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PATENTS

Federal Circuit: Not all mechanical medical devices are so predictable that disclosing a single example in a patent application supports broad patent protection

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In October, the Court of Appeals for the Federal Circuit in *Synthes USA, LLC v. Spinal Kinetics, Inc.* addressed a situation that is common in the medical device industry.[1] Synthes filed a patent application for a medical device that described a single example. Presumably after seeing its competitor Spinal Kinetics's devices, Synthes broadened the scope of its patent claims to ensnare the Spinal Kinetics devices and sued for patent infringement. Broadening a patent claim to cover a competitor's product is not improper as long as the patent application's disclosure supports the broadened patent scope.[2] And at issue in *Synthes USA* was whether Synthes's patent application provided the required written description support for the broadened patent scope.

Background

Synthes's patent application disclosed an intervertebral implant that included plates that had peripheral grooves (indicated at reference number 18) as shown below.[3]

Fibers (indicated at reference number 6) pass through the peripheral grooves. The patent application did not disclose any other examples of plates with grooves or openings. Five years after the patent application's filing, and after Spinal Kinetics's devices were on the market, Synthes amended its patent claim to include implants having plates with a plurality of *openings*. Presumably, this amendment was made to cover two Spinal Kinetics devices, which are shown below,

[1] No. 2013-1047 (Fed. Cir. Oct. 29, 2013) (7 MELR 714, 11/13/13).

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[2] No. 2013-1047, slip op. at 11 (citing *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 909 n.2 (Fed. Cir. 2004)).

[3] *Id.* at 4.

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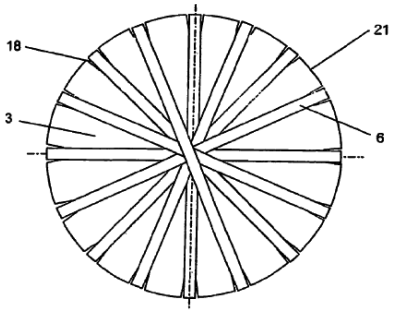
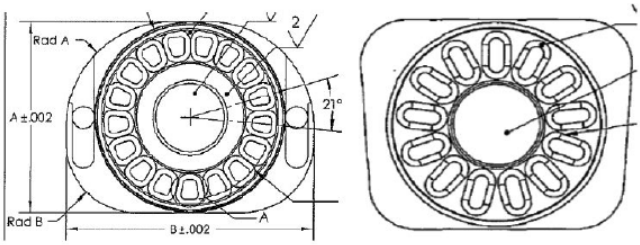


Figure 2 in Synthes's Patent Application

that have plates with internal trapezoidal and elliptical slots, not peripheral grooves.



Spinal Kinetics's Accused Devices

Subsequently, Synthes sued Spinal Kinetics for patent infringement.

Trial and Appeal

At trial, a jury found that Synthes's disclosure of an implant that included plates having only *peripheral grooves* did not provide the required written description support for an implant that includes plates having a plurality of *openings*, and thus, the patent was invalid. In response to Synthes's motion for judgment as a matter of law, the trial judge affirmed the jury verdict. And Synthes appealed.

On appeal, the Federal Circuit affirmed the jury's verdict.[4] Whether a patent satisfies the written description requirement is a question of fact, so the Federal Circuit examined whether there was substantial evidence to support the jury's verdict that the claims were invalid for lack of written description. The Federal Circuit considered Spinal Kinetics's expert testimony that the specification did not expressly disclose any *openings* other than peripheral grooves, and that there were biomechanical property differences and structural differences between peripheral grooves and interior slots.[5] The Federal Circuit also considered Spinal Kinetics's research and development manager's testimony that Spinal Kinetics rejected a prototype that included the disclosed peripheral grooves and that extensive resources were required to go from the prototypes having peripheral grooves to the commercial product having internal slots.

After considering this evidence, the Federal Circuit concluded that there was substantial evidence to support the jury's verdict that a person of ordinary skill in the art would not have understood that the disclosure of peripheral grooves would also disclose any and all openings on the plates.[6] The Federal Circuit noted that, although the mechanical field has been labeled ''fairly predictable,'' not all mechanical inventions are so predictable that disclosure of a single species supports a genus.[7]

What should patent prosecutors consider when amending medical device patent claims to cover a genus when only one species is disclosed?

The *Synthes USA* decision highlights important issues for a patent prosecutor to consider when broadening medical device claims to cover a genus and, perhaps, a competitor's product. First, the patent prosecutor should review the specification and identify the specific examples expressly disclosed. For example, in *Synthes USA*, the patent application expressly disclosed one example of openings—peripheral grooves.

Next, the patent prosecutor should evaluate the scope of potential genuses. Ideally, the claimed genus will encompass as many expressly disclosed examples as possible, leaving little doubt that the broadened genus is supported by the specification. But sometimes, as was the case in *Synthes USA*, the patent application expressly discloses only one example, introducing complexity and a degree of uncertainty to the analysis. When this is the situation, the patent prosecutor should choose a genus that is broad enough to cover the competitor's product, but not too broad that a person of ordinary skill in the art would not understand the genus to be disclosed by the single expressly disclosed example. Again, for example, in *Synthes USA*, the patent broadly claimed a plate having openings, but the patent application disclosed a plate having only peripheral grooves. But perhaps, instead of amending the *Synthes USA* patent claims to simply recite openings, the claims could have been amended to recite a narrower subgenus of openings that included both peripheral grooves, which were disclosed in the patent application, and internal slots, which were incorporated into the competitor's products. For example, the claims could have been amended to recite that the plates had a surface offset from the peripheral edge of the plate—a genus broader than the disclosed peripheral grooves, but potentially not as broad as the claimed openings. Alternatively, the claims might have been amended to simply recite that a fiber that passes through the plate is offset from the plate's peripheral surface. The narrower the claimed genus the more likely the disclosure of the single species will be deemed to adequately support the claimed genus.

And a patent prosecutor should consider whether there are any significant biomechanical differences between the disclosed specific example and other species covered by the claimed genus. Finding that there was substantial evidence to support the jury's verdict of a lack of written description support, the Federal Circuit in *Synthes USA* examined Spinal Kinetics's expert testimony that there were biomechanical differences between the disclosed peripheral grooves and internal slots. If significant biomechanical differences exist, the patent prosecutor should consider an alternative genus in which the biomechanical differences between the

[4] *Id.* at 2.
[5] *Id.* at 14.
[6] *Id.* at 16.
[7] *Id.* at 19.

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disclosed specific example and undisclosed species are minimized.

The *Synthes USA* decision also demonstrates the importance of identifying multiple examples when drafting a patent application. In *Synthes USA*, the Federal Circuit emphasized that the patent application disclosed a single example—a plate having only peripheral grooves. The decision in *Synthes USA* might have been different if the patent application had disclosed multiple exemplary passages for the fibers to pass through the plate. For example, the patent application might have disclosed different peripheral groove configurations that were deeper or had different shapes, or the patent application might have even disclosed internal holes like the competitor's products. Notably though, listing multiple examples must be weighed against patent examiners' tendencies to conclude that all identified alternatives are obvious when one alternative is known in the art.

Whether drafting a new patent application or amending the claims of an existing patent application for a medical device to cover a broader genus, the *Synthes USA* decision reveals the different issues a patent practitioner should consider.

At trial, what evidence can an accused infringer use to establish a lack of written description for a genus?

The *Synthes USA* decision provides many examples of what an accused infringer can use at trial to show a genus is unsupported by the disclosure of a single example in a patent application. First, an accused infringer should show that the specification does not expressly disclose alternative examples, including the features embodied in the accused device.[8] Second, the accused infringer should identify biomechanical differences and structural differences between the disclosed species and undisclosed species covered by the genus.[9] Third, the accused infringer can show that industry members, including itself, moved away from the disclosed species towards an undisclosed species, and that such transition was resource intensive.[10] And finally, the accused infringer should demonstrate that the differences between the disclosed species and the undisclosed species covered by the claimed genus are related to important design considerations, for example, wear considerations.

In sum, the *Synthes USA* decision is a reminder that, when broadening medical device patent claims to cover a genus when only one or a limited number of species is disclosed, written description support for the broad genus should be evaluated. And although medical devices are typically mechanical in nature, the disclosure of a single example may not support a genus on the basis of being predictable.

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[8] *See id.* at 14.
[9] *See id.*
[10] *See id.* at 14-15.