

An Expanded License to Sue:

The Lower Threshold for Prospective Patent Licensees in Two Recent Federal Circuit Decisions

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***Sandisk Corp. v. STMicroelectronics, Inc. et al.*, No. 05-1300
(Decided March 26, 2007)**

and

***Teva Pharma. USA Inc. v. Novartis Pharma. Co. et al.*, No. 06-1181
(Decided March 30, 2007)**

The familiar terrain in which patent owners/licensors and patent licensees/prospective licensees negotiated patent rights has recently experienced a tectonic shift. Two decisions in the last week of March 2007 by the Federal Circuit (“CAFC”) confirm that it is now far easier to bring suit for declaratory judgment of non-infringement, invalidity, or unenforceability of a patent, even if the patentee has not made any explicit threat or taken any action indicating that it intends to file a patent lawsuit.

In *MedImmune, Inc. v. Genentech, Inc. et al.*, 127 S. Ct. 764 (2007), the Supreme Court held that district courts can entertain suits by patent licensees in good standing seeking a declaratory judgment that the underlying patent is invalid, unenforceable or not infringed. On March 26, the CAFC in *Sandisk Corp. v. STMicroelectronics, Inc. et al.* applied the *MedImmune* decision to hold that where a patentee expresses it has patent rights that apply to the activity of a third party, but the third party (a prospective licensee) contends the patentee is wrong, a federal court has subject matter jurisdiction to hear a declaratory judgment action for patent invalidity, unenforceability or non-infringement. *Sandisk Slip Op.* at 15.

Just four days later, the CAFC decided *Teva Pharma. USA, Inc. v. Novartis Pharma. Co. et al.* In that decision, the CAFC substantially lowered the threshold for finding subject matter jurisdiction in declaratory judgment actions related to

abbreviated new drug applications (“ANDA”) under the Food, Drug And Cosmetics Act (“FDCA”).

Sandisk (along with *Teva*) discarded at least 20 years of CAFC case law requiring prospective licensees to show they had a “reasonable apprehension of imminent suit” by the patentee to establish jurisdiction. As a result, patentees, their licensees – and even prospective patent licensees – face an altered landscape in which they must now negotiate patent licenses.

THE CAFC DECISIONS

Sandisk

Background. Between April and October 2004, patentee STMicroelectronics, Inc. (“ST”) and Sandisk attempted to negotiate a patent cross-license agreement. At an August 27, 2004 meeting, ST gave a lengthy technical presentation about its patent claims, discussing Sandisk’s alleged infringement. ST’s IP counsel told Sandisk it realized documents exchanged during the presentation might be enough to give Sandisk a basis for a declaratory judgment action against ST, but ST also stated it had “absolutely” no plan to sue Sandisk. On October 15, 2004, Sandisk filed suit.

ST moved to dismiss for lack of subject matter jurisdiction. The district court agreed, dismissing the case. The district court stated in a footnote that even if it had jurisdiction, it would exercise its discretion under the Declaratory Judgment Act to decline to hear the case anyway.

The *Sandisk* Decision. The CAFC vacated and remanded the case. The CAFC relied on the *MedImmune* decision, paying particular attention to footnote 11 in which the Supreme Court criticized the “reasonable apprehension of imminent suit” element of the CAFC’s subject matter jurisdiction test. *Sandisk* Slip Op. at 12. The CAFC concluded:

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 the 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. *Id.* at 15.

The CAFC found the exchange of information at the parties' August 27 meeting significant, stating "[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." *Id.* at 17. ST's actions also overrode any oral promise not to sue. *Id.* at 18.

Finally, the CAFC observed that a district court's discretion not to hear a case under the Declaratory Judgment Act has boundaries. In addressing that discretion the CAFC cautioned, "[g]iven the change reflected in *MedImmune* and our holding in this case, 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." *Id.* at 19.

Teva

Background. In *Teva*, the patentee Novartis listed five patents covering different aspects of its drug Famvir® in the FDA's Orange Book. In 2004, Teva filed an ANDA under the FDCA asserting that its drug did not infringe Novartis' patents or the patents were invalid. Novartis sued Teva on one of its five patents, and Teva then sought declaratory judgment on the four others. Novartis then moved to dismiss for lack of subject matter jurisdiction. The district court dismissed, concluding that Teva lacked a "reasonable apprehension of imminent suit" on Novartis' four other patents.

The *Teva* Decision. As in *Sandisk*, the CAFC reversed. It discarded the "reasonable apprehension of imminent suit" requirement for ANDA applicants seeking a declaratory judgment of patent non-infringement or invalidity. *Teva* confirms that the CAFC will follow *Sandisk*, even in the context of FDCA procedures, though *Teva* involves the more specific circumstance of declaratory judgment suits brought by ANDA applicants within the FDCA's statutory structure.

The CAFC found that the facts and circumstances of the case strongly supported its decision to reverse, which was grounded in the *Sandisk*, and in turn the *MedImmune*, decisions. Novartis' listing of its patents in the Orange Book constituted a statement that a patent infringement action could be brought against an ANDA applicant such as Teva. *Teva Slip Op.* at 14. Teva's ANDA statement that it does not infringe Novartis' patents raised a "justiciable controversy" concerning infringement. *Id.* at 15. Novartis' patent infringement action asserting

just one of its five patents frustrated an FDCA provision requiring patentees to “reasonably cooperate in expediting the action” to determine infringement and validity issues. *Id.* at 15-16. Novartis’ patent litigation asserting one patent raised a controversy over the remaining and related patents. *Id.* at 18, 19. Teva’s declaratory judgment action was consistent with the intent of the Hatch-Waxman Amendments to reduce patent uncertainty for ANDA applicants. *Id.* at 18. Finally, Novartis’ decision to sue on even one patent created the real possibility of future litigation over the four remaining patents. *Id.* at 20.

POTENTIAL IMPLICATIONS

In *Sandisk*, and again in *Teva*, the CAFC answered a question the Supreme Court left open in *MedImmune* -- whether the “reasonable apprehension of imminent suit” requirement of its two-prong test might survive in the patentee/prospective licensee context. The answer is a resounding “no.” Any serious licensing discussion by a patentee that compares the claims of a patent to another party’s product or service will likely meet the threshold for subject matter jurisdiction over a prospective licensee’s declaratory judgment challenge.

***Sandisk* Has Serious Implications Beyond Its Facts.** Patentees should not assume that the holding is narrowly confined to the particular facts. Of course, determining whether an Article III case or controversy exists may remain particularly fact intensive and courts must look to “all the circumstances.” But as the CAFC’s Judge Bryson warned in his concurrence in the result in *Sandisk*, “[i]n practical application, the new test will not be confined to cases with facts similar to this one.” *Id.* Concurrence at 3. In fact, Judge Bryson “see[s] no practical stopping point short of allowing declaratory judgment actions in virtually any case in which the recipient of an invitation to take a license elects to dispute the need for a license and then sue the patentee.” *Id.* at 5. The *Teva* decision appears to confirm Bryson’s belief.

Negotiating Leverage For Prospective Licensees. The much lower jurisdictional hurdle may create additional leverage for prospective licensees during licensing negotiations. For example, prospective licensees might agree not to sue in exchange for more favorable licensing terms.

This type of leverage may be particularly effective in negotiations involving non-manufacturing patentees with limited litigation resources. Such patentees may have to make their license terms more attractive in hopes of reducing the risks of a declaratory judgment action.

Licensor's Options For Limiting Declaratory Judgment Suits By Prospective Licensees. Patentees will need to think long and hard regarding licensing negotiation tactics to reduce the risk of a declaratory judgment action, short of filing suit first. Patentees, however, might consider at least the following steps:

- *Further Careful Review Of Initial Letters Or Offers Of A Patent License.* Merely informing a prospective licensee that a patent is available for license might not be enough to trigger declaratory judgment jurisdiction. Nevertheless, initial letters or offers must be carefully worded to reduce the risk of crossing the jurisdictional threshold, and where the threshold lies is not clear. Those receiving such letters as licensing targets should carefully parse the language to assess whether they can file suit immediately under *MedImmune*, *Sandisk* and *Teva*, rather than waiting for discussions to proceed to a further stage (or waiting for a lawsuit to be filed against them in an unfavorable jurisdiction).
- *Agreement Not To Sue Or Confidentiality Agreement Restricting The Use Of Information Obtained During Licensing Negotiations.* Language in the *Sandisk* decision suggests that the exchange of licensing positions (even including infringement charts) might not trigger declaratory judgment jurisdiction if subject to a non-disclosure agreement. They may also ask for a covenant not to sue from the prospective licensee. Patentees will want to try to negotiate such agreements before initiating licensing discussions if declaratory judgment is a concern. But, there may be few options if the prospective licensee balks.
- *File First.* Licensors may want to file suit against prospective licensees even early in a negotiation and even if the likelihood of negotiating a license is high, in order to obtain a favorable venue. A “no challenge” clause (stating that the licensee will not challenge the validity or enforceability of the patent) included as part of a settlement agreement and/or consent judgment resolving litigation will likely be enforceable under prevailing law. *Sandisk* makes filing first that much more attractive because the patentee can retain some control over the venue for any patent litigation.