

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FUSION ORTHOPEDICS, LLC,
Petitioner,

v.

EXTREMITY MEDICAL, LLC,
Patent Owner.

Case IPR2023-00894
U.S. Patent No. 11,298,166

**PATENT OWNER'S REPLY IN SUPPORT OF ITS REVISED
CONTINGENT MOTION TO AMEND**

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Patent Owner's Updated List of Exhibits

Exhibit No.	Exhibit Description
2001	Declaration of Michael J. Zinna in Support of Patent Owner's Motion For Pro Hac Vice Admission Pursuant To 37 C.F.R. § 42.10(c)
2002	Complaint from Parallel District Court Case: <i>Extremity Medical, LLC vs. Fusion Orthopedics, LLC</i> , Case No. 2:22-cv-00723-PHX-GMS (D. Ariz.) (ECF 1)
2003	Case Management Order from Parallel District Court Case (ECF 49)
2004	July 10, 2023 Scheduling Order from Parallel District Court Case (ECF 74)
2005	July 28, 2023 Scheduling Order from Parallel District Court Case (ECF 76)
2006	Patent Owner's infringement contentions served in the Parallel District Court Case
2007	Petitioner's invalidity contentions served in the Parallel District Court Case and Exhibits A2 and A6 thereto
2008	<i>Markman</i> Order issued by the Court in the Parallel District Court Case (ECF 73)
2009	Printout from www.docketnavigator.com
2010	July 15, 2021 "List of References cited by applicant and considered by examiner" for U.S. Patent Application No. 17/323,923
2011	Selected Pages of the Transcript from the June 7, 2023 Deposition of Leonel Dominguez
2012	Declaration of Dr. Eric H. Ledet
2013	Transcript from the January 18, 2024 Deposition of Leonel

Exhibit No.	Exhibit Description
	Dominguez
2014	U.S. Patent Publication No. 2009/0240252 (“Chang”)
2015	Claim Construction Order issued in <i>Extremity Medical, LLC vs. Fusion Orthopedics, LLC</i> , Case No. 2:22-cv-00723-PHX-GMS (D. Ariz.)
2016	Transcript from the June 7, 2023 Deposition of Leonel Dominguez
2017	U.S. Patent No. 10,357,299
2018	Printout from the website https://www.machinistguides.com/counterbores-all-about/
2019	Reserved
2020	Prosecution History for U.S. Patent Application No. 17/323,923
2021	Prosecution History for U.S. Patent Application No. 12/658,680
2022	Transcript from the June 6, 2024 Deposition of Leonel Dominguez
2023	Second Declaration of Dr. Eric H. Ledet
2024	U.S. Patent No. 5,057,103
2025	U.S. Patent No. 5,139,499
2026	U.S. Patent No. 7,967,851
2027	U.S. Patent No. 8,221,478
2028	Enlarged image from paragraph 75 of Mr. Dominguez’s Declaration (Ex. 1002)
2029	Enlarged image from paragraph 57 of Mr. Dominguez’s Declaration (Ex. 1002)

Exhibit No.	Exhibit Description
2030	Marked up image of Figure 18 of U.S. Patent No. 11,298,166
2031	Image of Figure 25C from U.S. Patent No. 10,357,299 marked by Mr. Dominguez
2032	U.S. Patent No. 7,901,459
2033	U.S. Patent No. 8,105,327
2034	U.S. Patent No. 9,521,999
2035	U.S. Patent Application Publication No. 2004/0106950
2036	U.S. Patent Application Publication No. 2009/0192546
2037	Third Declaration of Dr. Eric H. Ledet
2038	Transcript from August 14, 2024 Deposition of Leonel Dominguez
2039	Screenshots from models related to Zhang's figure
2040	Screenshots from model related to Gooch's figure

I. INTRODUCTION

Petitioner has failed to meet its burden to show by a preponderance of the evidence that substitute claims 16-30 are unpatentable. On the contrary, the proposed substitute claims are patentable over all of the references cited in the Petition (Cognet, Brumfield, and Ferrante) (the “Original Prior Art”) and those cited for the first time in Petitioner’s Opposition (Mazur, Zhang, Melkent, and Gooch) (the “New Prior Art”). First, Mazur does not anticipate or render obvious any substitute claim because it does not disclose or suggest several limitations. Second, regarding Petitioner’s four grounds that rely on prior art combinations, Petitioner has failed to show that the references disclose or suggest all of the limitations and/or that a person of ordinary skill in the art (“POSA”) would have been motivated to combine the references with a reasonable expectation of success.

II. PETITIONER HAS FAILED TO MEET ITS BURDEN OF SHOWING THAT SUBSTITUTE CLAIMS 16-30 ARE UNPATENTABLE

A. Petitioner Has Not Shown That Mazur Anticipates Substitute Claims 16-30

1. Mazur’s Separate Embodiments Must Be Impermissibly Combined to Meet Limitations of Claims 16-30

Petitioner relies largely on Mazur’s Figures 16A-16E to show anticipation of claims 16-30, but seemingly asks the Board to envision modifications to that embodiment based on a *different* embodiment shown in Figure 7. See Opp., pp. 4, 7, 8. This is improper because Petitioner has not shown by a preponderance of the

evidence that Mazur “is sufficiently clear in disclosing the combinability of those elements such that a skilled artisan would at once envisage the claimed combination.” *The Chamberlain Grp., Inc. v. Techtronic Indus. Co.*, 935 F.3d 1341, 1350 (Fed. Cir. 2019) (internal quotations omitted).

Claims 16 and 27 require a *straight* third member: (1) “a third member comprising a third elongated body extending along a *straight* line from a first end to a second end along a third longitudinal axis” and (2) “the second bore *axis* is *substantially perpendicular* to the third longitudinal *axis*.” The embodiment in Figures 16A-16E indisputably has a curved body, and therefore, does not meet these limitations. Ex. 2037, ¶ 14.

Petitioner tries to patch this flaw by relying on Mazur’s statement in paragraph [0094] that a straight hub “may be used with the above combinations.” Opp., p. 5. But “above combinations” refers to combinations of components discussed earlier in paragraph [0094] with respect “[d]evice 300,” which is the embodiment in Figures 11A-11D and is different from that in Figures 16A-16E. See Ex. 1056, ¶¶ [0046], [0055]; Ex. 2037, ¶¶ 15-16. Importantly, the embodiment in *Figures 16A-16E* is not introduced until later in the specification. See Ex. 1056, ¶ [0110]; Ex. 2037, ¶ 16. When asked whether “device 300” is the embodiment in Figures 11A-11D and what “above combinations” refers to, Petitioner’s expert was unable or unwilling to answer. Ex. 2038, 29:7-11, 29:21-30:1, 31:7-32:24.

Mazur's other statements also fail to show that a POSA would "at once envisage the claimed combination." *Chamberlain*, 935 F.3d 1350; Ex. 2037, ¶¶ 17-18.

2. Petitioner Has Not Shown That Mazur Discloses the New Limitations of Claims 16-30

Claims 16 and 27 now require an aperture on *two* exterior surfaces of the third member, and claims 20 and 28 further limit claims 16 and 27, respectively, by requiring that the aperture be on a top exterior surface and a side exterior surface. Mazur, at best, discloses an aperture that is on a first exterior surface (*e.g.*, top) of its hub; but it does not disclose an aperture on both a first exterior surface *and* a second exterior surface (*e.g.*, side) of its hub. Ex. 2037, ¶¶ 20-24. In particular, Petitioner has failed to show that Mazur's "sidewall notch" is a part of the aperture, and thus, that Mazur anticipates claims 16-30. *Id.*

In the '166 Patent, the purpose and geometry of the claimed "aperture" is tied to the claimed "bore." Ex. 2037, ¶ 21. The purpose of the claimed aperture is to provide an opening for a first member (*e.g.*, a screw) to enter the third member (*e.g.*, a nail), and a surface of the bore for the first member to abut and rest on. *See, e.g.*, Ex. 1001, Figs. 9, 11, 17, 18; *id.* at claim 3; Ex. 2037, ¶ 21. And because the first member must fit through the aperture if it is to fit through the bore, the geometry of the aperture is dependent on that of the bore. Ex. 2037, ¶ 21. Mazur's figures show that the "open end" on the top surface of Mazur's hub serves this purpose. *Id.* at ¶ 22. Indeed, the screw abuts and rests on the top surface of the

hub, and does not engage with the notch. *Id.* The notch, in fact, serves an entirely different purpose: to allow the hub to engage with an insertion tool. Ex. 1056, ¶¶ [0072]-[0073], Figs. 4, 6; Ex. 1054, ¶¶ 16-18; Ex. 2038, 34:23-35:16; Ex. 2037, ¶ 22. Moreover, the geometry of Mazur’s notch is unrelated to the bore. Ex. 2037, ¶ 23. Petitioner has failed to address these facts, and therefore, has not shown that a POSA would consider the notch to be part of the aperture. *Id.*

3. Mazur Does Not Disclose “the first bore axis and second bore axis intersect outside the third member” of Claim 24

Substitute claim 24 recites the limitation “the first bore axis and the second bore axis intersect outside the third member.” Mazur does not disclose this. Ex. 2037, ¶¶ 25-28. Petitioner relies on an annotation of Figure 16A to show merely one possible instance in which the two axes intersect, but this mistakenly assumes that the first and second bore axes both lie on the same plane. *Id.* In fact, the axes may lie on any of an infinite number of planes, and may never intersect. *Id.*

Figure 16A alone does not (and cannot) show that the four apertures are necessarily oriented in a manner such that the two axes are on the same plane and intersect. *Id.* When Petitioner’s expert was asked about this issue in his deposition, he was unable or unwilling to answer any of the questions. Ex. 2038, 57:16-60:16. Thus, Petitioner has not shown that Mazur anticipates claim 24. *Id.*

B. Petitioner Has Not Shown That Mazur Renders Obvious Substitute Claims 16-30

“An obviousness determination requires finding that a person of ordinary

skill in the art would have been motivated to combine or modify the teachings in the prior art and would have had a reasonable expectation of success in doing so.” *Pfizer Inc. v. Sanofi Pasteur Inc.*, 94 F.4th 1341, 1347 (Fed. Cir. 2024). As to certain limitations of claims 16-30 that Mazur does not disclose as discussed above, *see supra* Section II.A.2. and II.A.3, Petitioner does not provide any obviousness analysis. Thus, if the Board agrees that Mazur does not disclose one or more of those limitations, then Petitioner has necessarily failed to show obviousness with respect to the respective claims that recite those limitations too.

Petitioner has also failed to show that a POSA would have been motivated to modify Mazur with a reasonable expectation of success, to arrive at the inventions of claims 16-30. Ex. 2037, ¶¶ 31-37. In particular, Petitioner says nothing about the differences between the straight hub embodiment (shown in Figures 1-9) and the curved hub embodiment (shown in Figures 16A-16E). The two embodiments have very different designs and different applications. *Id.* at ¶¶ 32-34. Thus, Petitioner should have provided, at the very least: (1) a comparison of the design and application of the embodiment in Figures 1-9 with those of the embodiment in Figures 16A-16E and (2) a comparison of the reasons that a POSA would want to use a straight hub with the reasons that a POSA would want to use a curved hub. Petitioner does neither of these things. *See, e.g.*, Ex. 2038, 52:11-15, 52:18-53:2, 56:22-57:12. Instead, it merely makes a conclusory statement that Mazur

“suggest[s] to [a POSA] to modify the embodiment in Figure 16A to have a straight hub.” Opp., p. 11. This is not enough. Ex. 2037, ¶¶ 29-30.

Mazur discloses only that a straight hub “may be used” for the embodiment in Figures 11A-11D. *Id.* at ¶ 31. This does not provide the requisite motivation because, as an initial matter, it says nothing about the embodiment in Figures 16A-16E, and in any event, suggests a mere possibility of a making modification to the embodiment in Figures 11A-11D without providing any reason for a POSA to make it. *Id.* As to a reasonable expectation of success, Petitioner has failed to consider that the straight hub in Figures 1-9 is dimensioned and configured for the proximal ulna, while the curved hub in Figures 16A-16E is dimensioned and configured for the distal radius, thereby failing to show that a POSA would consider a straight hub to be an appropriate substitute for the curved hub in Figures 16A-16E. *Id.* at ¶¶ 32-34. When asked whether the embodiment in Figure 7 could be used in a radial bone and about the purpose of the curvature in embodiment in Figures 16A-16E, Petitioner’s expert was unable or unwilling to answer. Ex. 2038, 22:6-24:6, 25:3-26:18. Even if a straight hub could somehow be used in place of a curved hub in the distal radius, due to additional modifications the hub would require, it could not possibly meet the new limitations of claims 16-30. *Id.* at ¶ 35.

C. Petitioner Has Not Shown That the Original Prior Art Discloses or Suggests the Original Limitations of Claims 16-30

Each one of Petitioner’s obviousness ground that is based on a combination

of prior art relies on: (1) Cognet’s disclosures for the original limitations contained in claims 16-22, 24, 27, and 28; (2) Cognet’s disclosures in combination with either Brumfield or Ferrante’s disclosures for the original limitations contained in claims 19, 23, 25, 26, 29, and 30 (including obviousness analysis); *and* (3) the disclosures from the New Prior Art for the new limitations of claims 16-30.

With respect to (1) and (2) (*i.e.*, the original limitations), Petitioner either is silent as to how Cognet discloses those limitations, or merely cites its Petition and Reply papers in arguing that Cognet, Brumfield, and Ferrante disclose or suggest the limitations “as detailed previously.” Opp., pp. 17, 23; *see also id.* at 18, 19, 23-24, 25. While Petitioner does not expressly state that it intends to incorporate its prior arguments into its Opposition here, that is what Petitioner *de facto* has done. Without such arguments, Petitioner is left with only scant, conclusory statements.

Incorporation by reference is improper. *See* 37 C.F.R. § 42.6(a)(3). Thus, Patent Owner requests the Board to disregard arguments made in other documents and improperly incorporated here. Patent Owner’s request is timely—this Reply is being filed a mere two weeks after Petitioner’s Opposition. Patent Owner could have moved to strike, but raises the issue here to avoid administrative burden.

The Federal Circuit has repeatedly blessed the Board’s disregarding arguments that violate 37 C.F.R. § 42.6(a)(3) as a proper exercise of the Board’s discretion. *See, e.g., Parus Holdings, Inc. v. Google LLC*, 70 F.4th 1365, 1370-73

(Fed. Cir. 2023); *3M Co. v. Evergreen Adhesives Inc.*, 860 Fed. Appx. 724, 728 (Fed. Cir. 2021); *Gen. Access Sols., Ltd. v. Sprint Spectrum LP*, 811 Fed. Appx. 654, 657-59 (Fed. Cir. 2020); *Bos. Scientific Neuromodulation Corp. v. Nevro Corp.*, 813 Fed. Appx. 572, 582-83 (Fed. Cir. 2020). Here, there is good cause to disregard the improper arguments, and doing so would serve the interests of justice. Petitioner's violation is highly prejudicial to Patent Owner. Petitioner has effectively expanded the twenty-five page limit for its Opposition by directing the Board to pages and pages of additional argument from other papers. Meanwhile, Patent Owner is limited in this Reply to twelve pages, leaving it unable to effectively respond to each of Petitioner's improperly incorporated arguments. If the Board disregards the incorporated arguments, then all of Petitioner's grounds of unpatentability except for those based on Mazur fail for the reason that Petitioner has not addressed in its Opposition how certain limitations of each of claims 16-30 is disclosed in, or suggested by, the Original Prior Art, or provided any motivation to combine the Original Prior Art references with one another.

Patent Owner feels strongly that the Board can and should disregard Petitioner's improperly-incorporated arguments, but if it considers them, it should also consider Patent Owner's prior arguments and evidence cited therewith that set forth in detail: (1) why Cognet does not disclose or suggest the limitations of claims 1, 3, 4, 7, 9, and 12, which correspond to substitute claims 16, 18, 19, 22,

24, and 27, respectively, *see* Patent Owner’s Response (Paper 22, “POR”), pp. 20-39; Patent Owner’s Sur-Reply (Paper 43, “Sur-Reply”), pp. 8-17 and (2) why the combinations of Cognet and either Brumfield or Ferrante do not render obvious claims 4, 8, 10, 11, 14, and 15, which correspond to substitute claims 19, 23, 25, 26, 29, and 30, respectively, *see* POR, pp. 39-50; Sur-Reply, pp. 17-20.

D. Petitioner Has Not Shown That Cognet and Zhang Render Obvious Claims 16-30

Zhang does not disclose the new limitations of claims 16-30 that require an aperture to be on a first/top exterior surface *and* a second/side exterior surface of the third member. Ex. 2037, ¶ 40. Zhang’s singular figure has very limited detail, and does not clearly show whether and where on an exterior surface of the intramedullary nail 1 an aperture is formed. *Id.* at ¶ 41. This ambiguity alone is enough to prevent Petitioner from meeting its burden regarding Zhang.

Faced with the fact that Zhang’s figure does not show what Petitioner contends, Petitioner concocted a 3D model (the “Interpreted Model”), contending that the aperture is “best seen” in the Interpreted Model. Opp., p. 15 (emphasis added). But the Interpreted Model is irrelevant for at least three reasons. *First*, the Interpreted Model literally adds an entire dimension to Zhang’s figure, which in turn adds a significant amount of speculative detail that Zhang’s two-dimensional figure, by definition, cannot provide. *Second*, Zhang’s figure has an extremely low resolution relative to that of the Interpreted Model. This is compounded by the fact

the Zhang's figure shows the entire nail, and does not focus on the miniscule head portion of Zhang's nail on which Petitioner contends an aperture is formed. *Third*, Zhang's figure shows only a cross-sectional view, which alone is not enough to create an accurate 3D model. Accordingly, to create the Interpreted Model, Petitioner's expert has necessarily made numerous assumptions. But he never detailed what those assumptions were, much less why or how they were supported. Ex. 2038, 74:6-75:14, 76:2-79:19.

Assuming *arguendo* that Zhang's figure is considered to disclose an aperture, Zhang's nail assembly still would not meet the new limitations of claims 16-30 because such an aperture would be formed entirely on the singular surface of the "nail tail region." Ex. 1058, 4:6, figure; Ex. 2038, 81:7-12; Ex. 2037, ¶ 42. As seen in Zhang's figure, and even in the (impermissible) Interpreted Model, this region is bulbous (*e.g.*, spherical), and thus, has a single surface. Ex. 2037, ¶ 42.

Even if, however, Zhang's "nail tail region" is considered to have multiple surfaces, Petitioner still has not shown that a POSA would consider Zhang's "groove 4" to be a part of the aperture for the reasons discussed above with respect to Mazur's notch. *See supra* Section II.A.2; Ex. 2037, ¶ 43. Like Mazur's notch, the purpose of Zhang's groove is to allow the nail to engage with an insertion tool (*i.e.*, "a screwdriver"). Ex. 1058, 4:32-36; Ex. 1054, ¶¶ 16-18; Ex. 2037, ¶ 43. Thus, each unpatentability ground that relies on Zhang fails in its entirety.

E. Petitioner Has Not Shown That It Would Be Obvious to Modify Cognet Based on Melkent or Gooch’s Disclosures (Claims 16-30)

Petitioner asserts that Melkent and Gooch show that “it is an obvious matter of design choice *depending upon context*” to choose a screw tunnel angle that causes the tunnel aperture to be on a top surface, a side surface, or on both simultaneously, and that “such design considerations are bone-agnostic.” Opp., pp. 21 (emphasis added), 23; *see also id.* at 22. Not so, although Petitioner is right that “context” matters. Ex. 2037, ¶¶ 48-49. In fact, there is a strong motivation *not* to modify Cognet’s nail by changing the screw tunnel angle from “A1” to “A2” as Petitioner contends. *Id.* Specifically, Petitioner does not explain how one could make this modification while ensuring that the screw does not partially or completely protrude through the articular surface of the bone depicted in Cognet’s Figure 1. *Id.* In any event, even if the screw did not necessarily protrude from the bone, it would certainly come dangerously close, creating a risk of great harm to the patient if the screw were inadvertently drilled through the articular surface—a risk no competent surgeon would want to take without good reason. *Id.* at 50. Petitioner has failed to even acknowledge this risk, much less provide a reason for a surgeon to take this risk, *id.*, as Petitioner’s expert himself had to admit in his deposition. Ex. 2038, 83:18-87:14. This strongly undercuts a reasonable expectation of success. Thus, each unpatentability ground that relies on a combination of Cognet and either Melkent or Gooch fails in its entirety.

F. Petitioner Has Not Shown That Cognet and Gooch Render Obvious Claims 16-30

Gooch does not disclose the new limitations of claims 16-30 that require an aperture to be on a first/top exterior surface *and* a second/side exterior surface of the third member. Gooch's Figure 20 is drawn in such a way that a POSA would have no certainty as to whether the figure shows that the aperture is on *both the top and side* exterior surfaces, *or* whether it shows that the aperture is on *only the side* exterior surface, of the bone anchor. Ex. 2037, ¶¶ 54-55. Figure 20 may reflect a perspective of the assembly such that the screw is inserted into the anchor through an aperture that lies entirely on a side surface, and the screw partially *obscures* the top surface, rather than being *inserted into* the top surface, of the anchor. Ex. 2037, ¶¶ 54-55. Petitioner's expert did not dispute this possibility in his deposition. Ex. 2038, 100:16-20, 102:3-14. Because the parties and their experts' competing interpretations of Figure 20 are arguably "equally plausible," Petitioner has failed to show by a preponderance of the evidence that Gooch discloses or suggests the new limitations. *See, e.g., Samsung*, 2024 WL 3451828, at *2-4. Thus, each unpatentability ground that relies on Gooch fails in its entirety.

III. CONCLUSION

For the foregoing reasons, if the Board finds one or more of original claims 1-15 unpatentable, Patent Owner respectfully requests that the Board grant its Revised Contingent Motion to Amend.

Respectfully submitted,

Dated: August 21, 2024

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e)(4), I hereby certify that on August 21, 2024, I caused a copy of the foregoing document to be served via electronic mail to the following addresses for counsel for Petitioner as indicated in Petitioner's Revised Mandatory Notices (Paper 18):

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