NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 13-2148

MICHAEL A. SMITH,
Appellant

v.

DEPUY ORTHOPAEDICS INC; DEPUY INC; DEPUY INTERNATIONAL LIMITED; JOHNSON & JOHNSON; JOHNSON & JOHNSON INTERNATIONAL

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
(D.C. No. 2-11-cv-04139)
District Judge: Hon. Joel A. Pisano

Submitted Under Third Circuit LAR 34.1(a)
January 7, 2014

Before: SMITH, SHWARTZ, and SCIRICA, Circuit Judges.

(Filed: January 14, 2014)

OPINION

SHWARTZ, Circuit Judge.

Plaintiff Michael Smith appeals the denial of his cross-motion for a continuance pursuant to Federal Rule of Civil Procedure 56(d) in his products liability action against

DePuy Orthopaedics, Inc., DePuy, Inc., DePuy International Limited, Johnson & Johnson, and Johnson & Johnson International (collectively, "Defendants"). Smith had two knee surgeries, during which he received components of Defendants' P.F.C. Sigma Knee that were approved through the Food & Drug Administration's ("FDA") premarket approval ("PMA") process as supplements to Defendants' LCS Total Knee System. Defendants moved for summary judgment, arguing that Smith's claims were preempted, and Smith cross-moved for a continuance to conduct additional discovery. The District Court denied Smith's cross-motion when it granted Defendants' motion for summary judgment. For the reasons set forth herein, we will affirm.

I.

As we write principally for the benefit of the parties, we recite only the essential facts and procedural history. Defendants manufacture the RP Knee, a medical device that is a part of Defendants' LCS Total Knee System. It is regulated through the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360c(a)(1)(C). In accordance with federal regulation, the RP Knee underwent the PMA process, which "provide[s] reasonable assurance of its safety and effectiveness," 21 U.S.C. § 360c(a)(1)(C)(ii)(II); Riegel v. Medtronic, 552 U.S. 312, 317 (2008), and in 1985, the FDA approved its use in the LCS Total Knee System.

In 1996, Defendants introduced the P.F.C. Sigma Knee, which at the time was a fixed-bearing system containing: (1) a femoral piece; (2) a patella; (3) a tibial tray; and (4) a tibial insert. The FDA approved the P.F.C. Sigma Knee through a less-rigorous

process called the 510(k) Pre-Market Notification process.[1]

In February 2000, Defendants submitted a PMA application to the FDA to supplement[2] the existing RP Knee with a new rotating platform, which was designed to be used with the 510(k)-cleared femoral and patella components of the P.F.C. Sigma Knee. The FDA approved this application in March 2000, memorialized as Supplement 69 to the LCS Total Knee System PMA.[3]

Soon after, in May 2000, Defendants submitted a PMA application to supplement the RP Knee to include the 510(k)-cleared rotating platform tibial trays and bearings from the P.F.C. Sigma Knee, thereby incorporating all components of the P.F.C. Sigma Knee

[1] Under the 510(k) process, the FDA will approve a new device that is "'substantially equivalent' to another device exempt from premarket approval." Riegel, 552 U.S. at 317. This is in contrast to the PMA process, which makes a determination regarding the safety and effectiveness of the new device. Id. at 318. Thus, the 510(k) process focuses on equivalence, and the PMA process focuses on safety. See Lewkut v. Stryker Corp., 724 F. Supp. 2d 648, 654 (S.D. Tex. 2010). If a component is approved only through the 510(k) process and it is later incorporated into a premarket approved device, it is subject to the federal regulations for the purpose of preemption. Id. at 657.

[2] Any change to a PMA-approved device requires supplemental approval, which "is evaluated largely by the same procedures, criteria, and extensive scrutiny as the original PMA process." Bass v. Stryker Corp., 669 F.3d 501, 508 (5th Cir. 2012) (internal quotation marks omitted).

[3] In its approval, the FDA acknowledged that certain components of the newly-approved RP Knee were from the P.F.C. Sigma Knee and thus had been previously cleared through the 501(k) process. Smith argued in the District Court that the components were only approved through the 510(k) process, not the PMA process, but on appeal, he has not challeneged the District Court's holding that those components from the P.F.C. Sigma Knee were incorporated into the RP Knee and thus received PMA approval.

into the RP Knee.[4] The FDA approved that application in June 2000, memorialized as Supplement 74 to the LCS Total Knee System PMA.

In February 2006, Defendants submitted yet another PMA application to supplement the RP Knee, this time to notify the FDA that an inspection was being added to the manufacturing process for certain tibial trays. The FDA approved this application in February 2006, memorialized as Supplement 95 to the LCS Total Knee System.

On October 15, 2007, Smith underwent total right knee replacement surgery (the "first surgery"), during which the RP Knee—including the P.F.C. Sigma tibial insert, tibial tray, patella, and femoral component—was implanted. In mid-2008, Smith allegedly experienced "chronic pain with swelling and locking of the joint." App. 177. Smith allegedly underwent a bone scan, which confirmed loosening of the femoral and tibial components, and on July 20, 2009, Smith underwent a revision of his loose knee implant (the "second surgery"), during which the tibial tray from the first surgery was kept in place, but revision components from the P.F.C. Sigma Knee were added, including a femoral component, tibial cemented stem, femoral adapter, femoral adapter bolt, distal augmentations, posterior augmentation combo, and tibial insert. In 2010, Smith allegedly developed a "snapping behind the patella-femoral joint." App. 178.

Smith thereafter filed a complaint against Defendants, alleging violations of state

[4]Among other things, the application to the FDA explains that the modifications included revised tibial tray stem lengths and locations to "allow the trays to be used with both the LCS Complete and Rotating Platform bearings and the P.F.C. Sigma RP bearings." App. 113.

law.[5] The Magistrate Judge ordered that summary judgment motions on the issue of preemption be filed by August 24, 2012 with a return date of September 17, 2012, and stayed discovery pending the resolution of the motions, "except for the production of manufacturing records requested by Plaintiff." App. 211. Smith thereafter served a request for documents related to both the regulatory approval and manufacture of the components identified in the chart stickers from his surgeries. In response, Defendants produced over 3,000 regulatory and manufacturing documents limited to the components of the P.F.C. Sigma Rotating Platform Total Knee System.

On August 24, 2012, Defendants filed for summary judgment, asserting that all of Smith's claims were preempted. Smith requested two adjournments of the September 17, 2012 return date, which the Magistrate Judge granted, ultimately pushing the return date to October 29, 2012. A day before his opposition to Defendants' motion was due, Smith asked Defendants for additional documents concerning the components used in the second surgery. The next day, Smith filed his opposition to the summary judgment motion and a cross-motion pursuant to Rule 56(d) for a continuance to allow for additional discovery.

The District Court: (1) granted Defendants' motion for summary judgment, holding that Smith's state law claims, which were related to the safety and effectiveness

[5] These include claims under New Jersey's Products Liability Act alleging a manufacturing defect, design defect, and failure to warn, as well as negligence, breach of express warranty, breach of implied warranty, negligent misrepresentation, fraudulent concealment, fraud and deceit, and a claim under the Virginia Consumer Protection Act.

of the device, were preempted under Riegel[6] because the RP Knee and all of its components were approved under the FDA's PMA process; and (2) denied Smith's cross-motion for a continuance, holding that the affidavit that Smith filed in support of his motion was deficient under Rule 56(d) because it failed to explain how further discovery would preclude summary judgment. This appeal of the denial of the cross-motion followed.

II.

The District Court had jurisdiction pursuant to 28 U.S.C. §1332. We exercise jurisdiction pursuant to 28 U.S.C. § 1291. We review the denial of a motion for additional discovery under Rule 56(d) for abuse of discretion. Murphy v. Millennium Radio Grp. LLC, 650 F.3d 295, 309-10 (3d Cir. 2011). We therefore will not disturb the District Court's exercise of discretion unless it was "arbitrary, fanciful or clearly unreasonable," and "no reasonable person would adopt [its] view." Stecyk v. Bell Helicopter Textron, Inc., 295 F.3d 408, 412 (3d Cir. 2002) (internal quotation marks omitted).

III.

A district court may grant summary judgment before discovery is completed as long as the party opposing summary judgment has had "an adequate opportunity to obtain

[6] In Riegel, the Supreme Court held that a state law is preempted if (1) "the Federal Government has established requirements applicable to" the device; and (2) plaintiff's claims are based upon state "requirements . . . that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." 552 U.S. at 321-22 (quoting 21 U.S.C. § 360k(a)).

discovery." Dowling v. City of Phila., 855 F.2d 136, 138-39 (3d Cir. 1988) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986)). If a party opposing summary judgment "believes that s/he needs additional time for discovery, Rule 56(d) specifies the procedure to be followed." Pa., Dep't of Pub. Welfare v. Sebelius, 674 F.3d 139, 157 (3d Cir. 2012) (quoting Dowling, 855 F.2d at 139, which addressed the predecessor to Rule 56(d), Rule 56(f)). Rule 56(d) provides:

> If a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may:
> (1) defer considering the motion or deny it;
> (2) allow time to obtain affidavits or declarations or to take discovery; or
> (3) issue any other appropriate order.

Fed. R. Civ. P. 56(d). The rule requires "a party seeking further discovery in response to a summary judgment motion [to] submit an affidavit specifying, for example, what particular information is sought; how, if uncovered, it would preclude summary judgment; and why it has not previously been obtained." Dowling, 855 F.2d at 139-40. Except in rare cases, "failure to comply with [Rule 56(d)] is fatal to a claim of insufficient discovery on appeal." Bradley v. United States, 299 F.3d 197, 207 (3d Cir. 2002).

On appeal, Smith argues that the District Court abused its discretion by proceeding with summary judgment before he received discovery on the components implanted during his second surgery because he needs to confirm that they went through the PMA process and received FDA approval. While the declaration submitted with Smith's cross-motion described what discovery he sought and why it had not previously been obtained,

it failed to discuss how the discovery sought, if provided, would preclude summary judgment.[7] As a result, Smith failed to submit a compliant Rule 56(d) affidavit. Thus, "as a procedural matter alone, [h]e has failed to comply with the rule," Dowling, 855 F.2d at 140, and cannot rely on the purported lack of discovery as a basis to reverse the District Court.

Moreover, because the components implanted during the second surgery all related to the P.F.C. Sigma femoral piece, tibial tray, and tibial tray bearings,[8] which were approved by the FDA through the PMA process in Supplements 69, 74, and 95, and which are components of the PMA-approved RP Knee, no discovery was necessary to determine that these components were also subject to PMA preemption. See Gross, 858 F. Supp. 2d at 487 (holding that a device that received pre-market approval cannot be

[7] In his brief and at oral argument, Smith told the District Court that he wished to take additional discovery because the documents Defendants produced only showed 510(k) clearance for the components, which he claimed contradicted Defendants' declaration that these components were included in the PM A process. As the District Court explained, Smith misunderstood the facts: PMA Supplements 69, 74, and 95 to the LCS Total Knee System incorporated the components of the P.F.C. Sigma Knee that had previously been cleared through the 510(k) process, and thus these components are subject to the same federal preemption. See Kemp v. Medtronic, Inc., 231 F.3d 216, 222 (6th Cir. 2000); Duggan v. Medtronic, Inc., 840 F. Supp. 2d 466, 471 (D. Mass. 2012). Thus, Smith did not provide the District Court with a reason to delay consideration of Defendants' summary judgment motion.

[8] While Smith argues that he cannot possibly know whether the components inserted in his second surgery received PMA approval, the chart stickers from the second surgery show that the pieces were related to the P.F.C. Sigma Knee, and the Supplements themselves indicated that all components and bearings associated with the P.F.C. Sigma Knee received PMA approval. Cf. Bass, 669 F.3d at 508 (looking to the language of the FDA approval to confirm that component was included in PMA); Gross v. Stryker Corp., 858 F. Supp. 2d 466, 485-86 (W.D. Pa. 2012) (same); Lewkut, 724 F. Supp. 2d at 654-56 (same).

separated into its component parts to avoid application of express preemption); Duggan, 840 F. Supp. 2d at 471 (same); Lewkut, 724 F. Supp. 2d at 656 (same); Riley v. Cordis Corp., 625 F. Supp. 2d 769, 780 (D. Minn. 2009) (same).

Furthermore, many PMA preemption motions are decided without any discovery.[9] Here, the Magistrate Judge allowed discovery limited to the production of manufacturing records, but regulatory documents were also produced. Smith's request for additional regulatory documents occurred just one day before his opposition brief was due and a month and a half after he received Defendants' production. Smith's delay, together with his failure to explain why the discovery was needed, provided the District Court with sufficient grounds to deny the continuance motion. Accordingly, the District Court "acted within the permissible bounds of its discretion when it ruled on the [Defendants'] summary judgment motion on the record before it," Dowling, 855 F.2d at 141, and properly denied Smith a continuance.

IV.

For the foregoing reasons, we will affirm the District Court's denial of Smith's cross-motion for a continuance.

[9] See, e.g., Bass, 669 F.3d at 508 n.1; Gross, 858 F.Supp. 2d at 505; Lewkut , 724 F. Supp. 2d at 653 n.1, 655; Desai v. Sorin CRM USA, Inc., Civ. No. 12-2995, 2013 WL 163298, at *9 (D.N.J. Jan. 15, 2013); Hayes v. Howmedica Osteonics Corp., Civ. No. 08-6104, 2009 WL 6841859, at *6-8 (D.N.J. Dec. 15, 2009); Delaney v. Stryker Orthopaedics, Civ. No. 08-03210, 2009 WL 564243, at *4 (D.N.J. Mar. 5, 2009).