



Life Sciences Industry Perspective on Declaratory Judgment Actions and Licensing Post-*MedImmune*:

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Roadmap for Presentation

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- I. Summary of DJ jurisprudence:
 - *Post-MedImmune*: What's different?
 - II. Potential strategies for transactional attorneys in a *post-MedImmune* world
 - III. Q & A

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Declaratory Judgment Act

- 28 U.S.C. § 2201: “In a case of actual controversy ... any court of the United States ... may declare the rights and other legal relations of any interested party”
- Subject to Art. III case or controversy requirements
 - standing, ripeness, mootness
- Policy of reducing uncertainty
- Patent infringement accusations figured prominently in enactment of the Declaratory Judgment Act

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Prior Federal Circuit Two-Prong Test

- Reasonable apprehension of suit if allegedly infringing activity continues; and
- Activity constituting infringement or demonstration of concrete steps taken with the intent to conduct such activity

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MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007) – Facts

- Genentech patent and patent application covering co-expression of immunoglobulin chains in recombinant host cells (“Cabilly II”)
- Genentech wrote MedImmune expressing its belief that the newly issued patent covers MedImmune’s product Synagis and its expectations that MedImmune would start paying royalties
- MedImmune paid the demanded royalties “under protest” and filed a declaratory judgment action

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MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007) – Lower Courts

- **Issue:** Does the “actual controversy” requirement require a patent licensee to be in breach of license agreement before seeking a declaratory judgment that the patent is invalid, unenforceable or not infringed?
- **Federal Circuit:** Affirmed District Court’s dismissal of declaratory judgment claims

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MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007) – Supreme Court

- **Supreme Court:** Reversed Federal Circuit decision (8-1 decision, Thomas, J., dissenting)
- **Answer:** No. Article III does not require patent licensee to breach license agreement before seeking declaratory judgment of invalidity, unenforceability or non-infringement.

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Reaffirmation of Totality of the Circumstances Test

- For a DJ action to satisfy the “actual controversy” requirement of Art. III, dispute must be:
 - “Definite and concrete, touching the legal relations of parties having adverse interests”
 - “Real and substantial” and
 - Amenable to “specific relief through a decree of a conclusive character”
- Facts must “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 judgment”

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Actions That Create Jurisdiction

- *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372 (Fed. Cir. 2007)
 - ST and SanDisk engaged in licensing negotiations that did not result in a license
 - ST never expressly threatened litigation
 - SanDisk sought a declaratory judgments of noninfringement and invalidity

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Actions That Create Jurisdiction

- The District Court’s dismissal was reversed by the CAFC
- Concurring opinion by Judge Bryson: “I see no practical stopping point short of allowing declaratory judgment actions in virtually any case in which the recipient of an invitation to take a patent license elects to dispute the need for a license and then to sue the patentee.”

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Actions That Create Jurisdiction

- *Honeywell Int'l v. Universal Avionics Sys.*, 488 F.3d 982 (Fed. Cir. 2007)
 - Withdrawing independent claims, but still asserting dependent claims warranted declaratory judgment jurisdiction

Actions That Create Jurisdiction

- *Sony Electronics, Inc. v. Guardian Media Technologies, Inc.*, 497 F.3d 1271 (Fed. Cir. 2007)
 - Warning letters accusing specific products and claims
 - Claim charts provided
 - Patentee's expressed willingness to continue negotiations does not defeat jurisdiction

Actions That Create Jurisdiction

- *Micron Technology, Inc. v. MOSAID Technologies, Inc.*, 518 F.3d 897 (Fed. Cir. 2008)
 - Warning letters
 - Pattern of suing to enforce patents
 - Public statements regarding aggressive litigation strategy

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Actions That Create Jurisdiction

- *Cat Tech LLC v. Tubemaster, Inc.*, 528 F.3d 871 (Fed. Cir. 2008)
 - Defendant obtained declaratory judgment that 3 designs that had never been used did not infringe
 - CAD drawings of proposed product existed
 - Final product would be created to customer's specifications after work order received

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Actions That Create Jurisdiction

- *Samsung Electronics Co. v. ON Semiconductor Corp.*, 541 F. Supp. 2d 645 (D. Del. 2008)
 - Patentee sent letters accusing Samsung of infringement
 - During negotiations, specific products were accused of infringing specific claims and analysis was provided
 - Patentee stated that it was considering litigation

Actions That Create Jurisdiction

- *WS Packaging v. Global Commerce Group*, 505 F. Supp. 2d 561 (E.D. Wisc. 2007)
 - Patent holder's habit of threatening to sue the customers of alleging infringing vendors gives the vendor the ability to file a declaratory judgment seeking patent invalidity

Actions That Create Jurisdiction

- *EchoStar Satellite LLC v. Finisar Corp.*, 515 F. Supp. 2d 447 (D. Del. 2007)
 - Patent holder’s successful enforcement of patent against a third party, coupled with a press release that patent holder wanted to “continue with its licensing negotiations” with others

Actions That Create Jurisdiction

- *Sabert Corp. v. Waddington North America, Inc.*, WL 2705157 (D. N.J. 2007)
 - Patent holder’s letter stating that it needed more information about the alleged infringer’s device, that the device “appeared” to infringe, but expressing an interest in “continuing a dialogue”

Actions That Create Jurisdiction

- *Teva Pharm. USA., Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007): “Famvir” case
 - Novartis listed 5 patents in Orange Book (OB)
 - Teva filed ANDA with a P.IV certification against all five patents (i.e., ANDA product will not infringe or the patents are invalid)
 - Novartis brought suit on one patent
 - Novartis refused to give Teva a covenant not to sue
 - Teva brought a DJ action on the other four patents
 - Federal Circuit found DJ jurisdiction
- Compare with *Teva Pharm. USA., Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005) where DJ jurisdiction was found even though Pfizer did not bring suit on all OB patents and refused to grant a covenant not to sue

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Actions That Create Jurisdiction

- *Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.*, 527 F.3d 1278 (Fed. Cir. 2008): “Lexapro” case
 - Ivax: 1st ANDA filer
 - P. IV certification against both OB patents ('712 expiring 2012 and the '941 expiring 2023)
 - Forest brought suit only on the '712 patent
 - '712 patent found valid, infringed and enforceable
 - Caraco: 2nd ANDA filer
 - Same certification as Ivax
 - Again, Forest only sued on the '712 patent
 - Forest granted covenant not to sue on '914 (after *Novartis*)
 - Forest would not concede '941 was invalid/not infringed
 - H-W does not grant Caraco the ability to enter the market as in typical infringement suit

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Actions That Create Jurisdiction

- Threaten to Sue
- Provide Claim Charts
- Identify Specific Claims
- Identify Specific Products
- Suing on only one of several patents identified in ANDA filing

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Actions That Defeat Jurisdiction

- *Merck & Co., Inc. v. Apotex, Inc.*,
287 Fed. Appx. 884 (Fed. Cir. 2008): “Fosamax” case
 - Merck listed 10 patents in the Orange Book
 - 1st ANDA: Teva filed an ANDA with a P.IV certification against the ‘077 basic COM patent
 - Merck sued Teva and won on validity and infringement
 - 2nd ANDA: Apotex filed an ANDA with a P.III certification against the ‘077 basic COM patent and a P.IV certification against the other nine patents
 - Merck brought suit on the nine patents
 - Merck later granted Apotex a covenant not to sue on all patents
 - **Case found to be moot** b/c 30-month stay triggered by Teva suit is dissolved and Teva triggered its 180 day period of exclusivity

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Actions That Defeat Jurisdiction

- *Janssen Pharmaceutical, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008): “Risperdal” case
 - Janssen listed three patents in the Orange Book
 - 1st ANDA: Teva filed an ANDA with a P.III certification against the basic COM patent ('663) and a P.IV certification against the other two patents
 - 2nd ANDA: Apotex filed an ANDA with a P.IV certification against all three patents
 - Janssen brought suit on the '663 patent only
 - Apotex later stipulated to the enforceability, validity, infringement, of the '663 patent
 - Janssen later granted Apotex a covenant not to sue on the other two patents
- Distinguished from *Caraco* b/c harm ceased to exist upon Apotex stipulation

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Actions That Defeat Jurisdiction

- *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340 (Fed. Cir. 2007)
 - Nucleonics' human testing fell within a statutory safe harbor and could not be infringing
 - FDA filings too far off to create jurisdiction
 - Plans to expand activities to include animal husbandry products likewise too far off when no concrete steps had been taken

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Actions That Defeat Jurisdiction

- *Prasco, LLC v. Medicis Pharmaceutical Corp.*, 537 F.3d 1329 (Fed. Cir. 2008)
 - Patentee sold competing product marked with patent numbers
 - Patentee had sued third parties for infringement of an unrelated patent
 - Between filing of initial and supplemental complaint, patentee refused request for covenant not to sue
 - Patentee unaware of product's existence until Plaintiff's suit

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Actions That Defeat Jurisdiction

- *Wooster Brush Co. v. Bercom International, LLC*, 2008 WL 1744782 (N.D. Ohio 2008)
 - Patentee sent letter stating that accused product appeared to be a copy of a patent pending product
 - Subsequent letter stated that patent claims had been allowed and invited consideration of claims with respect to specific products
 - Plaintiff's response provided noninfringement analysis
 - No jurisdiction over DJ claim because patentee never provided infringement analysis or identified specific claims as infringed

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Actions That Minimize Exposure to Jurisdiction

- Covenants not to sue
- Suing before product is defined
- Suing without contact from patentee
- Being prevented from entering the market due to a patent previously held to be valid and enforceable
- Speculative harm
- Possible delay of launch of ANDA holder having 180 d. exclusivity

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Potential strategies for transactional attorneys in a post-*MedImmune* world



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General Language for Licenses

- Forum selection clauses – If challenges are inevitable, consider controlling where challenges will be heard or arbitrated
- Have a good severability clause

Language for Licensors

- Pre-suit notification clauses – such language gives licensor the opportunity to evaluate the strength of the licensee's claim and possibly consider renegotiating the license
- Termination provisions – allows licensor to terminate the agreement in the event of a validity challenge to a patent licensed under the agreement

Language for the Licensors

- Provision that gives licensor the right to reduce the scope of the grant or field upon a validity challenge
- Litigation costs – licensor may want to insert a clause for payment of attorney's fees and other costs...win or lose
- Front-Loading – increase up-front payments or secure fully paid-up license

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Language for the Licensors

- Add a provision requiring the licensee to continue to pay milestones and royalties during a validity challenge
- Incorporate a step-down provision relating to Know-How provided by the licensor (i.e., switching the base of the royalties to the Know-How)
- Provision that precludes recovery of previously paid royalties

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Language for the Licensors

- Differing royalty rates – consider increasing fees in the event of a validity challenge, keeping in mind that courts frown upon liquidated damage penalties
 - Consider an automatic increase in royalty rates if licensee challenges validity and loses

Language for Licensees

- Expressly retain the right to challenge the licensed patents
- Place royalties in escrow during a challenge
- Inform licensee of prior art identified in third party challenge of patent



Questions?

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