IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE BIOLOGICALS SA and GLAXOSMITHKLINE LLC, Plaintiffs, v. PFIZER INC., PHARMACIA & UPJOHN CO. LLC, BIONTECH SE, BIONTECH MANUFACTURING GMBH, and BIONTECH US INC., Defendants.	)	C.A. No. 24-512 (GBW)

PLAINTIFFS' BRIEF IN SUPPORT OF THEIR PARTIAL MOTION TO DISMISS COUNTERCLAIMS AND STRIKE AFFIRMATIVE DEFENSES OF PATENT MISUSE AND PROSECUTION LACHES

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This patent infringement action concerns the revolutionary technology that provided the foundation for today's mRNA vaccines. In 2010, more than a decade before Defendants Pfizer Inc., Pharmacia & Upjohn Co. LLC, BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech US Inc. (collectively, "PBNT") first sought FDA authorization to market their Comirnaty® mRNA vaccines, a group of Novartis scientists described the first mRNA vaccines in a series of patent applications. The Asserted Patents[1] properly claim priority to those 2010 applications. PBNT has reaped billions of dollars in profit by infringing the Asserted Patents through sales of Comirnaty® mRNA vaccines.

Plaintiffs GlaxoSmithKline Biologicals SA and GlaxoSmithKline LLC (collectively, "GSK") now move the Court to dismiss PBNT's Counterclaims XVII–XXXII and strike PBNT's Third and Fifth Affirmative Defenses, which allege that the Asserted Patents are unenforceable for patent misuse and prosecution laches. Both theories of unenforceability rest on disputed claim constructions and non-infringement and invalidity defenses (which flatly conflict with positions PBNT has taken in other proceedings). But the Court need not reach those questions to resolve this dispute; both claims fail as pled.

First, with respect to patent misuse, PBNT's pleadings, taken as true, fail to plausibly show that GSK impermissibly broadened the scope of its patent rights to anticompetitive effect. Indeed, PBNT fails to allege a legally cognizable patent misuse theory, such as conditioning a patent license on post-expiry royalties or the purchase of separable, staple, goods. GSK's assertion of its

[1] 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) (collectively, the "Asserted Patents").

patent rights alone is protected by 35 U.S.C. § 271(d)(3). And PBNT's allegation that GSK's offer to license its patents to PBNT constitutes patent misuse fails as a matter of law.

Second, with respect to prosecution laches, PBNT's pleadings, taken as true, fail to plausibly show that GSK's prosecution practices constituted an egregious misuse of the patent system that prejudiced PBNT. This is not a pre-GATT submarine patent situation resulting in an extension of patent term—the expiration of each Asserted Patent is 20 years from the filing of the corresponding priority application. PBNT has not alleged that GSK suppressed public disclosure of the content of the Asserted Patents—indeed PBNT was citing to the GSK patent applications shortly after they first published, many years before Comirnaty® was ever contemplated. PBNT's allegations show only that GSK engaged in patent prosecution practices authorized by the patent statute and expressly endorsed by the Federal Circuit and this Court.

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

FACTUAL BACKGROUND

I. THE INVENTION, THE ASSERTED PATENTS AND ACCUSED PRODUCTS, AND THE NATURE AND STAGE OF PROCEEDINGS.

In 2008, a team of researchers at Novartis AG subsidiaries ("Novartis"), led by Christian Mandl ("Mandl team"), set out to overcome long-standing barriers to the development of mRNA vaccines. D.I. 26, ¶¶ 29–31, 40. In July and August 2010, the Mandl team first described novel lipid and mRNA formulations and methods for their preparation and use for vaccination in patent applications. D.I. 26, ¶¶ 32. Beginning in 2012, the Mandl team's inventions were publicly disclosed both in the form of patent applications and peer-reviewed journal articles. D.I. 26, ¶¶ 33,

37. In 2021, the prestigious science 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. 26, ¶¶ 3, 37 (quoting D.I. 26-1 at 254 (Exhibit 6 p. 323)).

GSK acquired a substantial portion of Novartis's vaccines business in 2015 and, in doing so, obtained rights to the Asserted Patents. D.I. 26, ¶¶ 40, 41. GSK continued the mRNA vaccine research and development program, and continues today, with multiple mRNA vaccines currently in human clinical trials. D.I. 26, ¶ 43, 50.

Since the first applications in each family of the Asserted Patents formally entered the process of review before the Patent Office in 2013 pursuant to 35 U.S.C. § 371 ("National stage: Commencement"), GSK has at various times filed divisional and continuation applications with claims to differing aspects of the Mandl team's inventions, but that shared identical disclosures with the preceding applications in each family. D.I. 26, ¶¶ 32, 42, 43. The Asserted Patents issued from such divisional and continuation applications and claim priority to and incorporate the Mandl team's 2010 applications. D.I. 26, ¶ 32.

PBNT began citing to and incorporating published patent applications within the families of the Asserted Patents ***into PBNT's own patent filings*** in 2013. D.I. 26, ¶ 47. As detailed in Section II.E, *infra*, PBNT has since relied on disclosures of "mRNA … encapsulated in LNPs" for vaccination from the GSK family of patent applications to challenge the patentability or validity of third-party patents asserted against Comirnaty® in various other proceedings. D.I. 26, ¶¶ 33–35.

PBNT started its collaboration that led to development of Comirnaty® in March 2020. D.I. 32, ¶ 46. Comirnaty® received its first emergency use authorization from FDA in December 2020,

and PBNT began "rolling out" vaccines "immediately thereafter." *See* D.I. 32, ¶ 49. PBNT has introduced several variants of Comirnaty® since the first authorization, D.I. 32, ¶¶ 55–92, with the 2024–2025 variant receiving FDA approval in August 2024.[2]

GSK filed suit against PBNT on April 25, 2024, for infringement of the '693, '694, '534, '401, and '467 patents by the accused Comirnaty® vaccines, D.I. 1, and amended its complaint to add the '422, '475, and '660 patents on August 14, 2024, D.I. 26. PBNT filed an Amended Answer on August 30, 2024, asserting, *inter alia*, defenses and declaratory judgment counterclaims that all Asserted Patents are unenforceable for patent misuse and prosecution laches. D.I. 32.

GSK now moves to dismiss PBNT's counterclaims and strike PBNT's defenses of patent misuse and prosecution laches under Federal Rules of Civil Procedure 12(b)(6) and 12(f).

II. PBNT'S ALLEGATIONS CONCERNING PATENT MISUSE AND PROSECUTION LACHES.

As further detailed in this section, PBNT alleges that GSK's Asserted Patents are unenforceable because GSK filed, prosecuted, and now asserts, patent applications with claims that encompass the Comirnaty® vaccine products only after detailed information regarding Comirnaty® was publicly known, and while supposedly knowing that those claims exceeded the disclosures of the underlying patent applications. D.I. 32, ¶¶ 2, 6, 7, 9, 10. Although GSK disputes those allegations, it takes them as true for the purposes of this motion.

A. Representative Allegations Concerning Disclosures Of The Asserted Patents.

PBNT alleges that the GSK patent disclosures do not cover Comirnaty® products in two respects: they "only" describe "liposomes," not the "lipid nanoparticles" (or LNPs) of Comirnaty®;

[2] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-receive-us-fda-approval-authorization.

and they "only" describe "self-replicating RNA," not the "mRNA" of Comirnaty®. PBNT's allegations about the disclosures of the Asserted Patents are captured by these paragraphs:

> 7. The patents asserted in GSK's original Complaint only describe liposomes and self-replicating RNA. They do not describe the lipid nanoparticle formulation or mRNA of Pfizer and BioNTech's COVID-19 vaccine.
>
> 9. The three new patents asserted in GSK's First Amended Complaint are similarly flawed. They only describe liposomes and self-replicating RNA, and they do not describe the lipid nanoparticle formulation or mRNA of Pfizer and BioNTech's COVID-19 vaccine.

D.I. 32; *see also id.* at ¶¶ 98, 102, 182, 183, 185, 194, 195, 197, 206, 207, 209, 218, 219, 221, 230, 231, 233, 241, 242, 244, 252, 253, 255, 263, 264, 266.

B. Representative Allegations Concerning Claim Scope Of The Asserted Patents.

PBNT alleges that Novartis and GSK prosecuted claims to "liposomes" and "self-replicating" RNA until Comirnaty® was developed, and only then prosecuted claims to "RNA" (as opposed to "self-replicating" RNA) where "lipids" (as opposed to "liposomes") "encapsulate" the RNA. PBNT's allegations about the scope of claims under prosecution may be illustrated by these paragraphs directed at one of the Asserted Patents:

> 180. For at least six years prior to December 22, 2021, all claims sought in the '080 Application family specified that the RNA was self-replicating RNA.
>
> 181. Prior to December 22, 2021, all claims sought were directed to a "liposome" encapsulating RNA.
>
> 184. GSK only began prosecuting the claims of the '693 Patent, directed to "RNA" where "the lipids encapsulate" the RNA, after the composition of Comirnaty® was published and years after the alleged priority date of the '693 Patent.

D.I. 32; *see also id.* at ¶¶ 96, 192, 193, 196, 204, 205, 208, 216, 217, 220, 228, 229, 232, 240, 243, 251, 254, 262, 265.

C. Representative Allegations Concerning Patent Misuse.

PBNT's allegations of patent misuse may be distilled down to: (1) GSK is knowingly enforcing patent claims that either do not cover Comirnaty® or that exceed the disclosures of the Asserted Patents; (2) with anticompetitive effect. The following allegations are representative of PBNT's patent misuse claims:

> 101. GSK now seeks to profit not from technology GSK or its predecessors invented, but rather from improperly contorting the specification and/or claims of the families of its recent patent applications to what it alleges covers Comirnaty®.
>
> 179. GSK has sought to enforce and/or license the '693 Patent for products and acts it knows are outside the claims of the '693 Patent.
>
> 186. GSK's conduct in seeking to license and enforce the '693 Patent against products and acts that it knows to be outside the scope of the claims of the '693 Patent and outside the scope of what was actually invented is an attempt to seek an improper economic benefit.
>
> 187. GSK has engaged in a course of conduct that seeks to broaden the scope of the '693 Patent with anticompetitive effect.

D.I. 32; *see also* ¶¶ 191–99, 203–11, 215–23, 227–35, 239–46, 250–57, 261–68.

Notably, PBNT does not allege that GSK has conditioned a license to practice the inventions of the Asserted Patents on payment of post-expiration royalties. Nor does PBNT allege that GSK has conditioned a license to practice the inventions of the Asserted Patents on payment of royalties from separable, staple, goods. Indeed, PBNT does not allege that any agreement concerning the right to practice the inventions of the Asserted Patents has been consummated between GSK and PBNT.

D. Representative Allegations Concerning Prosecution Laches.

PBNT's allegations of prosecution laches follow this pattern: (1) GSK supposedly unreasonably delayed prosecuting the claims of the Asserted Patents until learning about

Comirnaty®; and (2) PBNT has been prejudiced as a result. The following allegations are representative of PBNT's prosecution laches claims:

> 93. … [GSK] 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.
>
> 94. … [GSK] unreasonably delayed pursuing the claims of the '660 Patent for over a decade before it pursued claims reciting "lipid particles." Following the amendment to the claims of the '153 Application on October 7, 2014, Applicant unreasonably delayed pursuing the claims of the '475 Patent and '660 Patent for over seven years before it pursued claims reciting "RNA."
>
> 95. … [F]ollowing the amendment to the claims of the '077 Application on June 8, 2015, Applicant unreasonably delayed pursuing the claims of the '422 Patent for over four years before it pursued claims reciting "RNA."
>
> 96. It 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 '634 Patent, '694 Patent, '534 Patent, '401 Patent, '467 Patent, '475 Patent, and '660 Patent.
>
> 275. As a result of Applicant's unexplained and unreasonable delay in prosecuting the claims of the '693 Patent, Counterclaimants have been prejudiced.

D.I. 32; *see* ¶¶ 98, 272–75, 279–83, 286–90, 293–97, 300–04, 307–10, 313–16, 319–23.

Absent from PBNT's pleading is any allegation that Novartis, GSK, or the Mandl team delayed publicly disclosing the content of the Asserted Patents. Nor does PBNT allege that Novartis, GSK, or the Mandl team changed the disclosures of the applications in each family of the Asserted Patents after the first application published. PBNT also does not allege that Novartis, GSK, or the Mandl team's use of divisional or continuation applications practice violated any statutes or Patent Office procedures.

E. PBNT's Contradictory Allegations In Other Legal Proceedings.

The parties plainly disagree on questions of claim construction, infringement, and validity. The Court need not sort through any of those questions to grant the relief requested in this Motion. However, it is instructive—and revealing—to note how PBNT's litigation-driven positions in this action flatly conflict with positions it has taken in other patent disputes. Indeed, PBNT has relied on ***the Mandl team's patent disclosure of "mRNA … encapsulated in LNPs"*** to support invalidity positions against other patentees. D.I. 26, ¶¶ 33–35.

For example, contrary to PBNT's new allegations that the Asserted Patents do not disclose LNPs (D.I. 32, ¶¶ 7–9, 102, 183, 185, 195, 197, 207, 209, 219, 221, 231, 233, 242, 244, 253, 255, 264, 266), on August 23, 2023, in an *Inter Partes* Review ("IPR") proceeding, PBNT and its expert declarants pointed to one of GSK's published patent applications for "the use of [LNPs] (i.e., particles made of lipids that are nanosized, in the form of liposomes) for delivery of RNA." *See* D.I. 26, ¶ 33 (quoting D.I. 26-5 at 643 (Exhibit 91 ¶ 100)). On January 10, 2024, in an expert report submitted in a European litigation, PBNT characterized the same published application as "demonstrat[ing] that exogenous mRNA … encoding a selection of proteins … could be successfully encapsulated in LNPs, administered to large mammals, and expressed." *See* D.I. 26, ¶ 33 (quoting 26-6 at 357 (Exhibit 94 ¶ 345)).

As another example, PBNT's new allegations that the Asserted Patents do not disclose non-self-replicating mRNA (D.I. 32, ¶¶ 7–9, 102, 182, 185, 194, 197, 206, 209, 218, 221, 230, 233, 241, 244, 252, 255, 263, 266) contravene their repeated insistence in other patent actions that the "RNA" of GSK's patented inventions is not limited to "self-replicating RNA" (or "saRNA") but also includes non-self-replicating RNA like that used in Comirnaty®. *See* D.I. 26, ¶ 34. Indeed, in the aforementioned IPR, PBNT and its expert declarants specifically alleged that a "[d]elivery

[c]hemist would not consider the disclosure of [GSK's published application] to be limited to saRNA." *Id.* (quoting D.I. 26-6 at 457 (Exhibit 98 ¶ 16)).

Less than a year before filing its Amended Answer in this case, PBNT repeatedly stated—in public court filings and sworn expert statements—that the specifications of the Asserted Patents disclosed the very scope PBNT is now contesting. The Court is not required to accept PBNT's new, contradictory, unsupported, litigation-inspired conclusions as true. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009).[3] However, for the reasons provided below, even accepting PBNT's positions on these open disputed questions, their claims fail.

ARGUMENT

For a counterclaim to survive a motion to dismiss and for an affirmative defense to survive a motion to strike, the pleadings "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (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). However, the Court need not accept as true "bald assertions," "unsupported conclusions," "unwarranted inferences," or "legal conclusion[s] couched as … factual allegation[s]." *Iqbal*, 556 U.S. at 678–79 ("[L]egal conclusions … must be supported by factual allegations."); *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.

[3] Tellingly, the Patent Office examiners who examined and allowed the Asserted Patents never rejected any claims during prosecution for a lack of adequate § 112 support based on any of the supposed disclosure deficiencies raised by PBNT.

PBNT fails to sufficiently plead its counterclaims and defenses of patent misuse and prosecution laches. Instead, PBNT's attempts to shoehorn its claim construction, non-infringement, and invalidity contentions into these equitable doctrines only serve to demonstrate that GSK engaged in expressly lawful patent prosecution.

III. PBNT'S ALLEGATIONS, TAKEN AS TRUE, DO NOT STATE A LEGALLY COGNIZABLE CLAIM OR DEFENSE OF PATENT MISUSE.

Patent misuse is "grounded in the policy-based desire to prevent a patentee from using the patent to obtain market benefit beyond that which inheres in the statutory patent right." *Princo Corp. v. Int'l Trade Comm'n*, 616 F.3d 1318, 1328 (Fed. Cir. 2010) (internal quotations omitted). To prove patent misuse, a challenger must therefore establish: (1) "the patentee has impermissibly broadened the physical or temporal scope of [a] patent grant;" and (2) the patentee "has done so in a manner that has anticompetitive effects." *Id.* PBNT does not plausibly state a claim for patent misuse because PBNT has not pled facts sufficient to show that: (1) GSK engaged in *per se* impermissible broadening of patent scope or broadened the scope of its patent grants in a manner not protected by 35 U.S.C. § 271(d); or (2) GSK's alleged actions resulted in any anticompetitive effect.

Instead, PBNT's factual allegations, taken as true, simply ascribe actions to GSK that are lawful and without cognizable anticompetitive effect.

A. PBNT Has Not Pled Facts Sufficient To Show GSK Impermissibly Broadened The Physical Or Temporal Scope Of A Patent Grant.

1. PBNT Has Not Alleged Any "*Per Se*" Impermissible Broadening Of Patent Scope.

Patent misuse "has largely been confined to a handful of specific practices by which the patentee seemed to be trying to 'extend' his patent grant beyond its statutory limits." *Princo*, 616 F.3d at 1329 (quoting *USM Corp. v. SPS Techs. Inc.*, 694 F.2d 505, 510 (7th Cir. 1982)). "The

courts have identified certain specific practices as constituting *per se* patent misuse, including so-called 'tying' arrangements in which a patentee conditions a license under the patent on the purchase of a separable, staple good, and arrangements in which a patentee effectively extends the term of its patent by requiring post-expiration royalties." *Va. Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 869 (Fed. Cir. 1997) (internal citations omitted). Because PBNT has not alleged any of these arrangements or practices, it has not alleged any *per se* impermissible broadening of patent scope.

2. PBNT's Allegations Of Improper Procurement And Enforcement Of The Asserted Patents Are Insufficient To Show Impermissible Broadening Of Patent Scope.

While courts have established that certain practices are patent misuse, Congress has established that other practices are ***not*** patent misuse. *See* 35 U.S.C. § 271(d). Under § 271(d), it is not patent misuse for a patent owner to "enforce his patent rights against infringement or contributory infringement of the patent." *See also Dawson Chem. Co. v. Rohm & Hass Co.*, 448 U.S. 176, 201 (1980) ("[Section 271(d)(3)] plainly means that the patentee may bring suit without fear that his doing so will be regarded as an unlawful attempt to suppress competition."); *Glaverbel Société Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1558 (Fed. Cir. 1995) ("The bringing of a lawsuit to enforce legal rights does not itself constitute … patent misuse; there must be bad faith and improper purpose in bringing the suit, in implementation of an illegal restraint of trade."); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1373 (Fed. Cir. 1998).

Defendant Pfizer is well aware of this controlling law, as it recently took the position that a patent owner's assertion of infringement is not only insufficient to constitute patent misuse but also that any suggestion otherwise is "clearly contrary to law." Ex. 1 ¶ 64 (Pfizer Brief, *Wyeth LLC [Pfizer Inc.] v. AstraZeneca Pharms. LP*, 1:21-cv-01338-MFK, D.I. 488 (D. Del. June 17,

2024)).[4] Yet that is exactly what PBNT does here. PBNT's allegations underlying its patent misuse claim boil down to conclusory non-infringement assertions, *i.e.*, that the claims of the Asserted Patents do not cover Comirnaty®. *See* D.I. 32, ¶¶ 182–83, 185, 194–95, 197, 206–07, 209, 218–19, 221, 230–31, 233, 241–42, 244, 252–53, 255, 263–64, 266. "If denying an infringement contention were sufficient to establish patent misuse, the doctrine would know no bounds." Ex. 1 ¶ 65.

Here, PBNT attempts to go a step further by alleging GSK knowingly prosecuted and asserted claims to inventions that are not disclosed in the patents. *See, e.g.*, D.I. 32, ¶¶ 184–86, 196–98, 208–10, 220–22, 232–34, 254–56, 265–67. But such conclusory allegations of wrongdoing, without specifying the wrongdoer, the specific misrepresentation made to the Patent Office material to securing the Asserted Patents, or any other factual basis from which to infer malicious intent, are insufficient because they "fail to 'provide the essential factual background that would accompany the first paragraph of any newspaper story'—that is the 'who, what, when, where and how' of the events at issue." *Allergan Holdings Unlimited Co. v. MSN Labs. Priv. Ltd.*, 2024 WL 3444368, at *5 (quoting *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (internal quotations omitted)); *see also Allergan*, 636 F. Supp. 3d at 488 ("A counterclaim or affirmative defense that alleges fraudulent conduct must be pled with particularity under Rule 9(b)."); *Exergen Corp. v. Wal-Mart Stores*, 575 F.3d 1312, 1328–29 (Fed. Cir. 2009) (discussing the level of specificity necessary to state a claim based on fraud before the Patent Office). PBNT's conclusory and unsupported allegation that GSK knowingly sought to claim something it did not actually invent cannot alone provide the required inference of malicious intent.

[4] Wyeth LLC is a wholly-owned subsidiary of Pfizer Inc. Corporate Disclosure Statement, *Wyeth LLC [Pfizer Inc.] v. AstraZeneca Pharms. LP*, 1:21-cv-01338-MFK, D.I. 4 (D. Del. Sept. 22, 2021).

See, e.g., *Impact Engine, Inc. v. Google LLC*, 2020 WL 3414627, *2 (S.D. Cal. 2020) ("Google simply alleges that claims of the continuation patents asserted by Impact Engine are not supported by their common specification, a validity challenge under 35 U.S.C. § 112. … Without some allegation of misrepresented fact or material omission in the written description made or withheld to allow the claims to issue, there is no fraud."). Worse, that allegation flies in the face of PBNT's own prior sworn statements. *See* Section II.E, *supra*. Absent more, as discussed in Section IV.A., *infra*, PBNT's allegations concerning GSK's actions during prosecution amount to nothing more than common and lawful practices that facilitate prosecution of claims directed to different aspects of an invention in different applications.

Moreover, even if the Court were to overlook the conclusory and superficial nature of this pleading and consider the claim on its face, it still must fail. In *Artemi Ltd. v. Safe-Strap Co.*, accused infringer Safe-Strap, similar to PBNT here, alleged that patentee Artemi undertook a scheme during reexamination and reissue "to re-write its patent to cover the [accused product] and then file th[e] infringement action." *Artemi Ltd. v. Safe-Strap Co.*, 2013 WL 6860734, *4 (D.N.J. 2013). Granting Artemi's motion to dismiss, that court explained: "allegations concerning misrepresentations made to the [Patent Office during prosecution] cannot support a defense of patent misuse because … those alleged actions could only define the scope of the monopoly in the first place. The distinction is chronological. A patentee cannot exploit its monopoly power without first having the bounds of that power defined." *Id.* And once defined, GSK's "monopoly power (no matter what its bounds) does not enable it to bring this suit. Rather, [GSK] may pursue this suit by virtue of Congress's statutory grant of a remedy for patent infringement, namely 35 U.S.C. § 271." *Id.* at *5. The same logic applies here.

Accordingly, PBNT has not alleged any broadening of patent scope not protected by 35 U.S.C. § 271(d).

B. PBNT Has Not Pled Facts Sufficient To Show An "Anticompetitive Effect."

PBNT's conclusory statement that GSK's licensing offers sought an improper economic benefit are insufficient to show an anticompetitive effect supporting patent misuse. Unaccepted offers to license a patent ***cannot*** constitute patent misuse. *See Va. Panel*, 133 F.3d at 871 (holding that unconsummated license offer could not constitute *per se* tying or patent misuse); *see also Good Kaisha IP Bridge 1 v. TCL Commc'n Tech. Holdings, Ltd.*, 2017 WL 750700, at *8 (D. Del. Feb. 27, 2017) (holding that claim for patent misuse must be based on a "consummated" agreement). PBNT does not allege that GSK and PBNT actually consummated a licensing agreement—because they did not. PBNT merely alleges that GSK offered to license its Asserted Patents. D.I. 32, ¶¶ 186, 198, 210, 222, 234, 245, 256, 267. As Pfizer has articulated to another court in this District: "[a]s a matter of law, merely approaching an alleged infringer about a license is not patent misuse." Ex. 1 ¶ 65. PBNT therefore has failed to plead any cognizable anticompetitive effect through GSK's actions.

* * *

For at least these reasons, PBNT's patent misuse allegations fail as pled, and the Court should dismiss PBNT's patent misuse counterclaims and strike the corresponding defenses.

IV. PBNT'S ALLEGATIONS, TAKEN AS TRUE, DO NOT STATE A LEGALLY COGNIZABLE CLAIM OR DEFENSE OF PROSECUTION LACHES.

"Prosecution laches requires proving two elements: (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. Cir. 2023). PBNT does not plausibly state a claim

of prosecution laches because PBNT does not allege facts sufficient to show that any delay in GSK's patent prosecution of the Asserted Patents was "unreasonable and inexcusable." *Id.* This defect also renders PBNT's allegations insufficient to show prejudice because, without an "unreasonable and inexcusable" delay, there can be no "prejudice attributable to th[at] delay." *Id.*

Here again, PBNT's factual allegations, taken as true, simply ascribe actions to GSK that are expressly lawful and therefore without cognizable prejudice to PBNT.

A. PBNT Has Not Pled Facts Sufficient To Show Unreasonable And Inexcusable Delay During Prosecution Of The Asserted Patents.

The defense of prosecution laches requires that a patentee "delay" prosecution of a patent ***and*** that such delay be "unreasonable and inexcusable." *Id.* PBNT's factual allegations of delay alone are thus insufficient to state a claim for prosecution laches. As another court in this District has aptly noted, "prosecution laches is not simply a time-counting exercise." *Wirtgen Am., Inc. v. Caterpillar, Inc.*, 1:17-cv-00770-JDW, D.I. 448, at 9 (D. Del. Aug. 21, 2024) (quoting *Seagen Inc. v. Daiichi Sankyo Co.*, 2022 WL 2789901, at *7 (E.D. Tex. July 15, 2022)). "[The patentee's] ***conduct*** also matters." *Id.* (emphasis added). Accordingly, the law requires that a viable claim of prosecution laches include allegations of fact sufficient to show that the challenged delay was "unreasonable and inexcusable." *Personalized Media*, 57 F.4th at 1354. PBNT's allegations instead establish that GSK's actions were both reasonable and appropriate.

For a delay to be "unreasonable and inexcusable," a patentee's prosecution conduct must have "constitute[d] 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)). That is a demanding standard that PBNT's allegations fail to meet.

PBNT does not allege the type of "egregious misuse" that courts have recognized as potentially supporting a holding of prosecution laches. For example, PBNT does not suggest that

GSK "adopted an approach" of "overwhelm[ing] the PTO" to purposefully delay prosecution by submitting "atypically long and complex" applications, "adding hundreds of claims" through amendments, or "rewriting claims entirely or in significant part midway through prosecution." *Hyatt*, 998 F.3d at 1353, 1368; *see also Personalized Media*, 57 F.4th at 1354–57 (affirming application of prosecution laches and analogizing to *Hyatt*). Nor does PBNT allege that GSK "request[ed] the maximum extension of time to respond to office actions, repeatedly fail[ed] to file applications without []proper formalities to extend prosecution, or deliberately refile[d] continuation applications for claims that had already been adjudicated on the merits." *Natera, Inc. v. ArcherDX, Inc.*, 690 F. Supp. 437, 447 (D. Del. 2023).

At bottom, PBNT alleges that GSK engaged in common, lawful continuation and divisional practice. In particular, PBNT's sole factual allegation of prosecution misconduct is that GSK presented the claims of the Asserted Patents to the Patent Office only after the accused product Comirnaty® entered the market and information on its composition became public. Even ignoring that GSK had prosecuted the claim scope to which PBNT attaches this theory in various global patent applications long before information on Comirnaty® became public, D.I. 26, ¶ 42, this theory does not identify any misuse of the patent system. As the Federal Circuit has stated:

> 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); *see In re Bogese*, 303 F.3d 1362, 1369 (Fed. Cir. 2002) (explaining that "[a]n applicant's attempt to obtain new claims directed to inventions that he or she believes are fully disclosed and supported in an earlier application" does not give rise to prosecution laches). Indeed, as statutorily prescribed,

continuation and divisional application practice provides a patentee the ability to obtain such claims. *See* 35 U.S.C. §§ 120, 121, 365(c), 386(c). These rules balance the patentee's right to exclude with the public's right to disclosure by limiting the term of continuation and divisional claims to 20 years from the effective filing date of the original parent application. Accordingly, PBNT's unfounded allegations of GSK's prosecution misconduct, even if taken as true, are instead allegations of expressly lawful prosecution practices.

The fact that PBNT folds its conclusory claim construction, non-infringement, and invalidity arguments into its prosecution laches theory does not change the analysis. PBNT does not allege that GSK took steps to suppress public disclosure of the full content of its patent applications, altered the content of any new divisional or continuation application from that of the long-published priority applications in each family, or adopted any tactics to delay issuance of the Asserted Patents. No more need be considered to resolve this issue.

More fundamentally, the doctrine of prosecution laches does not apply to post-GATT patents. The equitable doctrine of prosecution laches developed to address a loophole in patent law that existed ***before*** Congress enacted the General Agreement on Trade and Tariffs ("GATT"), which went into effect in 1995. *See Hyatt*, 998 F.3d at 1359–62. Before GATT, each individual patent's term was measured from that specific 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 remains a vital tool 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.[5]

PBNT's deficient allegations illustrate why prosecution laches should not apply to post-GATT patents. The two underpinnings of prosecution laches are absent: the public received timely disclosure of the claimed inventions, and the Asserted Patents' terms do not extend beyond those of their ultimate parents. *Id.*; *see 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))). GSK properly filed and diligently prosecuted the applications that issued as the Asserted Patents based on the same disclosures in the earliest published patent applications to which priority is claimed. Those priority patent applications, in turn, confine the term of the Asserted Patents. The benefits and drawbacks of these earlier disclosures to GSK are thus functioning exactly as prescribed by statute, and PBNT's attempts to characterize GSK's typical prosecution conduct under these laws as an "egregious misuse" is exactly what the Federal Circuit instructed should not be done: prosecution laches "should be used sparingly lest statutory

[5] GSK knows of only one district court decision applying prosecution laches to a post-GATT patent: *Sonos, Inc. v. Google LLC*, 2023 WL 6542320 (N.D. Cal. Oct. 6, 2023). This case is currently on appeal to the Federal Circuit. Opening Brief, *Google LLC v. Sonos, Inc.*, 24-1097, D.I. 17, at 26–45 (Fed. Cir. 2024).

provisions"—like 35 U.S.C. §§ 120, 121, 365(c), 386(c)—"be unjustifiably vitiated." *Symbol Techs., Inc. v. Lemelson Med., Educ. & Rsch. Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005).

PBNT has not alleged any action on GSK's part that amounts to prosecution "delay," let alone "unreasonable and inexcusable" delay.

B. PBNT Has Not Pled Facts Sufficient To Show Prejudice "Attributable To" Unreasonable And Inexcusable Delay Of The Asserted Patents.

Prosecution laches also requires "the accused infringer [to] have suffered prejudice attributable to" the "unreasonable and inexcusable" delay. *Personalized Media*, 57 F.4th 1354. Because there can be no prejudice "attributable to" a non-existent delay, PBNT also fails to state a cognizable foundation for the doctrine's second element—prejudice.

* * *

For at least these reasons, PBNT's claims of prosecution laches also fail as pled, and the Court should dismiss PBNT's prosecution laches counterclaims and strike the corresponding defenses.

CONCLUSION

GSK respectfully asks this Court to dismiss with prejudice PBNT's Counterclaims XVII–XXXII and strike PBNT's Third and Fifth Affirmative Defenses because PBNT has not pled legally cognizable claims or defenses for patent misuse or prosecution laches.

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