

Post-MedImmune Patent Validity Challenges (attached, 14 pp. 104 KB, pdf), has been prepared for the presentation - *Patent Challenges after MedImmune and KSR, Implications for Practice*, Licensing Executives Society, Washington, D.C., January 17, 2007.

Summary of LES lecture (full text below)

Until 1969 and *Lear* it had been standard boilerplate in patent licenses to contractually bar a licensee from challenging patent validity. *Lear* held such boilerplate unenforceable; since then, licensors have generally refrained from contractual limitations on a licensee's right to sue, but have benefited from the Federal Circuit's strict jurisprudence that has thrown out invalidity suits absent threat of an *imminent* infringement suit. In practical terms this meant that a licensee would have to surrender its license – through breach or otherwise – to challenge validity, a costly price considering that if the litigation were unsuccessful the licensee's operation could be shut down through an injunction and high damage awards could be awarded.

In *MedImmune*, the Court opened the procedural door to declaratory judgment actions of invalidity: The Court overruled the Federal Circuit condition precedent to such a suit that there be a "reasonable apprehension of [an] *imminent* suit" by the patentee. Under the old regime of the Federal Circuit, the licensee itself blocked the "imminent" injury of suit by continuing to pay royalties so as not to breach the agreement. But, per the Supreme Court, "[t]he justiciability problem that arises, when the party seeking declaratory relief is himself preventing the complained-of injury from occurring [by continuing to pay the license fee], can be described in terms of standing (whether plaintiff is threatened with 'imminent' injury in fact' 'fairly ... trace[able] to the challenged action of the defendant," "or in terms of ripeness (whether there is sufficient 'hardship to the parties [in] withholding court consideration' until there is enforcement action[.]" Here, "standing and ripeness boil down to the same question in this case." The Court answered that an actual controversy *does* exist even where royalties continue to be paid. See § II, *The Narrow "Question" Decided in MedImmune*.

Perhaps more important from a macroscopic view of the patent system, the Court threw out the *Teva* requirement that there be a threat of an "imminent" suit. (Outside the licensing context, this opens the door to a wide-ranging set of factual issues, particularly where a warning letter is sent to an accused infringer but where there is no threat of an "imminent" suit.) See § III, *The Teva "Imminent" Suit Test is Thrown Out*.

MedImmune's victory in this case is procedural and does not necessarily provide a victory on the merits. The Court expressly left it to the trial court to consider merits-

based equitable, prudential, and policy arguments in favor of discretionary dismissal as well as merits-based arguments for denial of declaratory relief. *See* § II-C, *The Narrow Holding in MedImmune*.

While the Court considered justiciability in the context of a licensing dispute, the holding much more broadly throws out the narrow Federal Circuit test for justiciability that had required threat of an *imminent* suit. Federal Circuit precedent in *Teva* and *Gen-Probe* are specifically cited and may be considered overruled. *See* § III, *Teva "Imminent" Suit Test is Thrown Out*. It is wrong to see *MedImmune* as narrowly focused upon the very recent *Teva* and *Gen-Probe* precedents, as both cases are merely recent iterations of long-standing case law from the Federal Circuit. *See* § IV, *Teva Restates 1980's Federal Circuit Law*.

The classic and now anachronistic "licensee estoppel" boilerplate of the 1960's was a contractual provision whereby the licensee promised never to sue for invalidity of the patent. *See* § V, *Licensee Estoppel Silence in the Wake of Lear*. The licensing world was turned upside down in 1969 when the Court held that a licensee estoppel clause was unenforceable. *See* § V-A, *Lear Upsets the Licensing Applecart*. *Lear* was a component of a force in operation in the 1960's: There was an anti-patent sentiment at the Supreme Court in general that included an amorphous doctrine of patent misuse. *Lear* coupled with the threat of patent misuse led prudent licensing executives to refrain from providing any contractual muzzling of licensees for fear of creating a patent misuse issue. To be sure, within just a few years after *Lear* the threat of patent misuse evaporated for licensee estoppel provisions (which were merely unenforceable), yet boilerplate continued to be used that came from the immediate post-*Lear* period. *See* § V-B, *Muzzling Licensors, the Patent Misuse Threat*. Whatever doubts patent holders may or should have had about patent misuse and attempts to rein in *Lear* were dissipated by the creation of and the anti-*Lear* track record of the Federal Circuit. *See* § V-C, *Federal Circuit Hostility to Lear*.

Insofar as the actual license agreement in *MedImmune* is concerned, the parties followed the post-*Lear* boilerplate that does not address the licensee estoppel issue. Thus, the question that the trial court will need to address on remand of the case is to consider merits defenses to the *MedImmune* litigation where there is such contractual silence. While the Court offers no *holding* on point it does offer guidance that suggests that the licensee has the right to proceed with its declaratory judgment action. *See* § VI, *Dictum Addressing a Lear-Based Void*.

With *MedImmune* opening the procedural door to patent validity challenges, an immediate rethinking is taking place in the patent licensing community to address the

challenges posed by this case. *See* § VII, *Post-MedImmune Limits on Validity Challenges*.

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POST-MEDIMMUNE PATENT VALIDITY CHALLENGES*

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I. Overview

Until 1969 and *Lear*¹ it had been standard boilerplate in patent licenses to contractually bar a licensee from challenging patent validity. *Lear* held such boilerplate unenforceable; since then, licensors have generally refrained from contractual limitations on a licensee's right to sue, but have benefited from the Federal Circuit's strict jurisprudence that has thrown out invalidity suits absent threat of an *imminent* infringement suit. In practical terms this meant that a licensee would have to surrender its license – through breach or otherwise – to challenge validity, a costly price considering that if the litigation were unsuccessful the licensee's operation could be shut down through an injunction and high damage awards could be awarded.

In *MedImmune*,² the Court opened the procedural door to declaratory judgment actions of invalidity: The Court overruled the Federal Circuit

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¹*Lear, Inc. v. Adkins*, 395 U.S. 653 (1969).

²*MedImmune, Inc. v. Genentech, Inc.*, No. 05-608, ___ U.S. ___ (January 9, 2007), *proceedings below*, 427 F.3d 958 (Fed. Cir. 2005)(Newman, J.).

“MedImmune” refers to this specific lawsuit. However, there is a *second* case involving essentially the same issue, *MedImmune, Inc. v. Centocor, Inc.*, No. 05-656, *opinion below*, *MedImmune v. Centocor, Inc.*, 409 F.3d 1376 (Fed. Cir. 2005)(Schall, J.). Action on the *certiorari* petition in *MedImmune v. Centocor* was suspended during the pendency of the principal *MedImmune* appeal. It is now expected that on February 15, 2007, *certiorari* will be granted with the Federal Circuit opinion vacated and the case remanded for further consideration in light of the *MedImmune* decision.

condition precedent to such a suit that there be a “reasonable apprehension of [an] *imminent* suit” by the patentee.³ Under the old regime of the Federal Circuit, the licensee itself blocked the “imminent” injury of suit by continuing to pay royalties so as not to breach the agreement. But, per the Supreme Court, “[t]he justiciability problem that arises, when the party seeking declaratory relief is himself preventing the complained-of injury from occurring [by continuing to pay the license fee], can be described in terms of standing (whether plaintiff is threatened with ‘imminent’ injury in fact’ ‘fairly ... trace[able] to the challenged action of the defendant,’”⁴, “or in terms of ripeness (whether there is sufficient ‘hardship to the parties [in] withholding court consideration’ until there is enforcement action[.]”⁵ Here, “standing and ripeness boil down to the same question in this case.”⁶ The Court answered that an actual controversy *does* exist even where royalties continue to be paid. *See* § II, *The Narrow “Question” Decided in MedImmune*.

Perhaps more important from a macroscopic view of the patent system, the Court threw out the *Teva* requirement that there be a threat of an “imminent” suit. (Outside the licensing context, this opens the door to a wide-ranging set of factual issues, particularly where a warning letter is sent to an accused infringer but where there is no threat of an “imminent” suit.) *See* § III, *The Teva “Imminent” Suit Test is Thrown Out*.

MedImmune’s victory in this case is procedural and does not necessarily provide a victory on the merits. The Court expressly left it to the trial court to consider merits-based equitable, prudential, and policy arguments in favor of discretionary dismissal as well as merits-based arguments for denial of declaratory relief. *See* § II-C, *The Narrow Holding in MedImmune*.

³ *MedImmune*, __ U.S. at __ (quoting *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (2005)(emphasis added in *MedImmune*)).

⁴ *MedImmune*, __ U.S. at __, n.8 (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)).

⁵ *Id.*, quoting *Abbott Laboratories v. Gardner*, 387 U.S. 136, 149 (1967)).

⁶ *Id.*

While the Court considered justiciability in the context of a licensing dispute, the holding much more broadly throws out the narrow Federal Circuit test for justiciability that had required threat of an *imminent* suit. Federal Circuit precedent in *Teva* and *Gen-Probe* are specifically cited and may be considered overruled.⁷ See § III, *Teva “Imminent” Suit Test is Thrown Out*. It is wrong to see *MedImmune* as narrowly focused upon the very recent *Teva* and *Gen-Probe* precedents, as both cases are merely recent iterations of long-standing case law from the Federal Circuit. See § IV, *Teva Restates 1980’s Federal Circuit Law*.

The classic and now anachronistic “licensee estoppel” boilerplate of the 1960’s was a contractual provision whereby the licensee promised never to sue for invalidity of the patent. See § V, *Licensee Estoppel Silence in the Wake of Lear*. The licensing world was turned upside down in 1969 when the Court held that a licensee estoppel clause was unenforceable. See § V-A, *Lear Upsets the Licensing Applecart*. *Lear* was a component of a force in operation in the 1960’s: There was an anti-patent sentiment at the Supreme Court in general that included an amorphous doctrine of patent misuse. *Lear* coupled with the threat of patent misuse led prudent licensing executives to refrain from providing any contractual muzzling of licensees for fear of creating a patent misuse issue. To be sure, within just a few years after *Lear* the threat of patent misuse evaporated for licensee estoppel provisions (which were merely unenforceable), yet boilerplate continued to be used that came from the immediate post-*Lear* period. See § V-B, *Muzzling Licensors, the Patent Misuse Threat*. Whatever doubts patent holders may or should have had about patent misuse and attempts to rein in *Lear* were dissipated by the creation of and the anti-*Lear* track record of the Federal Circuit. See § V-C, *Federal Circuit Hostility to Lear*.

Insofar as the actual license agreement in *MedImmune* is concerned, the parties followed the post-*Lear* boilerplate that does not address the licensee estoppel issue. Thus, the question that the trial court will need to address on remand of the case is to consider merits defenses to the *MedImmune* litigation where there is such contractual silence. While the Court offers no *holding* on point it does offer guidance that suggests that the licensee has the right to proceed with its declaratory judgment action. See § VI, *Dictum Addressing a Lear-Based Void*.

⁷*Gen-Probe Inc. v. Vysis, Inc.*, 359 F. 3d 1376 (2004); *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F. 3d 1324 (2005).

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II. THE NARROW *MEDIMMUNE* “QUESTION”

While there is much meat that can be debated from the *MedImmune* case and its relation to *Lear*, in terms of the actual *holding* of *MedImmune*, the Court provides a very narrow answer to a specific “Question Presented.”⁸ This focuses on whether the licensee who sues for invalidity while continuing to pay royalties presents a “justiciable controversy” that can reach the merits.

A. An “Actual Controversy” between the Parties

The bulk of the *amici* briefing and public commentary on *MedImmune* focused upon the *substantive* question as to whether a licensee should be permitted to challenge patent validity while continuing to pay royalties. But, this was not the “Question Presented” to the Court. Rather, the Court was asked whether there is an “actual controversy” to permit a declaratory judgment action:

“Does Article III's grant of jurisdiction of 'all Cases ... arising under ... the Laws of the United States,' implemented in the 'actual controversy' requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), require a patent licensee to refuse to pay royalties and commit material breach of the license agreement before suing to declare the patent invalid, unenforceable or not infringed?”

⁸The Supreme Court does not simply take an appeal to decide whether the holding below was right or wrong, but rather focuses upon a *specific* “Question Presented”.

B. *Apotex*: A Far Stronger Challenge than *MedImmune*

In fact, *MedImmune* was expected to be only one of two cases during the current term of the Court to raise an issue of “actual controversy” concerning patents: Perhaps the more compelling case was the *Apotex* case,⁹ which the Court took with great seriousness as manifested by requesting the views of the Solicitor General before a vote on *certiorari*.¹⁰

In *Apotex*, the Federal Circuit had issued a summary affirmance, without opinion, of a trial court’s denial of a patent challenge by a generic pharmaceutical manufacturer who had not received a threatening letter that marketing its generic equivalent would infringe its patent. The Court refused to entertain a declaratory judgment action for invalidity of a pioneer drug patent because there was no “reasonable apprehension of [an] *imminent* suit” under *Teva*.¹¹ The *certiorari* petition expressly challenged the Federal Circuit rule.¹²

While there are numerous public policy issues that the patentee in *MedImmune* can argue militate against a declaratory judgment action by a willing licensee, there is no parallel set of arguments favoring the patentee under the *Teva* scenario. Thus, *Apotex* presented a far, far stronger case for entertaining a declaratory judgment action for invalidity than *MedImmune*.

But, *certiorari* was denied in *Apotex* – but only after the patentee-Respondent had given assurances to the potential accused infringer that it would not be sued, rendering the principal issue moot. Had the Patentee-

⁹ *Apotex, Inc. v. Pfizer, Inc.*, No. 05-1006.

¹⁰The order is more formally an invitation for the *certiorari* views of the Solicitor General – a “CVSG”.

¹¹ *Supra* note 3.

¹² Challenging this denial of review, the Supreme Court *certiorari* petition asks “whether ... a suit [brought by generic drug manufacturers seeking a declaratory judgment that a generic equivalent will not infringe a patent held by the brand-name manufacturer] states a justiciable controversy when... the failure to secure a court judgment prohibits the federal government from approving the generic equivalent and the prospect of massive patent liability deters the generic manufacturer from entering the marketplace.”

Respondent not mooted the issue, it was seemingly inevitable that the Court would grant *certiorari* in *Apotex* and throw out *Teva* in *that* case.

The very issuance of a CVSG order by the Court shows that there was far more than passing interest in this case; even though *certiorari* was ultimately denied in *Apotex* because of the mooted issue, it fueled interest in opening the *Lear* door to greater patent challenges.

C. The Narrow Holding in *MedImmune*

The Court introduces the issue: “The District Court granted [the patentees]’ motion to dismiss the declaratory-judgment claims for lack of subject-matter jurisdiction, relying on the decision of the ... Federal Circuit in *Gen-Probe Inc. v. Vysis, Inc.*, 359 F. 3d 1376 (2004). *Gen-Probe* had held that a patent licensee in good standing cannot establish an Article III case or controversy with regard to validity, enforceability, or scope of the patent because the license agreement ‘obliterate[s] any reasonable apprehension’ that the licensee will be sued for infringement. *Id.*, at 1381. The Federal Circuit affirmed the District Court, also relying on *Gen-Probe*. 427 F. 3d 958 (2005).”

While the Court repudiates *Gen-Probe*, the holding is very narrow and “leave[s] the equitable, prudential, and policy arguments in favor of ... a discretionary dismissal for the lower courts’ consideration on remand. Similarly available for consideration on remand are any merits-based arguments for denial of declaratory relief.”

The Court emphasizes its narrow holding:

“We hold that [the licensee] was not required, insofar as Article III is concerned, to break or terminate its 1997 license agreement before seeking a declaratory judgment in federal court that the underlying patent is invalid, unenforceable, or not infringed. The [Federal Circuit] erred in affirming the dismissal of this action for lack of subject-matter jurisdiction. The judgment of the [Federal Circuit] is reversed, and the cause is remanded for proceedings consistent with this opinion.”

III. TEVA “IMMINENT” SUIT TEST IS THROWN OUT

The Court clearly disapproved both *Gen-Probe* and its evolved *Teva* standard that a declaratory judgment plaintiff must have a “reasonable apprehension of *imminent* suit[.]”¹³

Thus, the Court expressly stated that its opinion in *Altvater v. Freeman*, 319 U.S. 359 (1943), “contradict[s] the Federal Circuit’s ‘reasonable apprehension of suit’ test [of *Gen-Probe Inc. v. Vysis, Inc.*, 359 F. 3d 1376 (2004),] (or, in its evolved form, the ‘reasonable apprehension of *imminent* suit’ test, *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F. 3d 1324, 1333 (2005)).”¹⁴

Thus, “[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.”¹⁵

¹³ *MedImmune*, __ U.S. at __, n.11 (quoting *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F. 3d 1324, 1333 (2005)(emphasis added in *MedImmune*).

¹⁴*Id.*

¹⁵*Id.*

IV. *TEVA* RESTATES 1980'S FEDERAL CIRCUIT LAW

Gen-Probe!

Teva!

There has been much talk about these two recent cases as somehow setting a new Federal Circuit standard requiring threat of an imminent law suit. But, the reality is that both cases are largely restatements of well settled Federal Circuit precedent that has been an evolving process since the earliest days of the court in the 1980's.

In *MedImmune v. Centocor*, the Federal Circuit quotes from *Teva* but in turn takes a *Teva* quote from *EMC* from a decade ago.¹⁶ Looking in turn to *EMC*, there was essentially nothing new at that time, either, as the court there was merely restating its own precedent going back as far the wisdom of its inaugural Chief Judge from 1988:

“This court has developed a two-part inquiry to determine whether there is an actual controversy in suits requesting a declaration of patent non-infringement or invalidity. First, the plaintiff must actually produce or be prepared to produce an allegedly infringing product. Second, the patentee's conduct must have created an objectively reasonable apprehension on the part of the plaintiff that the patentee will initiate suit if the activity in question continues.”¹⁷

The inaugural Chief Judge in his 1988 opinion in *Arrowhead* was merely approving an earlier restatement of the law: “A test often useful in evaluating complaints for declaratory judgments in patent cases has been variously stated, its most recent statement appearing in *Goodyear Tire*[]:

¹⁶*MedImmune v. Centocor*, *supra* note 1, 409 F.3d at 1778-79 (quoting *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1331 (Fed.Cir.2005), quoting *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed.Cir.1996)) (“[The [Declaratory Judgment] Act ‘requires an actual controversy between the parties before a federal court may exercise jurisdiction over an action for a declaratory judgment.’”).

¹⁷*EMC Corp. v. Norand Corp.*, 89 F.3d 807, 811 (Fed.Cir.1996)(citing *Spectronics Corp. v. H.B. Fuller Co., Inc.*, 940 F.2d 631, 634 (Fed. Cir. 1991)(Clevenger, J.); *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988)(Markey, C.J.)).

‘First, the defendant's conduct must have created on the part of plaintiff a reasonable apprehension that the defendant will initiate suit if the plaintiff continues the allegedly infringing activity. Second, the plaintiff must actually have either produced the device or have prepared to produce that device.’”¹⁸

A 1984 statement of the test is found in *Jervis B. Webb*: “The case or controversy requirement for a patent invalidity declaratory judgment action requires the presence of two elements. First, the defendant in such an action must have engaged in conduct that created on the part of the declaratory plaintiff a reasonable apprehension that it will face an infringement suit if it commences or continues the activity in question. Next, *the plaintiff seeking a declaration of invalidity must have actually produced the accused device or have actually prepared to produce such a device.*”¹⁹

V. LICENSEE ESTOPPEL SILENCE IN THE WAKE OF *LEAR*

Respondent and indeed many patent holders today typically follow a pattern of licensing conduct that can be traced back nearly forty full years to the 1969 *Lear* case. At the time, the boilerplate licensee estoppel clause that barred a licensee’s challenge of patent validity was held unenforceable. Since that time, despite an anti-*Lear* attitude at the Federal Circuit, licensors typically follow boilerplate licensing patterns and rely upon the strict requirements for a justiciable controversy in *Teva* and its antecedent precedents that have forced a licensee to vacate its license to challenge validity, a price too dear in most situations.

¹⁸*Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988)(Markey, C.J.)(quoting *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 955 (Fed.Cir.1987)).

¹⁹*Jervis B. Webb Co. v. Southern Sys., Inc.*, 742 F.2d 1388, 1398-99 (Fed.Cir.1984)(citations omitted to *C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 879, 219 USPQ 197, 202 (Fed.Cir. 1983); *International Harvester Co. v. Deere & Co.*, 623 F.2d 1207, 1210 (7th Cir.1980); *See Sweetheart Plastics, Inc. v. Illinois Tool Works, Inc.*, 439 F.2d 871, 875 (1st Cir.1971).)(emphasis added).

A. *Lear* Upsets the Licensing Applecart

To a great extent, the licensing world has been living in a time warp that jumps back to 1969 and the genuine shock felt by the patent community when the Court abolished the enforceability of the “licensee estoppel” clause that was standard boilerplate in every patent license agreement: By taking this license, licensee promises not to challenge the validity of the patent. Period. End of story.

Along came *Lear* and out went licensee estoppel: A licensee had the *right* to sue for invalidity of a patent.

B. Muzzling Licensors, the Patent Misuse Threat

In the immediate wake of *Lear*, licensors were very concerned about saying *anything* in their agreements that would smack of a “licensee estoppel” provision. The genuine concern in the immediate wake of *Lear* was that if an agreement included a licensee estoppel provision that the entire agreement would be rendered unenforceable based upon a patent misuse defense. While in hindsight this proved not to be the case, it was at the time most prudent to follow a course of action that was based upon silence as to any proscriptions on the licensee challenging patent validity that could be considered a patent misuse.

Hence, licensing practices that developed in the immediate panic reaction to the then-revolutionary holding of *Lear* have lead to boilerplate agreement provisions that even today often are overly generous to licensees and their rights versus patentees. Thus, a custom and usage has grown up in the patent licensing field that started immediately after *Lear* where an agreement would be silent as to the right to challenge validity of a patent. This silence grew out of a concern that any limitations in a license agreement that would lead to a proscription on the right to challenge validity might create an issue of “patent misuse”. Indeed, there were early cases where accused infringers sought to have a patentee found guilty of “patent misuse” where restrictions were placed on the right of the licensee to challenge validity. Some of these cases suggested that there might be merit

to such a position. .²⁰ Some courts recognized that the issue was undecided,²¹ and even in recent years accused infringers have sought (unsuccessfully) to be relieved of liabilities under a *Lear*-based patent misuse defense.²² However, case law developed shortly after *Lear* that denied a *Lear*-based patent misuse defense.²³ Yet, old habits are hard to break, so that an *express* proscription on continuing to operate under a license while challenging the validity of a patent have often been avoided.

²⁰*Bendix Corp. v. Balax, Inc.*, 471 F.2d 149, 155 (7th Cir. 1972), *cert. denied*, 414 U.S. 819 (1973) (“The district court apparently assumed that *Lear* was relevant and that the license restrictions constituted *per se* antitrust violations in the light of *Lear*.”).

²¹*Robintech, Inc. v. Chemidus Wavin, Ltd.*, 450 F.Supp. 817, 821 (D.D.C. 1978) (citing *Panther Pumps & Equip. Co. v. Hydrocraft, Inc.*, 468 F.2d 225, 231-32 (7th Cir. 1972), *cert. denied*, 411 U.S. 965 (1973)) (“ Though no-contest clauses indubitably are unenforceable against the licensee under *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), such a clause, standing alone, is unlikely to constitute patent misuse, particularly if the patentee has indicated... that the clause will not be enforced.”)(footnote omitted).

²²*Bayer AG v. Housey Pharmaceuticals, Inc.*, 228 F.Supp.2d 467, 474 (D.Del. 2002), *subsequent proceedings on other grounds*, 340 F.3d 1367 (Fed. Cir. 2003) (“The inclusion of a provision in a license agreement that is unenforceable under *Lear*, however, does not constitute patent misuse. *See Panther Pumps & Equipment Co. v. Hydrocraft, Inc.*, 468 F.2d 225, 232 (7th Cir.1972) (‘[I]t [is] inappropriate to preclude enforcement of a valid patent against an infringing non-licensee simply because an unenforceable provision has been included in a patent license agreement.’); *see also Wallace Clark & Co. v. Acheson Indus., Inc.*, 401 F.Supp. 637, 640 (S.D.N.Y.1975), *affirmed*, 532 F.2d 846 (2d Cir.1976) (‘[T]he inclusion therein of this unenforceable provision does not constitute patent misuse.’) (internal citation omitted); *Congoleum Indus., Inc. v. Armstrong Cork Co.*, 366 F.Supp. 220, 233 (E.D.Pa.1973), *affirmed*, 510 F.2d 334 (3d Cir.1975) (same); *Robintech, Inc. v. Chemidus Wavin, Ltd.*, 450 F.Supp. 817, 821 (D.D.C.1978) (same)... [T]he court finds that while [the clause] of the [] license may very well be unenforceable under *Lear*, the inclusion of the provision does not constitute patent misuse.”)(footnote omitted).

²³*Wallace Clark & Co., Inc. v. Acheson Industries, Inc.*, 401 F.Supp. 637, 640 (S.D.N.Y. 1975)(citing *Bendix Corp. v. Balax, Inc.*, 471 F.2d 149, 157-58 (7th Cir. 1972), *cert. denied*, 414 U.S. 819 (1973); *Panther Pumps & Equip. Co. v. Hydrocraft, Inc.*, 468 F.2d 225, 230-32 (7th Cir. 1972), *cert. denied*, 411 U.S. 965 (1973); *Congoleum Indus., Inc. v. Armstrong Cork Co.*, 366 F.Supp. 220, 232-34 (E.D. Pa. 1973), *aff'd*, 510 F.2d 334, 336 (3d Cir. 1975); *Blohm & Voss A.G. v. Prudential-Grace Lines, Inc.*, 346 F.Supp. 1116 (D. Md. 1972), *rev'd on other grounds*, 489 F.2d 231 (4th Cir. 1973), *cert. denied*, 419 U.S. 840 (1974)) (“Even if it were assumed that the license agreement seeks to prevent plaintiff from challenging the patent's validity [in violation of *Lear*], the inclusion therein of this unenforceable provision does not constitute patent misuse.”).

C. Federal Circuit Hostility to *Lear*

Long before the 1982 creation of the Federal Circuit there was no realistic concern that a licensee estoppel provision would be anything more than an unenforceable provision, and certainly not rise to the level of patent misuse. Today – or at least up until *MedImmune* – the Federal Circuit routinely distinguished *Lear* as an anachronism from a dark period of mistrust of the patent system.²⁴ An open hostility to *Lear* from the Federal Circuit has been observed²⁵ which has been suggested permits the careful draftsman to circumvent *Lear*.²⁶

²⁴*Studiengesellschaft Kohle m.b.H. v. Shell Oil Co.*, 112 F.3d 1561, 1567 (Fed. Cir. 1997)(Rader, J.)(dismissing *Lear* as being an “echo from a past era of skepticism over intellectual property principles...”).

²⁵Michael J. Meurer, *Vertical Restraints and Intellectual Property Law: Beyond Antitrust*, 87 Minn. L. Rev. 1871, 1907 n.219 (2003)(“*Brulotte* [*v. Thys Co.*, 379 U.S. 29 (1964),] and *Lear* [*Inc., v. Adkins*, 395 U.S. 653 (1969),] are not popular with the Federal Circuit. See *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1368-70 (Fed. Cir. 2001) (upholding a settlement agreement not to challenge a patent's validity); *Studiengesellschaft Kohle m.b.H. v. Shell Oil Co.*, 112 F.3d 1561, 1567-68 (Fed. Cir. 1997) (holding that “[n]othing in this license made payment of royalties contingent on the validity of [a] patent,” and describing *Lear* as ‘echo[ing] from a past era of skepticism over intellectual property principles’); *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 476-77 (Fed. Cir. 1991) (enforcing a consent decree on grounds that *Lear* does not abrogate principles of *res judicata*); *Hemstreet v. Spiegel, Inc.*, 851 F.2d 348, 350- 51 (Fed. Cir. 1988) (enforcing a litigation settlement to pay royalties regardless of enforceability of patent claims); *Universal Gym Equip., Inc. v. ERWA Exercise Equip., Ltd.*, 827 F.2d 1542, 1550 (Fed. Cir. 1987) (upholding a contract to pay royalties for use of an unpatented design).”

²⁶*Id.* (“As a result [of the Federal Circuit’s hostility to *Lear*], careful contract drafting usually avoids the threat of misuse or preemption.”)

VI. *DICTUM* ADDRESSING A *LEAR*-BASED VOID

Because the license agreement in *MedImmune* does not have any explicit licensee estoppel provision of any kind, the trial court on remand will need to assess the *merits* as to whether the licensee may proceed with its invalidity challenge.

In this regard, however, the Court issued *dictum* to guide the way:

“[Patentees] appeal to the common-law rule that a party to a contract cannot at one and the same time challenge its validity and continue to reap its benefits[.]”²⁷

The patentees “contend [that *Lear*] did not suspend that rule for patent licensing agreements, since the plaintiff in that case had already repudiated the contract.”²⁸

Since there is nothing in the license agreement that speaks to any proscription on challenging the validity of the patent, the Court expresses amazement over the argument that the license bars a challenge to patent validity:

“Even if *Lear*’s repudiation of the doctrine of licensee estoppel was so limited (a point on which, as we have said earlier, we do not opine), it is hard to see how the common-law rule has any application here. [Licensee] 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 [the patentees] were correct that the licensing agreement or the common-law rule precludes this suit, the consequence would be that [patentees] win this case *on the merits*—not that the very genuine contract dispute disappears, so that Article III jurisdiction is somehow defeated.”²⁹

²⁷ *MedImmune*, ___ U.S. at ___ (noting citations to *Commodity Credit Corp. v. Rosenberg Bros. & Co.*, 243 F. 2d 504, 512 (9th Cir. 1957); *Kingman & Co. v. Stoddard*, 85 F. 740, 745 (7th Cir. 1898)).

²⁸*Id.*

²⁹*Id.*

VII. POST-MEDIMMUNE LIMITS ON VALIDITY CHALLENGES

Beyond the immediate challenge that current parties to licensing agreements now face in terms of potential declaratory judgment actions that may be brought in the wake of *MedImmune*, patent holders often have ongoing streams of innovations and new technology that will be sought by eager licensees. Here, the immediate challenge is to present revised license agreements that address the void created by the overruling of *Teva* and which at the same time are compatible with *Lear*.

To be sure, the anti-patentee era of *Lear* does not exist at least in the same form as four generations ago. It was clear from the oral argument in *MedImmune* that there was a significant sentiment expressed from some members of the Court that the result sought by licensee was unfair: On what basis should the Court permit a potential or actual accused infringer to settle with a patentee through a license and then turn around and bring a litigation to challenge the validity of the patent *while still operating under the license*.³⁰

³⁰Both the Chief Justice and Justice Scalia openly expressed doubts about this result as a policy matter.