

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)

**JURY TRIAL DEMANDED**

**PLAINTIFFS’ OPENING BRIEF IN SUPPORT OF THEIR PARTIAL MOTION TO  
DISMISS COUNTERCLAIMS AND STRIKE AFFIRMATIVE DEFENSES  
OF PROSECUTION LACHES**

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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.<sup>1</sup> 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 dismiss, with prejudice, 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. These claims and defenses fail as pled.<sup>2</sup>

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. Likewise, Moderna has not plausibly alleged that GSK suppressed public disclosure

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<sup>1</sup> 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 ’534 patent”); and 11,786,467 (“the ’467 patent”) (collectively, “Asserted Patents”). Similarly, the ’534 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.

<sup>2</sup> Moderna asserts counterclaims and affirmative defenses of prosecution laches in both this action, *GlaxoSmithKline Biologicals SA v. Moderna, Inc.*, 1:24-cv-1135-GBW (“*GSK v. Moderna (Spikevax®)*”), and *GSK v. Moderna (mRESVIA®)*. Because GSK understands the prosecution laches theories in *GSK v. Moderna (Spikevax®)* and *GSK v. Moderna (mRESVIA®)* to be materially the same, GSK is filing substantially equivalent motions in each case. However, GSK reserves the right to modify its understanding of Moderna’s prosecution laches allegations if Moderna reveals substantive differences in its prosecution laches theories across the Spikevax® and mRESVIA® actions.

of the content 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.

For these reasons, as detailed within, GSK respectfully requests that the Court (a) dismiss all prosecution laches counterclaims with prejudice under Federal Rule of Civil Procedure (“Rule”) 12(b)(6), and (b) strike all defenses of prosecution laches 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. 1 ¶¶ 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. 1 ¶ 26.

These developments were a breakthrough in the field. In 2012, the Mandl team published the seminal paper on their work, which has been cited over 500 times and viewed over 60,000 times. D.I. 1 ¶ 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. 1 ¶ 28 (quoting D.I. 1-1 at 323 (Exhibit 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. 1 ¶ 31.

In 2011, GSK filed non-provisional international patent applications, stating 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. 1 ¶ 28 (quoting D.I. 1-2 at 888 (Exhibit 12 p. 241)). Moderna has also cited and fully incorporated GSK’s patent filings in its own patents and publications. D.I. 1 ¶ 35 (citing D.I. 1 Exs. 20–23). Moderna exploited its knowledge of the fundamental technologies invented by the Mandl team—as claimed in the Asserted Patents—to develop its Spikevax® SARS-CoV-2 S protein mRNA vaccine products (“Spikevax®”).

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.

## II. REPRESENTATIVE ALLEGATIONS 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.

160. 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.

163. During the decade-long period of delay, Moderna invested significant time and resources into developing the SPIKEVAX® vaccine.

164. 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. 17 ¶¶ 5, 76, 160, 163–64 (emphasis omitted); *see, e.g., id.* ¶¶ 29, 31, 33–37, 44–45, 48–49, 52–54, 56–57, 60–67, 75, 158, 161–62, 165.

Moderna does not allege that GSK delayed publicly disclosing the specifications of the Asserted Patents or that of their priority applications. Nor does Moderna allege that GSK's prosecution of the Asserted Patents violated any statute or Patent Office procedure. 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.

### **ARGUMENT**<sup>3</sup>

Moderna's counterclaims and affirmative defenses of prosecution laches should be dismissed and stricken, respectively, 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.*

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<sup>3</sup> Moderna's prosecution laches allegations in both *GSK v. Moderna* (Spikevax®) and *GSK v. Moderna* (mRESVIA®) fail for substantially the same reasons as those in *GSK v. PBNT*. *See GSK v. PBNT*, D.I. 35 at 14–19 (GSK Opening Brief); *GSK v. PBNT*, D.I. 43 at 6–10 (GSK Reply Brief); *see also GSK v. PBNT*, D.I. 42 (PBNT Opposition Brief). As such, GSK's arguments in *GSK v. PBNT* apply with equal force to *GSK v. Moderna* (Spikevax®) and *GSK v. Moderna* (mRESVIA®).

*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 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.

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. Nor can Moderna show that it suffered any prejudice as a result of GSK’s typical and lawful practices.

**I. MODERNA ALLEGES NO COGNIZABLE “UNREASONABLE AND INEXCUSABLE DELAY.”**

**A. Moderna Fails To Allege Any Misuse of The Patent System.**

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 recognized a number of different ways that a party can adequately 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, Inc. v. ArcherDX, Inc.*, 690 F. Supp. 3d 437, 447 (D. Del. 2023); (7) “repeatedly fail[ed] to file applications without improper formalities,” *id.*; (8) “deliberately refile[d] continuation

applications for claims that had already been adjudicated on the merits,” *id.*; or (9) “deceptively” added new matter to the specifications while “masquerading” it to the Patent Office as “previously disclosed,” *Sonos, Inc. v. Google LLC*, 2023 WL 6542320, at \*18, \*27 (N.D. Cal. Oct. 6, 2023). 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. 17 ¶¶ 5, 76. But that theory is legally irrelevant because the claimed inventions of the Asserted Patents were disclosed long ago in the original priority applications. D.I. 1 ¶¶ 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.

Prosecution laches does not focus on an alleged delay in presenting *claims* but a delay in presenting the *inventive disclosure*—*i.e.*, the specification and priority application as a whole. *See id.* (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 have been public since 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. 17 ¶ 160, 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. 17 ¶¶

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. 17 ¶ 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 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); *see Sonos*, 2023 WL 6542320, at \*18. 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.

At bottom, 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. 17 ¶¶ 29, 31, 34, 37, 158, 160. But that is a typical § 112 invalidity theory. *See Pandrol USA, LP v. Airboss Ry. Prods.*, 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 also to 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. Prosecution Laches Does Not Apply To Post-GATT Patents, Including The Asserted Patents.**

Moderna’s repeated attempts to mischaracterize typical, lawful patent prosecution conduct as egregious misuse also illustrates why prosecution laches does not (and should not) apply to post-GATT patents like the Asserted Patents. *See* D.I. 17 ¶¶ 28–63.

The doctrine of prosecution laches helped address a loophole in patent law that existed before Congress enacted the General Agreement on Trade and Tariffs (“GATT”), which became effective in 1995. *See Hyatt*, 998 F.3d at 1359–62. Before GATT, a patent’s term was measured from the patent’s issuance date, regardless of its effective filing date. “The fact that patent term was keyed to the date of issuance, rather than the date of filing, incentivized certain patentees to

delay prosecuting their patents by abandoning applications and filing continuing applications in their place.” *Id.* at 1351. This resulted in so-called “submarine” patents that patentees would sink into prosecution for decades through intentionally dilatory practices, “depriv[ing] the public of timely disclosure” in the process; patentees would then surface the patents to issuance after the market had developed to maximize the window for damages through the full patent term. *Id.* at 1351–52. GATT altered the way patent terms were measured, ensuring that patentees can no longer pursue submarine patents. Thus, while prosecution laches is still useful to combat any remaining pre-GATT submarine patents, it is obsolete as to post-GATT patents, for which the doctrine’s rationale does not apply. Indeed, the Federal Circuit has never deemed a post-GATT patent unenforceable based on the doctrine of prosecution laches.<sup>4</sup>

Moderna’s deficient allegations demonstrate why prosecution laches does not apply to post-GATT patents. The two fundamental underpinnings of prosecution laches are absent in this case: (1) GSK timely disclosed its inventions to the public; and (2) the terms of the Asserted Patents are tied to the respective parent applications. *Natera*, 690 F. Supp. 3d at 448 (“Use of the patent prosecution process to extend the patent term is an important commonality amongst cases finding prosecution laches.” (quoting *Seagen Inc. v. Daiichi Sankyo Co.*, 2022 WL 2789901, at \*7 (E.D. Tex. July 15, 2022))); *see Hyatt*, 998 F.3d at 1351–53 (regarding submarine patents pre-GATT). Significantly, Moderna has not alleged that GSK has either suppressed public disclosure of its patent filings or in any way attempted to extend the terms of the Asserted Patents. And if Moderna’s allegations about GSK’s filing of continuation or divisional patent applications suffice

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<sup>4</sup> With one exception, all district courts have followed suit. A single court in the Northern District of California issued the only decision applying prosecution laches to a post-GATT patent: *Sonos, Inc. v. Google LLC*, 2023 WL 6542320 (N.D. Cal. Oct. 6, 2023). This decision is currently on appeal at the Federal Circuit. Opening Brief, *Google LLC v. Sonos, Inc.*, 24-1097, D.I. 17, at 26–45 (Fed. Cir. 2024).

to plead prosecution laches, then any continuation or divisional patent asserted in litigation with claim scope different from its parent would face allegations of prosecution laches. Such an expansion of the prosecution laches doctrine would certainly risk statutory provisions—35 U.S.C. §§ 120, 121, 365(c), 386(c)—“be[ing] unjustifiably vitiated.” *See Symbol*, 422 F.3d at 1385.

**II. 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.

**CONCLUSION**

Even taking Moderna’s allegations as true, Moderna fails to allege facts sufficient to show “unreasonable and inexcusable delay” resulting from “egregious misuse” of the patent system and prejudice “attributable to” that delay. GSK respectfully asks this Court to dismiss, with prejudice, Moderna’s Counterclaims XVI–XXII and strike Moderna’s Twenty-First Affirmative Defense because Moderna has not pled a legally cognizable claim of prosecution laches.

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