

Stanford Law School

Licensing after *MedImmune*

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Licensee Litigation in the wake of MedImmune

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

- MedImmune took license to Cabilly II patent and continued to pay royalties “under protest.”
- MedImmune sued Genentech seeking a declaration that it owed no royalties under the contract and that the patent was not infringed, invalid and unenforceable.
- The patent license agreement provided that MedImmune had an obligation to pay royalties until the patent was held invalid.

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

- Federal Circuit decided *Gen-Probe v. Vysis*, 359 F.3d 1376 (Fed. Cir. 2004), holding that licensee in good standing lacked standing to sue for declaratory relief to contest patent validity, enforceability or scope because patent license “obliterated” any reasonable apprehension of suit.
- *MedImmune* district court dismissed action for lack of standing under *Gen-Probe*.
- Federal Circuit affirmed.

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

- United States Supreme Court granted cert. and reversed and remanded.
- Court held that MedImmune had stated a not frivolous claim that it had no obligation under the contract to pay royalties on an invalid patent.

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

- “We express no opinion on whether a non-repudiating licensee is similarly relieved of its contract obligation during a successful challenge to the patent’s validity – that is, on the application of licensee estoppel under these circumstances.”
- “All we need determine is whether the petitioner has alleged a contractual dispute. It has done so.”

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

- “Basically, the question in each case is 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 judgment.”
- “The rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80 percent of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III”
- “We find the threat of treble damages and loss of 80 percent of petitioner's business every bit as coercive as the modest penalties for misdemeanor trespass threatened in [Steffel](#).”

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

- Genentech argued that the parties settled any dispute about infringement, validity and enforceability when they entered into the 1997 license agreement. The Supreme Court was not persuaded.
- “[T]he prohibition against challenging the validity of the patents ... can hardly be implied from the mere promise to pay royalties on patents ‘which have neither expired nor been held invalid by a court or other body of competent jurisdiction from which no appeal has been or may be taken.’ 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.”

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

- “Petitioner is not repudiating or impugning the contract while continuing to reap its benefits. Rather, it is asserting that the contract, properly interpreted, does not prevent it from challenging the patents, and does not require the payment of royalties because the patents do not cover its products and are invalid.”
- “Of course even if respondents were correct that the licensing agreement or the common-law rule precludes this suit, the consequence would be that respondents win this case *on the merits-not* that the very genuine contract dispute disappears, so that Article III jurisdiction is somehow defeated.”

MedImmune v Genentech, 2:03cv02567-MRP-CV

- On remand, district court ruled on claim construction such that MedImmune conceded infringement of one claim.
- Genentech filed an irrevocable covenant not to sue as to the remaining claims.
- Concession and covenant removed infringement issues from the case, leaving declaratory judgment claims under the contract, for invalidity, and for unenforceability

MedImmune v Genentech, 2:03cv02567-MRP-CV

- District court struck MedImmune's own jury demand (at MedImmune's request)
- Held that no right to jury trial on contract claim because there were no factual disputes of contract interpretation regarding MedImmune's obligation to pay royalties.
- Held that Beacon Theaters did not give Genentech a right to jury trial because even had Genentech been the plaintiff, it would have had no damages claim because MedImmune had continued to pay royalties.

MedImmune v Genentech, 2:03cv02567-MRP-CV

- Genentech argued for a right to a jury trial on patent invalidity under *In re Lockwood*, 50 F.3d 966 (Fed. Cir. 1995), vacated, 515 U.S. 1182 (1995) which provides for such a right unless waived.
- Court held that no right to jury trial on validity because no possible claim for damages.

MedImmune v Genentech, 2:03cv02567-MRP-CV

- Genentech moved for summary judgment on the contract claim, arguing that once infringement was conceded, there was no dispute about MedImmune's present obligation to pay royalties under the contract because the patent had not been held invalid by court from which no appeal could be taken.
- Court declined to rule because ruling would be advisory until patent was invalidated.
- Court noted that contractual obligations were tied to validity of patent.

MedImmune v Genentech, 2:03cv02567-MRP-CV

- Genentech moved for summary judgment on declaratory relief claim for patent invalidity because patent invalidity is a defense, not a cause of action.
- Court declined to rule, noting that it did not need to resolve the issue because the contract put patent validity at issue.

MedImmune v Genentech, 2:03cv02567-MRP-CV

- Court also declined to hold that MedImmune was precluded under the doctrine of licensee estoppel
- Genentech argued that MedImmune could not seek to avoid its license obligations as a non-repudiating licensee, citing *Studiengesellschaft Kohle v. Shell Oil*, 112 F.3d 1561 (Fed. Cir. 1997).
- Court held that Kohle was not controlling and did not bar MedImmune's claim.

Stanford Law School

Licensing after *MedImmune*

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Friday, May 8, 2009

Licensee Estoppel

- “One of the oldest doctrines in the field of patent law establishes that so long as a licensee is operating under a license agreement he is estopped to deny the validity of his licensor’s patent in a suit for royalties under the agreement. The theory underlying this doctrine is that a licensee should not be permitted to enjoy the benefit afforded by the agreement while simultaneously urging that the patent which forms the basis of the agreement is void.” *Adkins v. Lear* (California Supreme Court 1967).

Lear v. Adkins

(U.S. Supreme Court 1969)

- In 1954, Adkins filed a patent application covering his invention, an improvement for gyroscopes.
- In 1955, Adkins entered into a license agreement with Lear granting Lear a royalty-bearing license to Adkins' invention.
- In 1957, Lear began to withhold royalty payments due Adkins on the basis of Lear's conclusion that Adkins' invention was not patentable.
- In 1959, Lear notified Adkins that it was terminating its license agreement with Adkins.
- In 1960, Adkins was granted a patent covering his invention and sued Lear for royalties due under the license agreement.

Lear v. Adkins

(U.S. Supreme Court 1969)

- Lear defended the suit by claiming that it did not owe Adkins royalty payments under the license agreement since it had terminated the agreement prior to the issuance of the Adkins patent and that the issued Adkins patent was not valid.
- The California Supreme Court concluded that Lear had not properly terminated the license agreement and, accordingly, that the doctrine of licensee estoppel prohibited Lear's challenge of the validity of the Adkins patent.

Lear v. Adkins

(U.S. Supreme Court 1969)

- Vacated the decision of the California Supreme Court
 - The U.S. Supreme Court held that licensee/Lear was not estopped from challenging the validity of licensor's/Adkins' patent and did not owe Adkins royalty payments after the patent issued if the Adkins' patent was found to be invalid.
- Overruled its prior holding in *Automatic Radio*
 - “We are satisfied that *Automatic Radio* ..., itself the product of a clouded history, should no longer be regarded as sound law with respect to its ‘estoppel’ holding, and that holding is now overruled.”

Lear v. Adkins

(U.S. Supreme Court 1969)

- *Lear* Balancing Test

- “Surely the equities of the licensor do not weigh very heavily when they are balanced against the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain. Licensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor’s discovery. If they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification. We think it plain that the technical requirements of contract doctrine must give way before the demands of the public interest....”

Lear v. Adkins

(U.S. Supreme Court 1969)

- The Court rejected as unenforceable a contract provision in the Adkins/Lear license agreement that required “... that royalties are to be paid until such time as the ‘patent ... is held invalid.’”
- The Court held that “... overriding federal policies would be significantly frustrated if licensees could be required to continue to pay royalties during the time they are challenging patent validity in the courts.”
- The Court concluded that “[t]he parties’ contract ... is no more controlling on this issue [of whether the important public interest in exposing invalid patents should trump the technical requirements of contract doctrine] than is the State’s doctrine of estoppel, which is also rooted in contract principles.”

Lear v. Adkins

(U.S. Supreme Court 1969)

- Protections of the *Lear* Doctrine
 - Patent licensee can challenge the validity of the licensed patent in a dispute regarding royalties due under the license.
 - Patent licensee is not obligated to pay royalties to licensor during the pendency of the patent challenge.

Lear v. Adkins

(U.S. Supreme Court 1969)

- Notes on *Lear*
 - The case did not involve a licensee in good standing.
 - The case did not involve an explicit “no challenge” clause.

Lear Progeny I

District and Regional Circuit Courts Extended *Lear* Holding

- Patent validity challenge by licensee permitted
 - in the context of a prior settlement of litigation involving the patent's validity
 - *Massillion* (9th Cir. 1971)
 - *Crane* (7th Cir. 1974)
 - *Kraly* (7th Cir. 1974)
 - despite explicit contractual prohibition
 - *Plastic Contact Lens* (U.S. Dist. Ct., SDNY 1970)
 - *Massillion* (9th Cir. 1971)
 - *Kraly* (7th Cir. 1974)
 - *Robintech* (U.S. Dist. Ct., DC 1978)

Lear Progeny I

District and Regional Circuit Courts Extended *Lear* Holding (continued)

- Explicit “no challenge” clause in third party license agreement held to be unenforceable in patent infringement suit
 - *Panther Pumps* (7th Cir. 1972)
 - *Bendix Corp.* (7th Cir. 1972)
 - *Blohm & Voss* (U.S. Dist. Ct., D. Maryland 1972)
 - *Congoleum Inds.* (U.S. Dist. Ct., E.D. Penn. 1973)

Lear Progeny II

Federal Circuit Limits *Lear* Holding

- Patent validity challenge not permitted
 - by patent assignor – *Diamond* (1988)
 - in settlement context – *Foster* (1991)
 - if contractually prohibited (in settlement context) – *Flex Foot* (2001)
- Prerequisites to challenge
 - *Shell Oil* (1997)
- Jurisdictional barrier to challenge
 - *Gen-Probe* (2004)

Federal Circuit's Position on Requirements for Protection under *Lear*

- “[A] licensee ... cannot invoke the protection of the *Lear* doctrine until it (i) actually ceases payment of royalties, and (ii) provides notice to the licensor that the reason for ceasing payment of royalties is because it has deemed the relevant claims to be invalid.”
 - *Studiengesellschaft Kohle, M.B.H. v. Shell Oil Co.*, (Fed. Cir. 1997)

Gen-Probe v. Vysis

359 F.3d 1376 (Fed. Cir. 2004)

- Federal Circuit established a jurisdictional barrier to a patent validity challenge by a nonrepudiating licensee in good standing.
- The court held that a licensee in good standing had no reasonable apprehension of suit and therefore there was no actual case or controversy.
- “The *Lear* doctrine ... does not grant every licensee in every circumstance the right to challenge the validity of the licensed patent. In several instances, this court has declined to apply the *Lear* doctrine [citing *Shell Oil*, *Foster*, *Sun Studs*, *Hemstreet* and *Diamond*.]”

The Licensor's Dilemma

- In light of the elimination of the jurisdictional barrier to a patent validity challenge by a licensee in good standing, is there a vestige of the doctrine of licensee estoppel to protect the patent licensor and, if one cannot rely on the doctrine, are there enforceable explicit contract provisions that will protect the licensor?

The Licensor's Dilemma – A Response

- If and when the issue is presented, the U.S. Supreme Court will interpret its prior *Lear* holding as having rejected the doctrine of licensee estoppel without qualification, permitting a patent licensee to challenge the validity of the licensed patent even if it neither repudiates nor terminates its patent license agreement and intends to continue to reap the benefits provided pursuant to the agreement.
- Accordingly, the patent licensor would be ill-advised to rely on some vestige of the common law doctrine of licensee estoppel to prevent such a challenge. Rather, the concerned licensor should consider introducing explicit contractual provisions in the patent license agreement to account for the increased likelihood of a patent validity challenge by its licensee.

U.S. Supreme Court Opines on “No Challenge” Clauses

- *Pope v. Gormully* (U.S. Sup. Ct. 1892)
 - The Court refused to enforce the specific performance of an “unusual and oppressive” “no challenge” clause that survived the termination of the patent license.
 - “It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly”
 - “...[licensee] could not bind himself by contract not to avail himself of such right [to challenge a worthless patent] if it be secured to him on grounds of public policy.”

U.S. Supreme Court Opines on “No Challenge” Clauses

- *Katzinger Co. v. Chicago Mfg. Co.* (U.S. Sup. Ct. 1947)
 - The Court held that “[a licensee], in a suit to recover royalties only [i.e. no attempt to also enforce the price-fixing provisions] under a terminated patent license agreement containing price-fixing provisions, can challenge the validity of the patent despite a covenant in the license contract that he would not do so.”
 - “... [Licensee’s] specific contract not to challenge the validity of Katzinger’s patent can no more override congressional policy [of eliminating invalid patents and restraints of trade] than can an implied estoppel. See *Scott Paper*”

Assessment of Contractual Protections of Patent Licensor

- (1) Does the contract provision eliminate one of the protections of the *Lear* doctrine?
 - Licensee cannot be prohibited from challenging the validity of the licensed patent in a dispute regarding royalties due under the license.
 - Licensee cannot be obligated to pay royalties during the pendency of the challenge.

Problematic Contract Provisions

- “During the life of this Agreement or any extension or continuation thereof, ... [licensee] agrees not to contest the validity of ... [licensor’s] Patent ... or any continuation, divisions or reissues thereof or any corresponding foreign patents....” *Panther Pumps*
- “... section 7.3 reserves to defendant [patent holder/licensor]: ... the right to require ... [licensee] to continue making royalty payments during a pending validity challenge.” *Bayer v. Housey*

Assessment of Contractual Protections of Patent Licensor

- (2) Where does the contract provision fall on the “disincentive-to-challenge” spectrum, and when does a disincentive constitute, in practice, a prohibition to challenge that was rejected under *Lear*?
 - *Lear* rejected a royalty payment contract provision because “overriding federal policies would be significantly frustrated” if the provision were enforced.
 - *Crane* prevented a licensor from terminating an agreement despite licensee’s material breach because of “the chilling effect on meritorious challenges to patents” that would result.

Example of a “Disincentive-to-Challenge” Clause

- “... section 7.3 reserves to defendant [patent holder/licensor]: ... the right to terminate the license if a challenge to validity is made [by licensee].” *Bayer v. Housey*

American Sterilizer v. Sybron

(3rd Cir. 1980)

- “One commentator has observed: “The 'spirit of Lear ' appears to be one of **providing some incentive to licensees to challenge patent validity** and to eliminate obstacles to suit by those disposed to challenge the validity of a patent.” McCarthy, “Unmuzzling” the Patent Licensee: Chaos in the Wake of Lear v. Adkins (Part I) 59 J. Patent Office Society, 475, 476 (1977).”
- “The Lear decision, although it discarded the undesirable contractual principle of licensee estoppel, has engendered considerable confusion regarding other contractual issues relating to licensing agreements. The problem has been succinctly stated: **‘How much of the law of contracts and patents must fall in order to give licensees sufficient encouragement to challenge (the validity of patents).’** Id.”

Timely Products v. Costanzo

(U.S. Dist. Ct., D. Conn. 1979)

- “In its holding, *Lear* does not go so far as to invalidate an agreement that only reduces the incentive of a licensee to challenge patent validity. However, *Lear* did invalidate an agreement which, if enforced, would have left the licensee with “little incentive” to challenge the patent. *Id.* at 674, 89 St. Ct. 1902. Thus, **at a minimum, *Lear* means that the policy of the patent laws must displace contract provisions which, if enforced, leave the licensee without any incentive to challenge the patent.**”
- “[Yet,]...*Lear* may defeat *any* license provision that...[in any way diminishes the benefits to a licensee of a patent validity challenge], on the basis that a licensee needs the maximum possible incentive to challenge arguably invalid patents.”

Morton-Norwich Products v. Intl. Salt

(U.S. Dist. Ct., N.D.N.Y. 1974)

- The district court holds that termination of a patent license agreement pursuant to an explicit contract provision following a licensee's breach of its obligation to pay royalties is permissible despite the *Lear* Court's public policy argument encouraging patent validity challenges.
- “[In] ... permitting the licensee to unilaterally and offensively ignore his contract obligation to make payments required under the contract, and at the same time denuding the licensor of the remedy of declaring a breach and seeking relief against the licensee as an infringer, ... the licensor is clearly being shortchanged.”
- “I have concluded that it would be inappropriate to extend the scope of *Lear* to such a point that **the licensee would be in a “heads I win—tails you lose” situation**. The shield that licensees would enjoy were *Lear* so extended might encourage more validity litigation, but at too high a price.”

Assessment of Contractual Protections of Patent Licensor

- BUT CONSIDER the Federal Circuit's "challenge but face-the-consequence" rulings.
 - *Bard v. Schwartz* (1983)
 - *Cordis v. Medtronic* (1985)
 - *Sun Studs v. ATA Equipment* (1989)
 - *SG Kohle v. Shell Oil* (1997)
 - *Dow Chemical v. U.S.* (2000)

Representative Federal Circuit “Challenge but Face-the-Consequence” Rulings

- In *Bard*, the court recognized the licensee’s right to challenge the licensed patent and withhold royalties but also acknowledged the licensor’s right to terminate the license agreement, which had an explicit contract provision providing licensor with a termination right in the event that licensee challenged the patent’s validity and stopped paying royalties.
- In *Cordis*, the court stated: “[the] public policy statement [in *Lear*] does permit a licensee to cease payments due under a contract while challenging the validity of a patent. It does not permit the licensees to avoid facing the consequences [i.e., contract termination] that such an action would bring.”

Assessment of Contractual Protections of Patent Licensor

- (3) If the provision is unenforceable in light of the Lear public policy argument, is the inclusion of the provision in a patent license agreement an act of patent misuse?
 - *Pope v. Gormully* (U.S. Sup. Ct. 1892)
 - *Blonder-Tongue Laboratories, Inc.* (U. S. Sup. Ct. 1971)
 - *Panther Pumps* (7th Cir. 1972)
 - *Bendix Corp.* (7th Cir. 1972)
 - *Blohm & Voss* (U.S. Dist. Ct., D. Maryland 1972)
 - *Congoleum Inds.* (U.S. Dist. Ct., E.D. Penn. 1973)
 - *Robintech* (U.S. Dist. Ct., DC 1978)
 - *Bayer v. Housey* (U.S. Dist. Ct., D. Del. 2002)

Pope v. Gormully
(U.S. Supreme Court 1892)

- The U.S. Supreme Court refused to enforce the specific performance of an “unusual and oppressive” “no challenge” clause **that survived the termination of the patent license.**

Blonder-Tongue Laboratories

(U.S. Supreme Court 1971)

- The U.S. Supreme Court reaffirmed and explained its decision in *Lear*
 - In so doing, the Court stated that “[t]he holding that licensee estoppel was no longer tenable was rooted in the ... line of cases eliminating obstacles to suit by those disposed to challenge the validity of a patent,” rather than the other line of cases relied on in *Lear*, i.e. “decisions in which the Court has condemned attempts to broaden the physical or temporal scope of the patent monopoly [i.e. the Court’s patent misuse holdings].”

Panther Pumps

(7th Cir. 1972)

- “In *Lear, Inc. v. Adkins* ..., the Supreme Court held that a licensee is not estopped to challenge the validity of a patent; in view of that holding, the ‘no contest’ provision in the ... license is plainly unenforceable.”
- “We hold that **the ‘no contest’ clause** in the ... license, though unenforceable under *Lear*, **does not constitute** the kind of ‘**misuse**’ of the patent which forecloses recovery of damages from an unlicensed infringer.”

Bendix Corp.

(7th Cir. 1972)

- “... the portion of plaintiff’s license agreements providing that the licensee ‘will not contest the validity of any [licensed] patent ... during the life of this agreement’ did not constitute a misuse of the patent [but was unenforceable under Lear].”
- “However, **some [patent] misuse may be inferred** from the mere presence of the ‘thereafter’ clause,” obligating the licensee not to challenge the validity of the plaintiff’s patent after the termination of the license agreement.

Assessment of Contractual Protections of Patent Licensor

- (4) If the provision is enforceable, does it protect the patent licensor as intended?
 - *Ebay* (U.S. Supreme Court 2006)

Ebay

(U.S. Supreme Court 2006)

- The U.S. Supreme Court rejected the Federal Circuit's "general rule" that courts will issue a permanent injunction against an infringer of a patent adjudged to be valid in the absence of exceptional circumstances, and held that courts must apply the "traditional four-factor" test when considering whether to award permanent injunctive relief to a prevailing patentee in a dispute arising under the Patent Act.

An Example of a Royalty Adjustment Provision

- “In the event that licensee challenges the validity of the licensed patent and the patent is adjudged by a court to be valid, then the royalties due licensor under the license agreement in consideration for the grant of rights to licensee under the patent shall be increased by X%.”

The Stanford Law School Conference on Intellectual Property Law and the Biosciences



Licensing after *MedImmune*: Analysis of post-*MedImmune* DJ actions

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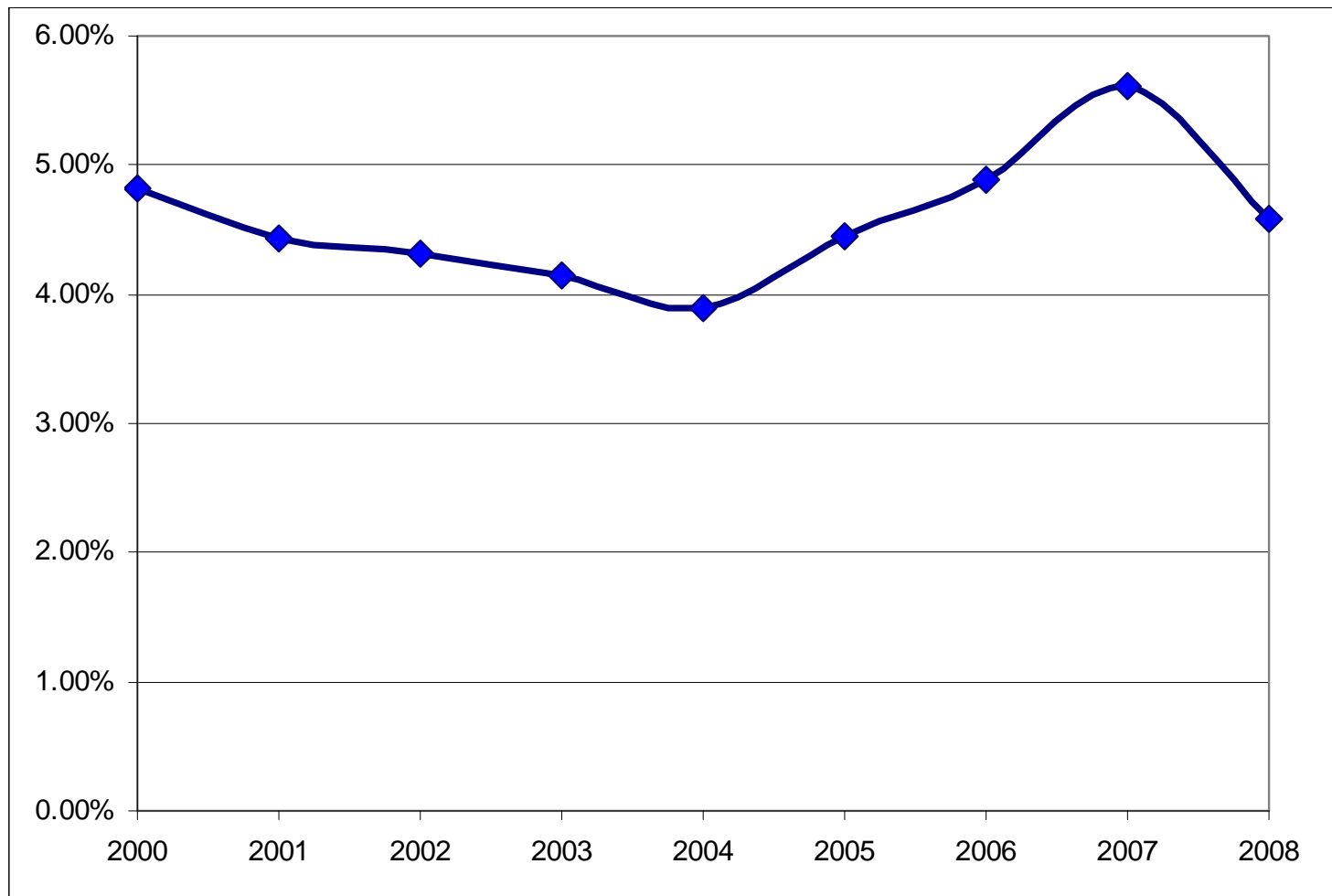
Methodology for assessing potential increase in number of DJ actions

Using the Stanford IPLC database, we identified all patent DJ actions filed in the two year period subsequent to the Supreme Court's decision in *MedImmune*.

We looked at all patent filings since 2000 (the period covered by the IPLC database) and assessed the portion accounted for by DJ actions over time

There was clearly a spike in 2007 after Medimmune

Results of 2000-2008 assessment of DJ action percentages



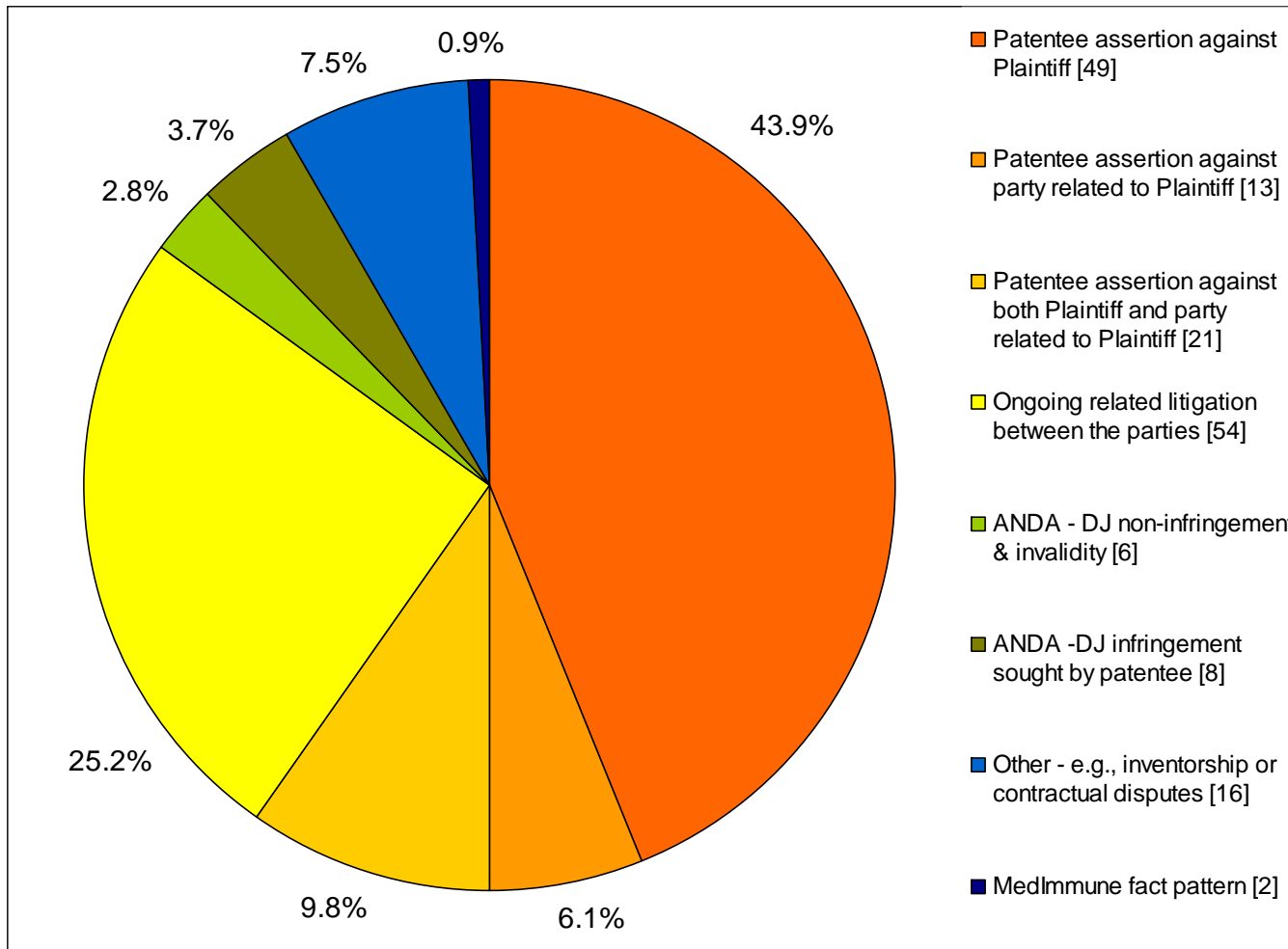
Methodology for characterizing post-*MedImmune* DJ filings

Of the 283 cases identified as patent DJ actions by IPLC coding, we were able to obtain from IPLC sufficient documents to characterize the impetus for 214 of the actions (we plan to complete the analysis over the summer by obtaining and analyzing the complaints in the other 69 cases).

We developed eight categories that accurately characterized the impetus for each of the suits.

- Patentee assertion against Plaintiff.
- Patentee assertion against related third party.
- Patentee assertion against both Plaintiff and related third party.
- Ongoing litigation between the parties.
- ANDA – DJ action of invalidity and/or noninfringement.
- ANDA – DJ action by patentee to declare infringement.
- Medimmune fact pattern (performing licensee sues licensor)
- Other

Results: impetus for patent DJ actions, Jan 10 '07 – Jan 10 '09



Conclusions

- Only 2 of 214 cases analyzed were *Medimmune* cases, and one of them was filed by *Medimmune*.
 - *Delano Farms Company et. al. v. The California Table Grape Commission* filed November 2, 2007 in the Eastern District of California.
 - *MedImmune, LLC v. PDL Biopharma, Inc.* filed December 15, 2008 in the Northern District of California.
- *Medimmune* has been immaterial to invalidity challenges by licensees.
- Patentees continue the practice of artfully worded “notice” letters.
- Hypothesis: *Medimmune*’s primary impact was an immediate and temporary increase in parties receiving notice letters going to court.
- Will further test hypothesis by looking at pre-*Medimmune* DJ actions and characterizing them in the same categories for comparison.

Filings by year – raw data

	Total patent suits filed	% change in total patent suits filed year over year	Patent DJ actions filed	% Change in total patent dj actions filed year over year	Patent DJ actions as a % of total patent actions	Increase in patent suits year over year	Increase in patent DJ's year-over-year	% of change caused by DJ actions
2000	2326		112		4.82%			
2001	2461	5.8%	109	-2.7%	4.43%	135	-3	-2.2%
2002	2554	3.8%	110	0.9%	4.31%	93	1	1.1%
2003	2779	8.8%	115	4.5%	4.14%	225	5	2.2%
2004	2802	0.8%	109	-5.2%	3.89%	23	-6	-26.1%
2005	2559	-8.7%	114	4.6%	4.45%	-243	5	-2.1%
2006	2638	3.1%	129	13.2%	4.89%	79	15	19.0%
2007	2830	7.3%	159	23.3%	5.62%	192	30	15.6%
2008	2703	-4.5%	124	-22.0%	4.59%	-127	-35	27.6%