KING & SPALDING

Client Alert

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D.C. Circuit Rejects FDA's Claim of Inherent Authority to Reclassify a Device by Rescinding a 510(k) Substantial Equivalence Order

On September 26, 2014, the D.C. Circuit issued an opinion holding that the Food and Drug Administration ("FDA") failed to follow the appropriate statutory procedure for reclassifying a device when the Agency relied on its "inherent authority" to rescind a 510(k) substantial equivalence determination by administrative order rather than using the reclassification procedure set forth in section 513(e) of the Food, Drug, and Cosmetic ("FD&C") Act.[1] While the holding can be construed narrowly to limit FDA's inherent authority to rescind a substantial equivalence determination in the specified circumstances, it could also be interpreted more broadly as a sign that courts are more willing to consider challenges when FDA appears to be overreaching or straining its statutory authority.

Background

The device at issue is a collagen scaffold, called Menaflex, that is intended to support and reinforce the meniscus in individuals with knee injuries. It is made by Ivy Sports Medicine, LLC ("Ivy Sports"), a successor in interest to ReGen Biologics, Inc. ("ReGen"), which filed for bankruptcy shortly after the Menaflex 510(k) was rescinded. FDA originally cleared the 510(k) for Menaflex in December 2008. Shortly thereafter, an article appeared in the Wall Street Journal that raised questions about the propriety of the clearance process and led to FDA's reevaluation of its determination.[2] On October 14, 2010, FDA informed ReGen of its intention to rescind the Menaflex 510(k). After providing ReGen an opportunity to request a hearing, FDA rescinded the Menaflex substantial equivalence determination in a letter sent March 30, 2011. The letter stated that the device "is not substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976… or to any device which has been classified into Class I (General Controls) or Class II (Special Controls)." Accordingly, ReGen would lose its authorization to market Menaflex and the device would be considered a Class III device.

Ivy Sports brought suit in the D.C. District Court in June 2011, challenging FDA's March 30, 2011 rescission under the Administrative Procedure Act, and seeking an injunction "barring FDA from attempting to reclassify [Menaflex] other than through the reclassification process set forth in § 513(e)" of the FD&C Act. Specifically, Ivy Sports requested judgment that

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(1) the rescission order be found illegal and null and void, and (2) the 2008 substantial equivalence order remain in effect. Both FDA and Ivy Sports moved for summary judgment. Ivy Sports argued that FDA had only a single option by which to reclassify a device—the statutory procedure provided in section 513(e) of the FD&C Act—and, because FDA did not follow this procedure, its action therefore violated the law. In contrast, FDA stated that it was not reclassifying the device, but rescinding the 510(k) based on "serious procedural irregularities in the approval process."[3] FDA argued, as well, that there was no statutory limitation on the Agency's authority to reconsider a determination.

The District Court found in favor of FDA based on three factors. First, the District Court distinguished *American Methyl Corp. v. EPA*,[4] the central case in Ivy Sports' argument, stating that the *American Methyl* holding denying inherent agency authority to reconsider a decision when an alternative statutory pathway was provided did not apply in cases such as this, where misconduct affected the integrity of an agency action. Moreover, the Court cited numerous cases that support inherent agency authority to reconsider decisions and correct mistakes, finding that FDA had inherent authority to rescind the Menaflex 510(k) without formally reclassifying the device. Second, the Court considered whether FDA had rescinded the determination in a timely manner, and found that, indeed, the Agency had acted in a timely manner given the considerable time and attention required to reevaluate a complex 510(k). Finally, the District Court considered whether FDA had acted properly within the scope of its statutory authority. The Court concluded that, contrary to Ivy Sports' contention that FDA had acted "arbitrarily and capriciously because it failed to properly limit its review of [Menaflex] to the description provided in the device's Indication for Use statement," FDA had properly considered the Indications for Use statement as well as other labeling to determine that Menaflex had an additional intended use, rendering it not substantially equivalent to its claimed predicate. Additional information on the District Court ruling and the events preceding it can be found in a prior King & Spalding Client Alert: *FDA 510(k) Rescission Authority Upheld: District Court Finds for FDA in ReGen Litigation*.[5]

Ivy Sports sought review by the D.C. Circuit, which reversed the District Court's holding in an opinion published September 26, 2014.

D.C. Circuit Opinion

The D.C. Circuit concluded that FDA "did not follow the proper statutory procedure for reclassifying a device," and therefore reversed the holding of the District Court.[6] The D.C. Circuit ordered the District Court to vacate FDA's 510(k) rescission determination and remand to the Agency for further proceedings. The Circuit Court's ruling was based primarily on its analysis of FDA's "inherent authority" to rescind.

Did FDA have inherent authority to rescind the 510(k)?

The Court first considered FDA's assertion that it had "inherent authority" to rescind its 510(k) determination that Menaflex was substantially equivalent to its predicate. FDA argued that the rescission had the default effect of making Menaflex a Class III device, requiring it to meet stringent premarket review requirements before going back on the market, but distinguished this rescission authority from its statutory reclassification authority. For that reason, the Agency did not follow the reclassification procedures (including notice and comment) included in section 513(e) of the FD&C Act. The Court agreed that agencies have inherent statutory authority to reconsider prior decisions, when done in a timely fashion, but pointed to *American Methyl* which states that "any inherent reconsideration authority does not apply in cases where Congress has spoken." The Circuit Court noted that, "our cases assume that Congress intends to displace an administrative agency's inherent reconsideration authority when it provides statutory authority to rectify the agency's mistakes." Acknowledging FDA's "forceful" argument that Ivy Sports was "conflating the underlying substantial equivalence determination with the potential consequences of the action—classification into Class I, II, or III," the Court nonetheless agreed with Ivy Sports' characterization of the action in question, stating that the "fundamental question both [the rescission and reclassification] provisions address—What is the appropriate

classification of a new device?—is the same. And as a practical matter, the decision to revoke a substantial equivalence determination in circumstances like those present here is a de facto reclassification of the device into Class III." Finding section 513(e) of the FD&C Act to address the "same concerns" and "achieve[] the same result" the Court determined that it would be unreasonable to infer that FDA retains inherent authority to "short-circuit" or "end-run" the statutorily prescribed reclassification process.

Is there a misconduct exception to statutory procedure that permits reconsideration under inherent authority?

The Court next considered FDA's theory that *American Methyl* recognized an exception to statutory reconsideration provisions where, in circumstances such as those at issue here, serious procedural inconsistencies and other misconduct warrant reconsideration on the basis of inherent agency authority. The Court noted that the record in *American Methyl* contained no evidence of misconduct, and cited a passage in which the District Court, referring to fraud and misconduct, described it as "an issue not before us today and on which we venture no opinion." Finally, the Court suggested that, even if the exception was not mere dicta, the mistakes on the record in this case "do not rise to the level of misconduct contemplated by *American Methyl*." Additionally, the Court found no evidence that the supposed defects in FDA's review process affected FDA's original 510(k) clearance decision. An exception for misconduct, the Court noted, poses a high bar and "connotes a clear legal or ethical violation." The absence of any disciplinary action against any FDA leader, ReGen executive, or Member of Congress was considered further evidence that no misconduct in the present case was sufficient to warrant the exercise of inherent authority for reconsideration.

The Dissent

Judge Pillard wrote an extensive dissent, characterizing the case, not as a question of whether FDA followed the appropriate procedural requirements to reclassify a device, but as a question of the Agency's authority to reconsider a decision made in a way that raises significant procedural concerns. The dissent argues that the reclassification provision (section 513(e)) was never intended to apply to substantial equivalence actions, whether clearance, modification, or rescission. In making its argument, the dissent points to the specific wording of the reclassification provision, its location within the statutory framework, and established agency practice. Among the reasons provided, the dissent points out that the provision is worded to apply when the Agency's reconsideration is based on "new information" not reevaluation of existing information. The provision also refers to a decision made by advisory committees used only in Class III device approval determinations. Additionally, the provision comes immediately after the premarket approval provisions for Class III devices, and long before any mention of substantial equivalence is made in the statute. Furthermore, in the Agency's established practices, the provision has only been used for groups or types of devices, not reclassification of a single product. The dissent closes by stating that, even if the procedure in section 513(e) would be required any time FDA chooses to reclassify a device, it is not mandatory when FDA acts only to rescind a device clearance. At this time, FDA has not announced whether it will seek review of the decision.

Implications of the Decision

As the majority recognized in its opinion, this holding has relatively limited effect.[7] The Court holds that Congress has provided a specific procedure for agency action in this particular circumstance. However, in a footnote, the Court acknowledges that the Agency may forego notice and comment in cases where it for good cause finds that notice and public comment are "impracticable, unnecessary, or contrary to the public interest."[8] Therefore, the court appears to acknowledge that there may be some limited circumstances in which FDA would not need to follow the prescribed reclassification process under section 513(e) to rescind a 510(k) clearance. Additionally, this ruling does not limit the Agency's exercise of inherent authority in actions outside the context of a 510(k) rescission.

The majority opinion, moreover, did not resolve the question of whether misconduct affecting the integrity of an agency determination could provide an exception to an otherwise controlling statutory procedure. Indeed, the opinion hints that misconduct meeting the standard of a "clear legal or ethical violation" might rise to a level that warrants Agency exercise of its inherent reconsideration authority.

Finally, this decision may make the Agency more careful and more deliberate in its review and clearance of 510(k) submissions. Recognizing that it generally will be unable to exercise its inherent authority to rescind a 510(k) clearance and will instead be required to go through the reclassification process with attendant procedural and evidentiary burdens, FDA could require stronger support for a 510(k) submission or review the supporting materials more closely before clearing a device in the first place.

As a consequence of this holding, FDA potentially could revive the 510(k) rescission rulemaking that it started in 2001. A proposed rule for "Rescission of Substantially Equivalent Decisions and Rescission Appeal Procedures" was published in the Federal Register on January 16, 2001.[9] However, the Agency never finalized the rule.

Although the holding in this case can be construed quite narrowly, the broader effect on industry morale is a serious one. As a general matter (and as illustrated in this particular case), industry often does not have the resources necessary to directly challenge FDA. Small companies with new or few products typically do not have the cash reserves on hand to pursue lengthy litigation with the Agency. Additionally, even those with the financial resources to fund litigation recognize that courts are reluctant to overturn agency actions that directly or indirectly relate to agency discretion within the agency's line of expertise. As the Court has indicated with this ruling, however, despite significant Agency advantages in litigation, judges may be open to challenges against FDA where the Agency may be overreaching or straining its statutory authority. Accordingly, it would not be a surprise to see that this opinion galvanizes industry to seek review more often of questionable Agency decisions.

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[1] *Ivy Sports Med., LLC, v. Burwell*, No. 13-5139 (D.C. Cir. Sept. 26, 2014).

[2] Alicia Mundy, *Political Lobbying Drove FDA Process*, WALL ST. J., Mar. 6, 2009, at A1.

[3] *Ivy Sports Med., LLC, v. Sebelius*, No. 11-cv-1006 (D.D.C. Apr. 10, 2013).

[4] 749 F.2d 826 (D.C. Cir. 1984).

[5] Edward M. Basile et al, King & Spalding Client Alert: *FDA 510(k) Rescission Authority Upheld: District Court Finds for FDA in ReGen Litigation* (May 21, 2013) Available at: http://www.kslaw.com/imageserver/KSPublic/library/publication/ca052113.pdf.

[6] *Ivy Sports Med., LLC, v. Burwell*, at 3.

[77] "The practical significance of our holding on this point is limited but important." *Ivy Sports Med., LLC, v. Burwell*, at 12.

[8] *Ivy Sports Med., LLC, v. Burwell*, at 13, FN 1; 5 U.S.C. § 553(b)(3)(B).

[9] 66 Fed. Reg. 3,523 (Jan. 16, 2001).