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SPECIAL
REPORT

POST-*MEDIMMUNE* DEVELOPMENTS REGARDING DECLARATORY JUDGMENT JURISDICTION

The Federal Circuit's Recent *SanDisk* and *Teva Pharmaceuticals* Decisions

April 13, 2007

On March 26 and 30, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") issued two decisions that rely upon the Supreme Court's January 9 decision in *MedImmune*[1] to further greatly expand the circumstances under which a party may seek a declaratory judgment that a competitor's patent is invalid, unenforceable and/or not infringed. The two Federal Circuit decisions, *SanDisk Corp. v. STMicroelectronics, Inc.*,[2] and *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*,[3] renounced the Federal Circuit's prior reasonable-apprehension-of-imminent-suit ("reasonable apprehension") test for determining the existence of declaratory judgment jurisdiction in a patent case, in favor of a more expansive "all circumstances" test that has generally been applied by courts in other types of declaratory judgment actions.

As reported in our January 26, 2007 Special Report, the Supreme Court in *MedImmune* reversed the Federal Circuit, holding that a patent licensee, under a license agreement that does not prohibit challenges to a licensed patent, may make royalty payments under protest and at the same time file an action seeking a declaratory judgment that the licensed patent is invalid, unenforceable and/or not infringed. More particularly, the Supreme Court held that, despite the existence of the license, there existed a genuine "case or controversy" under Article III of the U.S. Constitution, *i.e.*, a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

As noted by the Federal Circuit in *SanDisk* and *Teva Pharmaceuticals*, the Supreme Court in *MedImmune* also more broadly stated that the Federal Circuit's reasonable apprehension test conflicts with Supreme Court precedent. Although this statement by the Supreme Court was arguably *dicta* (*i.e.*, not necessary to resolve the issue in *MedImmune*), the two separate three-judge panels in *SanDisk* and *Teva Pharmaceuticals* felt bound to dispense with the reasonable apprehension test.[4] In its place, they adopted the more expansive general test, holding that declaratory judgment jurisdiction exists in any patent case in which the facts, under all the circumstances, demonstrate a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant a declaratory judgment. Moreover, while *SanDisk* and *Teva Pharmaceuticals* involved specific fact patterns relating to pre-license negotiations and drug applications, it is clear from the decisions that the decisions have broader applicability.

This Special Report discusses some key points of the *SanDisk* and *Teva Pharmaceuticals* decisions, and provides recommendations for dealing with some potential future impacts of the decisions. We invite you to contact us with any remaining questions that you may have after reviewing this Special Report.

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[1] *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 2007 WL 43797, 81 USPQ2d 1225 (U.S. 2007).
[2] 2007 WL 881008, 82 USPQ2d 1173 (Fed. Cir. 2007).
[3] 2007 WL 942201 (Fed. Cir. 2007).

[4] As expressly noted in *Teva Pharmaceuticals*, these panels of Federal Circuit judges were not required to follow Federal Circuit precedent that was overruled by the Supreme Court's intervening *MedImmune* decision.

I. Background

In its decisions prior to *MedImmune*, the Federal Circuit had articulated a two-part test for determining the existence of declaratory judgment jurisdiction: (1) whether conduct by the patentee created a reasonable apprehension on the part of the declaratory judgment plaintiff that it was faced with an imminent infringement suit, and (2) whether conduct by the declaratory judgment plaintiff amounted to infringing activity or demonstrated concrete steps taken with the intent to conduct such activity. *E.g.*, *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1332-33 (Fed. Cir. 2005); *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988). As noted above, the Supreme Court in *MedImmune* addressed the reasonable apprehension aspect of the Federal Circuit's two-part test and concluded that it conflicts with Supreme Court precedent. *MedImmune*, 127 S.Ct. at 774 n.11.

A. *SanDisk*

In *SanDisk*, Judge Fogel of the Northern District of California applied the Federal Circuit's long-established two-part test and dismissed SanDisk's declaratory judgment claims of noninfringement and invalidity of fourteen ST patents directed to flash memory storage. The parties had exchanged numerous letters, and had met on several occasions, relating to, among other things, the possibility of SanDisk entering into a license under ST's patents. In the course of those letters and meetings, after requesting that the parties' discussions be treated as protected settlement discussions under Federal Rule of Evidence 408, ST made detailed presentations to SanDisk, identifying and discussing specific claims of each ST patent alleged to be infringed by SanDisk and mapping the elements of each of the allegedly infringed claims to the aspects of the accused SanDisk products alleged to practice the elements. ST also provided SanDisk with copies of ST's presentation materials. However, during the discussions, ST's vice president of intellectual property and licensing stated that "ST has absolutely no plan whatsoever to sue SanDisk."

Judge Fogel dismissed SanDisk's declaratory judgment claims for lack of jurisdiction because, in his view, SanDisk did not have an objectively reasonable apprehension of suit. More particularly, Judge Fogel reasoned that SanDisk presented no evidence that ST threatened it with litigation at any time during the parties' negotiations, or any evidence of other ST conduct sufficient to indicate that ST intended to initiate an infringement action. Indeed, Judge Fogel noted that ST had told SanDisk that ST did not intend to sue SanDisk for infringement. Judge Fogel also indicated that, as an alternative basis for his ruling, even if the district court had jurisdiction, he would exercise his discretion and decline to hear the declaratory judgment claims.

Applying a more expansive test for declaratory judgment jurisdiction consistent with *MedImmune* as discussed more fully below, Federal Circuit Judges Bryson, Linn and Dyk vacated Judge Fogel's dismissal of SanDisk's declaratory judgment claims and remanded the case to Judge Fogel for further proceedings.

B. *Teva Pharmaceuticals*

In *Teva Pharmaceuticals*, Judge Linares of the District of New Jersey applied the Federal Circuit's two-part test and dismissed Teva's declaratory judgment action that sought a determination of noninfringement and invalidity of four Novartis patents directed to the drug Famvir®. In that case, Novartis had listed five patents in the "Orange Book" in conjunction with its New Drug Application ("NDA") for Famvir® filed with the U.S. Food and Drug Administration ("FDA"). One patent was directed to the active ingredient famciclovir and the other four patents were directed to methods of therapeutic use. Teva subsequently, in conjunction with its Abbreviated New Drug Application ("ANDA") with the FDA for generic famciclovir tablets, certified that it did not infringe any of the five Novartis patents or that the patents were invalid. Under the statutory scheme governing drug applications, Novartis had 45 days to sue on its patents in order to invoke a statutorily mandated 30-month stay of the FDA's approval of Teva's famciclovir application.

Novartis brought an infringement suit against Teva only on the active ingredient patent. In response, Teva brought a declaratory judgment action with respect to the four method patents. Judge Linares dismissed Teva's declaratory judgment action because, in his view, Teva had failed to establish a reasonable apprehension of imminent suit with respect to the four method patents.

Applying a more expansive declaratory judgment jurisdiction test consistent with *MedImmune* as discussed more fully below, but formulated in somewhat different words than in *SanDisk*, Federal Circuit Judges Mayer, Friedman and Gajarsa reversed Judge Linares' dismissal of Teva's declaratory judgment action.

II. The Federal Circuit's New Expansive Test For Determining The Existence Of Declaratory Judgment Jurisdiction

A. *SanDisk*

After thoroughly considering *MedImmune* and related Supreme Court decisions, the Federal Circuit panel in *SanDisk* stated that "[t]he Supreme Court's opinion in *MedImmune* represents a rejection of our reasonable apprehension of suit test."[5] Acknowledging that its jurisdiction extends only to Article III cases or controversies (and not to requests for advisory opinions concerning hypothetical facts), the Court further stated:

> In the context of conduct prior to the existence of a license, declaratory judgment 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. But Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do. 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. 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 its legal rights.

The Court then further held that, under the specific facts of the case, SanDisk had established an Article III case or controversy giving rise to declaratory judgment jurisdiction. The Court noted that "ST sought a right to a royalty under its patents based on specific, identified activity by SanDisk," and that "SanDisk, on the other hand, maintained that it could proceed in its conduct without the payment of royalties to ST." The Court concluded that "[t]hese facts evince that the conditions of creating 'a substantial controversy, between parties having adverse legal interest, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment' were fulfilled."

In the course of its holding, the Court expressly acknowledged that its decision is counter to earlier Federal Circuit decisions holding that (1) declaratory judgment jurisdiction was not supported where the patentee did nothing more than exercise its lawful commercial prerogative of requiring a competitor to choose between abandoning a business venture or engaging in arguably infringing activity, and (2) when there are proposed or ongoing license negotiations, a litigation controversy normally did not arise until the negotiations had broken down. The Court also held that ST's statement that it would not sue SanDisk did not eliminate the justiciable controversy created by ST's actions, but rather -- in the context of the other circumstances -- showed that "ST is engaging in the kinds of 'extra-judicial patent enforcement with scare-the-customer-and-run tactics' that the Declaratory Judgment Act was intended to obviate."

Finally, the Court noted that although a district court is given discretion to dismiss declaratory judgment claims, there are boundaries to that discretion. The Court indicated that "[w]hen there is an actual controversy and a declaratory judgment would settle the legal relations in dispute and afford relief from uncertainty or insecurity, in the usual circumstance the declaratory judgment is not subject to dismissal" and "the exercise of discretion must be supported by a sound basis for refusing to adjudicate an actual controversy." The Court went on to state that "we discern little basis for the district court's refusal to hear the case and expect that in the absence of additional facts, the case will be entertained on the merits on remand."

B. *Teva Pharmaceuticals*

Following a somewhat different path than the *SanDisk* panel, the *Teva Pharmaceuticals* panel also thoroughly considered *MedImmune* and related Supreme Court decisions, the Declaratory Judgment Act, and the statutes governing drug applications, and similarly noted that *MedImmune* "stated that our two-prong 'reasonable

[5] The Court stated that "we address only the first prong of this court's two-part test" and "leave to another day the effect of *MedImmune*, if any, on the second prong."

apprehension of suit' test 'conflicts' and would 'contradict' several cases in which the Supreme Court found that a declaratory judgment plaintiff had a justiciable controversy." The Court further stated:

> In *MedImmune*, the Court re-affirmed the correct standard for determining a justiciable declaratory judgment action: "Basically, the question in each case is 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."
>
> Thus, *MedImmune* teaches that in a declaratory judgment action, "all the circumstances" must demonstrate that a justiciable Article III "controversy" exists.

The Court then held that, under the specific facts of the case, Teva had established an Article III case or controversy ("the only limitation on our jurisdiction under the Declaratory Judgment Act") giving rise to declaratory judgment jurisdiction. The Court noted that "Novartis has already filed suit based on Teva's act of infringement in submitting the ANDA" and "while Teva's declaratory judgment action and the pending '937 suit [by Novartis] are different 'cases,' they arise from the same controversy created when Novartis listed its Famvir® patents in the Orange Book, Teva submitted its ANDA certifying all five Famvir® patents under paragraph IV, and Novartis sued Teva challenging the submission of Teva's ANDA." The Court further noted that at least five circumstances "taken as a whole ... establish a justiciable controversy with Novartis that can be resolved by allowing Teva to bring a declaratory judgment": (1) Novartis listed its Famvir® patents in the Orange Book, (2) Teva submitted its ANDA certifying that it did not infringe Novartis' Famvir® Orange Book patents or that the patents were invalid, (3) the drug application statutes favor a declaratory judgment action "to obtain patent certainty" among other reasons, (4) Novartis' pending related infringement litigation involved the same technology and the same parties, and (5) Novartis created the possibility of future litigation by electing to challenge Teva's ANDA on only one of the five Orange Book listed Famvir® patents. The Court concluded that, under the *MedImmune* standard, "we find that Teva has an injury-in-fact and a justiciable controversy that can be fully resolved by a declaratory judgment."

In the course of its holding, the Court also indicated that (1) "Although there can be a fine line between declaratory judgments and advisory opinions, the Supreme Court maintains the necessity of avoiding issuing advisory opinions based upon hypothetical facts," and (2) Congress by legislation may expand standing to the full extent permitted by Article III of the Constitution, and "[t]he Declaratory Judgment Act and 35 U.S.C. §271(e)(5) [relating to drug applications] are examples of legislation that expand standing to constitutional limits and provide a way for plaintiffs to bring actions in federal court when they might otherwise be barred." The Court also noted that "even if there is an actual controversy, the district court ... retains discretion under the [Declaratory Judgment] Act to decline declaratory judgment jurisdiction," but provided no comment specific to the *Teva Pharmaceuticals* case, since Judge Linares apparently had not exercised his discretion to dismiss regardless of the existence of a controversy.

Federal Circuit Judge Friedman wrote a concurring opinion, agreeing with the majority's conclusion but indicating that "I write separately because I take a somewhat different, and shorter, path than the court does in reaching that conclusion." Judge Friedman noted that Novartis listed all five of its closely related Famvir® patents in the Orange Book, and he succinctly concluded:

> There thus is an existing controversy between the parties over whether Teva's generic version of Famvir® would infringe the four other Famvir® patents listed in the Orange Book, and whether these patents are valid. Novartis' filing of the suit charging that Teva has infringed one of those five patents and Teva's filing a declaratory judgment suit relating to the other four patents confirms that the controversy between the parties is continuing.

C. The Outer Boundaries Of The New Test Announced In *SanDisk* And *Teva Pharmaceuticals*

As Judge Bryson's concurring opinion in *SanDisk* cogently explains, the *SanDisk* and *Teva Pharmaceuticals* decisions have potentially far-reaching implications. After agreeing with the majority in *SanDisk* that *MedImmune* "would appear to make declaratory judgments more readily available to parties who are approached by patentees seeking to license their patents" and "seems to require us to hold that the district court in this case had jurisdiction to

entertain SanDisk's declaratory judgment action," Judge Bryson noted that "the implications [of *MedImmune's* footnote 11] are broader than one might suppose from reading the court's opinion in this case."

Judge Bryson went on to state that *SanDisk's* "new test will not be confined to cases with facts similar to this one," that "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," and that "even a representation by the patentee that it does not propose to file suit against the prospective licensee will not suffice to avoid the risk that the patentee will face a declaratory judgment action." Indeed, Judge Bryson stated further that "[t]he court's legal test does not suggest that the case would come out differently if ST had been less forthcoming about why it believed SanDisk should take a license, or even if ST had simply contacted SanDisk, provided copies of its patents, and suggested that SanDisk consider taking a license."

Thus, Judge Bryson concluded:

> In sum, the rule adopted by the court in this case will effect a sweeping change in our law regarding declaratory judgment jurisdiction. Despite the references in the court's opinion to the particular facts of this case, 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. Although I have reservations about the wisdom of embarking on such a course, I agree with the court that a fair reading of footnote 11 of the Supreme Court's opinion in *MedImmune* compels that result, and I therefore concur in the judgment reversing the district court's dismissal order in this case.

It appears evident from the *Teva Pharmaceuticals* decision, particularly the Court's statements that the Declaratory Judgment Act expands standing to constitutional limits and that the need for an Article III justiciable controversy is the only limitation on jurisdiction under the Declaratory Judgment Act, that the *Teva Pharmaceuticals* panel shares Judge Bryson's views.

III. Conclusions And Recommendations

The Federal Circuit's *SanDisk* and *Teva Pharmaceuticals* decisions, in the wake of *MedImmune*, have greatly increased the potential for declaratory judgment actions. The *SanDisk* and *Teva Pharmaceuticals* decisions do not define the outer boundaries of declaratory judgment jurisdiction under the newly stated test, and, as expressed by Judge Bryson, it appears that virtually any concrete dispute between a patentee and a recipient of the patentee's patent notice letter or license offer may now potentially serve as a basis for a declaratory judgment action by the recipient.

Accordingly, even while awaiting further possible clarification in future Federal Circuit decisions, it is imperative for patentees to modify their traditional extra-judicial patent enforcement/licensing conduct so as to take into account the now easier access to courts by declaratory judgment plaintiffs seeking to challenge patents. That is, patentees who want to exploit their patents through extra-judicial activity must recognize that it will be much more difficult to control whether and when a justiciable controversy arises. Conversely, the new declaratory judgment jurisdiction test affords recipients of patentees' enforcement/licensing overtures greater opportunity to force resolution of patent disputes. In these regards, we offer a few recommendations below, but invite you to contact us with any specific questions that you may have.

In view of *SanDisk* and *Teva Pharmaceuticals*, patentees seeking to notify competitors of and/or license their patents, while hoping to avoid responsive declaratory judgment actions, should consider the following:

- As recommended in our January 26, 2007 Special Report, a patentee may wish to consider filing a patent infringement action before or early in the course of a license negotiation or other extra-judicial enforcement activity in an effort to preempt a declaratory judgment action by the recipient of the patentee's license offer or other communications. If deemed useful, a patent infringement complaint can be filed while withholding service of the complaint for up to 120 days. In addition to possibly preempting a declaratory judgment action, filing a patent infringement action may also improve the patentee's bargaining power in a negotiation and make it possible to incorporate agreed-upon license or other terms in a court-approved settlement agreement or consent judgment.

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- In at least initial letters offering patent licenses, or putting competitors or an industry on notice of a patent or patents, a patentee may wish to avoid allegations of infringement or even statements that the recipients of the letters need or require licenses. For example, consider identifying and providing copies of pertinent patents, indicating that they may be of interest to the recipients, and stating that licenses are available. This may serve to avoid declaratory judgment jurisdiction by not creating a dispute ("case or controversy"). However, keep in mind Judge Bryson's admonitions in his *SanDisk* concurring opinion that (1) declaratory judgment jurisdiction may be found even under these circumstances, and (2) if a recipient has any doubt that it has basis for a declaratory judgment action, it can simply inquire whether the patentee believes the recipient's activities to be within the scope of a patent. As Judge Bryson noted with respect to item (2), if the patentee says "no," it will likely effectively end its extra-judicial enforcement/licensing efforts, and if it says "yes" or equivocates, it will likely satisfy the Federal Circuit's new test and set itself up for a declaratory judgment action.

- A patentee should consider requesting a suitable confidentiality agreement before engaging in any conduct that might provide a basis for a declaratory judgment action. The majority in *SanDisk* indicated that if ST had entered into a confidentiality agreement with SanDisk, rather than merely requesting that the parties' discussions be treated as settlement discussions under Federal Rule of Evidence 408, ST could have avoided the risk of a declaratory judgment action. However, as Judge Bryson aptly noted in his concurring opinion, "[t]he problem with that suggestion is that it would normally work only when it was not needed -- only a party that was not interested in bringing a declaratory judgment action would enter into such an agreement."

In an effort to take advantage of the *SanDisk* and *Teva Pharmaceuticals* decisions, recipients of patent notice letters or license offers should consider the following:

- A recipient of a patent notice letter or license offer may wish to avoid entering into a confidentiality agreement with the patentee so as to maintain the possibility of an action seeking a declaratory judgment that a patent is invalid, unenforceable and/or not infringed. As stated by Judge Bryson, "[a] party that contemplates bringing a declaratory judgment action or at least keeping that option open [has] no incentive to enter into such an agreement."

- If a patentee has sent a patent notice letter or offered a license without explaining why the patentee believes that a recipient's products/activities infringe or that a license is necessary, the recipient may wish to send what Judge Bryson calls a "put up or shut up" response. More particularly, the recipient may wish to ask the patentee to state expressly whether the patentee considers the recipient's products or activities to be within the scope of the patentee's patents and to identify with particularity how the patent claims allegedly read on those products or activities. As noted above, any response by the patentee will likely either end the patentee's licensing efforts or provide a basis for a declaratory judgment action by the recipient as soon as the recipient disputes the patentee's assertions.

- A recipient of a patent notice letter or license offer may wish to avoid "cornering" the patentee so that the patentee does not feel that it should file a patent infringement action to preempt a possible declaratory judgment action by the recipient. In this regard, the recipient may wish to keep its communications cordial and non-threatening, while expressing continued interest in further communications and discussions toward an amicable resolution, e.g., a possible license.

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