Appeal No. 2017-1120

United States Court of Appeals

for the

Federal Circuit

JANSSEN BIOTECH, INC., NEW YORK UNIVERSITY,

Plaintiffs-Appellants,

– v. –

CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., HOSPIRA INC.,

Defendants-Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS IN CASE NOS. 15-CV-10698 AND 16-11117, SENIOR JUDGE MARK L. WOLF

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Janssen Biotech, Inc. and New York University **v.** Celltrion Healthcare Co., Ltd. et al.

Case No. 2017-1120

CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ☒ (appellant) ☐ (respondent) ☐ (appellee) ☐ (amicus) ☐ (name of party)

Janssen Biotech, Inc. and New York University

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10 % or more of stock in the party
Janssen Biotech, Inc.	Janssen Biotech, Inc.	Johnson & Johnson
New York University	New York University	None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (**and who have not or will not enter an appearance in this case**) are:

Patterson Belknap Webb & Tyler LLP (Andrew Cohen and Viviane Scott), Nutter McClennan & Fish LLP (Alison Casey and Heather Repicky)

April 20, 2017
Date

/s/ Gregory L. Diskant
Signature of counsel

Please Note: All questions must be answered

Gregory L. Diskant
Printed name of counsel

cc:

Reset Fields

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I. AS TO THE *GILEAD* RULING: THE DISTRICT COURT ERRED IN GRANTING SUMMARY JUDGMENT THAT CLAIMS OF THE PRE-URAA '471 PATENT ARE INVALID IN VIEW OF THE POST-URAA '444 PATENT

The district court's *Gilead* ruling is at odds both with the controlling statute and with this Court's precedent on obviousness-type double patenting. When Congress enacted the URAA, changing the term of U.S. patents from the traditional term of 17 years from issuance to the new regimen of 20 years from filing, it protected the settled expectations of parties who had filed patent applications before the URAA's effective date. Congress did so by providing in § 154(c)(1) that patents issuing from applications filed before the URAA's effective date would have: (a) the traditional term of 17 years from issuance, or (b) the new term for post-URAA patents of 20 years from the filing of the patent's earliest priority application, whichever is "the greater." 35 U.S.C. § 154(c)(1).

Where pre- and post-URAA patents descend from the same priority application, Congress could have limited pre-URAA patents to the same 20-years-from-filing term as post-URAA patents, but it did not. Instead, Congress decided that pre-URAA patents, without exception, should have "the greater" of the two statutory terms. 35 U.S.C. § 154(c)(1). *Gilead Sciences, Inc. v. Natco Pharma, Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014), does not address—and should not be used to frustrate—Congress's determination. The district court erred in relying on *Gilead*

to effectively re-write § 154(c)(1) to give pre-URAA patents the *lesser* term, rather than "the greater" term that Congress provided.

Although the district court recognized that *Gilead* addressed a situation unlike the one presented here and therefore is not controlling here (Appx675), it erred when it nonetheless elevated dicta in *Gilead* into a bright-line rule. In particular, the district court erred in treating as absolute the principle the *Gilead* majority cited, that once patent protection expires the public generally should be free to use what had been patented. In doing so, the district court failed to appreciate that acts of Congress can override that principle. The *Gilead* majority opinion itself recognizes that this principle is not absolute, noting that after a patent expires, "[t]he public's ability to practice an invention claimed in an expired patent may be . . . restricted," *e.g.*, by an act of Congress. 753 F.3d at 1214 n.5; *see* Janssen Br. 38-39.

In addition to § 154(c)(1), several other statutes allow a second patent to prevent the public from practicing an invention after a first patent expires. For example, the statutory safe harbor of 35 U.S.C. § 121 protects inventors whose applications are subjected to PTO restriction requirements from the inequity of losing protection due to other patents filed as a result of the same restriction requirement, even if such protection results in sequentially issued patents that may not be used to invalidate each other. *See* Janssen Br. 45. In addition, § 154(b)

allows the term of a patent to be extended, *i.e.*, "adjusted," as a result of delay caused by the PTO during its original examination, and a patent receiving such a term adjustment accordingly may expire later than related patents directed to the same or similar subject matter. Another example is the Hatch-Waxman Act (35 U.S.C. § 156), which allows holders of patents on pharmaceutical products to obtain an extended term of patent protection to compensate for delay in obtaining FDA approval; where there is a family of patents, the statute only allows the patentee to obtain such a term extension for "one patent," 35 U.S.C § 156(c)(4), and by statute, the term of that patent may be longer than the term of related patents covering similar subject matter. *See Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1319-21 (Fed. Cir. 2007); *Gilead*, 753 F.3d at 1215 n.6.

The *Gilead* majority did not address whether its double-patenting analysis overrides Congress's judgment in § 154(c)(1), much less decide that issue in Celltrion's favor. Rather, the *Gilead* majority clearly and repeatedly limited its holding to the "circumstances of this case." 753 F.3d at 1212, *see also id.* at 1217. Celltrion's assertion that "every judicial decision is in some sense 'under the circumstances' of the case" (Celltrion Br. 39) is not a reason to ignore the majority's explicit limitation of *Gilead*'s holding—at both the beginning and the end of its discussion—to the "circumstances of this case." 753 F.3d at 1212; *see also id.* at 1217.

Neither *Gilead* nor *Abbvie Inc. v. Mathilda & Terence Kennedy Institute of Rheumatology Trust*, 764 F.3d 1366 (Fed. Cir. 2014), which Celltrion also cites, presented any issue concerning § 154(c)(1). As Janssen has pointed out (Br. 35), the circumstances in *Gilead* involved: (a) two post-URAA patents, each with a statutory term of 20 years from its priority date, and (b) a patentee that "craft[ed] separate 'chain[s]' of applications" with different priority dates and then sued on a patent in the later chain that had a later priority date and therefore expired later. 753 F.3d at 1210. *Abbvie* presented the same fact pattern. 764 F.3d at 1373 n.2. Celltrion glosses over the latter point as if it did not exist, presenting charts that suggest, incorrectly, that the patents involved in *Gilead* both had the same priority date. Celltrion Br. 14.

Neither *Gilead* nor *Abbvie* addressed the issue presented here: whether a pre-URAA patent can be invalid for obviousness-type double patenting in view of a post-URAA patent, where both patents share the same earliest priority application date and the only reason the pre-URAA patent's statutory term extends beyond that of the post-URAA patent is that Congress decided that patents issuing from applications filed before the URAA's effective date should have a term of 17 years from issuance or 20 years from filing, whichever is "the greater." 35 U.S.C. § 154(c)(1).

Celltrion misses the mark when it argues that § 154(c)(1) does not give pre-URAA patents "immunity" from "other laws such as obviousness-type double patenting." Celltrion Br. 42. Obviousness-type double patenting, also referred to as "[n]onstatutory" double patenting, is not a statute or law—it is a "judicially created doctrine" that prevents the unjustified timewise extension of patent rights. *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1297 (Fed. Cir. 2012). As such, it must give way to acts of Congress that statutorily define the term of a given patent. Of course, § 154(c)(1) does not provide *all* pre-URAA patents with immunity from traditional obviousness-type double patenting scrutiny, and Janssen has never suggested that it does. *See*, *e.g.*, *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1383 (Fed. Cir. 2010) (applying obviousness-type double patenting where the patent-in-suit and the reference patent both had traditional terms of 17 years from issuance). But this does not mean that the statute may be judicially thwarted.

The district court's incorrect reasoning would have that effect here. Under the district court's reasoning, numerous pre-URAA patents that issued more than three years from their priority dates could be invalid merely because one or more post-URAA patents claim the same priority dates. For these pre-URAA patents, the practical effect of the district court's reasoning would be to rewrite

§ 154(c)(1) to substitute the word "lesser" in place of the word "greater" that Congress used in the statute.

The district court's *Gilead* ruling rests on this erroneous revision of the statute. Where, as here, a pre-URAA patent-in-suit and a post-URAA reference patent share the same earliest priority application and the operation of § 154(c)(1) is the only reason the pre-URAA patent has a longer term, then it is completely justified and proper for the pre-URAA patent to have "the greater" term as provided in § 154(c)(1).

Celltrion's reliance on the final clause in § 154(c)(1) also is unavailing. That clause states that the terms of pre-URAA patents are "subject to any terminal disclaimers" that the patent owner may have filed. That clause has no bearing here. It was not the basis for the district court's decision, nor could it have been. That clause merely preserves the effect of traditionally filed terminal disclaimers. *See*, *e.g.*, *Sun*, 611 F.3d at 1383. It does not make obviousness-type double patenting appropriate in *all* circumstances for *all* pre-URAA patents. It certainly does not support limiting pre-URAA patents to the shorter term of a post-URAA patent, when § 154(c)(1) provides that pre-URAA patents have "the greater" term.

In deciding whether obviousness-type double patenting applies here, the Court should be guided by the two principles that have always guided the

double-patenting analysis: (1) "'prevent[ing] unjustified time-wise extension of the right to exclude,'" and (2) "prevent[ing] multiple infringement suits by different assignees asserting essentially the same patented invention." *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013) (citation omitted). In enacting the URAA, "Congress could not have intended . . . to disturb" these principles. *Gilead*, 753 F.3d at 1216. Neither principle applies here. *See* Janssen Br. 40.

As Janssen has demonstrated—and as Celltrion concedes—this Court and its predecessor courts have repeatedly stated that obviousness-type double patenting addresses "unjustified" or "improper" or "undue" extensions of the patent term. *See* Janssen Br. 43-44 (collecting cases); Celltrion Br. 47-48 (collecting cases). Celltrion argues that the adjectives "unjustified," "improper," and "undue" are a meaningless redundancy that "merely express the conclusion that follows from a finding of obviousness-type double patenting." Celltrion Br. 48. But this language is neither meaningless nor redundant. Obviousness-type double patenting only addresses extensions of the patent term that are "unjustified" or "improper" or "undue." "*[O]nly* if the extension of patent right is *unjustified* is a double patenting rejection appropriate." *In re Braat*, 937 F.2d 589, 595 (Fed. Cir. 1991) (first emphasis added). "There are situations where [an] extension [of the right to exclude] is justified," and in those situations, obviousness-type double patenting does not apply. *Id*.

Here, the greater term of the pre-URAA '471 Patent, compared to the post-URAA '444 patent, results only from Congress's decision that patents issuing from applications filed before the URAA's effective date enjoy a term that is "the greater" of the traditional 17-year-from-issuance term or the new 20-year-from-filing term. 35 U.S.C. § 154(c)(1). This Court should reject Celltrion's invitation to extend obviousness-type double patenting to situations where a pre-URAA patent's longer term is justified by the operation of § 154(c)(1).

Celltrion emphasizes that double patenting "prevent[s] unjustified timewise extension of the right to exclude . . . *no matter how the extension is brought about*." Celltrion Br. 45 (quoting *Hubbell*, 709 F.3d at 1145) (italics added by Celltrion). But the phrase Celltrion italicizes does not broaden the doctrine. Read as a whole, the quote from *Hubbell* recognizes that an "unjustified" extension of the right to exclude can be achieved in various ways, while reaffirming that an extension must be "unjustified" to warrant the doctrine's application.

Where, as here, a pre-URAA patent and a related post-URAA patent share the same earliest priority application and the pre-URAA patent has a traditional term of 17 years from issuance, the "greater" term of the pre-URAA patent is justified under § 154(c)(1) and does not render that patent invalid. The district court erred in granting summary judgment that the pre-URAA '471 Patent

is invalid for obviousness-type double patenting in view of the post-URAA '444 Patent.

II. AS TO THE REEXAM RULING: THE DISTRICT COURT ERRED IN GRANTING SUMMARY JUDGMENT THAT CLAIMS OF THE '471 PATENT ARE INVALID IN VIEW OF THE '195 AND '272 PATENTS

A. The District Court Erred in Rejecting the Applicability of the Statutory Safe Harbor

Celltrion does not dispute key facts concerning the applicability of the safe harbor of 35 U.S.C. § 121:

1) Janssen filed the application for the '471 Patent in response to a restriction requirement, to pursue claims on the non-elected Group I of the restriction in its parent application.

2) The claims of the '471 Patent are consonant with Group I of the restriction.

3) Janssen advised the PTO that it was pursuing the application pursuant to a restriction requirement. Appx3938.

4) The '471 Patent disclosure supports all of the claims of the '471 Patent. Janssen did not seek or obtain any claims that are supported by any new matter.

5) To the extent the application for the '471 Patent contained new disclosures, those disclosures did not benefit Janssen because

they were not the subject of any claims. The additional disclosures only benefited the public by disclosing additional information that Janssen did not claim and thereby dedicated to the public.

6) The application for the '471 Patent was prosecuted as a divisional. Appx3789-3790.

7) During prosecution, Janssen responded to a provisional rejection by arguing that "35 U.S.C. § 121 precludes an obviousness-type double patenting rejection in this case." Appx4307. The Examiner agreed and withdrew the double-patenting rejection. Appx4322; Appx4110-4113.

8) In view of existing practice, it was reasonable for Janssen and the Examiner to believe that the application for the '471 Patent was entitled to the benefit of the safe harbor. Appx3789-3792; Appx4112-4113.

9) When the '471 Patent was reexamined, Janssen amended its disclosure to conform to the disclosure of its parent application and to designate the '471 Patent as a divisional, making the '471 Patent a divisional in form as well as in substance. Appx4104-4105; Appx3792.

Instead of giving these facts the weight they deserve, the district court adopted a new "bright line rule" that the statutory safe harbor can never apply to any patent that is not labeled as a divisional at the time of its original filing, regardless of the facts in a particular case. Appx33. If the facts do not matter, then the district court might be correct. But as this Court's precedent makes clear, the facts do matter, and the facts here make the safe harbor applicable to the '471 Patent.

The district court's "bright line" analysis rests on a misreading of *G.D. Searle LLC v. Lupin Pharms., Inc.*, 790 F.3d 1349 (Fed. Cir. 2015), which Celltrion describes as "conclusively reject[ing] Janssen's argument." Celltrion Br. 54. But *Searle* underscores the importance of the facts and equities in determining whether the safe harbor applies. The patent-in-suit in *Searle* initially issued with claims that were supported only by new matter that was added in a CIP application. Years after the patent issued, the patentee reissued it as a divisional, after deleting the new matter and the claims that depended on it. In declining to apply the safe harbor, this Court reasoned that "[f]airness to the public" did not permit application of the safe harbor when the patentee obtained the reissue by retroactively cancelling claims that already had "enjoyed years of patent protection" and had precluded the public from "practic[ing] the new matter." *Searle*, 790 F.3d at 1355.

Here, "fairness" points in the opposite direction. The '471 Patent's original disclosure fully supports that Patent's claims, and Janssen never sought any claims based on any new disclosures. Unlike the patentee in *Searle*, Janssen did not cancel claims that the public had been precluded from practicing. Unlike *Searle*, Janssen's cancellation of portions of the '471 Patent's disclosure did not affect any of the '471 Patent's claims, and the '471 Patent is a divisional in form as well as in substance. What is more, Janssen told the PTO that it was prosecuting the application for the '471 Patent to pursue examination of a non-elected invention, and reasonably relied on the Examiner's withdrawal of a double-patenting rejection after Janssen invoked the § 121 safe harbor. On these facts, fairness supports applying the safe harbor and doing so would not result in any "potential windfall" to Janssen. *Searle*, 790 F.3d at 1354 (citation omitted).

The other cases that Celltrion cites addressed different issues not presented here. *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008), for example, considered an issue that this case does not present, *i.e.*, whether § 121 applies "broadly to any type of continuing application filed as a result of a restriction." 518 F.3d at 1360. This Court reasoned that applying § 121 to a patent issuing on a CIP application might result in the patent having "the earlier priority date [of its parent application] even as to the new matter, contrary to the usual rule that new matter is not entitled to the priority date of the original

application." 518 F.3d at 1361. The concern that *Pfizer* addressed does not apply here because the '471 Patent does not include, and Janssen never sought, any claims addressed to new matter.

Likewise, in *Amgen, Inc. v. F. Hoffmann-La Roche, Ltd.*, 580 F.3d 1340 (Fed. Cir. 2009), this Court emphasized that the patentee "ha[d] not presented [it] with any persuasive reason why [it] should deem the . . . continuation applications divisional applications for purposes of § 121." *Id.* at 1354. Here, in contrast, Janssen prosecuted the application for the '471 Patent as a divisional, told the PTO it was doing so, relied on the Examiner's acquiescence to Janssen's invocation of the safe harbor, and obtained claims that covered nothing more than the disclosure of the parent application. In contrast to *Amgen*, the facts here provide "persuasive reason[s]" to deem the '471 Patent a divisional for purposes of § 121.

B. The District Court Further Erred in Rejecting the Applicability of the Two-Way Test

Separate and apart from the applicability of the safe harbor, the district court erred in concluding that the one-way test for double patenting is applicable and, in addition, committed legal error when it addressed the application of the two-way test.

1. The Same-Day Filing of the Applications for the '471 and '272 Patents Does Not Preclude Application of the Two-Way Test

The two-way test for double patenting is available where "through no fault of the applicants," the PTO decides two patent applications "in [the] reverse order of filing." *In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998).

Celltrion does not—and cannot—dispute that the applications for the '471 and '195 Patents were decided in the "reverse order of filing." The application for the '471 Patent was filed first, but the '471 Patent issued more than three years after the '195 Patent.

It also is undisputed that '471 Patent issued more than three years after the '272 Patent, even though the application resulting in the '471 Patent was filed first and thus has a lower serial number than the application that resulted in the '272 Patent. Nonetheless, Celltrion argues that the applications for the '471 and '272 Patents were "simultaneously-filed" because they were accorded the same filing date. Celltrion Br. 61. Celltrion's argument is not supported by any judicial decision, is at odds with the rationale for the two-way test, and is factually incorrect. As Janssen has demonstrated, the two-way test reflects a recognition that an applicant who files applications for both basic and improvement patents "should not be penalized by the rate of progress of the applications though the PTO, a matter over which the applicant does not have complete control." *In re*

Braat, 937 F.2d 589, 593 (Fed. Cir. 1991). This rationale applies with full force where, as here, the applications are accorded the same filing date and an obviousness-type double patenting challenge is directed at a basic patent that issued later due solely to the PTO's delays during the critical co-pendent period. Since both patent applications were filed as the result of the same restriction requirement and both claim priority back to the same application, it is hardly surprising (as the district court noted) that they were filed on the same day. That routine consequence of a restriction requirement is no reason to deny Janssen the benefit of the two-way test. Any other result would retroactively punish patent applicants for expediting their filings, and invite future gamesmanship in the filing of patents arising from restriction requirements. The law should not unfairly deny patent protection to patents that are delayed in issuing through no fault of the applicants.

Moreover, the serial numbers of the applications for the '471 and '272 Patents reflect their actual order of filing. Serial numbers are assigned sequentially to all patent applications in their order of filing. They are called "serial numbers" because they "indicat[e] place in a series." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY at 2072 (1993). The application for the '471 Patent bears a lower serial number than the application for the '272 Patent because it was actually filed first.

The serial numbers assigned to patent applications have practical implications in how they are examined, even for applications filed on the same day. PTO regulations in effect at the time provided that non-provisional applications "shall be taken up for examination by the examiner to whom they have been assigned *in the order in which they have been filed*," *e.g.*, in serial number order, subject to exceptions that are not applicable here. 37 C.F.R. § 1.101 (1997) (emphasis added). Other things being equal, an application bearing a lower serial number—in this case, the application for the '471 Patent—should be examined first. *Id*. Consistent with this regulation, the application for the '471 Patent received a first substantive office action more than eight months before the first substantive office action in the examination of the '272 Patent. Because the '471 Patent was both first-filed and first-examined, the '471 Patent should have issued before the '272 Patent. It did not, for reasons solely attributable to the PTO. The fact that the two applications were filed sequentially on the same day does not alter the analysis.

Celltrion cites MPEP § 804 as supporting its assertion that the two-way test is inapplicable because the applications for the '471 and '272 Patents were filed on the same day. Celltrion Br. 61. But this Court has never suggested that the two-way test is inapplicable in that situation. As Janssen has explained (Janssen Br. 55), MPEP § 804 is based on a misreading of *In re Berg*, 140 F.3d

1428. *Berg* does not support the proposition Celltrion advocates and it does not call into question the applicability of the two-way test for applications filed on the same day. *Berg* states:

> The two-way exception can only apply when the applicant *could not avoid separate filings*, and even then, only if the PTO controlled the rates of prosecution to cause the later filed species claims to issue before the claims for a genus in an earlier application. . . . In Berg's case, the two applications could have been filed as one, so it is irrelevant to our disposition who actually controlled the respective rates of prosecution.

140 F.3d at 1435 (emphasis added). Because of the restriction requirement, Janssen "could not avoid" filing separate applications for the '471 and '272 Patents. The misreading of *Berg* in MPEP § 804 is "not binding on this court." *Hubbell*, 709 F.3d at 1146.

Immersion Corp. v. HTC Corp., 826 F.3d 1357 (Fed. Cir. 2016), which Janssen cited (Br. 54), is on point and recognizes the reality that one event can take place "before" another event even if both occur in the PTO on the same day. *Id.* at 1360-61 (a continuation application is "filed before the patenting [of another application]" where both events occur "on the same day," so long as the continuation is filed before the patent issues). The same principle applies here.

2. As the District Court Recognized, There Are Disputed Fact Issues as to Whether the PTO Was Solely Responsible for the '471 Patent Issuing Later than the '272 and '195 Patents

The two-way test is applicable where "the PTO is solely responsible for the delay in causing the second-filed application to issue prior to the first." *Hubbell*, 709 F.3d at 1149 (quoting *Berg*, 140 F.3d at 1437). In ruling on Celltrion's motion for summary judgment, the district court could not rule out "a genuine dispute of fact concerning whether the PTO is solely responsible for the '471 Patent issuing after the '195 and '272 Patents." Appx5. Viewing the evidence "in the light most favorable to the non-moving party," as required on Celltrion's summary judgment motion, *MRC Innovations, Inc. v. Hunter Mfg., LLP*, 747 F.3d 1326, 1331 (Fed. Cir. 2014), the district court's determination on this fact issue was correct and should not be disturbed on appeal.

Celltrion challenges the district court's determination on this issue when it argues that the judgment should be affirmed on alternate grounds that the district court did not adopt. *See* Celltrion Br. 63-67. According to Celltrion, the one-way test applies because, in Celltrion's view, undisputed evidence establishes as a matter of law the PTO was not solely responsible for delays that caused the '471 Patent to issue later than the '272 and '195 Patents. *Id*. When Celltrion raised the same argument in the district court, the district court did not accept Celltrion's position. Appx5. Neither should this Court.

In assessing the applicability of the two-way test, the delay that matters is delay that "caus[es] the second-filed application to issue prior to the first." *In re Fallaux*, 564 F.3d 1313, 1316 (Fed. Cir. 2009) (quoting *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 969 n.7 (Fed. Cir. 2001)); *accord Hubbell*, 709 F.3d at 1149. The inquiry for the two-way test is limited to the "critical co-pendent period" when the application for the '471 Patent was co-pending in the PTO along with the applications for the '272 and '195 Patents; logically, only actions during that critical period can cause one patent to issue later than another. *In re Basell Poliolefine Italia S.P.A.*, 547 F.3d 1371, 1376 (Fed. Cir. 2008); *see also In re Emert*, 124 F.3d 1458, 1461 (Fed. Cir. 1997).

Here, the delay during the "critical co-pendent period" solely resulted from conduct by the PTO. At minimum, the district court was correct in recognizing that there are disputed facts on this issue.

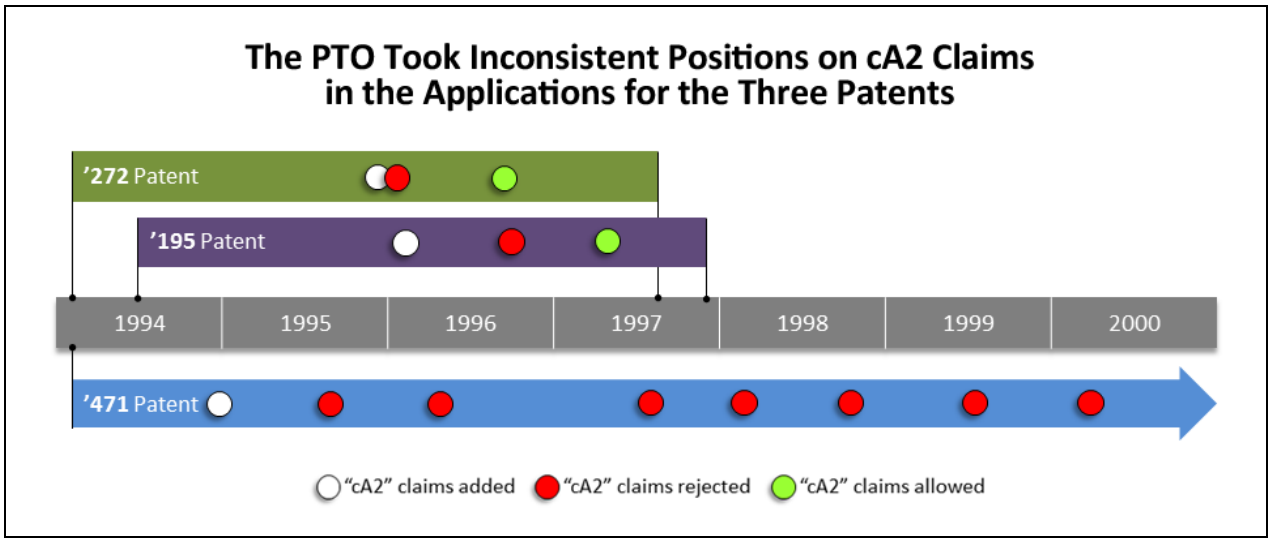
a. The PTO Was Solely Responsible for the Delay that Caused the '471 Patent to Issue Later Than the '272 and '195 Patents

The "critical co-pendent period" for the '272 Patent began on February 4, 1994 (when the applications for the '471 and '272 Patents were filed) and ended on August 12, 1997 (when the '272 Patent issued). Appx111, Appx294. The critical co-pendent period for the '195 Patent began on October 18, 1994 (when the application for the '195 Patent was filed) and ended on December 16,

1997 (when the '195 Patent issued). Appx381. The '471 Patent did not issue until September 4, 2001, more than three years after the issuance of the '272 and '195 Patents. Appx111.

The PTO's actions (and inaction) are the *sole* reason the '471 Patent issued later than the '272 and '195 Patents. The PTO actively delayed the issuance of the '471 Patent by applying and maintaining improper rejections of claims directed to a particular antibody, the "cA2" antibody. It did so even though the '471 specification expressly describes the cA2 antibody, *see*, *e.g.*, Appx158/col.20:8-39, and even though the PTO allowed similar claims to methods of using the cA2 antibody in both the '272 and '195 Patents. As shown in the chart on the next page, during prosecution of the '272 Patent the PTO rejected claims these cA2 claims once and withdrew that rejection promptly, nine months after issuing that rejection. Similarly, in the case of the '195 Patent, the PTO also issued a single rejection of claims on a method of using the cA2 antibody and withdrew that rejection only eight months later. In contrast, during prosecution of the '471 Patent the PTO maintained no fewer than five improper rejections of cA2 claims, starting in August 1995 and continuing over a period of nearly five years[1]:

[1] This court may take judicial notice of the prosecution histories of the '471, '195 and '272 Patents. *See Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 497 n.1 (Fed. Cir. 1997); *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 514 (Fed. Cir. 1990).



As the Board itself recognized in its decision that is the subject of Appeal No. 17-1257, the Examiner's rejection of cA2 claims "delayed issuance of [the '471] patent, especially in comparison to the '272 and '195 Patents in which the same rejection was not made." Appx37 in No. 17-1257.

Instead of treating the cA2 claims in the application for the '471 Patent the same way it did in the applications for the '272 and '195 Patents, *i.e.*, by promptly withdrawing the rejections of the cA2 claims within eight or nine months (as in the case of the '195 and '272 Patents, respectively), the PTO delayed the issuance of the '471 Patent by maintaining its rejection of cA2 claims in the application for the '471 Patent for nearly five years, long after the '272 and '195 Patents had issued. This delay by the PTO was unreasonable, and it caused the '471 Patent to issue later than the '272 and '195 Patents.

In addition, as demonstrated in Janssen's Brief in No. 17-1257 (at 49-53), the PTO further delayed the issuance of the '471 Patent by inaction at various stages during the application for that patent. But for these PTO delays, the '471 Patent would not have issued after the '272 and '195 Patents.

b. Janssen's Conduct Is Not the Reason the '471 Patent Issued After the '272 and '195 Patents

Celltrion argues that Janssen delayed the issuance of the '471 Patent by noticing an appeal to the Board that Janssen ultimately did not perfect, and by continuing prosecution of claims that were ultimately allowed (and which are asserted against Celltrion in this case) after the Examiner indicated that certain claims would be allowable if rewritten. On both points, Janssen's actions are not what "caus[ed] the . . . application[s] [for the '272 and '195 Patents] to issue prior to the [application for the '471 Patent]." *Fallaux*, 564 F.3d at 1316.

Janssen's appeal to the Board: First, Celltrion argues that Janssen delayed issuance of the '471 Patent by "filing a notice of appeal with the Board, then changing its mind." Celltrion Br. 64. This appeal is discussed in Janssen's Brief in the related Appeal No. 17-1257 at 58-60.

It was perfectly proper for Janssen to file the appeal, and the decision to discontinue that appeal was both proper and timely. Moreover, the appeal was not what "caus[ed] the . . . application[s] [for the '272 and '195 Patents] to issue prior to the [application for the '471 Patent]." *Fallaux*, 564 F.3d at 1316. As

noted above, the '272 Patent issued on August 12, 1997 and the '195 Patent issued on December 16, 1997. The '471 Patent did not issue until September 4, 2001—more than *three years* after the issuance of the '272 and '195 Patents. Janssen noticed its appeal to the Board on November 5, 1996 and then filed its Rule 129(a) Amendment on May 5, 1997. If Janssen had not noticed the appeal, and the timeline for PTO consideration of the '471 Patent were accelerated by the six-month period, the '471 Patent still would have issued long after the '272 and '195 Patents.

Janssen's decision to continue prosecution after the Examiner indicated that other claims would be allowable if rewritten: Celltrion's only other "delay" argument is that Janssen supposedly missed an opportunity to have the '471 Patent issue in 1997, when the Examiner issued a final rejection of certain claims (which ultimately issued as claims 5 and 6, which are asserted in this case against Celltrion), but stated that other claims would be allowable if rewritten. Celltrion Br. 64. This theory fails both on the law and the facts.

On the law, no case holds that an applicant engages in dilatory conduct or is otherwise blameworthy by simply continuing to seek prosecution of claims to which it is entitled (including claims that are ultimately allowed). A patentee is not obligated to abandon efforts to obtain claims to which it is entitled merely because an examiner initially says that other claims are allowable. If

Janssen had abandoned its efforts to obtain claims 5 and 6, then the '471 Patent would not include claims that are asserted against Celltrion in this case and that Celltrion has not disputed are infringing. The only blame here rests with the PTO, which failed to appreciate earlier that *all* of the issued claims (including claims 5 and 6) were allowable.

On the facts, Janssen's failure to pursue allowable claims immediately is plainly not the reason that the '471 Patent issued later than the '272 and '195 Patents. The relevant events began on August 5, 1997, when the Examiner issued a final rejection of some claims, but stated that other claims would be allowable if rewritten. Appx2183. Janssen "request[ed] reconsideration and withdrawal of the finality of the rejection," correctly explaining that "in light of the new grounds of rejection, the finality of the last Office Action was improper." Appx2192-2193. On November 12, 1997, the Examiner agreed with Janssen and withdrew "the finality of the previous Office action." Appx2196. By that time, the '272 Patent had already issued and the '195 Patent was about to issue. Any delay is attributable to the PTO's improperly labeling its rejection as "final" without a basis for doing so.

In Celltrion's view, after receiving the "final" rejection in August Janssen should had rewritten the allowable claims in independent form and cancelled the rejected claims. But if Janssen had done so, the '471 Patent still

would have issued after the '272 or '195 Patents. If Janssen had sought allowable claims within three months after the August 5, 1997 final rejection, its request would have been too late to allow the '471 Patent to issue before the '272 Patent and '195 Patents, which issued on August 12, 1997 and December 16, 1997, respectively. Thus, even apart from the delay caused by the PTO's improper finality designation, Janssen could not have caused the '471 Patent to issue before the '272 and '195 Patents. In short, Janssen's decision to continue prosecution to obtain claims to which it was entitled was entirely proper, and it was not the reason the '471 Patent issued after the '272 and '195 Patents. The PTO was entirely responsible for the delay that caused the '471 Patent to issue after those patents.

Emert, 124 F.3d 1458, which Celltrion cites, is not factually "similar" to this case (Celltrion Br. 65) and does not support Celltrion's position. *Emert* involved an egregious situation where the applicant "waited six months and twice filed a substantially similar continuation application" and "did not make any response to the PTO for more than two years after the original rejection." *Id.* at 1461. This case does not involve remotely similar facts.

C. The District Court Erred in Applying the Two-Way Test

1. The District Court Erred by Using the Specification of the '471 Patent as Prior Art in Analyzing Double Patenting

Although the district court applied the two-way test "in the interest of completeness," Appx38, it did so in a manner that is inconsistent with settled

principles of obviousness-type double patenting. Under established law, a patent's specification "cannot be used as prior art" in a double-patenting analysis because "[d]ouble patenting is altogether a matter of what is claimed." *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1277 (Fed. Cir. 1992); *see also Abbvie*, 764 F.3d at 1380. Contravening this settled rule, the district court used the '471 *specification* as prior art in concluding that the '471 *specification* would have rendered the '272 and '195 claims obvious. As Janssen has demonstrated (Br. 58-59), this was error.

In attempting to defend that error, Celltrion relies on a narrow exception to the general rule. That exception has been applied in three cases—*Sun*, 611 F.3d at 1383; *Pfizer*, 518 F.3d at 1358; and *Geneva Pharms., Inc. v. Glaxosmithkline PLC*, 349 F.3d 1373, 1385-86 (Fed. Cir. 2003). In each of these cases, it was necessary to look to the specification to find a utility for a claimed compound because none was disclosed in the claims. As Janssen has demonstrated (Br. 59), this exception has no application here because the claims of the '471 Patent expressly recite a utility for the claimed antibodies, *i.e.*, the "capab[ility] of binding an epitope specific to human tumor necrosis factor TNFα." Appx197. The exception Celltrion invokes has never been applied in these or similar circumstances. Nor should it.

The recitation in the claims that the claimed antibodies are "capable of binding an epitope specific to human tumor necrosis factor TNFα," Appx197, *i.e.*, that the antibodies have biologic activity, is a sufficient recitation of utility for purposes of 35 U.S.C. § 101. To satisfy the utility requirement of § 101, it is sufficient to describe an antibody's pharmacological or biologic activity, *i.e.*, its "capab[ility] of binding an epitope specific to human tumor necrosis factor TNFα," and there is no need to further describe using an antibody or pharmaceutical composition to treat a specific disease. *See Fujikawa v. Wattanasin*, 93 F.3d 1559, 1564 (Fed. Cir. 1996) ("[O]ur court has long held that practical utility may be shown by adequate evidence of any pharmacological activity"); *Nelson v. Bowler*, 626 F.2d 853, 856 (C.C.P.A. 1980) ("[T]ests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use. . . . Knowledge of the pharmacological activity of any compound is obviously beneficial to the public.").

Celltrion argues that "capab[ility] of binding an epitope specific to human tumor necrosis factor TNFα" is a "property of the compound—not a *separate* utility." Celltrion Br. 70-71 (italics added). That is a *non sequitur*. Whether this capability is a "separate" utility or a characteristic of the compound—or both— the claims here disclose a utility for the claimed antibodies that is real and substantial. That is sufficient to make the *Sun* line of cases inapplicable.

On the facts of this case, the applicable rule is the general rule that "a reference patent's specification cannot be used as prior art in an obviousness-type double patenting analysis." *Abbvie*, 764 F.3d at 1380; *see also Gen. Foods*, 972 F.2d at 1281. The district court erred in its double patenting analysis by incorrectly comparing the claims of the '272 and '195 Patents to the disclosure of the '471 *specification* when the correct analysis would involve considering whether the '272 and '195 Patent claims would have been obvious in view of the '471 Patent *claims*.

2. Celltrion Failed to Present Any Expert Evidence Addressing the Correct Claim-to-Claim Comparison

Under the correct claim-to-claim comparison, Celltrion failed to offer any expert evidence comparing the claims of the '272 and '195 Patents to the *claims* of the '471 Patent. That failure dooms Celltrion's position under the two-way test. *See* Janssen Br. 60-61. The only testimony on this subject came from Janssen's experts, Dr. van Deventer and Dr. Ghrayeb, and establishes that the '471 claims would not have rendered the '272 and '195 claims obvious.

Celltrion does not—and cannot—point to any evidence from any expert suggesting that the claims of the '272 and '195 Patents are obvious in view of the *claims* of the '471 Patent. Instead, Celltrion offers an irrelevancy—that Janssen's experts "did not address the '471 patent's specification in analyzing the obviousness of the '272 and '195 patents' claims." Celltrion Br. 72. But there was

no reason for Janssen's experts to address obviousness in view of the '471 specification because the '471 specification is not the correct basis for comparison. *See* Janssen Br. 58-59; *see also* pages 26-28, *supra*. Indeed, there was no need for Janssen to present experts at all. Celltrion is not entitled to summary judgment that the claims of the '471 Patent would have been obvious in light of the *claims* of the '272 and '195 Patents without presenting evidence that they would have been, and it presented none.

CONCLUSION

For the reasons set forth above and in Janssen's main brief, this Court should reverse the grant of summary judgment that claims 1-3, 5 and 7 of the '471 Patent are invalid for obviousness-type double patenting.

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Respectfully submitted,

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CERTIFICATE OF FILING AND SERVICE

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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