IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS AG, NOVARTIS PHARMACEUTICALS CORPORATION, MITSUBISHI TANABE PHARMA CORPORATION, and MITSUI SUGAR CO., LTD.,	:	
Plaintiffs,	:	C.A. No. 15-150-LPS
v.	:	
EZRA VENTURES, LLC,	:	
Defendant.	:	

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MEMORANDUM OPINION

September 22, 2016
Wilmington, Delaware

STARK, U.S. District Judge:

I. BACKGROUND

On February 2, 2015, Plaintiffs Novartis AG, Novartis Pharmaceuticals Corporation, Mitsubishi Tanabe Pharma Corporation, and Mitsui Sugar Co., Ltd. (collectively, "Plaintiffs") filed a complaint against Ezra Ventures, LLC ("Ezra" or "Defendant") alleging infringement of U.S. Patent No. 5,604,229 ("the '229 patent") based on Ezra's filing of an Abbreviated New Drug Application ("ANDA") relating to a generic version of Plaintiffs' Gilenya drug product. (D.I. 1) Ezra has moved for judgment on the pleadings (D.I. 70), arguing that the '229 patent should be ruled invalid, or otherwise terminally disclaimed for the time past the expiration date of unasserted U.S. Patent No. 6,004,565 ("the '565 patent"). The Court heard oral argument on the pending motion on April 19, 2016. (*See* D.I. 138 ("Tr."))

II. LEGAL STANDARDS

A motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c), alleging a failure to state a claim upon which relief can be granted, is analyzed under the same standard as a Rule 12(b)(6) motion to dismiss. *See Turbe v. Gov't of Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991). Federal Rule of Civil Procedure 12(b)(6) permits a court to dismiss all or part of an action for "failure to state a claim upon which relief can be granted." A motion to dismiss requires a court to accept as true all material allegations of the complaint. *See Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997). Thus, a court may grant a motion to dismiss only if, after "accepting all well-pleaded allegations in the complaint as

true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief." *Maio v. Aetna, Inc.*, 221 F.3d 472, 482 (3d Cir. 2000).

The Court may consider matters of public record, and authentic documents upon which the complaint is based if attached to the complaint or as an exhibit to the motion. *See Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1384 n.2 (3d Cir. 1994). The Court may also take judicial notice of the factual record of a prior proceeding. *See Oneida Motor Freight, Inc. v. United Jersey Bank*, 848 F.2d 414, 416 n.3 (3d Cir. 1988). Ultimately, a motion for judgment on the pleadings can be granted "only if no relief could be afforded under any set of facts that could be proved." *Turbe*, 938 F.2d at 428.

III. DISCUSSION

Ezra's motion challenges the validity of the patent term extension ("PTE") of the '229 patent. The '229 patent discloses compounds useful as immunosuppressants. Among these compounds is fingolimod, the active ingredient in Plaintiffs' Gilenya product.

The '229 patent was originally set to expire in February 2014, but Plaintiffs obtained a PTE under 35 U.S.C. § 156, extending the patent's life until February 2019. Because of this extension, the life of the '229 compound patent now ends after that of the later-issued, Orange Book[1]-listed '565 patent, which claims a method of using fingolimod to influence lymphyocyte activity. Ezra argues that extension of the '229 compound patent beyond the life of the '565 patent is impermissible because it: (1) *de facto* extends the life of the method patent, and thereby

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[1]The "Orange Book" is the shorthand name for the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*. *See Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1358 (Fed. Cir. 2015); *see also* 21 U.S.C. § 355(b)(1) (requiring listing of patents that "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug").

violates the provision of 35 U.S.C. § 156 requiring that "in no event [may] more than one patent be extended . . . for the same regulatory review period for any product;" (2) violates the "bedrock principle that the public may practice an expired patent; and (3) renders the '229 patent invalid for statutory and obviousness-type double patenting.

A. 35 U.S.C. § 156

The right to patent term extension based on FDA regulatory review is codified at 35 U.S.C. § 156. The statute provides for extension of "[t]he term of a patent which claims a product, a method of using a product, or a method of manufacturing a product" that is subject to FDA review. 35 U.S.C. § 156(a). The extension is limited to claims directed to approved products or methods of use. 35 U.S.C. § 156(b). A patentee may obtain such an extension by submitting a timely application to the FDA that identifies the product that was the subject of regulatory review, the patent for which PTE is being sought, and other details necessary to determine whether the patent is eligible for extension. 35 U.S.C. § 156(d)(1).

The statute also specifies that "in no event shall more than one patent be extended . . . for the same regulatory review period for any product." 35 U.S.C. §156(c)(4). The parties disagree about the meaning of this provision. Plaintiffs argue that it limits the patentee to selecting just one patent for PTE per approved product. Defendant agrees that only one patent may be selected per product, but argues that this language further limits the patentee to choosing a patent that does not "*de facto*" extend the life of any other patents. If Defendant is correct, then Plaintiffs' choice of the '229 patent, which covers the fingolimod compound, would be invalid because it effectively also extends the life of the earlier-expiring '565 patent on a method of using fingolimod.

Defendant's position essentially requires the Court to construe the word "extended" as it is used in § 156(c)(4) as "effectively extended." But, throughout the rest of § 156, "extend," "extension," and "extending" refer to the legal status conferred upon a patent chosen to benefit from PTE. *See, e.g.,* 35 U.S.C. § 156(a) and (b). Thus, to adopt Defendant's proposed construction of § 156(c)(4) would require the Court to depart from the meaning of "extend" as it is used elsewhere in § 156.

Defendant has not cited any statutory language or other authority to support its position that the term "extend" has a broader meaning in the context of § 156(c)(4) than it does elsewhere throughout § 156. In fact, the case law supports the opposite conclusion. Addressing a similar situation in *Merck & Co. v. Hi-Tech Pharmacal Co.*, the Federal Circuit found that the "legislative history of § 156 indicates that Congress was aware of concerns over the effects of extending related patents – at least as to parent, continuation, and continuation-in-part patents – and chose to provide the patentee with the option to select to extend the term of only one of either the parent patent or a continuation patent." 482 F.3d 1317, 1323 (Fed. Cir. 2007). In *Merck*, the defendant had challenged the plaintiff's decision to apply for PTE of a patent for which the patentee had filed a terminal disclaimer to overcome a double-patenting rejection. *Id.* at 1319-21. The defendant argued that to hold that a terminally-disclaimed patent is not barred from obtaining a term extension under § 156 would "effectively uncouple the terminal disclaimer from the original expiration date of the" patent over which the terminal disclaimer was filed, and thereby undermine the purpose of terminal disclaimers. *Id.* at 1321. The Federal Circuit rejected this argument, noting that "Congress chose not to limit the availability of a patent term extension to a specific parent or continuation patent but instead chose a flexible approach which gave the

patentee the choice." *Id.* at 1323. The Court saw "no reason why a patentee should not have the same choice as between an earlier patent and a later patent related by a terminal disclaimer." *Id.*

Extension of the term of a patent that has been terminally disclaimed "de facto" or "effectively" extends the life of the patent over which it was terminally disclaimed. Thus, the Federal Circuit's decision to allow such an extension in *Merck* suggests that § 156(c)(4) also permits the "de facto" patent term extension to which Defendant objects in this case. Accordingly, the Court concludes Defendant's argument does not provide a meritorious basis to grant it judgment on the pleadings.

B. Policy that Expired Patents are Dedicated to the Public

Defendant next contends that, because extension of the '229 patent on the fingolimod compound prevents others from practicing the methods of using fingolimod claimed in the '565 patent, extension of the '229 patent beyond the expiration date of the '565 patent violates the "fundamental" precept that "subject matter of an expired patent is dedicated to the public." (D.I. 71 at 10) (citing *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896)) Defendant overstates the principle. The expiration of a patent does not grant the public an affirmative right to practice a patent; it merely ends the term of the patentee's right to exclude others from practicing the patent. As a practical matter, use of the patented subject matter may still be limited by other rights (e.g., other patent rights or contractual obligations). Defendant has not identified authority supporting the view that even a "fundamental" policy precept should override the express statutory language adopted by Congress. Accordingly, again, Defendant's argument does not provide a basis to grant judgment on the pleadings.

C. Double Patenting

Finally, Defendant argues that extension of the '229 patent is invalid for both statutory- and obviousness-type double-patenting over the '565 patent. *See generally Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001) (explaining that obviousness-type double patenting analysis requires construction of claims in earlier patent and later patent, followed by determination of whether differences between claims render them patentably distinct). Even assuming that a double patenting analysis is applicable in the context of a PTE, the Court is not in a position to make this determination at the judgment on the pleadings stage of this case. Both the "same invention" and "obviousness" inquiries appear to raise fact issues (potentially requiring discovery and claim construction to resolve). At the appropriate time, Defendant may seek leave to file a motion for summary judgment based on double patenting should it have a good faith basis to do so.

IV. CONCLUSION

An appropriate Order follows.