No. 19-2346

In the United States Court of Appeals for the Federal Circuit

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IDORSIA PHARMACEUTICALS, LTD.,

Plaintiff/Appellant

v.

ANDREI IANCU, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

Defendant/Appellee

Appeal from the United States District Court for the Eastern District of Virginia in Case No. 1:17-cv-00922-TSE-TCB, Judge T.S. Ellis, III

PLAINTIFF/APPELLANT IDORSIA PHARMACEUTICALS, LTD.'S COMBINED PETITION FOR REHEARING AND/OR REHEARING *EN BANC*

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June 25, 2020

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 26.1, 28(a)(1) and 47.4, counsel for Plaintiff/Appellant Idorsia Pharmaceuticals, Ltd. certifies the following:

I. The full name of the party represented by me is:

Idorsia Pharmaceuticals, Ltd.

II. The name of the real party in interest represented by me is:

Idorsia Pharmaceuticals, Ltd.

III. All parent corporations and publicly held companies that own 10% or more of the stock in the party represented by me are:

Idorsia Ltd.

IV. The names of all law firms and the partners or associates that appeared for the party 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:

Antigone G. Peyton, Protorae Law PLLC (Tysons, Virginia)

V. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal are:

None

/s/ Thomas Hoxie
Thomas Hoxie

June 25, 2020

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes and Regulations

Other Authorities

STATEMENT OF COUNSEL PURSUANT TO FED. CIR. R. 35(b)

Based on my professional judgment, I believe the panel decision is contrary to the precedent of this court: *Pfizer v. Lee,* 811 F.3d 466 (Fed. Cir. 2016).

Based on my professional judgment, I believe that this appeal requires an answer to one or more precedent-setting questions of exceptional importance:

1. Whether an incomplete restriction requirement, which omits and excludes large portions of the claimed invention from further examination without any legitimate statutory basis, provides adequate notice enabling an applicant to fully respond on the merits, as required by 35 U.S.C. § 132.
2. Whether it is consistent with Section 154(b) and this Court's decision in *Pfizer v. Lee,* that a patentee should be denied patent term adjustment for a delay in commencing prosecution entirely caused by two facially incomplete notifications by the PTO to which no substantive response was possible.

Dated: June 25, 2020

/s/ Thomas Hoxie
Thomas Hoxie

I. POINTS OF LAW OR FACT OVERLOOKED OR MISAPPREHENDED BY THE PANEL[1]

The "A delay" provision of patent term adjustment (PTA), 35 U.S.C. § 154(b)(1)(A)(i), provides adjustment for PTO delay in commencing examination beyond 14 months from filing or national phase entry. In this case, commencement of substantive examination was substantially delayed because the examiner's first two incomplete restriction requirements excluded the subject matter of interest from the claims, without a statutory basis. While the Panel characterized this exclusion of certain scopes as "part of the typical back and forth process of patent prosecution," *Idorsia Pharms., Ltd. v. Iancu ("Idorsia Pharms.")*, No. 2019-2346, at 7 (May 11, 2020), the Panel overlooked that prosecution (and any associated "back and forth process") could not even commence until the PTO finally agreed to examine the subject matter of interest, which was well after the 14-month deadline.

To stop the "A" delay clock, the notification from the PTO must meet the requirements of 35 U.S.C. § 132, which requires that the PTO identify the reasons for any rejection, or objection or requirement. While Section 121 permits the PTO

[1] Appellant notes that oral hearing before the Panel scheduled for May 7, 2020, was cancelled *sua sponte* by order of the Court April 17, 2020, presumably due to the COVID-19 pandemic. As a result, the Panel did not have the benefit of oral argument on focusing the issues for consideration.

to divide claimed subject matter into groups and force the applicant to choose which group to pursue, the Panel misconstrues the statute as enabling the PTO to use Section 121 to exclude or refuse to examine certain subject matter altogether.

In this case, the examiner agreed that the initial restriction requirement was facially incomplete, and so he reissued the restriction requirement, then reissued it again. Only upon issuance of a ***complete*** restriction requirement, which included the subject matter of interest, could the applicant respond, allowing examination of the claimed subject matter of interest to commence. Now the question arises whether this extended delay in commencing examination, a direct result of acknowledged PTO error, should be counted against the patentee for purposes of patent term adjustment.

The Panel, confusing the *correctness* of the action with the *completeness* of an action, found that a restriction requirement that is incomplete, and thereby deletes claimed subject matter so that it cannot be examined (as opposed to dividing subject matter into groups or finding subject matter unpatentable), nevertheless satisfies Section 132, and therefore stops the "A" delay clock. But a restriction requirement that deletes over half the claimed scopes is no different from an office action missing over half its pages: in both cases, the PTO's omissions make a substantive response impossible. A facially incomplete notice

cannot comport with Section 132, and the Panel's holding that it does should be reconsidered.

The Panel relies on *Pfizer v. Lee*, in which this Court held that "Section 132 is violated when a rejection is so uninformative that it prevents the applicant from recognizing and seeking to counter the grounds for rejection." 811 F.3d 466, 472 (Fed. Cir. 2016) (quoting *Chester v. Miller*, 906 F.2d 1574, 1578 (Fed. Cir. 1990)). In *Pfizer,* unlike this case, all of the claimed subject matter was addressed, albeit miscategorized. Thus, the applicant could still respond by electing the subject matter of interest, so the issue presented here did not arise. The Panel's unexplained extension of *Pfizer* to a situation where the PTO issued a facially incomplete action, removing certain subject matter so that it could not be elected or examined *at all* (as opposed to restricting or rejecting subject matter as permitted under Sections 121 and 132), was inconsistent with *Pfizer* and with Sections 132 and 154(b). An *incomplete* action under Section 121 provides no statutory basis to exclude claimed subject matter from prosecution, nor any reasonable opportunity for the applicant to respond – other than by requesting that the PTO withdraw the action entirely and replace it with a corrected, complete action. *Pfizer* does not permit any PTO notification, no matter how incomplete, to meet the requirements of Section 132.

II. ARGUMENT IN SUPPORT OF PANEL REHEARING OR REHEARING EN BANC

A. This Case Presents an Issue of Exceptional Importance

The rules relating to patent term adjustment are undoubtedly confusing, but patent term is very important in many industries, particularly the pharmaceutical industry. While it would doubtless be administratively convenient for the PTO's PTA calculation that any office action, even one that is facially incomplete, will always satisfy the requirements of Section 132, making human review is unnecessary, the Patent Act and the decisions of this Court require a higher standard. Moreover, in defining a sufficient notification under Section 132 as any communication that causes the applicant to call and ask for clarification or further information, the Panel has devalued the standards promulgated by Congress in Section 132, and by this Court in other cases, including *Pfizer.*

The PTA provisions of the Patent Act provide for so-called "A-delay" in favor of the applicant for every day that the PTO takes to provide a first "notification[] under section 132" beyond the date 14-months from national stage commencement or filing. 35 U.S.C. § 154(b)(1)(A)(i). A restriction requirement is often the first office action issued by an examiner, and this often serves as the event which triggers the end of A-delay accumulation.

Unlike Office actions on the merits, the effect of a restriction requirement transcends the bounds of the pending application—it defines what subject matter, not elected by the applicant, may be pursued in a divisional application, gaining the benefit of the safe harbor provision of Section 121. *See* 35 U.S.C. § 121. While a restriction requirement may *divide* claimed subject matter, Section 121 provides no statutory basis to reject or exclude claimed subject matter. As this Court's predecessor explained,

> It is apparent that § 121 provides the Commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to reject a particular claim on that same basis.

In re Weber, 580 F.2d 455, 458 (CCPA 1978). Moreover, Section 112 allows the inventor to claim the invention as he contemplates it, so "[a]s a general proposition, *an applicant has a right to have each claim examined on the merits*," and "a rejection under § 121 violates the basic right of the applicant to claim his invention as he chooses." *Id.* at 458-459 (emphasis added). Plainly, for an applicant to have a meaningful opportunity to have each claim examined, the restriction requirement must address *all* claimed subject matter, because the applicant has no ability to elect for further examination any subject matter which is not included in the restriction requirement.

Section 132 of the Patent Act provides that an office action, including a restriction requirement, must "stat[e] the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application." 35 U.S.C. § 132(a).

This Court held, in *Pfizer*, that Section 132 "requires that an applicant 'at least be informed of the broad statutory basis for [the rejection of] his claims, so that he may determine what the issues are on which he can or should produce evidence.'" 811 F.3d at 472 (quoting *In re Hughes*, 345 F.3d 184, 185 (CCPA 1965)) (alteration in original). The Court further recognized that "Section 132 is violated when a rejection is so uninformative that it prevents the applicant from recognizing and seeking to counter the grounds for rejection." *Id.* (quoting *Chester*, 906 F.2d at 1578).

The Panel erred in finding that a facially incomplete restriction requirement—one that omits more than half of the claimed subject matter from the invention groups, including the subject matter of interests to the applicant, and *which the PTO did not dispute* needed to be withdrawn and replaced with a complete restriction requirement—nevertheless met the standard enunciated in *Pfizer,* as being sufficiently informative for an applicant to formulate a reasoned

and fully compliant response. Notably, while the Panel asserted a response could be made, the Examiner in this case did not think this was the case, which is exactly why he withdrew the first and second restriction requirements, without requiring any applicant response, and replaced them with new restriction requirements. Under the Panel's standard, it is difficult to imagine what would qualify as *insufficiently* informative – any incomplete notification that might trigger a request for clarification or further information (an action missing half its pages for example) would seem to be sufficient under Section 132. The Panel's decision thus eviscerates the standard enunciated in *Pfizer,* that to stop the "A" delay clock, the notification from the PTO must include at least the broad statutory basis for the rejection.

B. The Panel's Decision Conflicts with Section 132 as Interpreted by This Court's Decision in *Pfizer*

The Panel's ultimate conclusion is that "under *Pfizer*, the examiner's first restriction requirement met the notice requirement of § 132 and thus ended the accrual of A delay." *Idorsia Pharms.*, at 5. The Panel acknowledges that "Idorsia attempts to distinguish *Pfizer* on the ground that in *Pfizer*, the restriction requirement at issue omitted dependent claims . . . not subject matter from independent claims." *Id.* at 7. This is a big difference, but the Panel then proceeds to "reject Idorsia's

overly narrow reading of *Pfizer*," *id.*, without addressing what similarities with *Pfizer* compel the outcome of this case, or what policy rationale could possibly justify expanding *Pfizer* to cover cases where the PTO notification is facially incomplete.

There are important differences between the fact pattern in *Pfizer* and the fact pattern in this case. The rationale of *Pfizer*, as briefed by Idorsia extensively, supports Idorsia's position. *See* Op. Br. at 22-26; Reply Br. at 14-17. The critical difference between this case and *Pfizer* is that in *Pfizer* every independent claim was categorized in the examiner's invention groups. *Pfizer*, 811 F.3d at 472 & n. 2. The restriction requirement was complete insofar as no subject matter was excluded from examination. Although the Examiner omitted six dependent claims, the Court pointed out that each dependent claim necessarily would have fallen into the same invention group as its parent independent claim. Thus, the applicant in *Pfizer,* in contrast to the applicant in this case, was able to respond to the restriction substantively and was not effectively precluded from electing and prosecuting the subject matter of interest. *See* 37 C.F.R. § 1.143 (requiring that an applicant responds to a restriction by electing an invention).

This Court emphasized in *Pfizer* that its decision rested on such fact-specific considerations as:

- "At no time did the applicants dispute the examiner's definitions of the 21 inventions themselves." *Id.* at 473. In the present case, by contrast, the problem was that much of the scope was simply deleted from the examiner's proposed invention grouping.

- "[S]ignificantly, the examiner's defined invention groups remained identical between the two restriction requirements." *Id.* That was not the case here, as many scopes needed to be added.

- *Pfizer* "could have taken direction for their classification [the omitted dependent claims] from the fact that their respective independent claims were each included in the initial restriction requirement." *Id.* There was no way for the applicant to elect or claim the omitted subject matter in this case without violating Rule 1.143.

- "Here, the applicants responded to the restriction requirement by electing an invention group and suggesting reclassification of certain dependent claims." *Id.* at 475. But in this case, no election or response compliant with Rule 1.143 was possible, as the restriction requirement was incomplete.

On every single one of these important considerations, the facts of the present case are opposite those of *Pfizer*, and these are distinctions that the Panel failed to consider.

C. The Panel Confuses Correctness with Completeness

According to the Panel, "Actelion was able to respond to the first restriction requirement and successfully oppose the examiner's description of the multiple invention groups." *Idorsia Pharms.*, at 6. The Panel asserts that this alone "demonstrates that Actelion was able to understand the examiner's proposed invention groups and prepare responsive arguments." *Id.* at 7.

The record, however, is not consistent with this conclusion. The Panel notes that Actelion merely "notified the examiner by telephone that the examiner's defined invention groups omitted certain subject matter from the scope of the claims" and "did not elect any of the invention groups" presented by the examiner. *Id.* at 3. The Panel even noted that the examiner agreed that the restriction requirement omitted subject matter and needed to be replaced by a new restriction requirement. *Id.*

The Panel erred because Actelion's request to have the restriction requirement withdrawn and replaced with a complete restriction requirement was not a "response" challenging the correctness of the restriction requirement. The PTO's rules require that a compliant response to a restriction requirement must at least provisionally elect *one* of the invention groups identified by the examiner, and optionally, may include a traversal of the grounds for restriction. *See* 37

C.F.R. § 1.143; Manual of Patent Examining Procedure § 818 (9th Ed. Rev. 8, Jan. 2018) ("MPEP"). Even a traversal alone—arguing that the restriction itself is not proper for some reason—does not satisfy the PTO's rules for a compliant response. *Id.* The panel opinion failed to consider these issues, and thus erred, because a telephone call requesting that the incomplete action be withdrawn and replaced with a complete action plainly is not a "response" within the meaning of Rule 1.143.

In *Pfizer,* the Court held that "Section 132 is violated when a rejection is so uninformative that it prevents the applicant from recognizing and seeking to counter the grounds for rejection." *Pfizer*, 811 F.3d at 472. Here, we have exactly that situation. The invention ultimately elected was not encompassed by any of the invention groups defined by the first restriction requirement. It was not possible to make a compliant response and still seek examination of the subject matter of interest, because a compliant response would require provisional election of one of the inventions as defined by the examiner, which would exclude the subject matter of interest. Nor would it even be possible to later appeal the PTO's exclusion of this subject matter, as restriction requirements are not considered to be substantive rejections and so can only be challenged by petition to the Director. *See* 37 C.F.R. § 1.144. The PTO (at the time agreed)

with Actelion that a response was not possible, which is exactly why the examiner withdrew and replaced the *first and second* restriction requirements, without requiring responses under Rule 1.143.

Contrary to the Panel's findings that the PTO's reference to Section 121 placed the initial restriction requirement in compliance with Section 132, the fact is that the statutory scheme simply does not contemplate that Section 121 could ever be used as suggested by the Panel, to *delete* subject matter from the case, as opposed to merely restricting it into groups. *See In re Weber*, 580 F.2d at 458. The only sensible resolution of the PTO's error was that eventually taken: the *incomplete* restriction requirements had to be replaced with *complete* restriction requirements *before* any substantive response could be required or made.

The Panel confuses the "correctness" of an office action with the "completeness" of the office action. In rejecting Idorsia's argument, the Panel argues that a "restriction requirement need not be correct to satisfy the statutory notice requirement." *Idorsia Pharms.*,. at 7 (citing *Univ. of Mass. v. Kappos ("UMass"),* 903 F. Supp. 2d 77, 86 (D.D.C. 2012)). Yet, Idorsia did not argue that the restriction requirement was *incorrect*, but rather, that it was *incomplete*. There has been no suggestion that in response to the first restriction requirement Idorsia ever argued that the examiner was wrong in imposing a restriction

requirement—only that the examiner's invention groups omitted more than half of the subject matter of the claims.

As Judge Newman correctly observed in her dissent in *Pfizer*, in *UMass* there was no contention that the restriction requirement was incomplete—only that the applicant disagreed with its organization. *Pfizer*, 811 F.3d at 479 (Newman, J., dissenting). The patent "applicant is not required to guess, to fill in blanks erroneously left by the PTO" because the "applicant's guess cannot bind the PTO." *Id.* at 478. "Rather than guess, the applicant is entitled to a complete Office action." *Id.* This is all Actelion asked for in response to the first (and second) restriction requirement.

D. The Panel Fails to Consider That a Fully Responsive Election and Traverse of the First Restriction Requirement Could Not Have Been Made

The purpose of an examiner's restriction requirement is to identify what he or she believes to be the allegedly separate inventions and to require the applicant to elect *one* of those inventions for further prosecution in that application. MPEP § 1893.03(d). Because of the importance of this, the rules require that an examiner "must provide a clear and detailed record of the restriction requirement to provide a clear demarcation between restricted inventions so that it can be determined whether inventions claimed in a

continuing application are consonant with the restriction requirement." MPEP § 814 (emphasis in original) (citing *Geneva Pharms. Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1381 (Fed. Cir. 2003)).

An applicant's response to the restriction requirement *must* elect one of the allegedly separate inventions as defined by the examiner. MPEP § 818. Any traversal must be made in immediate response to the office action setting forth the requirement. *Id.* Should the examiner make the requirement final in the next office action (generally the first office action on the merits), that decision is not appealable. *In re Hengehold*, 440 F.2d 1395, 1400 (CCPA 1971). It is therefore essential that the restriction requirement address the entire scope of the claims and be sufficiently clear and specific to enable an applicant to elect an invention that will be the *exclusive basis* for further prosecution in the application.

The Panel recognized that the only independent claim pending at the first restriction requirement, claim 1, defined a chemical formula including the group $P(O)R^5R^8$, with various options for the R^5 and R^8 substituents. *Idorsia Pharms.*, at 2. The Panel also noted that the examiner's defined invention groups were based on the substituents R^8 and R^9. *Id.* at 3. Yet, while the Panel noted that the first (and second) restriction failed to include certain subject

matter, the Panel did not address the scope of this omission or its impact on Actelion's opportunities for election.

As explained in Idorsia's briefs, the first restriction requirement categorized only 6 of 18 scopes in the examiner's invention groups. *See* Op. Br. at 16-18, 39-46. Thus, approximately two thirds of the claimed subject matter was excluded from examination. Importantly, the examiner's invention groups omitted the very subject matter that Actelion ultimately elected for prosecution, in response to the third restriction requirement. *See* Op. Br. 18-19. This type of error by the examiner is on a completely different footing from errors made by the examiner in *Pfizer,* because in *Pfizer,* no claimed subject matter was excluded entirely from the invention group scheme. No matter what subject matter the applicant desired in *Pfizer*, the applicant could have made an appropriate election. Here, Actelion had no option to elect its desired subject matter in response to the first restriction requirement, because it was excluded. Therefore, Actelion lacked "such information . . . as may be useful in judging the propriety of continuing prosecution." 35 U.S.C. § 132(a).

E. The Panel Misapprehends this Court's Exception to PTA for Typical Back-and-Forth of Prosecution, contrary to both *UMass* and *Pfizer*

In *Pfizer*, this Court agreed with the District of Columbia District Court that there is a normal "back and forth" process in prosecution that is not entitled to PTA. 811 F.3d at 475. As this Court put it, "the prosecution process involves a 'back and forth' process wherein applicants advocate for the broadest and strongest claims, and examiners provide reasons for rejecting unsupported or unpatentable claims." *Id.* (citing *UMass*, 903 F. Supp. 2d at 86). Similarly, in *UMass*, the court described the typical back-and-forth as including "reexamination of rejected applications," "request[ing] reconsideration and withdrawal or modification of the [restriction] requirement," and "reply[ing] and request[ing] reconsideration or further examination." *UMass*, 903 F. Supp. 2d at 86. These examples clearly invoke the back-and-forth discussion of the merits of an office action, not the mere suggestion that a facially incomplete office action should be rendered complete *so that a complete response on the merits* can be made.

But in this case, prosecution could not even commence until the PTO finally agreed to examine the subject matter of interest, so the normal "back and forth" process of prosecution did not get started until well after the 14-month

deadline. Pointing out to the Examiner that his action is missing over half the claimed scopes so that no response is possible is like pointing out that an office action appears to be missing half its pages – this cannot be equated with a back-and-forth dialogue on the merits.

The Panel concluded that "Idorsia's alleged delay is 'not the type of error for which the Act was intended to compensate,'" referring to this Court's instruction that PTA is not intended to "guarantee the correctness of the agency's every decision." *Idorsia Pharms.*, at 8 (quoting *Pfizer*, 811 F.3d at 476). But Section 154(b)(1)(A) is not concerned with "type of error" – it simply sets a deadline. Here, the PTO's error meant that examination of the subject matter of interest could not commence until the error was corrected and a complete restriction requirement was provided. As a result of this PTO delay, commencement of examination was delayed well beyond the 14-month deadline contemplated by Section 154(b)(1)(A)(i)(II). An extended delay in commencing examination, resulting from *two* facially incomplete restriction requirements issued by the PTO, is *exactly* the kind of delay that should result in PTA.

CONCLUSION

For the foregoing reasons, Idorsia respectfully requests that this Court grant panel rehearing or rehearing *en banc*.

Dated: June 25, 2020

Respectfully submitted,

/s/ Thomas Hoxie

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CERTIFICATE OF SERVICE

On June 25, 2020, the foregoing brief was submitted to the Court through the CM/ECF system. All parties are represented by CM/ECF users and will be served by the CM/ECF system.

/s/ Thomas Hoxie

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

This brief complies with the type-volume limitations of Federal Rules of Appellate Procedure 35(b)(2)(A) and 40(b)(1). According to the word

processing system used to prepare it, the relevant portions of this brief contains 3886 words.

/s/ Thomas Hoxie

ADDENDUM

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

IDORSIA PHARMACEUTICALS, LTD.,
Plaintiff-Appellant

v.

ANDREI IANCU, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Defendant-Appellee

2019-2346

Appeal from the United States District Court for the Eastern District of Virginia in No. 1:17-cv-00922-TSE-TCB, United States District Judge T. S. Ellis, III.

Decided: May 11, 2020

THOMAS HOXIE, Hoxie & Associates, LLP, Millburn, NJ, for plaintiff-appellant. Also represented by CORY S. POKER.

PETER JOHN SAWERT, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, for defendant-appellee. Also represented by KAKOLI

CAPRIHAN, BRIAN RACILLA, THOMAS W. KRAUSE; G. ZACHARY TERWILLIGER, KIMERE JANE KIMBALL, Office of the United States Attorney for the Eastern District of Virginia, United States Department of Justice, Alexandria, VA.

Before CHEN, HUGHES, and STOLL, *Circuit Judges*.

STOLL, *Circuit Judge*.

Idorsia Pharmaceuticals, Ltd. appeals the district court's summary judgment upholding the U.S. Patent and Trademark Office's patent term adjustment (PTA) determination for U.S. Patent No. 8,518,912. Specifically, Idorsia challenges the PTO's calculation of "A Delay," whereby a patent's term is adjusted when the PTO fails to respond to certain events or filings by statutorily enumerated examination deadlines. Because the district court correctly concluded that the PTO examiner's first of three restriction requirements satisfied the notice requirement of 35 U.S.C. § 132, and thus ended the accumulation of A Delay for the '912 patent, we affirm.

BACKGROUND

I

Idorsia's predecessor in interest in the '912 patent, Actelion Pharmaceuticals, Ltd., filed U.S. Patent Application No. 12/745,358 as a national stage application under 35 U.S.C. § 371. Following a preliminary amendment, the '358 application included independent claim 1 and dependent claims 2–14 and 16. Claim 1 is a compound claim reciting a chemical formula with the group $P(O)R^5R^8$. Claim 1 also recites various options for substituents R^5 and R^8.

On March 14, 2012, the PTO examiner issued a restriction requirement. The examiner identified six invention groups for all pending claims that were "independent

and distinct from each other because they [we]re directed to structurally dissimilar compounds that lack a common core" based on the possible variations for the group $P(O)R^5R^8$. J.A. 598. The examiner stated that "[r]estriction [wa]s required under 35 U.S.C. [§]121," J.A. 597, which grants the PTO the authority to limit a patent application claiming "two or more independent and distinct inventions" to one invention for continued prosecution. In response to the restriction requirement, Actelion notified the examiner by telephone that the examiner's defined invention groups omitted certain subject matter from the scope of the claims. The examiner agreed and indicated that he would issue a new restriction requirement. Actelion did not elect any of the invention groups in the initial restriction requirement.

About one month later, on April 18, 2012, the examiner issued a second restriction requirement that superseded and replaced the first restriction requirement. The examiner divided all pending claims into eight distinct invention groups. Actelion notified the examiner by telephone that the invention groups set forth in the second restriction requirement omitted claimed subject matter. The examiner agreed and indicated that he would issue a third restriction requirement. Actelion did not elect any of the invention groups in the second restriction requirement.

On June 21, 2012, the examiner issued a third restriction requirement, which divided all pending claims into three distinct invention groups. Actelion filed a response to the third restriction requirement, electing one of the three invention groups, and traversed the restriction.

The '358 application issued as the '912 patent on August 27, 2013. That same day, the PTO issued an initial PTA determination for the '912 patent of 314 days, which included 229 days of A Delay. The PTO awards A Delay for delays arising from the PTO's failure to act by certain enumerated deadlines. Relevant to this case, A Delay is based

on the time that passes between the date that is "14 months after" the "date of commencement of the national stage under section 371 in an international application" and the date that the PTO "provide[s] at least one of the notifications under section 132 or a notice of allowance under section 151." 35 U.S.C. § 154(b)(1)(A)(i); *see also* 37 C.F.R. § 1.703(a)(1).

Following Actelion's request for reconsideration of PTA, the PTO issued a final decision calculating a total of 346 days of PTA, including 261 days of A Delay, based on its determination that the examiner's second restriction requirement stopped the accrual of A Delay. Actelion then sued the PTO in the U.S. District Court for the Eastern District of Virginia, challenging the PTA determination. In March 2016, the district court remanded the case to the PTO to reconsider its PTA calculation in light of *Pfizer, Inc. v. Lee*, 811 F.3d 466 (Fed. Cir. 2016). Order, *Actelion Pharm. Ltd. v. Lee*, No. 15-1266 (E.D. Va. Mar. 2, 2016), ECF No. 23. Thereafter, the PTO issued its final determination of PTA for the '912 patent, which totaled 311 days of PTA, including 226 days of A Delay, based on its finding that A Delay stopped accruing after the examiner's first restriction requirement.

II

Idorsia brought the instant lawsuit pursuant to 35 U.S.C. § 154(b)(4)(A), the Administrative Procedure Act (APA), and the Fifth Amendment of the U.S. Constitution, challenging the PTO's PTA determination. Specifically, Idorsia argued that A Delay continued to accrue for an additional 99 days after the date calculated by the PTO because the first and second restriction requirements did not meet the notice requirement of 35 U.S.C. § 132.

The parties cross-moved for summary judgment. The district court granted summary judgment in favor of the PTO, holding that the first restriction requirement complied with § 132 based on the standard set forth in this

court's *Pfizer* decision. *Idorsia Pharm. Ltd. v. Iancu*, 393 F. Supp. 3d 445, 453–54 (E.D. Va. 2019).

Idorsia appeals. We have jurisdiction pursuant to 28 U.S.C. §§ 1295(a)(1), (a)(4)(C).

DISCUSSION

We review the district court's grant of summary judgment de novo, "applying the same standard as the district court." *Pfizer*, 811 F.3d at 470 (quoting *Voter Verified, Inc. v. Premier Election Sols., Inc.*, 698 F.3d 1374, 1379 (Fed. Cir. 2012)). The PTO's PTA decisions are reviewed in accordance with the APA. 35 U.S.C. § 154(b)(4)(A). Under the APA, a court may set aside the PTO's actions only if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). We hold that under *Pfizer*, the examiner's first restriction requirement met the notice requirement of § 132 and thus ended the accrual of A Delay for the '912 patent.

I

A Delay stops accruing when the PTO "provide[s] at least one of the notifications under section 132." 35 U.S.C. § 154(b)(1)(A)(i). A written restriction requirement qualifies as a "notification[] under section 132." *Pfizer*, 811 F.3d at 471–72. Section 132 provides, in pertinent part:

> Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application . . . .

35 U.S.C. § 132(a).

In *Pfizer*, we held that § 132 "merely requires that an applicant 'at least be informed of the broad statutory basis for [the rejection of] his claims, so that he may determine what the issues are on which he can or should produce evidence.'" 811 F.3d at 472 (alteration in original) (quoting *Chester v. Miller*, 906 F.2d 1574, 1578 (Fed. Cir. 1990)). We explained that § 132 also requires that the examiner's rejection be "sufficiently informative to allow [the applicant] to counter the grounds for rejection." *Id.* at 473–74 (citations omitted). As to this second requirement for notice, we reaffirmed our precedent holding that § 132 "is violated when a rejection is so uninformative that it prevents the applicant from recognizing and seeking to counter the grounds for rejection." *Id.* at 471–72 (quoting *Chester*, 906 F.2d at 1578).

II

In this case, Idorsia does not dispute that the examiner's first restriction requirement provided notice of the statutory basis for the examiner's rejection, namely, that restriction was required under 35 U.S.C. § 121. Rather, the parties' dispute focuses on whether the first restriction requirement was "sufficiently informative to allow [Actelion] to counter the grounds for rejection." *Pfizer*, 811 F.3d at 473–74. We agree with the district court and the PTO that under *Pfizer*, the examiner's first restriction requirement for the '912 patent satisfied the notice requirement of § 132.

The examiner's first restriction requirement asserted that all pending claims of the '358 application were subject to the restriction requirement. The first restriction requirement also defined the invention groups available for election, and articulated the reasons that the examiner believed that the '358 application claimed multiple distinct inventions. Moreover, Actelion was able to respond to the first restriction requirement and successfully oppose the examiner's description of the multiple invention groups,

which demonstrates that Actelion was able to understand the examiner's proposed invention groups and prepare responsive arguments. Thus, as in *Pfizer*, the first restriction requirement, when "[v]iewed as a whole," provided "adequate grounds on which" Actelion could "recogniz[e] and seek[] to counter the grounds for rejection." 811 F.3d at 472 (alterations in original) (quoting *Chester*, 906 F.2d at 1578).

Idorsia contends that neither the first nor the second restriction requirements qualifies as sufficient notice under § 132. In particular, Idorsia argues that the examiner's defined invention groups' omission of subject matter from the scope of the claims violates § 132 because "Actelion plainly lacked the necessary information to determine how to proceed." Appellant's Br. 26. Idorsia attempts to distinguish *Pfizer* on the ground that in *Pfizer*, the restriction requirement at issue omitted dependent claims from the defined invention groups, not subject matter from independent claims.

We reject Idorsia's overly narrow reading of *Pfizer*. A restriction requirement need not be correct to satisfy the statutory notice requirement. *See Univ. of Mass. v. Kappos*, 903 F. Supp. 2d 77, 86 (D.D.C. 2012) ("*UMass*") (rejecting as "irrelevant to . . . calculating A delay" the question of whether or not "it was necessary [for the applicant] to persuade the Examiner to revise the restriction requirement" to correct certain errors). Actelion's and the examiner's "exchanges concerning the challenged restriction requirement were part of the typical 'back and forth' process of patent prosecution." *Pfizer*, 811 F.3d at 475–76 (quoting *UMass*, 903 F. Supp. 2d at 86). Although this process "often involves changes in both the applicant's and examiner's positions, an examiner's reissuance of an office action in response to an applicant's suggestion does not automatically mean that an application has been 'delayed' for purposes of patent term adjustment." *Id.* at 475 (quoting *UMass*, 903 F. Supp. 2d at 86). Section 132 "does not

award additional A delay if an applicant successfully convinces the PTO that the Office action was erroneous." *UMass*, 903 F. Supp. 2d at 86–87. Indeed, the "underlying purpose of PTA is to compensate patent applicants for *certain reductions* in patent term that are not the fault of the applicant, not to guarantee the correctness of the agency's every decision." *Pfizer*, 811 F.3d at 476 (internal quotation marks omitted) (quoting *UMass*, 903 F. Supp. 2d at 86). Based on the record evidence, we agree with the PTO and the district court that Idorsia's alleged delay is "not the type of error for which the Act was intended to compensate." *Id.*

We have considered Idorsia's other arguments, but we do not find them persuasive. The PTO properly calculated the length of PTA for the '912 patent. Accordingly, we conclude that the district court did not err in granting summary judgment in favor of the PTO.

CONCLUSION

For the foregoing reasons, we affirm the judgment of the district court.

AFFIRMED

COSTS

No costs.