

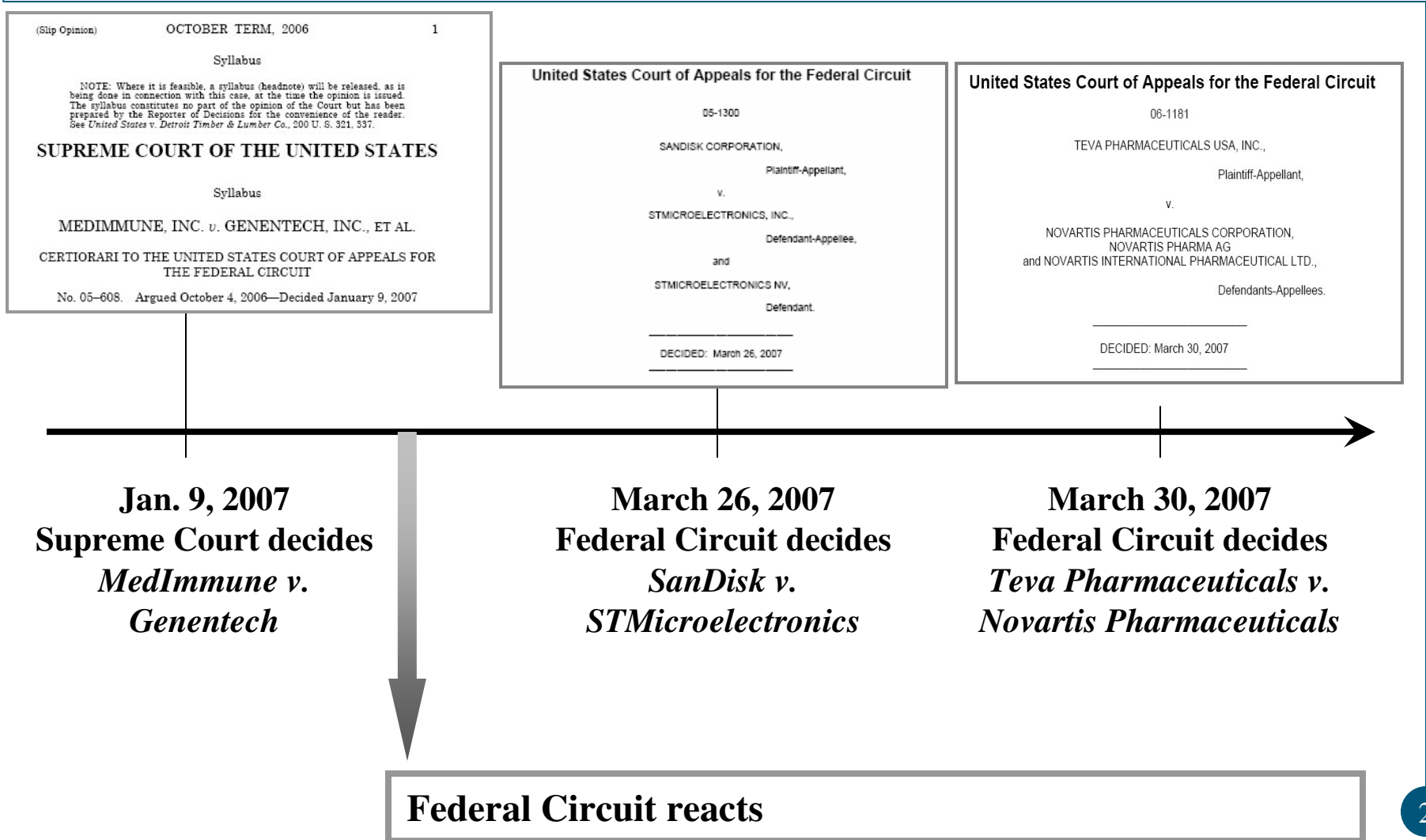


FR

FISH & RICHARDSON P.C.

**Fish & Richardson Declaratory
Judgment Post-Medimmune
Presentation**

Where are we now?



Supreme Court: *MedImmune v. Genentech*



- ❖ Decided January 9, 2007
- ❖ 8-1, with Justice Scalia delivering the opinion of the Court and Justice Thomas dissenting
- ❖ Reversed a Federal Circuit decision and effectively overruled *Gen-Probe v. Vysis* that a patent licensee must terminate or breach the license in order to create a case or controversy to support an action for declaratory judgment

Supreme Court: *MedImmune v. Genentech*, cont.



- ❖ **No bright-line test:** Supreme Court declaratory judgment case law does “not draw the brightest of lines between those declaratory-judgment actions that satisfy the case-or-controversy requirement and those that do not.”
- ❖ **Announced the All Circumstances Test:** “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.”

Supreme Court: *MedImmune v. Genentech*, cont.



- ❖ The Court criticized the Federal Circuit, in footnote 11, noting that the Federal Circuit’s “reasonable apprehension of suit” test conflicts with multiple Supreme Court cases:
- *Altwater v. Freeman*, 319 U.S. 359 (1943)
 - *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)
 - *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239 (1937)
 - *Cardinal Chemical Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 98 (1993)

Supreme Court: *MedImmune v. Genentech*: Facts



- ❖ MedImmune accepted a license obliging payment of royalties for any drug covered by patent(s) issued from certain pending patent applications
- ❖ License provided that MedImmune was obliged to pay royalties until patent was held invalid in unappealable, final judgment
- ❖ License did *not* bar MedImmune from challenging patent's validity
- ❖ When patent issued, Genentech sent letter demanding royalty payments
- ❖ MedImmune replied stating patent was believed to be invalid and unenforceable

Supreme Court: *MedImmune v. Genentech*: Facts, cont.



- ❖ MedImmune paid royalties “under protest and with reservation of all of its rights”
- ❖ MedImmune filed declaratory judgment action “on contractual rights and obligations,” alleging that its drug “did not infringe” and “did not infringe any valid claim”
- ❖ Federal Circuit applied *Gen-Probe* and held that a licensee in good standing can have no reasonable apprehension of suit and affirmed the district court’s dismissal of the declaratory judgment action

Supreme Court: *MedImmune v. Genentech*: Holding



- ❖ The underlying DJ action was interpreted to be both a contract dispute and a validity challenge
- ❖ The issue: “The factual and legal dimensions of the dispute are well defined and, but for petitioner’s continuing to make royalty payments, nothing about the dispute would render it unfit for judicial resolution.”
- ❖ Citing *Altwater v. Freeman*, 319 U.S. 359 (1943), the Court held that a licensee’s failure to cease its payment of royalties did not render non-justiciable a dispute over the validity of the patent

Federal Circuit: *SanDisk v. STMicroelectronics*



- ❖ Decided March 26, 2007
- ❖ Judge Linn authored panel decision
- ❖ Relying on footnote 11 of *MedImmune*, the court abolished the reasonable apprehension of suit test prong of the Federal Circuit’s former two-part test for declaratory judgment



Judge Bryson



Judge Linn



Judge Dyk

Federal Circuit: *SanDisk v. STMicroelectronics*: Facts



United States Court of Appeals for the Federal Circuit

05-1300

SANDISK CORPORATION,

Plaintiff-Appellant,

v.

STMICROELECTRONICS, INC.,

Defendant-Appellee,

and

STMICROELECTRONICS NV,

Defendant.

- FR Context: license negotiations
- FR SanDisk filed declaratory judgment for noninfringement or invalidity with respect to various STMicroelectronics' patents

Federal Circuit: *SanDisk v. STMicroelectronics*: Facts, cont.



United States Court of Appeals for the Federal Circuit

05-1300

SANDISK CORPORATION,

Plaintiff-Appellant,

v.

STMICROELECTRONICS, INC.,

Defendant-Appellee,

and

STMICROELECTRONICS NV,

Defendant.



SanDisk established the requisite case or controversy because “ST sought a right to a royalty under its patents based on specific, identified activity by SanDisk,” including:

- STMicroelectronics’ presentation of a thorough, element-by-element infringement analysis by seasoned litigation experts as part of license negotiations
- STMicroelectronics’ liberal discussion of SanDisk’s present, ongoing infringement of STMicroelectronics’ patents and the need for SanDisk to license those patents during negotiations

Federal Circuit: *SanDisk v. STMicroelectronics*: Facts, cont.



United States Court of Appeals for the Federal Circuit

05-1300

SANDISK CORPORATION,

Plaintiff-Appellant,

v.

STMICROELECTRONICS, INC.,

Defendant-Appellee,

and

STMICROELECTRONICS NV,

Defendant.

- Exchange of material including copies of patents, reverse engineering reports, and infringement analysis diagrams
- STMicroelectronics' communication that it had a right to a royalty
- SanDisk's insistence it could proceed without paying royalties

Federal Circuit: *SanDisk v. STMicroelectronics*: Holding



United States Court of Appeals for the Federal Circuit

05-1300

SANDISK CORPORATION,

Plaintiff-Appellant,

v.

STMICROELECTRONICS, INC.,

Defendant-Appellee,

and

STMICROELECTRONICS NV,

Defendant.

- FR Federal Circuit adopts all circumstances test: “We need not define the outer boundaries of declaratory judgment jurisdiction, which will depend on the application of the principles of declaratory judgment jurisdiction to the facts and circumstances of each case.”

Federal Circuit: *SanDisk v. STMicroelectronics*: Holding, cont.



United States Court of Appeals for the Federal Circuit

05-1300

SANDISK CORPORATION,

Plaintiff-Appellant,

v.

STMICROELECTRONICS, INC.,

Defendant-Appellee,

and

STMICROELECTRONICS NV,

Defendant.



“We hold only that where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of legal rights.”

Federal Circuit: *SanDisk v. STMicroelectronics*: Holding, cont.



United States Court of Appeals for the Federal Circuit

05-1300
SANDISK CORPORATION,
Plaintiff-Appellant,
v.
STMICROELECTRONICS, INC.,
Defendant-Appellee,
and
STMICROELECTRONICS NV,
Defendant.



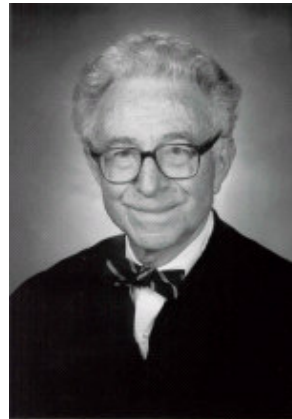
Footnote 1:

- Suitable confidentiality agreements can avoid the risk of a declaratory judgment action
- Rule 408 is not sufficient to prevent use of negotiation communications as a basis for declaratory judgment jurisdiction

Federal Circuit: *Teva v. Novartis*



Judge Mayer



Judge Friedman



Judge Gajarsa

- ❖ Decided March 30, 2007
- ❖ Judge Gajarsa authored panel decision
- ❖ Relying on *MedImmune*'s "all the circumstances test" and acknowledging footnote 11, indicating the Federal Circuit's former two-part test for declaratory judgment conflicts or would contradict several Supreme Court cases, the court adopts the "all the circumstances" test

Federal Circuit: *Teva v. Novartis*, Facts



United States Court of Appeals for the Federal Circuit

06-1181

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff-Appellant,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,
NOVARTIS PHARMA AG
and NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.,

Defendants-Appellees.

- FR Teva filed an Abbreviated New Drug Application (ANDA) with the FDA for a generic drug and certified as part of the ANDA application that its drug did not infringe any of Novartis-related patents or that the patents were invalid
- FR Novartis filed suit for infringement for only one of its patents
- FR Teva filed a declaratory judgment action on other related therapeutic use patents

Federal Circuit: Teva v. Novartis, Holding



United States Court of Appeals for the Federal Circuit

06-1181

TEVA PHARMACEUTICALS USA, INC.,

Plaintiff-Appellant,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,
NOVARTIS PHARMA AG
and NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.,

Defendants-Appellees.

FR

‘We hold that under “all the circumstances” as found in this case, Teva has an injury-in-fact and therefore has a justiciable Article III controversy.’”

Declaratory Judgment: “All the Circumstances” in lieu of reasonable apprehension of suit” prong of the Federal Circuit’s former two-part test

“where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise”

-- *SanDisk v. STMicroelectronics*



A glimpse of things to come??????

(Slip Opinion) OCTOBER TERM, 2006 1

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

MEDIMMUNE, INC. v. GENENTECH, INC., ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 05-608. Argued October 4, 2006—Decided January 9, 2007

United States Court of Appeals for the Federal Circuit

05-1300

SANDISK CORPORATION,
Plaintiff-Appellant,

v.

STMICROELECTRONICS, INC.,
Defendant-Appellee,

and

STMICROELECTRONICS NV,
Defendant.

DECIDED: March 26, 2007

United States Court of Appeals for the Federal Circuit

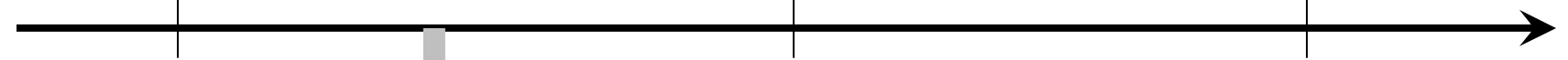
06-1181

TEVA PHARMACEUTICALS USA, INC.,
Plaintiff-Appellant,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,
NOVARTIS PHARMA AG
and NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.,
Defendants-Appellees.

DECIDED: March 30, 2007



Jan. 9, 2007
Supreme Court decides
MedImmune v. Genentech

March 26, 2007
Federal Circuit decides
SanDisk v. STMicroelectronics

March 30, 2007
Federal Circuit decides
Teva Pharmaceuticals v. Novartis Pharmaceuticals

Concurrence by
Judge Bryson

Concurrence by
Judge Friedman

Federal Circuit reacts

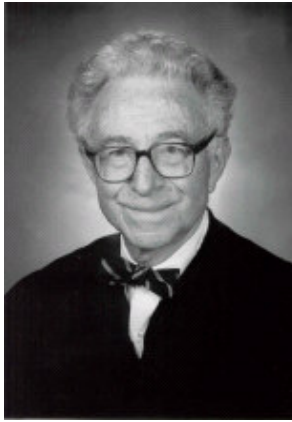
SanDisk v. STMicroelectronics: Concurrence by Judge Bryson



Judge Bryson

- ❖ The footnote in *MedImmune* “calls our case law into question and would appear to make declaratory judgments more readily available to parties who are approached by patentees seeking to license their patents.”
- ❖ But “the rule adopted by the court will effect a sweeping change in our law regarding declaratory judgment jurisdiction.”
- ❖ It would appear that under the court’s standard, a declaratory judgment action would be allowed 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 licensee.”

Teva v. Novartis: Concurrence by Senior Judge Friedman



Judge Friedman

- FR “In these unusual circumstances, where the Supreme Court went out of its way to state its disagreement with our ‘reasonable apprehension of *imminent* suit’ test, which was not an issue in the case before it, it appears incumbent on us to stop using that test and hereinafter to apply the general declaratory judgment standards that the Supreme Court applied in *MedImmune*”

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