

MedImmune v. Genentech and its Consequences

Ramifications and Strategies for
Licensors and Licensees

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Outline

- MedImmune Background
- Licensee Estoppel
 - Public Policy Considerations
- Declaratory Judgment Standard
- MedImmune Decision
- MedImmune Applied
- License Clauses
- Notice Letters



Background

- MedImmune produces Synagis, a drug for the prevention of respiratory infections in infants
- Synagis accounted for over \$1 billion of its revenue for 2005. Source – MedImmune Financial Report 2005



Background

- April 8, 1983 – Cabilly et al.
- Genentech Cabilly I - U.S. Pat. 4,815,567
- Celltech Boss U.S. Pat. 4,816,397
- June 10, 1988 Genentech files continuation application (Cabilly II) and amends the claims after grant of Boss Patent to provoke an Interference



Background

- February 28, 1991 Interference declared between Cabilly II and Boss
- June 4, 1997 MedImmune obtains License from Genentech for Cabilly I and any patent issuing on the Cabilly II application
- MedImmune also obtains a license from Celltech under the Boss patent



Background

- August 13, 1998 - BPAI rules against Genentech and Cabilly II in the interference
- Genentech challenged the BPAI ruling by filing a civil interference action against Celltech
- “While the case was pending Genentech located a draft application for Cabilly I . . . a month before Celltech’s British application.” See Genentech Supreme Court Brief.
- Genentech and Celltech settle the case with Boss conceding priority to Cabilly II. Celltech received money payments and rights under the Cabilly II patent.



Background

- December 18, 2001 - Cabilly II granted as U.S. Patent No. 6,331,415 Cabilly II expires in 2018 (Note Boss expired 3/06)
- January 7, 2002 Genentech notified MedImmune that it owed royalties for the Synagis drug under the existing License Agreement between the parties.



Background

- MedImmune seeking to minimize its risk of paying damages (and facing an injunction if Genentech were to prevail in a suit) paid the royalty under protest; AND
- Filed a declaratory judgment action seeking to invalidate the Cabilly II patent or obtain a ruling that the Synagis drug was not covered by the patent
- Genentech sought to dismiss the case



MedImmune v Genentech

- **Issue:** Whether a Licensee must terminate or be in breach of its license before it can seek a declaratory judgment that the underlying patent is invalid, unenforceable, or not infringed?



Background

- Declaratory Judgment Act - 1934
 - “In a **case of actual controversy** within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought”



Background

- Automatic Radio Manufacturing Co. v. Hazeltine Research, 340 U.S. 846 (1950)
 - Licensee Estoppel – A licensee under a patent license agreement may not challenge the validity of the licensed patent in suit.



Policy

■ Licensee Estoppel

- A licensee cannot both accept the benefit of a license and challenge the licensed patent's validity
- Common Law of Contracts forbids a purchaser from repudiating his promises simply because he later becomes dissatisfied with the bargain he made



Policy

- **Lear, Inc. v. Adkins, 395 U.S. 653 (1969)**
 - U.S. Supreme Court negated the doctrine of Licensee Estoppel. A licensee may not be stopped from challenging patent validity.
 - Free Competition: Public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain.
 - “No challenge” clause not enforceable



Background

- Gen-Probe, Inc. v. Vysis, Inc. (Fed. Cir. 2004)
 - Federal Circuit held that a licensee cannot establish an Article III case or controversy and file a declaratory judgment action if the licensee continues to pay royalties under the license to the patent.



Background

- Teva Pharmaceuticals U.S.A, Inc. v. Pfizer Inc. (Fed. Cir. 2005)
- Two Prong Test
 - (1) a reasonable apprehension of imminent suit by the patentee, and
 - (2) activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken by the declaratory judgment plaintiff with the intent to conduct such activity.



Policy

- Balance of Interests
 - Contract Law
 - Public Interest
 - Jurisdiction



MedImmune Holding

- MedImmune does not need to terminate or be in breach of its license agreement before seeking a declaratory judgment in federal court that the licensed patent is invalid, unenforceable, or not infringed.



MedImmune Basis

- Standard for Declaratory Judgment:
 - Whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory action



MedImmune Basis

- “There is no dispute that these standards would have been satisfied if petitioner (MedImmune) had taken the final step of refusing to make royalty payments under the 1997 license agreement”
- “Where threatened action by the government is concerned, we do not require a plaintiff to expose himself to liability before bring suit to challenge the basis for the threat”



MedImmune Basis



■ Footnote 11

- Even if Altvater could be distinguished as an "injunction" case, it would still contradict the Federal Circuit's "reasonable apprehension of suit" test (or, in its evolved form, the "reasonable apprehension of imminent suit" test)



MedImmune Basis

■ Footnote 11

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. The reasonable-apprehension-of-suit test also conflicts with our decisions in *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U. S. 270, 273 (1941), where jurisdiction obtained even though the collision-victim defendant could not have sued the declaratory-judgment plaintiff-insurer without first obtaining a judgment against the insured; and *Aetna Life Ins. Co. v. Haworth*, 300 U. S. 227, 239 (1937), where jurisdiction obtained even though the very reason the insurer sought declaratory relief was that the insured had given no indication that he would file suit. It is also in tension with *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U. S. 83, 98 (1993), which held that appellate affirmance of a judgment of noninfringement, eliminating any apprehension of suit, does not moot a declaratory judgment counterclaim of patent invalidity.



Licensing after MedImmune

Impact of the MedImmune Decision

- Standard for Declaratory Judgment
 - Does an offer to license now create the basis for declaratory Judgment?
- Existing Agreements
 - Can Licensees now challenge the validity of licensed patents without first breaching the agreement?
- Future Licensing Agreements
 - What provisions will now be included in License Agreements to address this new risk?



SanDisk v. STMicroelectronics

Does an offer to license now create the basis for declaratory Judgment?

- SanDisk Corp. v. STMicroelectronics, Inc., 480 F.3d 1372 (Fed. Cir. 2007)
 - April 16, 2004: ST sent a letter to SanDisk listing 8 patents that “may be of interest to SanDisk”
 - April 28, 2004 SanDisk replies that it needs time to look into the patents and would be in touch in a few weeks
 - July 12, 2004 ST sends a letter suggesting a cross license and a meeting in July



SanDisk v. STMicroelectronics

- ST Expressly stated that it did not intend to sue SanDisk
- ST prepared claim charts demonstrating that SanDisk infringed the ST patents and offered a license.
- October 15, 2004 SanDisk filed a DJ action
- District Ct. dismisses suit holding that SanDisk did not have an objectively reasonable apprehension of suit.
- Federal Circuit Reverses



SanDisk v. STMicroelectronics

- DJ Jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee.



SanDisk v. STMicroelectronics

- Promise not to sue does not prevent DJ Jurisdiction where the patentee “has engaged in a course of conduct that shows a preparedness and willingness to enforce its patent rights”



Teva v. Novartis

- Teva v. Novartis (March 30, 2007)
- ANDA Context
 - Novartis listed five patents in the FDA Orange Book covering various aspects of Famvir®
 - Teva filed an ANDA and certified that its drug did not infringe any of the five Novartis Famvir® Orange Book patents



Teva v. Novartis

- Novartis filed suit against Teva on only one of the five patents
- Teva filed a Declaratory Judgment action on the four remaining patents
- Novartis moved to dismiss arguing that Teva had no reasonable apprehension that it would be sued by Novartis on the four patents



Teva v. Novartis

- District Court dismisses DJ action based on application of two prong test finding no “reasonable apprehension of imminent suit”
- Federal Circuit Overrules
 - Applies MedImmune Test: 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

Licensing after MedImmune

Future Licensing Agreements

- Termination Clause: Allowing for termination if the Licensee challenges the patent
- Enhanced Royalty: Providing an increased royalty payment if the patent is found to be valid and infringed
- Cost of Defending the Challenge: providing for a fee or increased royalty payment during the challenge
- Jurisdiction/Venue

Proposed License Agreement Clauses

31
51

- “Licensor may terminate this Agreement and any license granted hereunder if Licensee, for any reason, does not make payment to Licensor as specified on a timely basis or if Licensee challenges the validity of any of the Licensed Patents in any judicial or administrative proceeding.”

Proposed License Agreement Clauses

32
52

- “Licensee recognizes that the value of the Licensed Patents is enhanced by any judicial or administrative determination that the Licensed Patents are not invalid. Therefore, if Licensee challenges the validity any of the Licensed Patents in any judicial or administrative proceeding and the challenged patents are not found to be invalid, if Licensor has not terminated the Agreement, the royalties shall double, retroactive to the date of the filing of the challenge.”



Licensing after MedImmune

- Licensee has increased bargaining power in existing licenses to renegotiate terms without the risk of willful infringement and injunction
- Licensors should consider how to reallocate the risk created by the MedImmune Decision




Notice after MedImmune

- Outline
 - Notice Requirements
 - Pre-MedImmune Notice Letters
 - Effect of MedImmune on Notice Letters/Negotiations
 - Options for Post-MedImmune Notice/Negotiations



Notice Requirements

- Limitations on Patent Damages
 - See 35 U.S.C. § 287(a)
 - Mark products or place infringer on actual notice
 - Notice requirements:
 - Communication from patentee
 - Identify patent owner
 - Specific charge of infringement
 - Specific accused product or device



Notice Requirements

- Willful Infringement Damages
 - See 35 U.S.C. §§ 284-285
 - Knowledge is required, but not necessarily from patentee
 - An allegation of infringement is not required
 - Specific identification of a product or device is not required



Notice and Negotiation

- Key Question:
 - How do you place a potential licensee on notice and engage in licensing discussions without triggering declaratory judgment jurisdiction?



Pre-MedImmune Notice

- “We have noted from your advertising literature that [your specific products] may infringe one or more claims of [our specific patent]. . . . [We] would be pleased to provide [you] with a nonexclusive license under the patent.” *SRI Intern., Inc. v. Advanced Technology Laboratories, Inc.*, 127 F.3d 1462 (Fed. Cir. 1997).

Effect of MedImmune on Notice/Negotiations

39

- Previous Federal Circuit test:
 - Reasonable apprehension of suit
 - Infringing activity or concrete steps to conduct such activity
- Teva indicates that both prongs of test have been overruled by MedImmune

Effect of MedImmune on Notice/Negotiations

40
40

- “Therefore, it would appear that under the court’s standard virtually any invitation to take a paid license relating to the prospective licensee’s activities would give rise to an Article III case or controversy if the prospective licensee elects to assert that its conduct does not fall within the scope of the patent.”
Bryson, concurring in *SanDisk* opinion.

Options for Handling Post-MedImmune Notice

41
41

- If a letter is received that does not satisfy Section 287(a), inquire as to whether the patentee believes that the activity is within the scope of the patent.
- Increased importance of marking
 - Provide notice of patent number for willful infringement notice purposes and mark products to provide notice for damages purposes

Options for Handling Post-MedImmune Notice/Negotiations

42
42

- Send notice triggering obligation of due diligence but not declaratory judgment jurisdiction to begin negotiations
- Engage in license negotiations under the terms of a confidentiality agreement

THANK YOU

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