IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE BIOLOGICALS SA and GLAXOSMITHKLINE LLC, Plaintiffs, v. MODERNA, INC., MODERNATX, INC., and MODERNA US, INC., Defendants.	)	C.A. No. 24-1135 (GBW)

PLAINTIFFS' OPENING BRIEF IN SUPPORT OF THEIR PARTIAL MOTION TO DISMISS COUNTERCLAIMS AND STRIKE AFFIRMATIVE DEFENSES OF PROSECUTION LACHES AND OBVIOUSNESS-TYPE DOUBLE PATENTING

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This action concerns GSK's revolutionary technology that formed the foundation for modern mRNA vaccines. In 2010, the same year Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. (collectively, "Moderna") were founded, a group of scientists at Novartis filed a series of provisional patent applications describing the first mRNA vaccines. The Asserted Patents properly claim priority to those 2010 applications.[2] Moderna has made billions of dollars in profits from its Spikevax® mRNA vaccine products that infringe the Asserted Patents.

Plaintiffs GlaxoSmithKline Biologicals SA and GlaxoSmithKline LLC (collectively, "GSK") now move the Court to, with prejudice: (1) dismiss Moderna's Counterclaims XVI–XXII and strike Moderna's Twenty-First Affirmative Defense, each of which alleges that the Asserted Patents are unenforceable for prosecution laches;[3] and (2) dismiss the portions of Moderna's Counterclaims VIII–XIV and strike the portions of Moderna's Eighth through Fourteenth Affirmative Defenses that allege that the Asserted Patents are invalid due to obviousness-type double patenting ("OTDP"). Moderna's prosecution laches and OTDP claims and defenses fail as pled.

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[2] 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"); 11,666,534 ("the '6534 patent"); and 11,786,467 ("the '467 patent") (collectively, "Asserted Patents"). Similarly, the '6534 and '467 patents are also at issue in *GlaxoSmithKline Biologicals SA v. Pfizer Inc.*, 1:24-cv-00512-GBW ("*GSK v. PBNT*"). *GSK v. PBNT*, D.I. 26. In *GlaxoSmithKline Biologicals SA v. Moderna, Inc.*, 1:24-cv-1136-GBW ("*GSK v. Moderna* (mRESVIA®)"), the '770 and '467 patents are also at issue. *GSK v. Moderna* (mRESVIA®), D.I. 1.

[3] GSK previously moved to dismiss and strike Moderna's counterclaims and affirmative defenses of prosecution laches in this action, *see* D.I. 23; D.I. 27; D.I. 36; D.I. 88, but that motion is now moot in view of subsequently filed pleadings, namely GSK's First Amended Complaint (D.I. 91) and Moderna's Counterclaims and Answer to the First Amended Complaint (D.I. 103). This opening brief updates GSK's previous prosecution laches arguments, *see* D.I. 23, to reflect new prosecution laches opinions issued since the filing of GSK's fist motion to dismiss. *See* Part I, *infra*. Part II, *infra*, regarding OTDP is new, reflecting Moderna's addition of OTDP counterclaims and affirmative defenses in D.I. 103.

With respect to prosecution laches, Moderna's pleadings, even when taken as true, fail to plausibly state a claim that GSK has egregiously misused the patent system and prejudiced Moderna as a result. Moderna does not allege that GSK sought to extend the terms of the Asserted Patents through submarine patent tactics; each Asserted Patent expires 20 years from the filing of the corresponding priority application in accordance with 35 U.S.C. § 154. Likewise, Moderna has not plausibly alleged that GSK suppressed public disclosure of the contents of the Asserted Patents. Instead, Moderna argues that by filing continuation applications with new claims, which were deemed to be within the scope of the original applications by the United States Patent and Trademark Office ("the Patent Office"), GSK somehow amended the disclosure of those original applications. Moderna's actual allegations, stripped of hyperbole and irrelevant facts, are merely that GSK engaged in patent prosecution practices authorized by the patent statute and expressly endorsed by the Federal Circuit and this Court. In short, Moderna's allegations are legally insufficient to plead a claim or defense of prosecution laches.

Moderna's OTDP pleadings do not even bother to allege facts. Instead, Moderna offers a single paragraph per patent in its counterclaims alleging that the Asserted Patents are invalid for OTDP over other GSK patents. Those allegations fail to acknowledge the publicly available fact that each of the Asserted Patents expires on the same day—July 6, 2031—pursuant to terminal disclaimers. Moderna's OTDP allegations thus fail as a matter of law.

For these reasons, as detailed within, GSK respectfully requests that the Court dismiss all prosecution laches and OTDP counterclaims with prejudice under Federal Rule of Civil Procedure ("Rule") 12(b)(6) and strike all defenses of prosecution laches and OTDP under Rule 12(f).

BACKGROUND

I. NATURE OF PROCEEDINGS

In 2008, researchers at Novartis AG subsidiaries ("Novartis"), led by Christian Mandl ("Mandl team"), sought to overcome the long-standing hurdles that hindered development of mRNA vaccines. D.I. 91 ¶¶ 23–26, 30. In July and August 2010, the Mandl team filed a series of provisional patent applications that first described their novel lipid and mRNA formulations and methods for their preparation and use for vaccines. D.I. 91 ¶ 26.

These developments were a breakthrough in the field. In 2012, the Mandl team published a seminal paper on their work, which has been cited over 500 times and viewed over 60,000 times. D.I. 91 ¶ 28. In 2021, the prestigious academic journal, *Nature*, identified the Mandl team as "the first team to combine [lipid nanoparticles ("LNPs")] with an RNA vaccine" and noted that "[e]very mRNA company now uses some variation of [the Mandl team's] delivery platform and manufacturing system." D.I. 91 ¶¶ 28–29 (quoting D.I. 91-1 at 323 (Ex. 8, p. 323)).

GSK acquired a substantial portion of Novartis's vaccines' business in 2015, including the rights to the Asserted Patents, which properly claim priority to the 2010 provisional applications. To this day, GSK continues researching mRNA vaccines and has multiple mRNA vaccines in human clinical trials. D.I. 91 ¶ 31.

In 2011, GSK filed non-provisional international patent applications with claims of priority to the 2010 provisional applications in each family. Those non-provisional applications were published in 2012 and entered national stage prosecution in the Patent Office in 2013. Since then, GSK has filed various divisional and continuation patent applications, claiming different aspects of the Mandl team's inventions. These divisional and continuation applications share identical specifications with the preceding non-provisional applications in their family. The Asserted Patents issued from those divisional and continuation applications, incorporating in full by

reference and claiming priority to the same 2011 non-provisional and 2010 provisional applications.

Moderna was well aware of the Mandl team's breakthroughs long before the development of the accused products. As far back as 2017, Moderna researchers recognized that the Mandl team was "the first" to employ lipid formulations to "form stable particles with mRNA and effectively release the mRNA for protein translation in vivo." D.I. 91 ¶ 28 (quoting D.I. 91-2 at 888 (Ex. 12, p. 241)). Moderna has also cited and fully incorporated GSK's patent filings in its own patents and publications. D.I. 91 ¶ 35 (citing D.I. 91 Exs. 20–23). Moderna exploited its knowledge of the fundamental technologies invented by the Mandl team—as claimed in the Asserted Patents—to develop the accused products.

On October 12, 2024, GSK filed this suit against Moderna, alleging infringement of the Asserted Patents by the accused Spikevax® products. D.I. 1. Moderna filed an Answer on December 12, 2024, asserting, among other things, declaratory judgment counterclaims and affirmative defenses that each of the patents are unenforceable under the doctrine of prosecution laches. D.I. 17. GSK then filed a First Amended Complaint on September 4, 2025, D.I. 91, to add "Moderna's mNEXSPIKE® SARS-CoV-2 vaccine as an accused product" and "state bases for infringement under 35 U.S.C. § 271(f)," D.I. 90. Moderna filed its Answer and Counterclaims to GSK's First Amended Complaint on October 2, 2025, adding, among other invalidity theories, declaratory judgment counterclaims and affirmative defenses that each of the patents are invalid under the doctrine of OTDP. D.I. 103.

II. REPRESENTATIVE ALLEGATIONS BY MODERNA CONCERNING PROSECUTION LACHES

Moderna's prosecution laches allegations generally assert that (1) GSK purportedly unreasonably delayed prosecuting the claims of the Asserted Patents until learning about

Moderna's products; and (2) those claims lack written description support. The following paragraphs are representative of Moderna's factual allegations concerning prosecution laches:

> 5. . . . [W]hile Moderna was revolutionizing the healthcare industry with novel mRNA vaccines and responding to the need for a pandemic-ending solution, GSK was filing a series of U.S. patent applications—with claims drawn to publicly disclosed information—that improperly broadened the scope of the Novartis srRNA Vaccine Portfolio far beyond its written descriptions and enabling disclosures. This was a transparent attempt to retroactively cover Moderna's SPIKEVAX®, . . . product[s] GSK was (and, to date, has been) unable to make itself.
>
> 76. Although the original application[s] w[ere] filed in 2010, neither GSK nor Novartis (GSK's predecessors-in-interest to the Novartis srRNA Vaccine Portfolio) sought patent claims that purportedly covered Moderna's proprietary technology until after the structure of Moderna's SM-102 lipid and the composition of its FDA approved mRNA vaccines were made public. Only then did GSK cobble together claims it hoped would retroactively cover Moderna's proprietary components used in Moderna's groundbreaking LNP technology for mRNA delivery and SPIKEVAX®. But those claims are fatally flawed, having been stretched far beyond the [Asserted Patents'] limited disclosures.
>
> 174. In the event the [Asserted Patents] or any claim of the [Asserted Patents] is afforded a priority date before [Moderna's asserted priority date in 2019 or 2021], then such claim of the [Asserted Patents] is 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 [Asserted Patents] purport[] to claim priority.
>
> 177. During the decade-long period of delay, Moderna invested significant time and resources into developing the SPIKEVAX® vaccine.
>
> 178. Any enforcement of any claim of the [Asserted Patents] against Moderna's SPIKEVAX® vaccine would not only unfairly prejudice Moderna's investment, but prejudice Moderna's ability to effectively bring its non-infringement defenses and counterclaims. For example, as a result of the delay, certain prior art may no longer be available. The delay also unfairly afforded GSK the opportunity

> to draft claims in view of new information and products that did not exist at the time of the initial filing.

D.I. 103 ¶¶ 5, 76, 174, 177–78 (emphasis omitted); *see, e.g.*, *id.* ¶¶ 29, 31, 33–37, 44–45, 48–49, 52–54, 56–57, 60–67, 75, 172, 175–76, 179.

Moderna does not allege that GSK delayed publicly disclosing the specifications of the Asserted Patents or those of their priority applications. Nor does Moderna allege that GSK's prosecution of the Asserted Patents violated any statute or Patent Office procedure. Additionally, between Moderna's initial Counterclaims and Answer (D.I. 17) and its second Counterclaims and Answer (D.I. 103), ***Moderna does not allege a single new or different fact*** in support of its prosecution laches allegations. *Compare* D.I. 17 ¶¶ 5, 29, 31, 33–37, 44–45, 48–49, 52–54, 56–57, 60–67, 75–76, 158, 160–65, *with* D.I. 103 ¶¶ 5, 29, 31, 33–37, 44–45, 48–49, 52–54, 56–57, 60–67, 75–76, 172, 174–79.

Accordingly, GSK moves to dismiss Moderna's counterclaims and strike Moderna's affirmative defenses of prosecution laches under Rules 12(b)(6) and 12(f), respectively.

III. REPRESENTATIVE ALLEGATIONS BY MODERNA CONCERNING OTDP

Moderna's OTDP allegations assert, without further explanation or analysis, that each Asserted Patent is invalid in light of other GSK patents. The following ***singular*** paragraph is representative of Moderna's factual allegations concerning OTDP:

> 124. Moderna alleges that the claims of the [Asserted Patents] are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, improper inventorship, obviousness-type double patenting, and/or any judicially created requirements for patentability and enforceability of patents, and/or in view of the defenses recognized in 35 U.S.C. § 282. For example, there are no patentable distinctions between the claims of the [Asserted Patents] and at least [certain of the Asserted Patents and/or 11,883,534 ("the '3534 patent") and/or 11,717,529 ("the '529 patent") ("OTDP References")], which are commonly owned and/or have common inventors, rendering them invalid under the doctrine of obviousness

> type double patenting. The [OTDP References] are all currently purportedly owned by GSK. (Amended Complaint ¶ 9). Thus, the [OTDP References] are available as double-patenting references. 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. Because the Asserted Claims of the [Asserted Patents] are not patentably distinct from one or more other GSK patent claims, the Asserted Claims of the [Asserted Patents] are invalid for obviousness-type double patenting.

D.I. 103 ¶ 124; *see, e.g.*, *id.* ¶¶ 130, 136, 142, 148, 154, 160.

Moderna does not mention that each patent is subject to terminal disclaimers that provide a July 6, 2031 expiration date for all Asserted Patents. GSK thus moves to dismiss the portions of Moderna's counterclaims and strike the portions of Moderna's affirmative defenses of invalidity that allege the Asserted Patents are invalid due to OTDP under Rules 12(b)(6) and 12(f), respectively.

ARGUMENT

Moderna's counterclaims and affirmative defenses of prosecution laches and OTDP should be dismissed and stricken because they do not "contain sufficient factual matter," that even if accepted as true, would "'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see Idenix Pharms., Inc. v. Gilead Scis., Inc.*, 2014 WL 4222902, at *5 (D. Del. Aug. 25, 2014); *Allergan USA, Inc. v. Sun Pharm. Indus., Ltd.*, 636 F. Supp. 3d 483, 486 (D. Del. 2022). Indeed, Moderna's prosecution laches and OTDP allegations consist of "bald assertions," "unsupported conclusions," "unwarranted inferences," and "legal conclusion[s] couched as . . . factual allegation[s]," none of which are sufficient to meet the pleading standard. *Iqbal*, 556 U.S. at 678–79; *Diogenes Ltd. v. DraftKings, Inc.*, 623 F. Supp. 3d 423, 433 (D. Del. 2022) (citing *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997)); *Allergan*, 636 F. Supp. 3d at 486.

I. MODERNA'S ALLEGATIONS THAT GSK DELAYED CLAIMING THE INVENTIONS FAIL TO PRESENT A COGNIZABLE THEORY OF PROSECUTION LACHES AS A MATTER OF LAW.

Prosecution laches is an equitable doctrine designed to police "egregious misuse" of the patent system; when applicable, it renders ***an entire patent unenforceable***. *See United States v. Am. Bell Tel. Co.*, 167 U.S. 224, 250–51 (1897). For that reason, the Federal Circuit has cautioned that the doctrine "should be ***used sparingly*** lest statutory provisions be unjustifiably vitiated." *Symbol Techs., Inc. v. Lemelson Med., Educ. & Rsch. Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005). For prosecution laches to apply, Moderna must prove "(1) the patentee's delay in prosecution [was] . . . unreasonable and inexcusable under the totality of circumstances[;] and (2) the accused infringer . . . suffered prejudice attributable to the delay." *Personalized Media Commc'ns, LLC v. Apple Inc.*, 57 F.4th 1346, 1354 (Fed. Cir. 2023). To prove "an unreasonable and unexplained delay," Moderna must establish that the delay "constitutes an egregious misuse of the statutory patent system." *Hyatt v. Hirshfeld*, 998 F.3d 1347, 1360 (Fed. Cir. 2021) (quoting *Cancer Rsch. Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 728 (Fed. Cir. 2010)).

Moderna has not pled the facts necessary to state a plausible claim of prosecution laches under either required element. Moderna merely pleads that GSK engaged in typical and lawful prosecution practices, falling far short of the requisite egregious misuse of the patent system standard. Moderna's fundamental complaint underlying its prosecution laches allegations is Moderna's contention that GSK delayed presenting ***claims*** of the Asserted Patents to the Patent Office. *E.g.*, D.I. 103, ¶¶5, 76. But, as further explained below, this Court has rejected that theory of prosecution laches under the delay prong of prosecution laches, *Natera, Inc. v. ArcherDX, Inc.*, 690 F. Supp. 3d 437, 445–48 (D. Del. 2023); and the Federal Circuit has rejected that theory under the prejudice prong, *Google LLC v. Sonos, Inc.*, 2025 WL 2473258, at *6–7 (Fed. Cir. Aug. 28,

2025) ("At bottom, [the defendant] presents no evidence that it suffered prejudice attributable to [the patentee]'s delay in claiming, but not disclosing, overlapping zone scenes.").

A. Moderna Fails To Allege "Unreasonable And Inexcusable Delay."

To adequately plead prosecution laches, Moderna must assert facts that, if true, would "constitute an ***egregious misuse*** of the statutory patent system." *Hyatt*, 998 F.3d at 1360. Not only does Moderna fail to allege "egregious misuse," it fails to allege any misuse at all. Delays between application filings and patent issuance, without more, as Moderna alleges, do not constitute misuse of the patent system and are not sufficient to support Moderna's prosecution laches pleadings. *Wirtgen Am., Inc. v. Caterpillar, Inc.*, 2024 WL 3888116, at *4 (D. Del. Aug. 21, 2024) ("[P]rosecution laches is not simply a time-counting exercise." (quoting *Seagen Inc. v. Daiichi Sankyo Co.*, 2022 WL 2789901, at *7 (E.D. Tex. July 15, 2022))).

In contrast, courts have found allegations of certain conduct sufficient to plead a counterclaim or an affirmative defense of prosecution laches. For example, a party could plead facts that a patentee: (1) filed hundreds of "atypically long and complex" applications, *Personalized Media*, 57 F.4th at 1350; *Hyatt*, 998 F.3d at 1367; (2) filed thousands of claims with "identical language across different applications," *Personalized Media*, 57 F.4th at 1350–51; *Hyatt*, 998 F.3d at 1367; (3) used patent applications as "placeholders," *Hyatt*, 998 F.3d at 1367; (4) "went many years failing to identify written description support for [the] claims" to the Patent Office, *id*. at 1368; (5) adopted a prosecution approach to "overwhelm[]" the Patent Office, *id.*; (6) "repeatedly request[ed] the maximum extension of time to respond to office actions," *Natera*, 690 F. Supp. 3d at 447; (7) "repeatedly fail[ed] to file applications without []proper formalities," *id.*; or (8) "deliberately refile[d] continuation applications for claims that had already been adjudicated on the merits," *id.* Moderna makes ***no such allegations***.

Because Moderna cannot allege any facts that courts have recognized as potentially supporting a legally cognizable prosecution laches theory, it merely alleges that GSK delayed presenting claims of the Asserted Patents to the Patent Office. D.I. 103 ¶¶ 5, 76. But that theory is legally irrelevant because the claimed inventions of the Asserted Patents were disclosed long ago in the original 2010 priority applications. D.I. 91 ¶¶ 2, 26. Indeed, this Court has specifically rejected virtually the same allegations as failing to present a cognizable prosecution laches theory where the patent owner supposedly delayed "presenting the claims" for a decade but the claimed inventions "were disclosed in [a priority] application." *Natera*, 690 F. Supp. 3d at 447–48; *see Mojo Mobility, Inc. v. Samsung Elecs. Co.*, Case No. 2:22-cv-00398, D.I. 352, at ¶¶ 40–51 (E.D. Tex. Mar. 13, 2025) (rejecting a prosecution laches theory because, as a matter of law, "there is nothing wrong with . . . seeking improved or more complete claims through the continuation process before bringing a patent infringement" suit) (attached as Ex. 1).

The prosecution laches inquiry does not focus on an alleged delay in presenting ***claims***; it focuses on a delay in presenting the ***inventive disclosure***—*i.e.*, the specification and priority application as a whole. *See Natera*, 690 F. Supp. 3d at 447–48 (reasoning that "the inventions claimed in the [asserted patents] were in the public domain as early as . . . 2012," when the priority application was published). And Moderna has not pled any facts to support that GSK delayed presenting the inventive disclosures of the Asserted Patents. Nor can it—the specifications and priority applications underlying the Asserted Patent were made public by the Patent Office in 2012. To the extent Moderna purports to assert that GSK "changed the disclosures of the application[s] to which the [Asserted Patents] . . . claim priority" without any elaboration, D.I. 103 ¶ 174, those assertions should be disregarded, *see Iqbal*, 556 U.S. at 681. Moderna's allegations fail to identify any changes that GSK supposedly made to the specification of the Asserted Patents since the

earliest non-provisional filings, which are all already public documents. *Cf.* D.I. 103 ¶¶ 48, 52–54, 56 (alleging amendments to claim language but not specification language). Having failed to plead any facts to support its bald allegations that GSK supposedly changed the disclosures of the Asserted Patents, those allegations should not be taken as true for purposes of this Motion. *Iqbal*, 556 U.S. at 681.

Moderna's allegation that GSK allegedly "redr[ew]" claims in then-pending patent applications to encompass Moderna's accused products also fails to articulate a viable prosecution laches theory. D.I. 103 ¶ 48. Moderna seeks to imply that GSK somehow retroactively claimed Moderna's invention, but that is untrue. GSK invented the technology underlying the accused products and "fully disclosed and supported [those inventions] in an earlier application," which is why the Patent Office granted claims covering that technology based on those disclosures. *See In re Bogese*, 303 F.3d 1362, 1369 (Fed. Cir. 2002). Even taking Moderna's allegations as true for the purposes of this Motion, GSK did not misuse the patent system in obtaining patent claims that cover Moderna's accused products. Indeed, the Federal Circuit has repeatedly explained that

> ***there is nothing improper, illegal or inequitable*** in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; ***nor is it in any manner improper to amend or insert claims*** intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application.

Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 874 (Fed. Cir. 1988). Moreover, it is, in fact, part of the very purpose of the patent system for a patent applicant to "broaden his claims during prosecution in order to encompass a competitor's products, ***as long as the disclosure supports the broadened claims***." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 909 n.2 (Fed. Cir. 2004). If anything, Moderna's allegations in this case are evidence of GSK's "reasonable business considerations"—not prosecution laches. *See Natera*, 690 F. Supp. 3d at 448

(finding that prosecuting patents "when other people are threatening [the patentee's] position in the market" to be a "reasonable business consideration[]" counseling against a determination of "unreasonable and unexplained delay").

Fundamentally, Moderna's "prosecution laches" allegations are nothing more than allegations of invalidity under 35 U.S.C. § 112 and lack of entitlement to priority for lack of written description. Indeed, Moderna alleges that the Asserted Patents' claims supposedly exceed the disclosure of the priority applications. *See, e.g.*, D.I. 103 ¶¶ 29, 31, 33, 34, 37, 172, 174. But that is a typical § 112 invalidity theory. *See Pandrol USA, LP v. Airboss Ry. Prods., Inc.*, 424 F.3d 1161, 1165 (Fed. Cir. 2005). Prosecution laches and written description are separate legal doctrines with distinct rationales that offer different forms of relief. Prosecution laches renders an ***entire patent*** unenforceable to punish egregious misuse of the patent system, while written description enforces the public disclosure rationale of the patent system and is assessed on a ***claim-by-claim*** basis. *See id.* If run-of-the-mill lack of written description allegations were sufficient to also plead prosecution laches, prosecution laches would be pled in virtually every case. Therefore, the Court should reject Moderna's attempt to repurpose standard invalidity allegations as prosecution laches, which would fly in the face of the Federal Circuit's warning to use "the doctrine [of prosecution laches] . . . sparingly lest statutory provisions be unjustifiably vitiated." *Symbol*, 422 F.3d at 1385.

B. Moderna Alleges No Cognizable Prejudice "Attributable To" The Delay.

Moderna must also plead prejudice "attributable to" the "unreasonable and inexcusable delay." *Personalized Media*, 57 F.4th at 1354. As described above, Moderna fails to plead any unreasonable or inexcusable delay. Because there can be no prejudice "attributable to" that non-existent delay, Moderna fails to adequately plead the "prejudice" element of prosecution laches in addition to its failure to adequately plead the delay element. *See Natera*, 690 F. Supp. 3d at 449.

Even if Moderna had properly pled unreasonable or inexcusable delay, Moderna's prosecution laches allegations would still fail as a matter of law under the prejudice prong. The only purported prejudice to Moderna is GSK's alleged delays in claiming. But the Federal Circuit has established that alleged delays in presenting claims cannot constitute prejudice for the purpose of prosecution laches "as a matter of law." *Sonos*, 2025 WL 2473258, at *6–7 (reversing *Sonos, Inc. v. Google LLC*, 2023 WL 6542320 (N.D. Cal. Oct. 6, 2023), as to prosecution laches). Indeed, like Moderna's theory here, the district court in *Sonos* reasoned that the defendant established prejudice for prosecution laches by showing that the defendant had invested in its infringing products during the period in which the patentee purportedly "delay[ed] in . . . pursuing claims" in certain patents. *Sonos*, 2025 WL 2473258, at *6. The Federal Circuit reversed the district court, however, reasoning that the 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.* at *7 (citing *Liebel-Flarsheim*, 358 F.3d at 909 n.2; and citing *Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1334 (Fed. Cir. 2019)). Thus, *Sonos* makes clear that the focus of the prejudice inquiry is the timing of the inventive disclosure—not the timing of claims. *See Sonos*, 2025 WL 2473258, at *7 ("At bottom, [the defendant] presents no evidence that it suffered prejudice attributable to [the patentee]'s delay in claiming, but not disclosing, overlapping zone scenes."). And, again, Moderna has not and cannot allege that GSK delayed publication of the inventive disclosures.

* * *

Moderna's prosecution laches allegations fail to state a plausible claim or defense. Because a purported delay in claiming—the sole theory underlying Moderna's prosecution laches

allegations—cannot constitute the requisite delay or prejudice for prosecution laches, Moderna's prosecution laches counterclaims and defenses should be dismissed and stricken.

II. OTDP IS INAPPLICABLE AS A MATTER OF LAW FOR THE ASSERTED PATENTS, ALL OF WHICH ARE ASSIGNED TO GSK AND EXPIRE ON THE SAME DAY.

"There are two justifications for" OTDP: (1) "to prevent unjustified timewise extension of the right to exclude granted by a patent;" and (2) "to prevent multiple infringement suits by different assignees asserting essentially the same patented invention." *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013). Moderna merely alleges, without elaboration, that the asserted claims are not "patentabl[y] distinct" from other GSK-owned patents. D.I. 103, ¶¶ 124, 130, 136, 142, 148, 154, 160. But even accepting that allegation as true for the purposes of this motion, Moderna's OTDP allegations fail as a matter of law and should be dismissed and stricken.

First, for the "extension" theory of OTDP, the purportedly obvious patents must be "***second, later expiring patent[s]***." *AbbVie Inc. v. Mathilda & Terrence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1373 (Fed. Cir. 2014); *see Allergan USA, Inc. v. MSN Labs. Priv. Ltd.*, 111 F.4th 1358, 1367–71 (Fed. Cir. 2024). But none of the Asserted Patents are "second, later expiring" patents. Pursuant to the Asserted Patents' terminal disclaimers, each Asserted Patent expires on the same day: July 6, 2031. App'x A.[4] "Therefore, obviousness-type double patenting does not apply as a matter of law." *Zimmer Surgical, Inc. v. Stryker Corp.*, 365 F. Supp. 3d 466, 485 (D. Del. 2019) ("As the '663 patent and the '920 patent claim the same priority date . . . , I determine that the patent term for both patents expires on the same day."). Moderna, notably, makes no mention of this fact, despite GSK informing Moderna of this defect

[4] GSK counsel compiled the information present in Appendix A from Exhibits 2–8 for ease of reference. Exhibits 2–8 are the terminal disclaimers filed for each of the Asserted Patents.

prior to Moderna filing its OTDP counterclaims.[5] Ex. 9 (September 16, 2025 GSK Counsel to Moderna Counsel Email). Indeed, Moderna's allegations are devoid of any mention of the expiration dates of the Asserted Patents according to the publicly available terminal disclaimers that GSK has already produced in this case. *See* Exs. 2–8.

Second, for the "multiple infringement suits" theory of OTDP, there must be "different assignees" for the purportedly obvious patents. *In re Hubbell*, 709 F.3d at 1145; *see Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1059 (Fed. Cir. 2020). But there are no "different assignees" for the Asserted Patents or any of the patents Moderna purports render the Asserted Patents invalid under OTDP. "Moderna admits that GSK Biologicals is listed as the assignee on the face of the Patents-in-Suit." *See* D.I. 103 at 51–52.

Moderna offers no allegations to support OTDP beyond the bald assertion that the Asserted Patents are invalid for OTDP. OTDP is, as a matter of law, inapplicable to the Asserted Patents due to their terminal disclaimers—which ensure they all expire on the same date—and singular assignments, so Moderna's OTDP counterclaims and affirmative defenses should be dismissed and stricken.

CONCLUSION

Because Moderna has not pled legally cognizable claims of prosecution laches or OTDP, GSK respectfully asks this Court to, with prejudice: (1) dismiss Moderna's Counterclaims XVI–XXII and strike Moderna's Twenty-First Affirmative Defense, each of which alleges that the Asserted Patents are unenforceable for prosecution laches; and (2) dismiss the portions of

[5] Even if Moderna did not perform the requisite reasonable inquiry into the expiration dates of the Asserted Patents, Moderna has at least been on notice of the fact that all Asserted Patents expire on July 6, 2031 since GSK informed Moderna of the common expiration of all Asserted Patents on September 16, 2025. Ex. 9 (September 16, 2025 GSK Counsel to Moderna Counsel Email).

Moderna's Counterclaims VIII–XIV and strike the portions of Moderna's Eighth through Fourteenth Affirmative Defenses that allege that the Asserted Patents are invalid due to OTDP.

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