

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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REGENERON PHARMACEUTICALS, INC.,  
Petitioner,

v.

NOVARTIS PHARMA AG,  
NOVARTIS TECHNOLOGY LLC,  
NOVARTIS PHARMACEUTICALS CORPORATION,  
Patent Owner.

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IPR2020-01317 (Patent 9,220,631 B2)  
IPR2020-01318 (Patent 9,220,631 B2)

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Before ERICA A. FRANKLIN, ROBERT L. KINDER, and  
KRISTI L. R. SAWERT, *Administrative Patent Judges*.

KINDER, *Administrative Patent Judge*.

ORDER  
Conduct of the Proceeding  
*37 C.F.R. §§ 42.5, 42.20*

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## INTRODUCTION

On October 29, 2020, a conference call was held among counsel for the parties, including Anish Desai for Regeneron Pharmaceuticals, Inc. (“Petitioner”) and Elizabeth Holland for Novartis Pharma, AG, et al. (“Patent Owner”), and Judges Erica A. Franklin, Robert L. Kinder, and Kristi L. R. Sawert. A transcript of the call is entered as Exhibit 1065 in each proceeding.

The purpose of the call was to discuss Petitioner’s request to file a reply to address Patent Owner’s arguments in the Preliminary Responses (a) that we should exercise our discretion under 35 U.S.C. § 314(a) to deny institution, and (b) that we should exercise our discretion under 35 U.S.C. § 325(d) to deny institution. *See* Ex. 3001 (email requesting teleconference to discuss these issues).

For the reasons that follow, Petitioner’s request is granted.

## DISCUSSION

Patent Owner argues in its Preliminary Responses that we should exercise our discretion to deny institution under § 314(a), providing an analysis discussing the factors identified in *Apple Inc. v. Fintiv, Inc.*, IPR2020–00019, Paper 11 (Mar. 20, 2020) (designated precedential May 5, 2020) (“*Fintiv*”). *See* IPR2020-01317, Paper 10, 5–14; IPR2020-01318, Paper 10, 4–13.<sup>1</sup> Patent Owner also contends that we should exercise our discretion to deny institution under § 325(d). *Id.* at 15–17. Petitioner did not address either discretionary issue in its Petitions. Below, we first address the issues pertinent to § 314(a) and then § 325(d).

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<sup>1</sup> Later citations are to IPR2020-01317 only; the briefing in each proceeding is similar in scope.

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35 U.S.C. § 314(a)

During the conference call, Petitioner asked for briefing to address Patent Owner's *Fintiv* arguments. Petitioner argued that it did not include a detailed *Fintiv* analysis in the Petition because Petitioner "filed these IPRs five days before the ITC case was instituted," and "if 314 precludes PTAB review, then the PTAB review is effectively foreclosed." Ex. 1065, 7:1–10.

Petitioner also believed it necessary to correct timing issues raised in the Preliminary Responses as to when the ITC proceeding will conclude. *Id.* at 8:12–25. Petitioner noted that, although "the ALJ initial determination" is set for July 29, 2021, "[t]he Commission's decision is due November 29, 2021," with the "60-day precedential review period" set for January 29, 2022. *Id.* at 8:22–9:13.

Petitioner contended that Patent Owner's § 314 briefing largely relies upon a Board decision that recently issued in October 2020, whereas the Petitions were filed in July 2020. *Id.* at 7:15–25. More specifically, Petitioner noted that "Novartis hinged its argument to the Board's decision in IPR2020-00772 involving *FitBit*," yet, "that decision issued on October 19, 2020," so Petitioner "could not have addressed and distinguished that specific case" in its Petition. *Id.* at 7:15–25.

Petitioner also argued that, even though the *Fintiv* decision was made precedential in May 2020, shortly before the Petition was filed in July, that does not mean "Regeneron should have predicted Novartis's argument and addressed it in the petition." *Id.* at 11:10–13. Petitioner noted that at least one other Board decision "rejected a § 314 argument based on an ITC case, noting that the ITC does not have authority to invalidate a patent," and the ITC also has different evidentiary standards. *Id.* at 11:14–20.

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Finally, Petitioner argued that requiring petitioners to address discretionary factors in a petition is “contrary to the statutory requirements” and nothing in the Board’s regulations or “Trial Practice Guide . . . make it a requirement for a petitioner to address 314 and 325 arguments in the petition.” *Id.* at 12:11–23.

At the outset, even before highlighting Patent Owner’s opposition to additional briefing, we reject Petitioner’s attempt to excuse itself from addressing §§ 314(a) and 325(d) by contending that nothing in the statutes, the Board’s regulations, or the 2019 Consolidated Trial Practice Guide (“Practice Guide”) require petitioners to address §§ 314(a) and 325(d) discretionary factors in their petitions.

Whether we, on behalf of the Director, institute review is discretionary. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (“[T]he agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion.”); 37 C.F.R. § 42.4(a); *see also Deeper, UAB v. Vexilar, Inc.*, Case IPR2018-01310 (PTAB Jan. 24, 2019) (Paper 7) (informative). Whether we allow a petitioner to file a reply brief to address issues raised in a patent owner preliminary response is predicated upon petitioner showing “good cause.” 37 C.F.R. § 42.108(c) (2019); *see also Xactware Sols., Inc. v. Pictometry Int’l Corp.*, IPR2016-00593, Paper 11, 3 (PTAB Jul. 1, 2016) (determining mere alleged misstatements in the preliminary response do not give rise to good cause). The Practice Guide explains that “the Board does not expect that such a reply will be granted in many cases due to the short time period the Board has to reach a decision on institution.” Practice Guide, 52. Good cause to file a reply brief may not exist for issues that were reasonably known and could have been addressed

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in a petition, but were not. *ARM, Ltd. v. Godo Kaisha IP Bridge 1*, IPR2016-00825, Paper 11 (PTAB Sep. 29, 2016) (denying a petitioner’s request to file a reply, explaining that “Petitioner had notice and opportunity to raise this issue” as demonstrated by the fact that the petition “makes clear that Petitioner at least contemplated the possibility” that the patent owner would rely on foreign priority).

Petitioners are expected to address all material issues relevant to institution of trial in their petitions, including discretionary factors that could be case dispositive. In determining whether or not to exercise our discretion to institute review, the Board considers “at a minimum whether or not a party has satisfied the relevant statutory institution standard.” Practice Guide, 55. The Practice Guide further elaborates, “[t]he Board *will* also take into account whether various considerations . . . warrant the exercise of the Director’s discretion to decline to institute review.” *Id.* (citing 35 U.S.C. §§ 314(a), 324(a)) (emphasis added). These “various considerations” include discretionary factors related to §§ 314(a) and 325(d). Ultimately, as with many arguments, a petitioner may decide whether to address discretionary factors in a petition. However, when it would have been reasonably foreseeable that such factors may be at issue, choosing not to address those factors in a petition does not later entitle a petitioner to further briefing. Indeed, that choice may result in the petition being denied based upon our consideration of the discretionary factors without input from the petitioner.

Accordingly, a good cause showing for requesting a reply brief to address §§ 314(a) and 325(d) discretionary factors is required. To show good cause, the moving party must explain why patent owner’s discretionary

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