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vTv Therapeutics LLC 4170 Mendenhall Oaks Parkway High Point, NC 27265			EXAMINER	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PER SAUERBERG, PAVEL PIHERA, ZDENEK POLIVKA, MIROSLAV HAVRANEK, INGRID PETTERSSON, and JOHN PATRICK MORGENSEN

Application 14/016,442¹ Technology Center 1600

Before MELANIE L. MCCOLLUM, ULRIKE W. JENKS and DAVID COTTA, *Administrative Patent Judges*.

COTTA, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims directed to a method of arresting development of a disease-state, slowing development of a disease state, causing regression of a disease-state, or causing regression of a symptom of a disease-state, wherein the disease-state is type I diabetes, type II diabetes, impaired glucose tolerance, insulin resistance, or obesity. The Examiner rejected the claims on appeal on the ground of non-statutory obviousness type double patenting.

We affirm.

¹ According to Appellants, the real party in interest is vTv Therapeutics. Apr. 11, 2016 Statement of Ownership.

STATEMENT OF THE CASE

The claims stand rejected as follows:

Claims 1–5 on the ground of non-statutory obviousness-type double patenting over claims 1–24 of the '613 Patent.²

Claims 6–9 on the ground of non-statutory obviousness-type double patenting over claims 1–11 of the '016 Patent.³

Claims 10–15 on the ground of non-statutory obviousness-type double patenting over claims 1–12 of the '993 Patent.⁴

Appellants do not challenge the Examiner's conclusion that the claims of the present application would have been obvious over the claims of the '613, '016 and '993 patents. Rather, Appellants argue that the safe harbor provision of 35 U.S.C. § 121 shields the present application from double patenting. This case thus turns on the resolution of a single issue: is the pending application entitled to the benefit of the safe harbor set forth in 35 U.S.C. § 121 such that the Examiner cannot rely on '613, '016, and '993 patents to reject the pending application on the grounds of non-statutory obviousness-type double patenting?

FINDING OF FACTS/SUMMARY OF PROSECUTION HISTORY

1. On October 23, 2008, Appellants filed Application No. 12/097,564 ("the Original Application") with claims directed to both

² Sauerberg et al., US Patent No. 7,943,613 B2, issued May 17, 2011 ("the '613 Patent").

³ Sauerberg et al., US Patent No. 8,362,016 B2, issued Jan. 29, 2013 ("the '016 Patent").

⁴ Sauerberg et al., US Patent No. 8,551,993 B2, issued Oct. 8, 2013 ("the '993 Patent").

compounds and methods of use. The Original Application is the great grandparent of the present application. During prosecution of the Original Application, the Examiner issued a restriction requirement requiring Appellants to elect from among two groups of claims for further prosecution: Group I (claims 1–21 and 23–27) drawn to compounds, and Group II (claims 30–32) drawn to methods of use. App. Br. 10.

- 2. The '613 patent, with claims directed to compounds within Group I, issued from the Original Application on May 17, 2011. *Id*.
- 3. Prior to the issuance of the '613 patent, Appellants filed a continuation application with claims directed to the subject matter of Group I ("the First Continuation Application"). The First Continuation Application resulted in the '016 patent, which issued on January 29, 2013. *Id.* at 11.
- 4. Prior to the issuance of the '016 patent, Appellants filed a second continuation application with claims directed to the subject matter of Group I ("the Second Continuation Application"). The Second Continuation Application resulted in the '993 patent, which issued on October 8, 2013. *Id.*
- 5. Prior to the issuance of the '993 patent, but subsequent to the issuance on the '613 and '016 patents, Appellants filed the present application with claims directed to the subject matter of Group II ("the Present Application"). The Present Application was designated a divisional application based on the restriction requirement mailed in connection with the Original Application. *Id*.

ANALYSIS

The Examiner rejected claims 1–15 on the grounds of non-statutory obviousness-type double patenting. Claims 1–5 were rejected over the '613

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Patent, claims 6–9 were rejected over the '016 Patent, and claims 10–15 were rejected over the '993 Patent. Ans. 3, 4, and 6. In rejecting these claims, the Examiner found that the safe harbor provision of 35 U.S.C. § 121 did not apply. Ans. 7–16. The safe harbor provision of 35 U.S.C. § 121 states:

A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application *filed as a result of such a requirement*, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, *if the divisional application is filed before the issuance of the patent on the other application*.

35 U.S.C. § 121 (emphasis added). The Examiner found that the safe harbor provision did not shield the present application from double patenting rejections with respect to the '613, '016, and '993 patents because the applications that led to these patents were not filed "as a result of" a restriction requirement and because the present application was not filed "before the issuance of the patent on the other [restricted] application." Ans. 13–14, see generally 7–16.

Issue 1: Did the '016 and '993 patents issue from applications filed "as a result" of a restriction requirement?

The "as a result of" requirement of the safe harbor provision must be satisfied with respect to both the present application and reference patents (i.e. the '613, '016, and '993 patents). *Boehringer Ingelheim International GmbH v. Barr Laboratories, Inc.*, 592 F.3d 1340, 1353 (Fed. Cir. 2010) ("We agree with the district court that the 'as a result of' requirement must

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be satisfied by both the '086 reference patent and the '812 challenged patent.").

The '613 patent issued from the Original Application. FF1 and FF2. The '016 and '993 patents issued from continuation applications with claims directed to the same subject matter as is claimed in the '613 patent. FF3 and FF4. The restriction requirement thus did not preclude Appellants from pursuing the claims obtained in the '016 and '993 patents in the Original Application. As the restriction requirement was not responsible for these applications being filed separately from the Original Application, we fail to see how these applications can be considered to meet the "as a result of a restriction requirement" of the safe harbor provision. See, Gerber Garment Technology, Inc. v. Lectra Systems, Inc., 916 F.2d 683, 687 (Fed. Cir. 1990) ("The prohibition against use of a parent application 'as a reference' against a divisional application applies only to the divisional applications that are 'filed as a result of' a restriction requirement. Plain common sense dictates that a divisional application filed as a result of a restriction requirement may not contain claims drawn to the invention set forth in the claims elected and prosecuted to patent in the parent application."); St. Jude Medical, Inc. v. Access Closure, Inc., 729 F.3d 1369, 1379 (2013) (finding that application of the safe harbor provision required determining "whether any of the same restricted inventions are claimed in the challenged patent (the Janzen patent), the reference patent (the sibling patent), or the restricted patent (the grandparent patent)").

Appellants contend that "the 'as a result of' requirement does not prohibit intervening continuation applications," App. Br. 9, and that "there is no requirement under § 121 that the divisional application being shielded by

the safe harbor must immediately follow the parent." *Id.* at 15 (citing *Boehringer*, 592 F.3d at 1352). We do not disagree. But, in order for the safe harbor provision to apply, the applications at issue must still have been filed "as a result of a restriction requirement." Appellants have not provided persuasive argument or evidence establishing that the applications that led to the issuance of the '016 and '993 patents were attributable to the restriction requirement filed in the Original Application. Accordingly we find that the safe harbor provision does not shield the present application from double patent rejections based on the '016 and '993 patents.

Issue 2: Was the present application filed before the issuance of the '613 patent?

The safe harbor provision expressly states that it applies only "if the divisional application is filed before the issuance of the patent on the other application." 35 U.S.C. § 121 (emphasis added). Appellants contend that the present application is entitled to the filing date of the Original Application under 35 U.S.C. § 120, which describes circumstances under which an application is entitled to the benefit of the filing date of an earlier filed application. App. Br. 15. Appellants argue that because the present application is entitled to the filing date of the Original Application, and because the filing date of the Original Application predates the issue date of each of the reference patents relied upon by the Examiner (including the patent issuing from the Original Application), the requirement that the divisional application be filed "before the issuance of the patent on the other application" does not preclude Appellants from relying upon the safe harbor protection afforded by 35 U.S.C. § 121. *Id.* at 15–16.

Appellants' arguments present the question: does the phrase "the divisional application is filed" in the safe harbor provision of 35 U.S.C. § 121 refer to the actual date on which the divisional application is filed or to the effective filing date of the divisional application under 35 U.S.C. § 120. We find that the phrase "the division application is filed" refers to the actual date on which the divisional application is filed.

The Federal Circuit requires strict application of the safe harbor provision of section 121. *G.D. Searle LLC v. Lupin Pharmaceuticals Inc.*, 790 F.3d 1349, 1354 (Fed. Cir. 2015) ("We apply 'a strict test' for application of section 121, '[g]iven the potential windfall [a] patent term extension could provide to a patentee."") (*citing Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F3d 1373, 1382 (Fed. Cit. 2003); *and Amgen Inc. v. F. Hoffman-La-Roche Ltd.*, 580 F.3d 1340, 1353 (Fed. Cir. 2009)).

Appellants' interpretation of 35 U.S.C. § 121 would render meaningless the requirement to file the divisional application "before the issuance of the patent on the other application." A properly filed divisional application necessarily complies with the requirements of 35 U.S.C. § 120 and will thus always be entitled to the effective filing date of its parent application. If the relevant filing date for determining whether the safe harbor applies is the effective rather than the actual filing date of the divisional application, what would be the point of requiring a divisional application to be filed "before the issuance of the patent on the other application?" A divisional application will always be "effectively filed" before a patent issues from the restricted application. A statutory interpretation, like that proposed by Appellants, that renders entire provisions superfluous is unlikely to be the correct. *Hibbs v. Winn*, 542 U.S.

88, 101 (2004) ("A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant") (quoting N. Singer, *Statutes and Statutory Construction* § 46.06, pp. 181-186 (rev. 6th ed. 2000)).

Moreover, the effective filing date of a patent application has little relevance to a double patenting rejection. *See, In re Dunn,* 349 F.2d 433, 436 (C.C.P.A. 1965) (finding that a Rule 131 affidavit filed in an attempt to antedate the reference patents in a double patenting rejection was "inappropriate to the facts here since the rejection was based on the claims rather than on the disclosure of the applications."). Given that the effective filing date of a patent application is largely irrelevant in the context of a double patenting rejection, it would be incongruous to look to the effective filing date to determine the availability of a patent as a double patenting reference with respect to the safe harbor provision.

Appellants argue that the timeline in *Boehringer Inhelheim Intern*. *GmbH v. Barr Laboratories, Inc.*, 592 F.3d 1340 (Fed. Cir. 2010) supports their interpretation of the statute because a patent issued from an application in which the restriction requirement was raised before the application that resulted in the challenged patent was filed. App. Br.16. But the *Boehringer* court did not address the requirement that the divisional be filed before the issuance of the other patent. And the application for the patent challenged in *Boehringer* (US Patent No. 4,886,812 ("the '812 patent")) was filed before the application that resulted in the reference patent (US Patent No. 4,843,086 ("the '086 patent")). *Boehringer*, 592 F.3d at 1344. *Boehringer* thus does not speak to the issue present here: whether the safe harbor provision shields a divisional application from the double patenting effect of a patent that

issued before the divisional application was filed. Accordingly, we find that the safe harbor provision does not shield the present application from double patent rejections based on the '613 patent.

SUMMARY

For these reasons and those set forth in the Examiner's Answer, and the Final Office Action, the Examiner's final decision to reject claims 1–15 is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1).

AFFIRMED