**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| GLAXOSMITHKLINE BIOLOGICALS SA and GLAXOSMITHKLINE LLC,<br><br>Plaintiffs,<br><br>v.<br><br>PFIZER INC., PHARMACIA & UPJOHN CO. LLC, BIONTECH SE, BIONTECH MANUFACTURING GMBH, and BIONTECH US INC.,<br><br>Defendants. | Civil Action No. 24-512-GBW |
| GLAXOSMITHKLINE BIOLOGICALS SA and GLAXOSMITHKLINE LLC,<br><br>Plaintiffs,<br><br>v.<br><br>MODERNA, INC., MODERNATX, INC., and MODERNA US, INC.,<br><br>Defendants. | Civil Action No. 24-1135-GBW |
| GLAXOSMITHKLINE BIOLOGICALS SA and GLAXOSMITHKLINE LLC,<br><br>Plaintiffs,<br><br>v.<br><br>MODERNA, INC., MODERNATX, INC., and MODERNA US, INC.,<br><br>Defendants. | Civil Action No. 24-1136-GBW |

**MEMORANDUM ORDER**

Pending before the Court are three partial motions to dismiss counterclaims and strike affirmative defenses brought by Plaintiffs Glaxosmithkline Biologicals SA and GlaxosmithKline LLC ("GSK") against Defendants Pfizer Inc., Pharmacia & Upjohn Co. LLC, BioNTech SE, BioNTech Manufacturing GMBH, BioNTech US Inc. ("PBNT") (C.A. No. 24-512, D.I. 34), Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. ("Moderna") (C.A. No. 24-1135, D.I. 120; C.A. No. 24-1136, D.I. 22) (collectively, "Defendants"). These actions arise from GSK's allegations that Defendants infringed its patents. For the reasons set forth below, the Court denies-in-part and grants-in-part GSK's Motions.

## I. LEGAL STANDARDS

### A. Motion to Dismiss

"To state a viable claim, a plaintiff must offer a short and plain statement showing that he is entitled to relief, including 'allegations plausibly suggesting (not merely consistent with)' such entitlement." *Bah v. United States*, 91 F.4th 116, 119 (3d Cir. 2024) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)). A complaint must include more than mere "labels and conclusions" or "a formulaic recitation of the elements of a cause of action." *Twombly*, 550 U.S. at 555. The complaint must set forth enough facts that, if accepted as true, "state a claim to relief that is plausible on its face." *Id.* A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

"[A]t the motion-to-dismiss stage, the Court assumes the truth of 'well-pleaded factual allegations' and 'reasonable inference[s]' therefrom." *Nat'l Rifle Ass'n of Am. v. Vullo*, 602 U.S. 175, 181 (2024) (second alteration in original) (quoting *Iqbal*, 556 U.S. at 678-79). "In ruling on a motion to dismiss," a court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Wood v. Moss*, 572 U.S. 744, 755 n.5 (2014) (quoting *Iqbal*, 556 U.S. at 678). Thus,

"[t]he primary question in deciding a motion to dismiss is not whether the plaintiff will ultimately prevail, but rather whether they are entitled to offer evidence to establish the facts alleged in the complaint." *Fenico v. City of Philadelphia*, 70 F.4th 151, 161 (3d Cir. 2023). In other words, "when a complaint adequately states a claim, it may not be dismissed based on a district court's assessment that the plaintiff will fail to find evidentiary support for his allegations or prove his claim to the satisfaction of the factfinder." *Twombly*, 550 U.S. at 563 n.8.

**B. Motion to Strike**

"The court may strike from a pleading . . . any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). "Immaterial matter 'has no essential or important relationship to the claim for relief or the defenses being pleaded,' and impertinent matter similarly 'consists of statements that do not pertain, and are not necessary, to the issues in question.'" *Dufresne Spencer Grp., LLC v. Han Nara Enters. LP*, C.A. No. 21-1857, 2022 WL 1978686, at *1 (D. Del. June 6, 2022) (quoting *Del. Health Care v. MCD Holding Co.,* 893 F. Supp. 1279, 1291-92 (D. Del. 1995)).

"As a general matter, motions to strike under Rule 12(f) are disfavored." *Aoki v. Benihana, Inc.*, 839 F. Supp. 2d 759, 764 (D. Del. 2012) (citing *Seidel v. Lee*, 954 F. Supp. 810, 812 (D. Del. 1996)). "[T]he purpose of a motion to strike is to clean up the pleadings, streamline litigation, and avoid unnecessary forays into immaterial matters." *Sepracor Inc. v. Dey, L.P.*, C.A. No. 06-113, 2008 WL 4377570, at *2 (D. Del. Sept. 26, 2008) (alteration in original). "In proceeding on a motion to strike for relevancy, the movant must show that the allegations being challenged are so unrelated to the plaintiff's claims as to be unworthy of any consideration and that their presence in the pleadings will be prejudicial." *Karpov v. Karpov*, 307 F.R.D. 345, 348 (D. Del. 2015). Therefore, "even where the challenged material is redundant, immaterial, impertinent, or scandalous, a motion to strike should not be granted unless the presence of the surplusage will

prejudice the adverse party." *Symbol Techs., Inc. v. Aruba Networks, Inc.*, 609 F. Supp. 2d 353, 359 (D. Del. 2009) (cleaned up).

## II. DISCUSSION

### A. The Court Denies GSK's Motion to Dismiss PBNT's Counterclaims and Related Affirmative Defenses of Prosecution Laches

In C.A. No. 24-512, GSK filed its First Amended Complaint against PBNT, asserting claims for infringement of eight patents: U.S. Patent Nos. 11,638,693 (the "'693 Patent"), 11,638,694 (the "'694 Patent"), 11,666,534 (the "'534 Patent"), 11,766,401 (the "'401 Patent"), 11,786,467 (the "'467 Patent"), 11,759,422 (the "'422 Patent"), 11,655,475 (the "'475 Patent"), and 11,851,660 (the "'660 Patent"). *See* C.A. No. 24-512, D.I. 26. On August 30, 2024, PBNT filed their Answer, Affirmative Defenses, and Counterclaims, which included, but not limited to, counterclaims and affirmative defenses for patent misuse and prosecution latches. D.I. 32. On September 20, 2024, GSK moved to dismiss PBNT's counterclaims for patent misuse and prosecution laches and strike the related affirmative defenses. D.I. 34. On October 24, 2024, the parties stipulated to the dismissal of the counterclaims related to patent misuse and to strike the related affirmative defenses without prejudice. D.I. 41. Thus, the remaining issue before the Court concerns GSK's motion to dismiss and strike PBNT's counterclaims and affirmative defenses related to prosecution laches for the '693 Patent, '694 Patent, '534 Patent, '401 Patent, '467 Patent, '422 Patent, '475 Patent, and '660 Patent (the "PBNT Counterclaim Patents").

#### 1. PBNT Sufficiently Pleads Prosecution Laches

GSK contends that PBNT "fail[s] to plausibly show that GSK's prosecution practices, constituted an egregious misuse of the patent system that prejudiced PBNT." *Id.* at 2. Specifically, GSK contends that PBNT does not allege facts sufficient to show that any delay in GSK's patent prosecution was "unreasonable and inexcusable." *Id.* at 15.

The doctrine of prosecution laches "may render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution that constitutes an egregious misuse of the statutory patent system under the totality of circumstances." *Cancer Rsch. Tech Ltd. v. Barr Lab'ys Inc.*, 635 F. 3d 724, 728 (Fed. Cir. 2010) (citation and quotation marks omitted); *see also Hyatt v. Hirshfeld*, 998 F.3d 1347, 1369-60 (Fed. Cir. 2021). At the motion to dismiss stage, prosecution laches requires the accused infringer to allege that: "(1) the patentee's delay in prosecution must be unreasonable and inexcusable under the totality of circumstances and (2) the accused infringer must have suffered prejudice attributable to the delay." *Personalized Media Commc'ns, LLC v. Apple Inc.*, 57 F. 4th 1346, 1354 (Fed. Circ. 2023). While there are no "firm guidelines" to determine when prosecution laches should apply, courts should weigh the totality of the circumstances as a matter of equity to determine the reasonableness of prosecution. *Symbol Techs., Inc. v. Lemelson Med., Educ. & Rsch. Found.*, 422 F. 3d 1378, 1385 (Fed. Cir. 2005).

**a. PBNT Plausibly Alleges that GSK's Prosecution Delay was Unreasonable and Inexcusable**

PBNT alleges that GSK, collectively with its predecessors-in-interests Novartis Vaccines and Novartis AG: (1) "unreasonably delayed in filing the applications that issued as the '693 Patent, '694 Patent, '534 Patent, '401 Patent, and '467 Patent for over eleven years," (C.A. No. 24-512, D.I. 32 ¶ 93); (2) "unreasonably delayed pursuing the claims of the '693 Patent, '694 Patent, '534 Patent, '401 Patent, and '467 Patent for over eleven years before it pursued claims reciting 'RNA' wherein 'the lipids encapsulate' the RNA molecules," (*id.*); (3) "unreasonably delayed in filing the applications that issued as the '475 Patent and '660 Patent for over nine years and twelve years, respectively," (*id.* ¶ 94); (4) "unreasonably delayed pursuing the claims of the '475 Patent and '660 Patent for over seven years before it pursued claims reciting 'RNA,'" (*id.*); (5) "unreasonably delayed in filing the application that led to the '422 Patent for over nine years,"

(*id.* ¶ 95) and; (6) "unreasonably delayed pursuing the claims of the '422 Patent for over four years before it pursued claims reciting 'RNA,'" (*id.*). PBNT further alleges that "[i]t was not until the details of [PBNT's] COVID-19 vaccine became publicly available that GSK pursued the patent claims it now asserts against them from the [PBNT Counterclaim Patents]." *Id.* ¶ 96.

According to GSK, PBNT's allegations fail because "prosecution laches is not simply a time-counting exercise." C.A. No. 24-512, D.I. 35 at 15 (citing *Wirtgen Am., Inc. v. Caterpillar, Inc.*, 746 F. Supp. 3d 218, 226 (D. Del. 2024)). GSK contends that the allegations reflect conduct that was "reasonable and appropriate" because "GSK engaged in common, lawful continuation and divisional practice." *Id.* at 15-16. GSK further contends that PBNT's "sole factual allegation" - that GSK presented the claims of the PBNT Counterclaim Patents to the USPTO only after Comirnaty® entered the market and information concerning its composition became public - fails to identify any misuse of the patent system. *Id.* at 16-17. Importantly, GSK also asserts that "the doctrine of prosecution laches does not apply to post-GATT patents." *Id.* at 17.

In PBNT's view, it has sufficiently alleged facts to establish the presumption that GSK's delay was unreasonable, inexcusable, and prejudicial. C.A. No. 24-512, D.I. 42 at 14. Specifically, PBNT contends that GSK began filing the applications for PBNT Counterclaim Patents "over six years after the first patent application," which "alone establish[es] a presumption of unreasonable delay." *Id.* PBNT further contends that GSK's conduct is analogous to the patentee's conduct in *Sonos v. Google LLC*, where the district court held that the patents-in-suit were unenforceable under the doctrine of prosecution laches. *Sonos v. Google LLC* (*Sonos I*), No. 20-6754, 2023 WL 6542320 (Fed. Cir. Aug. 28, 2025). In *Sonos I,* the patentee "filed the provisional application from which the patents in suit claim[ed] priority in 2006, but it did not file the applications for these

patents and present[ed] the asserted claims for examination until 2019." *Id.* at *1.[1] PBNT asserts that GSK's conduct is "no better" because GSK made multiple requests for continued examinations for each patent and took "nearly a decade after the provisional applications [were filed] to begin pursuing claims broader than the claims of the initial parent applications." C.A. No. 24-512, D.I. 42 at 16. PBNT further asserts that "GSK's prosecution conduct enabled it to draft claims based on new public information concerning Pfizer and BioNTech's COVID-19 vaccine that did not exist when the first provisional applications were filed in 2010," which "resulted in final issued claims in the [PBNT Counterclaim Patents] without adequate written support." *Id.* at 16-17. According to PBNT, "seven of the eight [PBNT Counterclaim Patents] were filed on or after April 1, 2020, two weeks after Pfizer and BioNTech announced they were co-developing an mRNA vaccine for COVID-19." *Id.* at 17.

Before turning to the merits of PBNT's counterclaim for prosecution laches, the Court addresses two issues raised by the parties: (1) whether prosecution laches applies to post General Agreement on Trade and Tariffs ("GATT") patents and (2) whether the presumption for prosecution laches is applicable in this case.

The Court first addresses GSK's contention that prosecution laches does not extend to post-GATT patents. *See* C.A. No. 24-512, D.I. 35 at 17. The Court rejects GSK's contention for the reasons set forth in *Mojo Mobility, Inc. v. Samsung Elecs. Co.*, where Magistrate Judge Payne explained that:

> Federal Circuit precedent for prosecution laches "post-GATT" initially focused on "submarine patents." However, recent

[1] The Court acknowledges that *Sonos I* has been reversed by the Federal Circuit. *See Google LLC v. Sonos, Inc (Sonos II)*, No. 24-1097, 2025 WL 2473258 at *6-7 (Fed. Cir. Aug. 28, 2025). However, that reversal does not affect the Court's analysis at this stage, which is limited to whether the facts in the complaint, as alleged, are sufficient to state a plausible claim. *See Iqbal*, 556 U.S. at 678.

> precedent indicates prosecution laches is still available as an equitable defense. *See Personalized Media Communications, LLC v. Apple Inc.*, 57 F.4th 1346, 1354–58 (Fed. Cir. 2023); *Hyatt v. Hirshfeld*, 998 F.3d 1347, 1360–61 (Fed. Cir. 2021) (outlining the establishment of Federal Circuit precedent with regards to prosecution laches). In *Personalized Media Communications*, the Federal Circuit declined to hold that all prosecution laches cases must match a specific fact pattern, rather choosing to focus on whether prosecution of the patent was done in an equitable way. 57 F.4th at *1354. While the Federal Circuit found that the *Personalized Media Communications* fact pattern was similar to other pre-GATT prosecution laches decisions, the holding does not seek to foreclose other factual circumstances from giving rise to the equitable defense of prosecution laches. *Id.* ("[Plaintiff's] argument rests on the faulty premise: that [plaintiff's] conduct has to look like *Hyatt* or the handful of other [laches] cases . . . Setting this aside, this case is very similar to *Hyatt* . . . "). The Court is not persuaded that a lack of explicit applicability of prosecution laches to "post-GATT" patents at the Federal Circuit has abrogated prosecution laches for "post-GATT" patents as Mojo suggests. Accordingly, the Court finds that Mojo has not demonstrated that prosecution laches is unavailable as a matter of law in this case.

No. 22-398, 2024 WL 3354705, at *1 (E.D. Tex. June 11, 2024), *report and recommendation adopted*, No. 22-398, 2024 WL 3350884 (E.D. Tex. July 9, 2024).

Turning to the second issue, the Federal Circuit has held that "in the context of a § 145 action, the PTO must generally prove intervening rights to establish prejudice, but an unreasonable and unexplained prosecution delay of six years or more raises a presumption of prejudice, including intervening rights." *See Hyatt*, 998 F. 3d at 1369. PBNT seeks to invoke this presumption in its favor. *See* C.A. No. 24-512, D.I. 14. The Court, however, is not convinced that the presumption applies when prosecution laches is asserted as a defense against infringement. The Federal Circuit's holding in *Hyatt* expressly limits the presumption to "the context of a § 145 action," and the Court is not persuaded that the presumption should extend beyond that setting. *Hyatt*, 998 F.3d at 1370; *see also Personalized Media Commc'ns, LLC v. Apple, Inc.*, 552 F. Supp. 3d 664, 685 (E.D. Tex. 2021), *aff'd*, 57 F.4th 1346 (Fed. Cir. 2023) (discussing the same); *Allergan*

*Holdings Unlimited Co. v. MSN Lab'ys Priv. Ltd.*, No. 23-794, 2024 WL 3444368, at *4 (D. Del. July 17, 2024) (same).

The Court now turns to the merits. Whether an applicant's delay is unreasonable is a fact-intensive inquiry that turns on the particular circumstances of the case. *Hyatt*, 988 F. 3d at 1366-67. Determinations of unreasonable delay are not limited to the specific patent application in question, rather, "an examination of the totality of the circumstances, including the prosecution history of all of a series of related patents and overall delay in issuing claims, may trigger laches." *Id.* at 1362. To satisfy the first element of prosecution laches, PBNT focuses on the length of the prosecution history for the PBNT Counterclaim Patents and that GSK pursued broader claims in response to publicly available information regarding PBNT's COVID-19 vaccine. While the duration of prosecution does not provide a "bright-line" rule as to the reasonableness of prosecution, *see Cordance Corp. v. Amazon.com*, 631 F. Supp. 2d 484, 491 (D. Del. 2009), PBNT also alleges that, GSK submitted multiple requests for continued examination, and then sought claims of broader scope directed to subject matter reflected in PBNT's technology that had entered the public domain. From these allegations and at this stage in the proceedings, the Court may reasonably infer that GSK's prolonged prosecution was used not merely to obtain allowance of the invention as originally claimed, but to adjust the claim scope, without proper disclosure, in light of intervening developments, such as PBNT's public disclosure of its technology, occurring during the pendency of the application. Such allegations raise the precise concern that animates prosecution laches: whether an applicant may effectively await intervening technological developments and then seek claim language broad enough to capture those developments, even where no new matter has been added to the specification. *See Schering Corp. v. Amgen, Inc.*, 25 F. Supp. 2d 293, 297 (D. Del. 1998) (addressing the broadening of claim language during

prosecution to capture later-developed technology). Accepting these allegations as true and drawing all reasonable inferences in favor of PBNT, the Court finds that PBNT has plausibly alleged that GSK's delay in prosecution was unreasonable and inexcusable.

**b. PBNT Plausibly Alleges That It Suffered Prejudice Due to the Delay**

"[T]o establish prejudice an accused infringer must show evidence of intervening rights, i.e., that either the accused infringer or others invested in, worked on, or used the claimed technology during the period of delay." *Cancer Rsch Tech Ltd.*, 625 F. 3d at 729. In other words, the accused infringer must allege that "the holder of intervening rights would have either done something differently or experienced a change in economic position as a result of the alleged delay in issuance of the patent-in-suit." *Id.* at 731.

PBNT alleges that, due to the delay, it has been prejudiced because PBNT "invested time and resources in the development of the Accused Products" during the delay and "developed the first COVID-19 vaccine to combat COVID-19." C.A. No. 24-512, D.I. 32 at Counterclaims ¶ 97. PBNT further alleges that it has been prejudiced because "certain prior art may no longer be available now that over a decade has passed since [GSK] filed the first provisional application." *Id.* ¶ 99. In sum, PBNT alleges that it incurred investments and commitments, during the period of delay, only to face claims of broader scope that enlarged after those investments had been made, and that PBNT would not have incurred those investments and commitments if GSK timely prosecuted its applications to obtain the claim scope it now asserts in this action. Accepting these allegations as true and drawing all reasonable inferences in PBNT's favor, as the Court is required to do at the current procedural posture, the Court concludes that such allegations are sufficient to show intervening rights and plausibly allege that PBNT suffered prejudice attributable to the delay. *See Luna Sols., LLC v. USV Optical, Inc.*, No. 24-196-GBW, 2025 WL 2817786, at *2 (D. Del.

Oct. 3, 2025) ("A counterclaim is facially plausible when the counterclaim plaintiff pleads factual content that allows the court to draw the reasonable inference that the counterclaim defendant is liable for the misconduct alleged.") (cleaned up).

#### 2. The Court Will Not Strike PBNT's Affirmative Defense for Prosecution Laches

For substantially the same reasons discussed *supra*, the Court declines to strike PBNT's affirmative defense for prosecution laches. The factual allegations that plausibly support PBNT's counterclaims for prosecution laches likewise provide adequate notice of the related affirmative defense. *See Long v. Wilson*, 393 F.3d 390, 397 (3d Cir. 2004) ("The purpose of requiring the defendant to plead available affirmative defenses in his answer is to avoid surprise and undue prejudice by providing the plaintiff with notice and the opportunity to demonstrate why the affirmative defense should not succeed."); *Hoover v. Drivetrain*, No. 20-50966, 2023 WL 7311168, at *1 (Bankr. D. Del. Nov. 6, 2023) ("A Rule 12(f) motion should be denied, however, unless the inadequacy of the defense is clearly apparent, meaning in essence that there is no set of facts that might be proven at trial under which the affirmative defense would be successful."). Thus, GSK's motion to strike PBNT's fifth affirmative defense of prosecution laches is denied.

For the foregoing reasons, the Court denies GSK's Partial Motion to Dismiss Counterclaims and Strike Affirmative Defense of Prosecution Laches (C.A. No. 24-512, D.I. 34).

### B. The Court Denies-in-Part and Grants-in-Part GSK's Motion to Dismiss Moderna's Counterclaims and Related Affirmative Defenses of Prosecution Laches and Obviousness-Type Double Patenting

In C.A. No. 24-1135, GSK filed its First Amended Complaint against Moderna, alleging claims for infringement of seven patents: U.S. Patent Nos. 11,291,682 (the "'682 Patent"), 11,324,770 (the "'770 Patent"), 11,596,645 (the "'645 Patent"), 11,690,862 (the "'862 Patent"), 11,707,482 (the "'482 Patent"), the '534 Patent, and the '467 Patent. *See* C.A. No. 24-1135, D.I.

91. On October 2, 2025, Moderna filed its Counterclaims and Answer to GSK's First Amended Complaint, asserting, among other things, counterclaims for prosecution laches and obviousness-type double patenting, as well as the related affirmative defenses. C.A. No. 24-1135, D.I. 103. On November 6, 2025, GSK moved to dismiss Moderna's counterclaims of prosecution laches and obviousness-type double patenting and strike the related affirmative defenses for the '682 Patent, '770 Patent, '645 Patent, '862 Patent, '482 Patent, '6534 Patent, and '467 Patent (together, the "Moderna Counterclaim Patents"). *See* C.A. No. 24-1135, D.I. 120.

**1. Moderna Sufficiently Pleads Prosecution Laches**

GSK contends that Moderna's counterclaims and affirmative defense of prosecution laches should be dismissed because Moderna "fail[s] to plausibly state a claim that GSK has egregiously misused the patent system and prejudiced Moderna as a result." C.A. No. 24-1135, D.I. 121 at 2. According to GSK, "Moderna's fundamental complaint underlying its prosecution laches allegations is Moderna's contention that GSK delayed presenting claims of the [Moderna Counterclaim Patents] to the Patent Office." *Id.* at 8. GSK contends, however, that this Court and the Federal Circuit have rejected that theory under the prejudice prong. *Id.* at 8. Thus, GSK concludes that, Moderna's prosecution laches counterclaims fail.

**a. Moderna Plausibly Alleges that GSK's Prosecution Delay was Unreasonable and Inexcusable**

Moderna alleges that the Moderna Counterclaim Patents are unenforceable due to prosecution laches because GSK "intentionally, and inexplicably, (1) rewrote claims unrelated to, and unsupported by, the pending specification and claims, and (2) delayed publicly disclosing the content of those claims and/or that GSK changed the disclosures of the application to which the [Moderna Counterclaim Patents] purport to claim priority." C.A. No. 24-1135, D.I. 103 ¶¶ 174, 184, 194, 204, 214, 224, 234. Moderna further alleges that, prior to its development of the mRNA

and LNP technology used in the SPIKEVAX® vaccine, the pending specifications and claims of the applications that issued the Moderna Counterclaim Patents "did not disclose, describe or enable a composition or formulation (or method or use thereof) purporting to encompass" the accused product. *Id.* ¶¶ 175-176, 195-196, 205-206, 215-216, 225-226, 235-236. Moreover, Moderna alleges that, after information regarding its success with mRNA vaccines was publicly available, GSK filed continuation applications "with claims redrawn to improperly ensnare prior art compositions comprising mRNA," which are the patent claims it now asserts against Moderna. *Id.* ¶ 48, 52-63.

In GSK's view, Moderna "merely alleges that GSK delayed presenting claims of the [GSK Counterclaim Patents] to the Patent Office," which is "legally irrelevant" because the claimed inventions of the Moderna Counterclaim Patents were disclosed "long ago in the original 2010 priority application." C.A. No. 24-1135, D.I. 121 at 10 (citing C.A. No. 24-1135, D.I. 91 ¶¶ 2, 26). GSK asserts that the inquiry for prosecution laches "does not focus on an alleged delay in presenting claims," but rather, "delay in presenting the inventive disclosure – i.e. the specification and priority application as a whole." *Id.* GSK further asserts that Moderna has not alleged any facts supporting its allegation that GSK delayed in presenting the inventive disclosures underlying the Moderna Counterclaim Patents. *Id.* GSK contends that Moderna's allegation that GSK redrafted claims in pending patent applications to cover Moderna's products likewise fails, since the claimed inventions were fully disclosed and supported in earlier filed applications. *Id.* at 11. GSK asserts that, even accepting Moderna's allegation as true, patent applicants are permitted to broaden claims during prosecution to encompass a competitor's products, provided that the broadened claims are adequately supported in the application's disclosure. *Id.* (citing *Libel-Flarsheim Co. v. Medrad, Inc.*, 358 F. 3d 898, 909 n.2 (Fed. Cir. 2004)).

According to Moderna, GSK did not begin filing claims directed to the subject matter of the Moderna Counterclaim Patents until more than nine years after the provisional applications were filed. C.A. No. 24-1135, D.I. 130 at 12 (citing D.I. 103 ¶¶ 42-63). Moderna asserts that the nine year delay, standing alone, is sufficient to establish the presumption of unreasonable and inexcusable delay. *Id.* However, as discussed *supra* III.A.1.a, the Court is not persuaded that the presumption applies where prosecution laches is asserted as a defense to infringement. In addition to the lapse of time, Moderna asserts that GSK's delay was unreasonable and inexcusable because GSK's provisional applications were directed exclusively to compositions comprising srRNA and liposomes, rather than mRNA and LNPs. *Id.* at 12 (citing C.A. No. 24-1135, D.I. 103 ¶¶ 29, 31, 33, 44, 48, 49, 67, 75, 76). Moderna contends that, more than nine years later and only after Moderna publicly disclosed its composition, GSK sought claims encompassing mRNA and LNPs. *Id.* at 12-13 (citing C.A. No. 24-1135, D.I. 103 ¶¶ 42-76). Moderna further contends that the broadened claims were improperly drafted to ensnare the prior art. D.I. 103 ¶ 62.

As explained above, the determination of whether an applicant's delay was unreasonable is a fact-intensive inquiry that turns on the specific circumstances of each case. *See Hyatt*, 988 F. 3d at 1366-67. Like PBNT, Moderna bases its arguments on both the length of the prosecution delay and the allegation that GSK pursued broadened claims, without proper disclosure, only after information regarding Moderna's composition became publicly available. Again, as with PBNT, and given the procedural posture of this case, where the allegations must be accepted as true, the Court may reasonably infer that the extended prosecution was not pursued solely to obtain allowance of the inventions originally disclosed. Moderna's allegations support the inference that GSK sought to broaden the scope of the claims, without proper disclosure, in response to intervening developments arising during the pendency of the applications, including the public

disclosure of Moderna's composition. As discussed above, these allegations raise the very concerns underlying the doctrine of prosecution laches.

GSK attempts to rebut Moderna's allegation that GSK pursued broadened claims by arguing that the technology underlying the accused products was already disclosed in an earlier application. *See* C.A. No. 24-1135, D.I. 121 at 10-11. The Court finds GSK's argument unavailing because GSK relies on conclusory statements to address the central issues of whether the claims extend beyond what was originally described in the specification and whether the claims in the Moderna Counterclaim Patents were improperly broadened after the public disclosure of Moderna's composition. Additionally, even if GSK provided more than conclusory statements, the Court finds that these issues are more appropriately addressed on a more developed factual record. Thus, accepting Moderna's allegations as true and drawing all reasonable inferences in its favor, the Court finds that Moderna has plausibly alleged that GSK's delay was unreasonable and inexcusable.

**b. Moderna Plausibly Alleges That It Suffered Prejudice Due to the Delay**

Moderna contends that, due to the delay, it has been prejudiced because it "invested nearly ten (10) years and extensive resources developing its mRNA and LNP platform technologies at a time when the only public disclosures of the subject matter described in the [Moderna Counterclaim Patents] was specifically (and solely) directed to srRNA (i.e. not mRNA and liposome delivery systems (i.e., not LNPs)." C.A. No. 24-1135, D.I. 130 (citing C.A. No. 24-1355, D.I. 103 ¶¶ 10-12).

GSK contends that "the only purported prejudice to Moderna is GSK's alleged delays in claiming," thus Moderna's allegations fail as a matter of law under the prejudice prong. C.A. No. 24-1135, D.I. 121 at 13. GSK cites to *Sonos II*, the Federal Circuit decision reversing *Sonos I*, for

the proposition that "the Federal Circuit has established that alleged delays in presenting claims cannot constitute prejudice for the purpose of prosecution laches." *Id.* at 13 (citing *Sonos II*, 2025 WL2473258 at *6-7). Specifically, GSK contends that the Federal Circuit concludes that a "defendant could not 'be prejudiced by incorporating into its products a feature that was publicly disclosed' in the specification of a predecessor application of the asserted patents 'prior to [the defendant's investment].'" *Id.* (citing *Sonos II*, 2025 WL2473258 at *7). Thus, according to GSK, *Sonos II*, "makes clear that the focus of the prejudice inquiry is the timing of the inventive disclosure – not the timing of the claims." *Id.* In GSK's view, "Moderna has not and cannot allege that GSK delayed publication of the inventive disclosures." *Id.*

The Court finds that Moderna has sufficiently alleged it suffered prejudice resulting from GSK's delay. GSK's reliance on *Sonos II* does not warrant dismissal at this stage. Unlike this action, *Sonos II* was reviewed by the Federal Circuit following a bench trial on prosecution laches and the entry of a final judgment, after the district court had made factual findings based on a fully developed evidentiary record. By contrast, at the pleading stage, the factual record is undeveloped, and the Court must accept Moderna's allegations as true and draw all reasonable inferences in Moderna's favor. Moreover, contrary to GSK's view, Moderna has alleged that GSK not only delayed publication of its claims but also of its inventive disclosures. *See* D.I. 103 ¶¶ 5, 29, 31, 33-36, 37, 42, 44-45, 48-49, 52-57, 60-61. To establish prejudice, an accused infringer must allege facts demonstrating intervening rights. *See Cancer Rsch Tech Ltd.*, 625 F. 3d at 729. Moderna alleges that it invested extensive resources for more than a decade in developing its mRNA and LNP technology, while GSK delayed prosecution of the Moderna Counterclaim Patents. *See* C.A. No. 24-1355, D.I. 103 ¶¶ 10-12. Moderna further alleges that, after those investments were made, GSK broadened pending claims to encompass Moderna's technology. *Id.* at ¶¶ 174, 184, 194, 204,

214, 224, 234. Thus, Moderna has sufficiently alleged that it "invested in, worked on, or used the claimed technology during the period of delay." *Cancer Rsch Tech Ltd.*, 625 F. 3d at 729. At this stage in the proceedings and accepting all allegations as true, these allegations are sufficient to support a plausible inference of prejudice.

The Court emphasizes that there are no bright-line rules governing the application of the doctrine of prosecution laches. *See Symbol Techs., Inc.*, 422 F. 3d at 1385. Rather, courts are instructed to evaluate the totality of the circumstances, an inquiry that is inherently fact-intensive and dependent on the facts of each case. *Id.* At this juncture, the Court is required to accept Moderna's well-pleaded allegations as true and draw all reasonable inferences in its favor. *Nat'l Rifle Ass'n of Am.*, 602 U.S. at 181. For the reasons discussed above, Moderna has plausibly alleged facts supporting its counterclaims for prosecution laches. Whether the evidence ultimately supports a finding of prosecution laches is a matter for summary judgment or trial, where the factual record will be more fully developed.

### 2. Moderna Fails To Sufficiently Plead Obviousness-Type Double Patenting

GSK contends that Moderna's counterclaims and affirmative defense of obviousness-type double patenting should be dismissed because the theory is inapplicable to this case. C.A. No. 24-1135, D.I. 121 at 14.

An inventor may obtain only one patent for any single invention. *See Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F. 3d 1280, 1297 (Fed. Cir. 2012) (citing U.S.C. § 101). "The double patenting doctrine precludes one person from obtaining more than one valid patent for either (a) the 'same invention' or (b) an 'obvious' modification of the same invention." *Id.*; *see also Pharmacyclics LLC v. Alvogen Pine Brook LLC*, 556 F. Supp. 3d 377, 388-89 (D. Del. 2021), *aff'd sub nom., Pharmacyclics LLC v. Alvogen, Inc.*, No. 21-2270, 2022 WL 16943006 (Fed. Cir. Nov. 15, 2022)

("Double patenting arguments come in two flavors: 'same invention' and 'obviousness-type.'"). Same invention or statutory double patenting means that the later claim is identical in scope to the earlier claim. *See Vasu Holdings, LLC v. Samsung Elecs. Co.*, No. 24-34, 2026 WL 675680, at *2 (E.D. Tex. Jan. 26, 2026). Obviousness-type double patenting ("OTDP") means that the later claim, though not identical, is only an obvious variation of the earlier claim. *See id.* "Unlike 'same invention' double patenting, OTDP can be overcome by filing a terminal disclaimer." *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 940 (Fed. Cir. 1992). "By disclaiming that [the] portion of the second patent which would extend beyond the expiration of the first, the patentee gives up any extension of patent protection that might have resulted." *Id.* Thus, a patent may be invalid under OTDP, where two patents are commonly owned and the later-expiring patent would have been obvious in light of the earlier-expiring patent. *See AbbVie Inc. v. Mathilda*, 764 F. 3d 1366, 1373-74 (Fed. Cir. 2014). The Federal Circuit has held that there are two justifications for obviousness-type double patenting: (1) to prevent inventors from extending the patent beyond the statutory patent term, through a later-expiring patent and (2) "prevent multiple infringement suits by different assignees asserting essentially the same patented invention." *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013) (internal citations omitted).

For each declaratory judgment invalidity counterclaim, Moderna alleges that "no patentable distinctions" exists between the claims of the Moderna Counterclaim Patents and the claims of two to three other patents owned by GSK. C.A. No. 24-1135, D.I. 103 at ¶¶ 124, 130, 136, 142, 148, 154, 160. Moderna further alleges that the patents are "commonly owned and/or have common inventors, rendering them invalid under the doctrine of obviousness type double patenting." *Id.* Moderna also alleges that "GSK's actions before the Patent Office, seeking and

obtaining hundreds of claims to the same purported invention, raises the prospect of harassment and serial litigation." *Id.*

In GSK's view, OTDP is inapplicable because the patents identified in each counterclaim are assigned to GSK and share the same expiration date. C.A. No. 24-1135, D.I. 121 at 14. GSK contends that OTDP is intended to prevent unjustified extension of patent term through "second, later expiring patent[s]." *Id.* (quoting *AbbVie Inc.*, 764 F. 3d at 1373). GSK further contends that, because the Moderna Counterclaim Patents expire on the same day, July 6, 2031, no such extension exists and OTDP is therefore inapplicable as a matter of law. *Id.* GSK also contends that the "multiple infringement suits" theory of OTDP does not apply because it requires different assignees, which is not present in this action, as GSK is the assignee of the Moderna Counterclaim Patents. *Id.* at 15.

In response, Moderna focuses on the second justification for OTDP – multiple infringement suits. Moderna contends that GSK misstates the relevant law because the Federal Circuit, in *In re Hubbell*, did not confine OTDP to cases lacking common ownership. C.A. No. 24-1135, D.I. 130 at 18. Rather, Moderna relies on *AbbVie Inc.* for the proposition that "common ownership does not insulate a patentee from OTDP." *Id.* (citing *AbbVie Inc.*, 764 F. 3d at 1368, 1372-74). Moderna asserts that OTDP rests on two disjunctive rationales – timewise extension and litigation harassment. *Id.* Thus, Moderna contends, even without term extension, GSK's conduct has created the very serial litigation risk described in *In re Hubbell. Id.*

The Court agrees with GSK that Moderna has not alleged a plausible basis for OTDP. One of the principal concerns underlying OTDP – "prevent[ing] inventors from extending their monopoly beyond the statutory patent term, through a later-expiring patent" – is absent here. *Vasu Holdings, LLC*, 2026 WL 675680, at *2. GSK has submitted that, which Moderna does not

dispute, the Moderna Counterclaim Patents are subject to a terminal disclaimer. *See* C.A. No. 24-1135, D.I. 122, Exs. B-G; D.I. 123-1.[2] As a result, the Moderna Counterclaim Patents expire on the same date, which eliminates any risk that GSK could obtain an unjustified extension of patent exclusivity through a later-expiring date. *See Ortho Pharm. Corp.*, 959 F.2d at 940; *AbbVie Inc.*, 764 F. 3d at 1373. Thus, the first rationale for OTDP is not implicated.

The second rationale for OTDP – multiple infringement suits by different assignees asserting essentially the same patented invention – is likewise not implicated. Moderna admits that GSK is the assignee of the Moderna Counterclaim Patents. *See* C.A. No. 24-1135, D.I. 103 at 52 ("Moderna admits that GSK Biologicals is listed as the assignee on the face of the Patents-in-Suit."). Thus, the common ownership required by the terminal disclaimers remains intact, and any future concerns about differing ownership or serial litigation are mooted by the terminal disclaimers. *See* 37 CFR §§ 1.321 (c)(3), (d)(3). Critically, Moderna does not allege any facts suggesting that the ownership of the Moderna Counterclaim Patents has diverged, that the terminal disclaimers are ineffective, or that any other circumstances exist that would permit separate entities to independently assert the Moderna Counterclaim Patents. Therefore, Moderna has failed to identify the type of ownership or enforcement concerns that this rationale is intended to address. Thus, the second rationale is inapplicable, and Moderna fails to plead a plausible basis for the application of OTDP.

### 3. The Court Will Not Strike Moderna's Affirmative Defense for Prosecution Laches, But Strikes Moderna's Affirmative Defenses for Obviousness-Type Double Patenting

The Court declines to strike Moderna's affirmative defense of prosecution laches. As detailed above in III.B.1, Moderna has plausibly alleged prosecution laches. Thus, the allegations

[2] In deciding a motion to dismiss, a court may consider public records, including patent prosecution histories. *See Data Engine Techs. LLC v. Google LLC*, 906 F.3d 999, 1008 n.2 (Fed. Cir. 2018).

supporting Moderna's counterclaims provide adequate notice of the related affirmative defenses. *XpertUniverse, Inc. v. Cisco Sys., Inc.*, 868 F. Supp. 2d 376, 383 (D. Del. 2012) ("A court should not strike a defense unless the insufficiency is clearly apparent and motions to strike are generally disfavored."). However, Moderna's affirmative defenses of OTDP rests on the same allegations addressed *supra* II.B.2. Thus, it fails for the same reasons, and the Court strikes Moderna's affirmative defenses of OTDP.

For the foregoing reasons, the Court denies-in-part and grants-in-part GSK's Partial Motion to Dismiss Counterclaims and Strike Affirmative Defenses of Prosecution Laches and Obviousness-Type Double Patenting (C.A. No. 24-1135, D.I. 120).

### C. The Court Denies GSK's Motion to Dismiss Moderna's Counterclaims and Related Affirmative Defense of Prosecution Laches

In C.A. No 24-1136, GSK filed its Complaint against Moderna, asserting claims for infringement of six patents: U.S. Patent Nos. 11,690,861 (the "'861 Patent"), 11,690,864 (the "'864 Patent"), 11,717,529 (the "'529 Patent"), 11,883,534 (the "'3534 Patent"), the '467 Patent, and the '770 Patent. C.A. No. 24-1136, D.I. 1. On December 12, 2024, Moderna filed its Counterclaims and Answer to the Complaint, including, but not limited to, counterclaims for prosecution laches and the related affirmative defense. D.I. 17. On January 9, 2025, GSK moved to dismiss Moderna's counterclaims of prosecution laches and strike the related affirmative defense. D.I. 22.

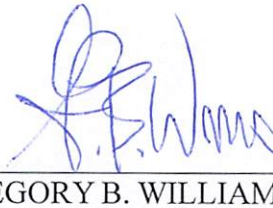
Moderna's allegations in this action mirror those asserted in C.A. No. 24-1135, differing only with respect to the patents and product asserted. GSK likewise advances arguments that are, in all material respects, identical to those previously considered in C.A. No. 24-1135. *See* C.A. No. 24-1135, D.I. 23 at 1, fn. 2 ("Moderna asserts counterclaims and affirmative defenses of prosecution laches in both this action, [C.A. No. 24-1136] (mRESVIA®), and [C.A. No. 24-1135]

(Spikevax®). Because GSK understands the prosecution laches theories to be materially the same, GSK is filing substantially equivalent motions in each case.") (cleaned up); D.I. 26 at 1 fn. 1 ("Moderna has likewise file substantially equivalent oppositions in both matters.") Given this overlap, and because the arguments do not materially differ from those addressed above, the Court finds no basis to depart from its prior analysis. Thus, the Court denies GSK's Partial Motion to Dismiss Counterclaims and Strike the Affirmative Defense of Prosecution Laches (C.A. No. 24-1136, D.I. 22).

* * * * *

WHEREFORE, at Wilmington this 16th day of June, 2026, **IT IS HEREBY ORDERED** that:

1. GSK's Partial Motion to Dismiss Counterclaims and Strike Affirmative Defenses of Patent Misuse and Prosecution Laches (C.A. No. 24-512, D.I. 34) is **DENIED**;
2. GSK's Partial Motion to Dismiss Counterclaims and Strike Affirmative Defense of Prosecution Laches and Obviousness-Type Double Patenting (C.A. No. 24-1135 D.I. 120) is **DENIED-IN-PART** with respect to the counterclaims and affirmative defense of prosecution laches, and **GRANTED-IN PART** with respect to the affirmative defenses of obviousness-type double patenting;
3. GSK's Partial Motion to Dismiss Counterclaims and Strike the Affirmative Defense of Prosecution Laches (C.A. No. 24-1136, D.I. 22) is **DENIED**; and
4. Moderna's Request for Oral Argument (C.A. No. 24-1136, D.I. 31) is **DENIED-AS-MOOT**.



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE