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MedImmune v. Genentech

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PANELISTS

David A. Segal

Gibson, Dunn & Crutcher LLP

David Burgert

Porter & Hedges

Michael O'Shea

Akin Gump Strauss Hauer & Feld

I. DECLARATORY JUDGMENT JURISDICTION – SETTING THE STAGE

A. ARTICLE III

B. DECLARATORY JUDGMENT ACT

C. FEDERAL CIRCUIT STANDARD

- pre-*MedImmune*

II. *MedImmune v. Genentech*

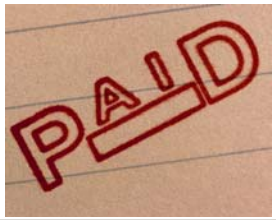
A. FACTS

1. 1997: Genentech granted MedImmune a license to practice an existing patent as well as then-pending patent application
2. Dec. 2001
   - Genentech issued a patent on its application after interference and settlement of priority claims
   - Genentech writes a letter to MedImmune asserting that MedImmune's respiratory disease drug is covered by the new patent and royalties are due

II. *MedImmune v. Genentech*

A. FACTS

3. MedImmune contended that the new patent was likely invalid or unenforceable, and wasn't convinced its drug was covered by the patent
4. Because the drug accounted for 80% of MedImmune's sales, however, an injunction and liability for infringement (including potential treble damages) would be devastating
5. MedImmune thus opted to pay the royalties "under protest and with reservation of all [its] rights"



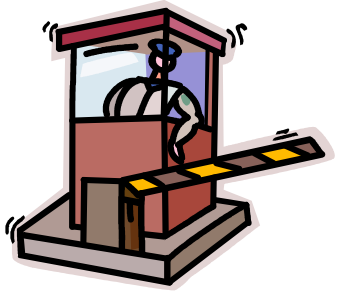
B. DISTRICT COURT

MedImmune Sues

- MedImmune filed a declaratory relief action arguing that it did not infringe and that the patent was invalid and unenforceable
  - MedImmune also files antitrust and unfair competition claims arising out of the settlement of the interference claims. Those claims were dismissed under *Noerr-Pennington*
- MedImmune argued that Genentech's letter constituted a threat of litigation that created an "actual controversy"
- The parties proceeded with discovery and, on the eve of the *Markman* hearing, Genentech files a motion to dismiss for lack of subject matter jurisdiction
- The district court, believing it was compelled by the Federal Circuit's 2004 *Gen-Probe* decision and the federal circuit's "reasonable apprehension test," "reluctantly" dismissed the case for lack of jurisdiction
  - *Gen-Probe Inc. v. Vysis, Inc.,* 359 F.3d 1376 (2004): a licensee who continues to make royalty payments has no reasonable expectation of being sued because the license agreement "obliterate[s] any reasonable apprehension" that the licensee will be sued

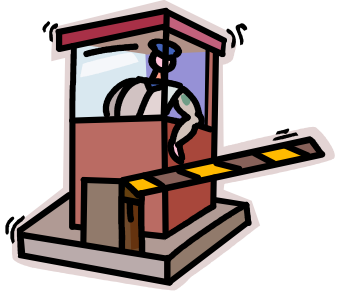
C. THE FEDERAL CIRCUIT'S RULING

- Affirms district court dismissal
- Concludes that concession that MedImmune was "free of apprehension of suit" while paying royalties means that there was no standing
- Distinguishes *Lear* because, unlike licensee in *Lear*, Genentech had no grounds to cancel the license or otherwise bring suit on the licensed products
- Also, unlike *Lear*, MedImmune did not cease payment and disavow its license obligations
- Agreed district court properly relied on *Gen-Probe*



D. THE SUPREME COURT'S DECISION: Licensees Can Sue

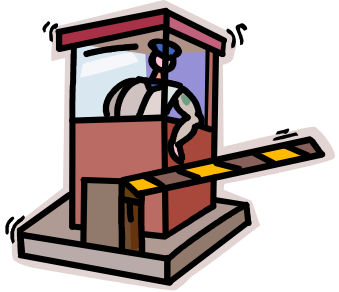
- The Supreme Court reversed in an 8-1 decision by Justice Scalia
- The only issue was whether there was jurisdiction -- a "case or controversy" under Article III
- The Court held that, under these circumstances, the license could be viewed as coercive
  - Litigants need not "bet the farm"
  - MedImmune faced "the threat of treble damages and loss of 80 percent of [its] business," which the Supreme Court found "every bit as coercive" as a criminal sanctions



D. THE SUPREME COURT'S DECISION

1. The issue as framed by the Court, citing to *Maryland Casualty*:

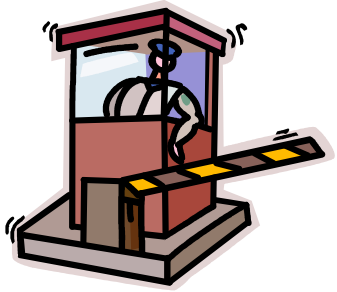
"Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." (at 8)



D. THE SUPREME COURT'S DECISION

2. Comparison to a situation where action is threatened by the government

"Petitioner's own acts, in other words, eliminate the imminent threat of harm. The question before us is whether this causes the dispute no longer to be a case or controversy within the meaning of Article III." (at 9)

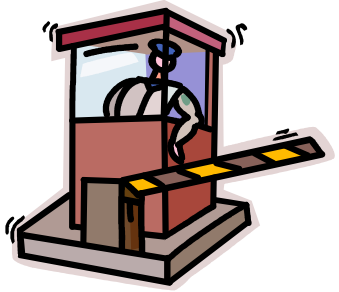


D. THE SUPREME COURT'S DECISION

2. Comparison to a situation where action is threatened by the government

Terrace v. Thompson: forfeiture of farm at risk

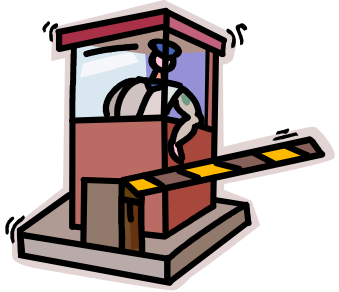
"The dilemma posed by that coercion – putting the challenger to the choice between abandoning his rights or risking prosecution – is 'a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate.'" (at 10)



D. THE SUPREME COURT'S DECISION

3. *Altvater* Case

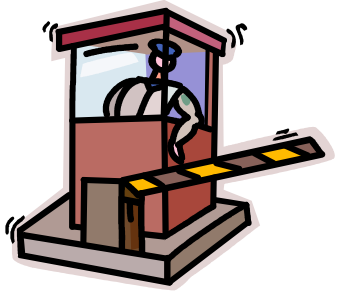
"We concluded that 'the requirements of [a] case or controversy are met where payment of a claim is demanded as of right and where payment is made, but where *the involuntary or coercive nature of the exaction* preserves the right to recover the sums paid or to challenge the legality of the claim.'" (at 12)



D. **THE SUPREME COURT'S DECISION**

4. Footnote 11: "Fatal to his business"

"A licensee who pays royalties under compulsion of an injunction has no more apprehension of imminent harm than a licensee who pays royalties for fear of treble damages and an injunction *fatal to his business*."



D. THE SUPREME COURT'S DECISION

5. What was promised?

"Promising to pay royalties on patents that have not been held invalid does not amount to a promise *not to seek* a holding of their invalidity." (at 16)

III. **THE IMPACT OF *MEDIMMUNE***

A. More licensees can challenge patents without risking an injunction or liability
   - They at least get into the courthouse

III. **THE IMPACT OF *MEDIMMUNE***

B. There is significant uncertainty about the scope and impact of the decision

- The Court relied heavily on the level of coercion in MedImmune
- The Court also *expressly* did *not* conclude that MedImmune would prevail on the merits
- Additionally, the Court noted that the district court has *discretion* as to whether it will entertain declaratory relief

III. **THE IMPACT OF *MEDIMMUNE***

C. The Impact of *Lear* on "no challenge" clauses

- Are termination clauses if the licensee challenges the agreement enforceable?

III. **THE IMPACT OF *MEDIMMUNE***

D. Things to do in negotiating licenses

- Favorable venue provisions or arbitration
- Document "voluntary" nature of agreement
- Higher up front royalties
- No Refund Clauses
- File Litigation First?
  - Is there an actual dispute?

III. **THE IMPACT OF *MEDIMMUNE***

E. How easy is it to become a *MedImmune Plaintiff*?

1. Will there be a distinction between the facts in *MedImmune* and other cases?

III. **THE IMPACT OF *MEDIMMUNE***

E. How easy is it to become a *MedImmune plaintiff*?

2. The *MedImmune facts*

   a. *Warning letter*
   b. *Real threat of suit*
   c. *Patent Issues on Application*
   d. *Products represent 80% of sales*

III. **THE IMPACT OF *MEDIMMUNE***

E. How easy is it to become a *MedImmune plaintiff*?

3. Does a future *MedImmune* plaintiff need to create a paper trail?
   - "We are taking a license under duress"
   - Or can ***all*** licensees become *MedImmune* plaintiffs?

III. **THE IMPACT OF *MEDIMMUNE***

E. How easy is it to become a *MedImmune plaintiff*?

4. How should a Licensor react to a Licensee's acceptance under "duress"?
   - What clauses can penalize a future challenge?
   - Are any enforceable?

III. **THE IMPACT OF *MEDIMMUNE***

F. Looking to the future

1. <u>Cost-Benefit Analysis</u>

A licensee who pays a large annual fee may consider challenging the patent

- Cost of litigation may be far less than the license

III. **THE IMPACT OF *MEDIMMUNE***

F. Looking to the future

2. Possible workarounds

- Increase royalty/minimum annual payment
- Preclude challenges to validity, enforceability or infringement
- High up-front payment

III. **THE IMPACT OF *MEDIMMUNE***

F. Looking to the future

3. New item to negotiate:

   Whether the licensee will agree to be precluded from challenging the patent

III. **THE IMPACT OF *MEDIMMUNE***

F. Looking to the future

4. More litigation may be on the horizon

III. **THE IMPACT OF *MEDIMMUNE***

G. Policy

MedImmune, like *Lear*, is consistent with the public interest in encouraging challenges to invalid patents. However, *MedImmune* runs counter to the policy of settling litigation

III. **THE IMPACT OF *MEDIMMUNE***

H. Beyond IP

- To what extent can *MedImmune* be applied outside of IP?
- All contracts?

III. **THE IMPACT OF *MEDIMMUNE***

I. Clauses to consider

- Change in royalty

"Whereas LICENSOR agrees to license without the benefit of a final decision on validity and infringement, LICENSOR agrees to license the subject patents for less than their worth …"