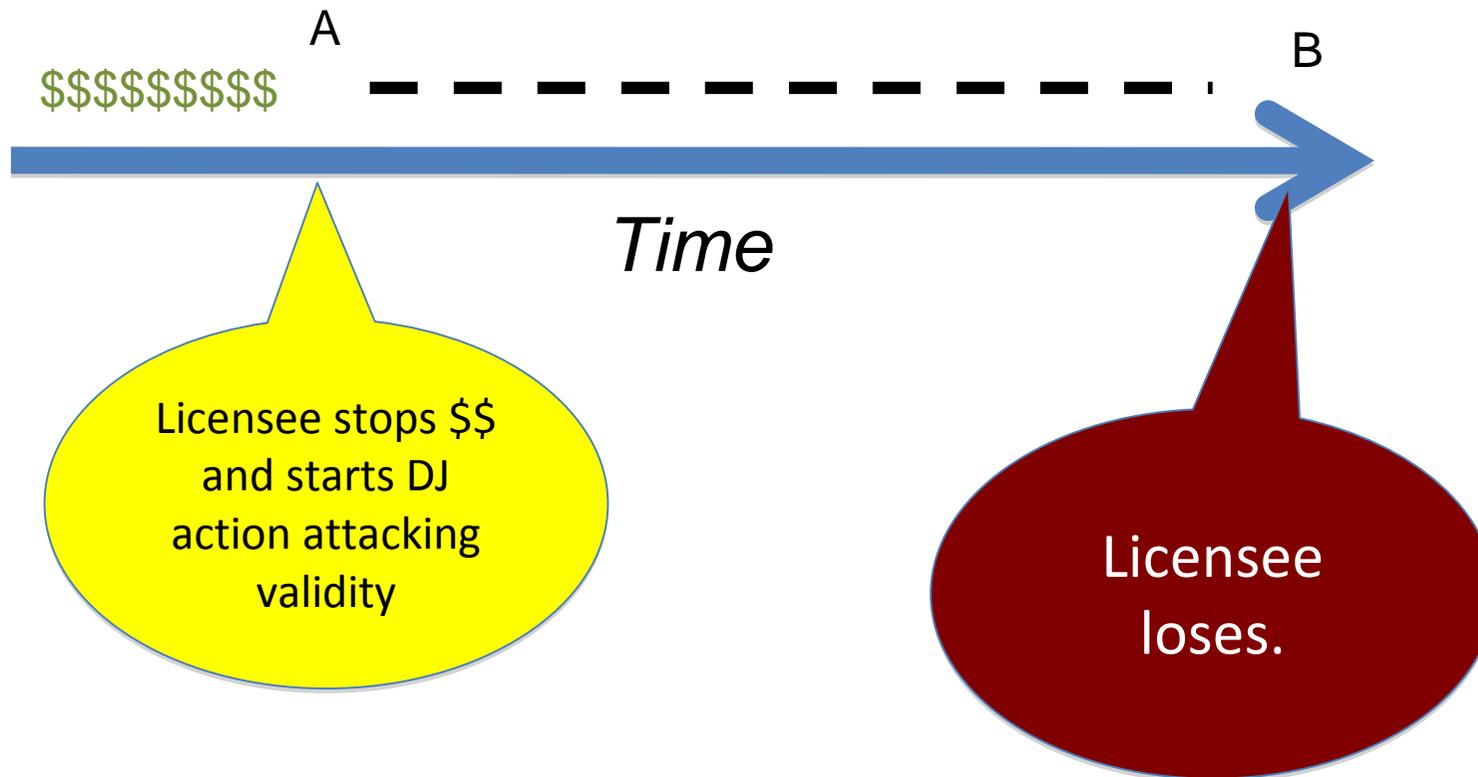
Royalty shall accrue and be payable so long as at least one valid, unexpired claim of the Licensed Patents cover the making, using, selling, offering to sell, importing or other commercial transfer of any Licensed Products. A claim is deemed to be valid and enforceable in a particular territory unless and until the claim is held to be invalid or unenforceable in a non-appealed decision by a government tribunal, international tribunal, or arbitrator(s).

7. MedImmunizations: Repudiation v. Royalty Obligation



7. MedImmunizations: Repudiation v. Royalty Obligation

Repudiation v. Royalty obligation



8. MedImmunications: Negotiations

Can License negotiations trigger DJ jurisdiction even if no threats of litigation are made?

Sony Electronics Inc. v. Guardian Media Technologies Ltd., 83 USPQ2d 1798 (Fed. Cir. 2007)

SanDisk Corp. v. STMicroelectronics Inc., 82 USPQ2d 1173 (Fed. Cir. 2007)

Answer:

9. MedImmunizations: Negotiations

Can License negotiations trigger DJ jurisdiction even if no threats of litigation are made?

Sony Electronics Inc. v. Guardian Media Technologies Ltd., 83 USPQ2d 1798 (Fed. Cir. 2007)

SanDisk Corp. v. STMicroelectronics Inc., 82 USPQ2d 1173 (Fed. Cir. 2007)

Answer:

Absolutely

10. MedImmunications: Know how

Grant Licenses to both patents and know how (Aronson)

- Separate grant and royalty for know how
- Now if patent challenge successful, know how still in play
- Condition access to know how upon payment of minimum royalty?

This can be a great MedImmunications

11. MedImmunications: *Settlement Agreements*

Lear v. Adkins: Licensee has right to challenge validity. No more licensee estoppel. The following clause is not enforceable under Lear:

Licensee shall not during the term of this agreement or thereafter challenge or cause to be challenged, directly or indirectly, the validity or enforceability of any Licensed Patent in any court or other tribunal anywhere in the world.

“Blocking clause”

Settlement Agreements are an exception to Lear.

11. MedImmunizations: *Settlement Agreements*

Blocking clauses in settlement agreements, consent decrees, etc. are enforceable . . . But only if the language clearly blocks validity/enforceability attacks. Ambiguous language won't support blocking.

- Settlement policies v. Lear policy
- Narrowly construed
- Licensees love to challenge settlement agreements

Issue: Does Blocking Clause actually block as intended?

11. MedImmunications: *Settlement Agreements*

Cases where settlement language clear enough to block validity attacks by Licensee:

- Hemstreet v. Spiegel, Inc., 7 USPQ2d 1502 (Fed. Cir. 1988)
- Flex-Foot, Inc. v. CRP, Inc., 57 USPQ2d 1635 (Fed. Cir. 2001)
- Foster v. Hallco Mfg. Co., Inc., 20 USPQ2d 1241 (Fed. Cir. 1991)

These were all decided prior to MedImmune. The last two were cited with approval after MedImmune, indicating these cases are still good law.

11. MedImmunications: *Settlement Agreements*

Cases where settlement language too ambiguous or too narrow to block licensee:

- Baseload Energy Inc. v. Roberts, 96 USPQ2d 1521 (Fed. Cir. 2010)
- Ecolab, Inc. v. Paracclipse, Inc., 62 USPQ2d 1349 (Fed. Cir. 2002)
- Diversey Lever, Inc. v. Ecolab, Inc., 52 USPQ2d 1062 (Fed. Cir. 1999)
- Howmedica Osteonics Corp. v. Wright Medical Technology, Inc., 88 USPQ2d 1129 (Fed. Cir. 2008)

Last 4 cited with approval after MedImmune

11. MedImmunizations: *Settlement Agreements*

This language worked (Flex Foot style):

Licensee shall not during the term of this agreement or thereafter challenge or cause to be challenged, directly or indirectly, the **validity or enforceability** of any Licensed Patent in **any court or other tribunal anywhere in the world**. Licensee waives any and all invalidity and unenforceability defenses in **any future litigation, arbitration, administrative proceeding, mediation, or any other proceeding**. This clause shall apply to any product or component thereof, composition or component thereof, or method or portion thereof that is made, used, sold, offered for sale, imported, or otherwise transferred by or for Licensee or any assignees, successors or those who act in concert with any of these parties at any time during the life of the Licensed Patents

11. MedImmunizations: *Settlement Agreements*

This language failed to block validity attack (Ecolab. v. Paraclype style):

“[T]he ‘690 patent is a valid patent.”

11. MedImmunizations: *Settlement Agreements*

This language **AMAZINGLY** failed to block validity attack (Baseload style):

The parties mutually **forever release and discharge** the other parties . . . From **ANY AND ALL** losses, liabilities, claims, expenses, demands, and causes of action of **EVERY KIND AND NATURE**, known and unknown, suspected or unsuspected, disclosed or undisclosed, fixed or contingent, whether direct or indirectly that the parties ever had, now have, or hereafter may have or be able to assert against the other parties . . .

Rationale: Agreement structure evidences intent not to release patent claims and defenses!!!

11. MedImmunizations: *Settlement Agreements*

Language that takes a middle ground to settle a patent dispute:

LICENSEE shall not itself contest, or assist any third party in any manner to contest, the validity or enforceability of any LICENSOR PATENT RIGHTS in any mediation, arbitration, court or tribunal, including any national or regional patent office anywhere in the world; provided, however, that LICENSEE in its sole discretion may contest or assist third parties in contesting the validity and/or enforceability of the LICENSED PATENT RIGHTS if: (a) LICENSOR as the aggressor initiates or asserts a claim or counterclaim in any mediation, arbitration, litigation, or other dispute resolution proceeding against LICENSEE (or a Licensee AFFILIATE or customer) for any cause of action relating to the LICENSED PATENT RIGHTS; or (b) LICENSEE is required to act by operation of law. LICENSEE shall give notice to LICENSOR prior to its compliance with any duly issued subpoena or process so that LICENSOR shall have the reasonable opportunity under the circumstances to object.

11. MedImmunications: *Settlement Agreements*

Important lessons for Settlement Agreements:

- Lots of cases out there
- Draft with knowledge of law, not in a vacuum
- Licensees love to challenge settlement agreements

12. MedImmunizations: *Covenants not to Sue*

Covenants not to sue = “CN2S”

- Licensors exit strategy
- Licensee has secured DJ jurisdiction and is attacking validity/infringement
- Licensors want out. Often, Licensee wants in.
- Licensors file/offers up CN2S along with motion to dismiss
- Eliminates case and controversy so DJ jurisdiction is extinguished

Unilateral action by Licensors; Licensee cooperation results in settlement agreement

12. MedImmunications: *Covenants not to Sue*

Cases on point:

- Dow Jones & Co. v. Ablaise Ltd., 95 USPQ2d 1366 (Fed. Cir. 2010)
- Revolution Eyewear Inc. v. Aspex Eyewear Inc., 89 USPQ2d 1885 (Fed. Cir. 2009)
- Benitec Australia, Ltd. V. Nucleonics, Inc. 83 USPQ2d 1449 (Fed. Cir. 2007)
- Fort James Corp. v. Solo Cup Co., 75 USPQ2d 1257 (Fed. Cir. 2005)
- Intell. Prop. Dev., Inc. . TCI Cablevision of Calif., Inc., 58 USPQ2d 1681 (Fed. Cir. 2001)
- Amana Refrig., Inc. v. Quadlux, Inc. 50 USPQ2d 1304 (Fed. Cir. 1999)
- Super Sack Mfg. Corp. v. Chase Packaging Corp. 35 USPQ2d 1139 (Fed. Cir. 1995)

12. MedImmunications: *Covenants not to Sue*

General rule:

Timely CN2S of appropriate scope extinguishes DJ Jurisdiction.

Rationale:

Eliminates actual controversy between the parties

12. MedImmunications: *Covenants not to Sue*

Elements:

- CN2S (analogous to grant clause)
- The right scope:
 - Current, past, and specific (non-speculative) future products at issue
 - Past and future infringement
 - Encompasses all the “accused” parties who are to be released
- Timely

12. MedImmunizations: *Covenants not to Sue*

Revolution Eyewear (Fed Cir. 2009): Is the CN2S too narrow?

- CN2S covered only past infringement of current products
- Did not cover past products that were pulled from market due to litigation
- Did not cover any future acts for any products.
- DJ Attacker (Licensee) says CN2S no good; must cover future infringement as to the current and past products

Held: ???????????

12. MedImmunications: *Covenants not to Sue*

Dow Jones (Fed. Cir. 2010): Is the CN2S too narrow?

- Past and future infringement of all products at issue
- Covered subsidiaries, but not parent; no subs or parents were parties.
- DJ Attacker says CN2S no good; must cover corporate parent

Held: ????????????

12. MedImmunications: *Covenants not to Sue*

Is the CN2S too broad? (not yet litigated as far as I know)

- Patentee covenants not to sue ACME under any LITIGATED PATENT RIGHTS for any making, using, selling, offering for sale, or importing of any LITIGATED PRODUCTS that has occurred or shall occur in the future.
- ACME shall not challenge validity or enforceability of any LITIGATED PATENT RIGHT in any tribunal anywhere in the world as to any LITIGATED PRODUCTS or other past or present products or methods.

12. MedImmunications: *Covenants not to Sue*

CN2S must be timely:

- CN2S filed after jury verdict is too late.
- Fort James Corp. v. Solo Cup Co., 75 USPQ2d 1257 (Fed. Cir. 2005)
- Amazingly, the Fed. Cir had to reverse the DCt on this one.

12. MedImmunications: *Covenants not to Sue*

CN2S Summary:

- Licensor exit strategy forsaking \$\$\$
- Right scope
- Patent weakened
- Lots of cases to guide drafting (Flex Foot is helping hand)

No pun intended

13. MedImmunications: *Drafting strategies*

Not much case law to answer if the following are enforceable or not (misuse/antitrust risk?):

- Right to terminate if validity/enforceability challenge
- Bump in royalty if challenge started or fails
- Loser pays litigation fees
- Treble damages for unpaid royalty during challenge if challenge fails
- Higher initial fee
- Know how

13. MedImmunications: *Drafting strategies*

More:

- Royalty minimums
- Concede infringement
- Obligation to keep paying during period of any challenge; no right to refund
- Non-waiver clause
- Severability (blue pencil)
- Favorable arbitration clause (e.g., one arbitrator selected by Licensor)

13. MedImmunications: *Drafting strategies*

Still yet more:

- Royalty minimums
- Advance notice before challenge started
- Obligation to negotiate/mediate prior to challenge
- Right to terminate if unsuccessful challenge
- Specify favorable law and venue

14. DJ jurisdiction for FDA/Hatch-Waxman disputes

- Caraco Pharmaceutical Labs. Ltd. v. Forest Labs., Inc., 86 USPQ2d 1289 (Fed. Cir. 2008)
- Innovative Therapies Inc. v. Kinetic Concepts Inc., 94 USPQ2d 1307 (2010)
- Teva Pharma. USA Inc. v. Eisai Co., 96 USPQ2d 1808 (Fed. Cir. 2010)
- Teva Pharma. USA Inc. v. Novartis Pharma. Corp., 82 USPQ2d 1225 (Fed. Cir. 2007)

Thank You.



Intellectual Property Attorneys
All the right elements.