

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

PAR PHARMACEUTICAL, INC.,  
Petitioner,

v.

NOVARTIS AG,  
Patent Owner.

---

Case IPR2016-01479  
Patent 9,006,224 B2

---

Before LORA M. GREEN, CHRISTOPHER L. CRUMBLEY, and  
ROBERT A. POLLOCK, *Administrative Patent Judges*.

CRUMBLEY, *Administrative Patent Judge*.

DECISION  
Institution of *Inter Partes* Review  
35 U.S.C. § 314(a) and 37 C.F.R. § 42.108

## I. INTRODUCTION

Par Pharmaceutical, Inc. filed a Petition requesting an *inter partes* review of claims 1–3 of U.S. Patent No. 9,006,224 B2 (Ex. 1001, “the ’224 patent”). Paper 1 (“Pet.”). Novartis AG, the owner of the ’224 patent, filed a Preliminary Response to the Petition. Paper 7 (“Prelim. Resp.”).

Pursuant to 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless the information presented in the Petition and any Preliminary Response shows “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” Taking into account the information presented, we conclude that the record establishes a reasonable likelihood that Par will prevail in proving that claims 1–3 of the ’224 patent are unpatentable. Accordingly, we institute an *inter partes* review of these claims.

### A. Related Matters

We are informed that the ’224 patent has been asserted in two patent infringement actions in the United States District Court for the District of Delaware: *Novartis Pharm. Corp. et al. v. Roxane Labs., Inc.*, No. 15-474-RGA, and *Novartis Pharm. Corp. et al. v. Par Pharm., Inc.*, No. 15-475-RGA. Pet. 3; Paper 4, 2–3. Claims 1 and 2 of the ’224 patent were challenged by a different petitioner in IPR2016-01461; the Board denied institution of trial in that proceeding.

### B. The ’224 Patent

The ’224 patent, titled “Neuroendocrine Tumor Treatment,” issued April 14, 2015, from U.S. Patent Application No. 12/094,173. Ex. 1001,

(54), (45), (21). The patent describes treating neuroendocrine tumors using mTOR (mammalian target of rapamycin) inhibitors, including rapamycin and its derivatives. *Id.* at 1:2–5, 1:17–43. One specifically listed rapamycin derivative is 40-O-(2-hydroxyethyl)-rapamycin, also known as everolimus. *Id.* at 1:46–47; 11:50.

The '224 patent discloses that mTOR inhibitors have activity as immunosuppressants, and have also been found useful for the treatment of solid tumors, particularly advanced solid tumors, including pancreatic neuroendocrine tumors (PNETs). *Id.* at 2:35–67. PNETs are particularly lethal, having a 5-year patient survival rate of 55.3%; the '224 patent states that most are malignant at the time of diagnosis, and 60% or more present with liver metastases. *Id.* at 3:1–10. The '224 patent concludes that there is an unmet need for treatment of PNETs in patients whose disease has progressed following one or more courses of chemotherapy. *Id.* at 3:10–12.

The '224 patent describes a method of treatment using mTOR inhibitors, specifically with everolimus (“compound A”). *Id.* at 11:66–67. The patent proposes a clinical study in which patients with advanced PNETs are treated with 10 mg/day of everolimus after failure of cytotoxic chemotherapy. *Id.* at 26:56–60.

### *C. Illustrative Claim*

Of the challenged claims, claims 1 is independent and illustrative of the challenged claims:

1. A method for treating pancreatic neuroendocrine tumors, comprising administering to a human subject in need thereof a therapeutically effective amount of 40-O-(2-hydroxyethyl)-

rapamycin as a monotherapy and wherein the tumors are advanced tumors after failure of cytotoxic chemotherapy.

Ex. 1001, 26:66–27:4. Claim 2 specifies a unit dose of 10 mg/day, and claim 3 requires that the tumor be an islet cell tumor. *Id.* at 27:5–8.

*D. Asserted Grounds of Unpatentability*

Par challenges claims 1–3 of the '224 patent on the following grounds of unpatentability:

References	Basis <sup>1</sup>	Challenged Claims
Öberg 2004, <sup>2</sup> Boulay 2004, <sup>3</sup> and O'Donnell <sup>4</sup>	§ 103(a)	1–3
Öberg 2004, Boulay 2004, O'Donnell, and Tabernero <sup>5</sup>	§ 103(a)	2

---

<sup>1</sup> The relevant sections of the Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, took effect on March 16, 2013. Because the application from which the '224 patent issued was filed before that date, our citations to Title 35 are to its pre-AIA version.

<sup>2</sup> K. Öberg, *Treatment of neuroendocrine tumors of the gastrointestinal tract*, 27 ONCOLOGIA 57 (2004) (Ex. 1027).

<sup>3</sup> A. Boulay et al., *Antitumor efficacy of intermittent treatment schedules with the rapamycin derivative RAD001 correlates with Prolonged Inactivation of Ribosomal Protein S6 Kinase 1 in Peripheral Blood Mononuclear Cells*, 64 CANCER RES. 252 (2004) (Ex. 1005).

<sup>4</sup> A. O'Donnell et al., *A phase I study of the oral mTOR inhibitor RAD001 as a monotherapy to identify the optimal biologically effective dose using toxicity, pharmacokinetic (PK) and pharmacodynamics (PD) endpoints in patients with solid tumors*, 22 PROC. AM. SOC'Y OF CLINICAL ONCOLOGY 200(803ab) (2003) (Ex. 1029).

<sup>5</sup> J. Tabernero et al., *A phase I study with tumor molecular pharmacodynamics (MPD) evaluation of dose and schedule of the oral mTOR-inhibitor Everolimus (RAD001) in patients (pts) with advanced solid*

References	Basis <sup>1</sup>	Challenged Claims
Boulay 2004, O'Donnell, and Duran <sup>6</sup>	§ 103(a)	1–3
Boulay 2004, O'Donnell, Duran, and Tabernero	§ 103(a)	2

Par contends that Öberg 2004, Boulay 2004, and O'Donnell are prior art to the '224 patent under 35 U.S.C. § 102(b), whereas Duran and Tabernero are prior art under 35 U.S.C. § 102(a). Pet. 29–36. Novartis does not, at this stage of the proceeding, challenge the prior art status of any reference.

## II. ANALYSIS

### A. Claim Construction

In an *inter partes* review, we construe claims by applying the broadest reasonable interpretation in light of the specification. 37 C.F.R. § 42.100(b); *see also In re Cuozzo Speed Techs., LLC*, 136 S. Ct. 2131, 2144–46 (2016). Under the broadest reasonable interpretation standard, and absent any special definitions, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech. Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms or phrases

---

*tumors*, 23 J. CLINICAL ONCOLOGY 3007 (2005) (Ex. 1038).

<sup>6</sup> I. Duran et al., *A Phase II Trial of Temsirolimus in Metastatic Neuroendocrine Carcinomas (NECs)*, 23 SUPPLEMENT TO J. CLINICAL ONCOLOGY 3096 (2005) (Ex. 1011).

must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Par proffers constructions for four claim terms: “pancreatic neuroendocrine tumor,” “advanced tumor,” “unit dose,” and “islet cell tumor.” Pet. 18–21. Novartis addresses only the construction of “advanced tumor,” agreeing with Par that the term should be construed to refer to a tumor that is unresectable or metastatic. Prelim. Resp. 7–8. Novartis also asks that we state that “advanced” does not mean “after failure of cytotoxic chemotherapy,” though this is not a construction Par asserts. *Id.* at 9–11.

We agree with the parties that the broadest reasonable interpretation of “advanced” tumors, when viewed in light of the ’224 patent specification, is “metastatic or unresectable.” The specification refers to “patients with measurable advanced (metastatic or unrese[c]table) pancreatic neuroend[o]crine tumors,” suggesting that metastatic and unresectable tumors are subsets within advanced tumors. Ex. 1001, 26:57–58. We also note that the specification discusses the use of mTOR inhibitors for cancer chemotherapy “particularly for the treatment of solid tumors, especially of advanced solid tumors,” implying that not all solid tumors are “advanced.” *Id.* at 2:39–40. The parties’ agreed construction is also consistent with the evidence of ordinary and customary usage, such as the Cancer Glossary published by the American Cancer Society. Ex. 2005, 3 (“advanced cancer” definition).

We decline, at this stage of the proceeding, to include in our construction of “advanced” that it does not mean “after failure of cytotoxic chemotherapy,” as Novartis asks. Although we did make such a distinction

in our Decision denying institution in the related case IPR2016-01461, neither party has argued that the two terms are synonymous here. Though we do not consider that construction inconsistent with the one we adopt here, it is unnecessary to further complicate the construction in this case with language that is not relevant to the dispute between the parties. We, likewise, find no present need to construe the terms “unit dose,” and “islet cell tumor” as Par requests. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (stating that only claim terms which are in controversy need to be construed, and then only to the extent necessary to resolve the controversy).

For these reasons, we adopt the parties’ proposed construction for “advanced,” as meaning “metastatic or unresectable.”

*B. Obviousness over Öberg 2004, Boulay 2004, and O’Donnell*

Par contends that claims 1–3 are unpatentable under 35 U.S.C. § 103(a) as having been obvious over the combined teachings of Öberg 2004, Boulay 2004, and O’Donnell. Pet. 40–47. Par relies upon the Declaration of Mark J. Ratain, M.D. (Ex. 1003) to support its positions.

1. The Asserted Ground of Unpatentability

Öberg 2004 discusses methods of treatment for neuroendocrine tumors of the gastrointestinal tract and pancreas. Ex. 1027, 57. Öberg 2004 specifically discusses treatment of metastatic tumors, which Dr. Ratain testifies would fall within the skilled artisan’s understanding of advanced tumors. *Id.*; *see also* Ex. 1003 ¶ 101. Included in Öberg 2004 is the

following figure, which discloses an algorithm for the therapy of neuroendocrine tumors:

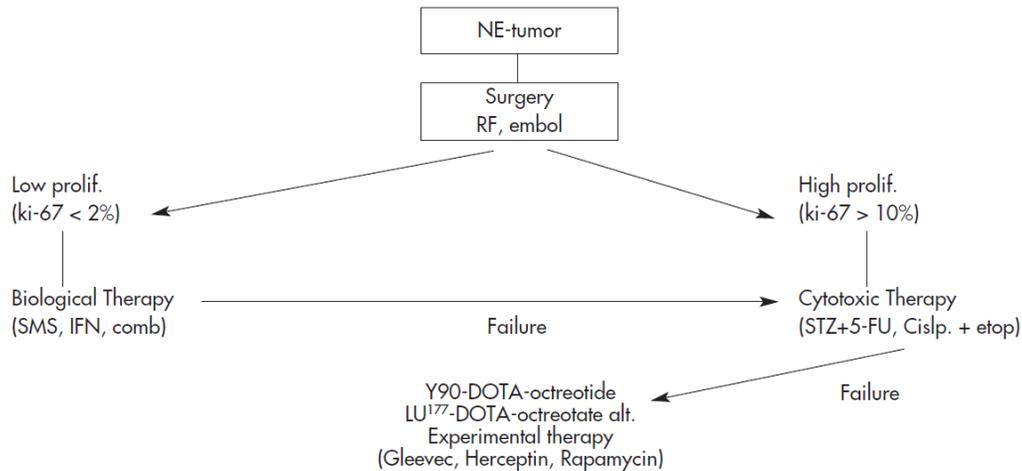


Fig. 1. Algorithm for the therapy of Neuroendocrine Tumours.

Figure 1 of Öberg 2004 discloses an algorithm for therapy of neuroendocrine (NE) tumors beginning with surgery, radiotherapy, or embolization as a first therapy, followed by (in the case of high-proliferative tumors) cytotoxic therapy and, after failure of cytotoxic therapy, experimental therapies such as rapamycin. Ex. 1027, 60. Öberg 2004 discusses rapamycin as an “interesting new compound” and suggests clinical trials with rapamycin as a single agent or in combination with cytotoxic chemotherapy. *Id.* According to Par, “Öberg 2004 only differs from claims 1 and 3 of the ’224 patent in that it does not explicitly disclose the use of everolimus,” and, as to claim 2, it does not include a specific reference to the 10 mg/day unit dose required by that claim. Pet. 31–32.

Boulay 2004 is a study of the efficacy of treatment with “rapamycin derivative RAD001” (everolimus) in the CA20948 synergistic rat pancreatic tumor model. Ex. 1005, 252. According to Dr. Ratain, CA20948 is a rat

tumor line used as a model for PNET in laboratory studies, and a person of ordinary skill in the art would have recognized that activity in the model would support clinical development to treat human PNETs. Ex. 1003 ¶ 112. Boulay 2004 also notes that everolimus was a rapamycin derivative being clinically developed at that time, for use in treatment of human cancer. Ex. 1005, 252. Boulay concludes that everolimus “displays significant antitumor activity in the synergistic CA20948 rat pancreatic tumor model,” and is “well tolerated, with no significant body weight loss or mortalities observed.” *Id.* at 253–54.

O’Donnell is the abstract of a poster presented at the 2003 Annual Meeting of the American Society of Clinical Oncology, describing a phase I study of everolimus. Ex. 1029, 200. The study was a dose escalation study, performed “to identify the optimal biologically effective dose based on toxicity” in patients having solid tumors. *Id.* O’Donnell concluded that dosages of 5, 10, 20, and 30 mg weekly were “well tolerated” with only mild degrees of side effects. *Id.*

Par contends that a person of ordinary skill in the art, seeking to treat patients with PNET after failure of cytotoxic chemotherapy, would have looked to Öberg 2004’s disclosure of rapamycin as an “interesting new compound,” and would have understood these teachings to extend to other rapamycin derivatives known to be mTOR inhibitors. Pet. 42. Dr. Ratain testifies that, by 2005, there was a “significant body” of data on the administration of everolimus to humans, but no reported clinical data on rapamycin. Ex. 1003 ¶ 135. Dr. Ratain concludes that a person of ordinary skill in the art would have had reason to administer a rapamycin derivative,

such as everolimus, with similar biological activity to rapamycin. *Id.* According to Par, that reason would have been further strengthened by Boulay 2004's disclosure of everolimus' activity in treating a rat PNET model, and O'Donnell's disclosure that administration of everolimus to human cancer patients was effective and safe. Pet. 43–44. Par also contends that this treatment would have had a reasonable expectation of success, particularly in view of Boulay 2004's disclosure of the effectiveness in the rat model. *Id.* at 45.

With respect to the unit dosage specified in claim 2, Par concedes that O'Donnell and Boulay 2004 do not specify 10 mg/day. Pet. 46. Nevertheless, Par contends that determining the optimal dosage would have required nothing more than routine experimentation, and Novartis has not shown any particular effectiveness of 10 mg/day as compared to other dosages. *Id.* at 46–47.

## 2. Reasonable Expectation of Success

Novartis argues that a person of ordinary skill in the art would not have had a reasonable expectation that everolimus would successfully treat advanced PNETs after failure of cytotoxic chemotherapy, relying on the declaration of Matthew H. Kulke, M.D. Prelim. Resp. 19–33 (citing Ex. 2001). In particular, Novartis contends that—even if the art suggested treatment of advanced PNETs with everolimus—patients with advanced PNETs that had failed cytotoxic chemotherapy had a more resistant or aggressive form of the disease. *Id.* at 20. These resistant PNETs, according to Novartis, presented “unique challenges” and showed far lower response rates to treatment. *Id.* at 21.

In view of these hurdles to treatment, Novartis argues, the art cited by Par would not have provided a reasonable expectation of success. Novartis observes that Öberg 2004 lists rapamycin, not everolimus, as a treatment after cytotoxic chemotherapy, and recognizes rapamycin was “experimental” at the time. *Id.* at 24–25. With respect to Boulay 2004, Novartis contends that even if the CA20948 rat model is a model for advanced PNET in humans, it is not a model for advanced PNET after failure of cytotoxic chemotherapy and would not have provided a reasonable expectation of success in these hard-to-treat cases. *Id.* at 26. Finally, with respect to O’Donnell, Novartis observes that the reference does not state that the patients had advanced PNET, let alone advanced PNET after failure of cytotoxic chemotherapy. *Id.* at 27.

At this stage of the proceedings, we cannot conclude, as Novartis asserts, that a person of ordinary skill in the art would have had no reasonable expectation of success in treating advanced PNET after failure of cytotoxic chemotherapy. Novartis’ arguments address the disclosures of each reference individually, and the expectation of success that might be drawn from each reference alone. But Par’s proposed ground of unpatentability is based in the combined disclosures of the three references, and the reasonable expectation of success must be evaluated on the basis of the prior art as a combination. To that end, Par has set forth sufficient evidence that a person of ordinary skill, viewing Öberg 2004, Boulay 2004, and O’Donnell in combination, would have had a reasonable expectation of success in treating advanced PNET after failure of cytotoxic chemotherapy. In particular, we note the testimony of Dr. Ratain supporting Par’s

assertions. *See* Ex. 1003 ¶ 150. Although Dr. Kulke provides testimony to the contrary (*see* Ex. 2001 ¶¶ 85–88), conflicting expert testimony creates a genuine issue of material facts, which we must view in the light most favorable to a petitioner when deciding whether to institute trial. *See* 37 C.F.R. § 42.108(c).

### 3. Secondary Considerations of Nonobviousness

Par addresses secondary considerations of nonobviousness in its Petition, contending that any considerations that might be raised by Novartis in reply are insufficient to support nonobviousness. Pet. 54–55. Though Par addresses indicia such as long-felt need, commercial success, and copying, it is notably silent as to unexpected results. *Id.* This is significant, Novartis argues, because evidence of unexpected results was made of record during prosecution of the application that issued as the '224 patent, and the Examiner cited those unexpected results in the Statement of Reasons for Allowance. Prelim. Resp. 40–41; Ex. 1002, 1114–16. As such, Novartis contends that Par had the burden of acknowledging this evidence in its Petition, and should have addressed unexpected results in order to establish a reasonable likelihood of success on the merits. *Id.* (citing *Praxair Distrib., Inc. v. INO Therapeutics, Inc.*, Case IPR2015-00522, 16–17 (PTAB July 29, 2015) (Paper 12)).

Even if it is proper, in some cases, to place the burden on a petitioner to address in its petition previously-introduced evidence of unexpected results, we do not consider it appropriate in the case at hand. It does not appear, on the present record, that the evidence of unexpected results that was before the Examiner is commensurate in scope with the claims before us

today. Notably, at the time the evidence of unexpected results was presented, the claims pending before the Office were not limited to advanced tumors after the failure of cytotoxic chemotherapy. *See* Ex. 1002, 935.

The Declaration of Dr. Lebwohl, submitted under 37 C.F.R. § 1.132 as evidence of unexpected results, is similarly not limited to treatment after failure of cytotoxic chemotherapy. *See id.* at 1005–08. Dr. Lebwohl’s Declaration describes the RADIANT-3 clinical study as “the first clinical study that confirmed that patients having advanced neuroendocrine tumors of pancreatic origin when treated with [everolimus] more than doubled the time without tumor growth,” but does not mention treatment following failure of cytotoxic chemotherapy. *Id.* at 1007, ¶ 7. Nor does the Appendix to the Declaration, a Novartis press release, mention failure of cytotoxic chemotherapy, or describe any particular results in patients who had previously undergone chemotherapy. *Id.* at 1009. Given the emphasis in the Preliminary Response on the failure of cytotoxic chemotherapy limitation as being central to the patentability of the claims, Novartis provides no reason why should overlook that distinction when evaluating the previously-submitted evidence of unexpected results.

We note that, in its Preliminary Response, Novartis cites the Yao paper describing the RADIANT-3 study as further evidence of unexpected results. Prelim. Resp. 41–42. While Yao does note that some portion of patients in the study had previously received chemotherapy (Ex. 2022, 517–18) this evidence does not appear to have been before the Examiner during prosecution. As such, we decline to place the burden on Par to anticipate this evidence of unexpected results and address it in its Petition.

For these reasons, although we acknowledge Novartis' evidence of unexpected results, the current evidence of objective indicia does not persuade us of the nonobviousness of the challenged claims. The parties will have the opportunity to further develop the record regarding unexpected results during the instituted trial.

#### 4. Conclusion

We find that, at this stage of the proceeding, Par has sufficiently established a reasonable likelihood it will prevail in proving claims 1–3 to be unpatentable over Öberg 2004, Boulay 2004, and O'Donnell. With respect to claims 1 and 3, Par has made a sufficient showing that the prior art teaches the elements of the claims, there was a reason to combine the disclosures, and that there was a reasonable expectation of success. With respect to claim 2, we note that Novartis does not, at this stage of the proceeding, separately argue the claim, or contend that determining the proper dosage would not have been routine experimentation at the time of the invention.

#### *C. Obviousness over Öberg 2004, Boulay 2004, O'Donnell, and Tabernero*

Par also contends that, even if the dosage limitation of claim 2 is not obvious as being routine experimentation in light of Öberg 2004, Boulay 2004, and O'Donnell, Tabernero explicitly teaches such a dosage. Pet. 48.

Tabernero is a presentation abstract regarding a Phase I study of the use of everolimus in patients with advanced solid tumors. Ex. 1038. Tabernero discloses that everolimus inhibits mTOR, a protein kinase involved in “the regulation of cell growth, proliferation, and survival.” *Id.*

Tabernero recommends further Phase II–III development of everolimus, at a dosage of 10 mg daily, as a single agent tumor treatment. *Id.*

Novartis does not separately address this ground, or contend that Tabernero does not teach a 10mg/day unit dose of everolimus. We are persuaded, on this record, that Par has sufficiently established that a person of ordinary skill in the art would have had reason to administer such a dosage of everolimus in view of Tabernero and the other cited prior art.

*D. Obviousness over Boulay 2004, O’Donnell, and Duran*

Par also contends that claims 1–3 would have been obvious over the combined disclosures of Boulay 2004, O’Donnell, and Duran. Pet. 49–52. The disclosures of Boulay 2004 and O’Donnell relied upon by Par are set forth above.

Duran discusses the administration of the rapamycin derivative temsirolimus to patients having metastatic neuroendocrine carcinomas (NECs), which Dr. Ratain testifies are a subset of advanced NETs. Ex. 1011, 215s; Ex. 1003 ¶ 129. Specifically, Duran notes islet cell carcinomas as a subset of the treated NECs. Ex. 1011, 215s. Of the 23 patients in the study, 11 had undergone prior chemotherapy. *Id.* Duran concludes that temsirolimus appears to have antitumor activity in NECs. *Id.*

Par contends that Duran teaches that temsirolimus, which is related to everolimus, had been shown to be safe and effective as monotherapy in patients with advanced NET previously treated with cytotoxic chemotherapy. Pet. 49. This, combined with Boulay 2004’s teaching that everolimus was successful in a rat pancreatic NET model, and O’Donnell’s disclosure that everolimus was tolerated and effective in humans, allegedly

would have led a person of ordinary skill in the art to administer everolimus to a patient having advanced NETs after failure of cytotoxic chemotherapy. *Id.* at 49–50. Relying on the testimony of Dr. Ratain, Par contends that such a treatment would have had a reasonable expectation of success. *Id.* at 50 (citing Ex. 1003 ¶ 167).

With respect to claim 2, Par again contends that the dosage limitation would have been the result of routine experimentation. Pet. 51–52. As with the prior ground, Novartis does not address claim 2 separately or contend at this stage of the proceeding that the proper dosage would not have been determined via routine experimentation.

Novartis again argues that Par has failed to establish a reasonable expectation of success in using everolimus to treat advanced PNET after failure of cytotoxic chemotherapy, and also notes the alleged unexpected results of the invention. Prelim. Resp. 33–38, 40–45. We find these arguments unpersuasive at this stage of the proceeding, for the reasons discussed in the prior ground.

Novartis also argues that institution of this ground of unpatentability should be denied, because the three cited references do not disclose treatment after failure of cytotoxic chemotherapy. *Id.* at 11–19. With respect to Duran,<sup>7</sup> Novartis contends that because not all NECs are advanced PNETs, there is no way to know from Duran’s disclosure whether any of the

---

<sup>7</sup> Though Novartis also addresses Boulay 2004, O’Donnell, and Taberero in its Preliminary Response (Prelim. Resp. 11–15, 17–18), we understand Par’s contention to be that Duran alone teaches treatment after cytotoxic chemotherapy.

treated patients had advanced PNETs. *Id.* at 15–16. Similarly, Novartis contends that Duran does not specify whether any of the patients previously treated with chemotherapy had advanced PNETs, and cites Dr. Kulke’s testimony that a person of ordinary skill would have understood the Duran patients who underwent chemotherapy did not have advanced PNETs. *Id.* at 16 (citing Ex. 2001 ¶ 43).

Though we agree with Novartis that Duran does not explicitly specify treatment of patients with advanced PNET after failure of cytotoxic chemotherapy, we do not find this fatal to the Petition at this stage of the proceeding. Duran does disclose the treatment of patients with advanced NEC, and that some of the patients had previously undergone chemotherapy. Par’s contention that this disclosure would have suggested temsirolimus to a person of ordinary skill in the art seeking to treat advanced PNET after failure of cytotoxic chemotherapy is reasonable on the present record. Given this suggestion, we also find it reasonable that the skilled artisan would have investigated other rapamycin derivatives, including everolimus in light of Boulay 2004 and O’Donnell.

For the foregoing reasons, we find that Par has sufficiently established a reasonable likelihood it will prevail in proving claims 1–3 to be unpatentable over Boulay 2004, O’Donnell, and Duran.

*E. Obviousness over Boulay 2004, O’Donnell, Duran, and Tabernero*

As with the prior ground involving Öberg 2004, Par contends that even if Boulay 2004, O’Donnell, and Duran do not teach or suggest claim 2’s dosage limitation of 10 mg/day, this dosage is explicitly set forth by Tabernero. Pet. 53. Again, Novartis does not address this ground separately

or contend that Taberero does not disclose this dosage of everolimus. We conclude, for the reasons stated above, that Par has established a reasonable likelihood of prevailing on this ground.

### III. CONCLUSION

Upon consideration of the Petition and the Preliminary Response, and for the reasons set forth above, we conclude that Par has demonstrated a reasonable likelihood that claims 1–3 of the '224 patent are unpatentable. Accordingly, we institute *inter partes* review with respect to these claims as set forth in the following Order.

### IV. ORDER

Accordingly, it is

ORDERED that, pursuant to 35 U.S.C. § 314, an *inter partes* review is instituted on the following grounds, the trial commencing as of the date of this Decision:

- (1) Whether claims 1–3 are unpatentable under 35 U.S.C. § 103(a) as having been obvious over the combined disclosures of Öberg 2004, Boulay 2004, and O'Donnell;
- (2) Whether claim 2 is unpatentable under 35 U.S.C. § 103(a) as having been obvious over the combined disclosures of Öberg 2004, Boulay 2004, O'Donnell, and Taberero;
- (3) Whether claims 1–3 are unpatentable under 35 U.S.C. § 103(a) as having been obvious over the combined disclosures of Boulay 2004, O'Donnell, and Duran;
- (4) Whether claim 2 is unpatentable under 35 U.S.C. § 103(a) as having been obvious over the combined disclosures of Boulay 2004, O'Donnell, Duran, and Taberero; and

IPR2016-01479  
Patent 9,006,224 B2

FURTHER ORDERED that no ground other than those specifically granted above are authorized for *inter partes* review as to the claims of the '224 patent.

IPR2016-01479  
Patent 9,006,224 B2

For PETITIONER:

Daniel Brown  
[Daniel.brown@lw.com](mailto:Daniel.brown@lw.com)

Jon Strang  
[Jonathan.strang@lw.com](mailto:Jonathan.strang@lw.com)

For PATENT OWNER:

Nicholas Kallas  
[nkallas@fchs.com](mailto:nkallas@fchs.com)

Raymond Mandra  
[rmandra@fchs.com](mailto:rmandra@fchs.com)