IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

SEAGEN INC.,	§	
	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION NO. 2:20-CV-00337-JRG
	§	
DAIICHI SANKYO CO., LTD.,	§	
	§	
Defendant,	§	
	§	
ASTRAZENECA PHARMACEUTICALS LP, and ASTRAZENECA UK LTD	§	
	§	
Intervenor-Defendants.	§	

MEMORANDUM OPINION AND ORDER
SUPPORTED BY FINDINGS OF FACT AND CONCLUSIONS OF LAW

A bench trial was held on June 28, 2022, wherein the Court heard evidence and argument on Defendant Daiichi Sankyo Company, Limited's ("DSC") counterclaim of prosecution laches. (Dkt. No. 421). The Court has considered the totality of the evidence presented at the jury trial, the bench trial, and in the written record, including the post-trial submissions from the parties (Dkt. Nos. 406, 408, 426, 427). The Court now issues this opinion concerning prosecution laches supported by the following Findings of Fact ("FF") and Conclusions of Law ("CL") pursuant to Fed. R. Civ. P. 52(a)(1) and 52(c). In view thereof and as discussed herein, the Court rejects DSC's prosecution laches argument and finds that such does not bar enforceability of Plaintiff Seagen Inc.'s ("Seagen") asserted patent, U.S. Patent No. 10,808,039 (the "'039 Patent").

I. FINDINGS OF FACT

A. Procedural History

[FF 1] This is an action for patent infringement. Seagen sued DSC in October 2020 asserting the '039 Patent. (Dkt. No. 1). The patent is entitled "Monomethylvaline Compounds Capable of Conjugation to Ligands." (PX-0001 at 1). Seagen alleged that the '039 Patent is infringed by Enhertu®, an antibody-drug conjugate ("ADC") that has been approved by the United States Food and Drug Administration ("FDA") for the treatment of certain breast, gastric, and gastroesophageal cancers. (Dkt. No. 1 ¶ 4).

[FF 2] In July 2021, Intervenor-Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca UK Ltd. (collectively, "AstraZeneca")—which are involved in the domestic commercialization and marketing of Enhertu®—intervened in this action as a defendant. (Dkt. Nos. 126, 128).

[FF 3] A jury trial was held during the week of April 4, 2022. (Dkt. No. 361). On April 8, 2022, the jury returned a verdict finding that Seagen had proven by a preponderance of the evidence that DSC infringed at least one of Claims 1–5, 9, and 10 of the '039 Patent (the "Asserted Claims") and that Seagen had proven by a preponderance of the evidence that such infringement was willful. (Dkt. No. 370).

[FF 4] The jury also found that DSC and AstraZeneca had not proven by clear and convincing evidence that any of the Asserted Claims were invalid. (*Id.*). At trial, DSC and AstraZeneca argued that the '039 Patent was invalid for lack of written description and enablement. (*E.g.*, Dkt. No. 328 at 9; Dkt. No. 379 at 188:2–6). DSC and AstraZeneca argued that the '039 Patent specification did not disclose the claimed ADCs containing a glycine phenylalanine tetrapeptide linker. (*See, e.g.*, Dkt. No. 378 at 111:4–125:2). DSC and AstraZeneca contended, both at trial and throughout this case, that the '039 Patent only disclosed ADCs where

the drug moieties were auristatin/dolastatin drugs. (*E.g.*, Dkt. No. 328 at 9; Dkt. No. 378 at 111:4–125:2; Dkt. No. 379 at 188:2–6). Therefore, DSC and AstraZeneca argue the claimed ADC with a glycine phenylalanine tetrapeptide linker is outside the scope of the specification. (*Id.*). This argument failed to persuade the jury to find for DSC and AstraZeneca.[1] (Dkt. No. 370).

[FF 5] On May 14, 2022, the Court entered an order setting a date for the bench trial and setting a date for Seagen and DSC to submit bench trial briefs. (Dkt. No. 403).

[FF 6] On June 26 and 27, 2022, the Parties submitted, and the Court received, the expert report and deposition transcripts and designations of DSC's expert witness regarding prosecution laches, David Manspeizer, and Seagen's expert witness regarding prosecution laches, Richard Smith. (Dkt. Nos. 416, 417, 419, 420).

[FF 7] The bench trial was held on June 28, 2022. The Court heard evidence and argument on DSC's defenses under prosecution laches and 35 U.S.C. § 112(b).[2] The Court entered into the record at the bench trial all of the evidence admitted and testimony presented during the jury trial, the expert reports of Mr. Manspeizer and Mr. Smith as if those expert witnesses had testified live, deposition transcript excerpts designated by the parties, and additional numbered exhibits read into the record at the bench trial. (Dkt. No. 422 at 54:8–66:10).

B. The '039 Patent and its Prosecution

[FF 8] Seagen is the assignee of the '039 Patent. (PX-0001 at 1).

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[1] Before the jury rejected this argument, DSC and AstraZeneca raised numerous legal theories that all related to this issue regarding the '039 Patent specification and claims as it relates to ADCs and linkers. (Dkt. No. 130 at 10 ("Consistent with the title and abstract, every working example in the '039 patent involves an ADC with dolastatin/auristatin-type drugs."); Dkt. No. 255 at 15 ("Neither the 2004 application nor any other earlier-filed application described the claimed subgenus of Gly/Phe-Only tetrapeptide linkers recited in the Asserted Claims.")). The Court rejected these pre-trial arguments. (Dkt. No. 155 at 12 ("On balance, the Court is not persuaded by Defendants' arguments. In particular, the Court is not convinced that the section on drug moiety in section 9.4 of the specification is a lexicographical definition as opposed to a non-limiting embodiment."); Dkt. No. 347 at 2).

[2] Although DSC's §112(b) defense was stated in the Joint Pre-Trial Order (Dkt. No. 328 at 9), DSC did not raise this issue at claim construction. (*See* Dkt. No. 422 at 53:3–8).

[FF 9] Seagen did not seek or receive any term adjustment or extension for the '039 Patent. (PX-0001 at 1; DX-1212 at 77:2–23; DX-1209 ¶ 51; *see also* Dkt. No. 422 at 28:19–20).

[FF 10] Seagen requested, and was granted, expedited prosecution for the patent application leading to the '039 Patent (U.S. Patent Application No. 16/507,839 or the "'839 Application") via a request for prioritized examination under 37 C.F.R. § 1.102(e)(1). (DX-0006 at 448; DX-1209 ¶¶ 38, 65; DX-1212 at 111:10–112:02, 141:09–10).

[FF 11] The '839 Application is the seventh application filed in a direct series of divisional and continuing applications with the same specification that were filed between November 5, 2004 and July 10, 2019, starting with U.S. Patent Application No. 10/983,340 (the "'340 Application"). (DX-1209 ¶¶ 51–66).

[FF 12] The '340 Application published as U.S. Patent Application Publication No. 2005/0238649 on October 27, 2005, and accordingly, the invention disclosure of the claimed invention of the '039 Patent was available to the public as of October 27, 2005. (PX-0019 at 1; DX-1209 ¶ 53; DX-1212 at 121:3–16).

[FF 13] Seagen filed the '839 Application shortly after DSC announced its plan to accelerate submission of the Biologics License Application (BLA) for Enhertu®, the infringing product. (Dkt. 422 at 40:3–9; DX-1209 ¶ 47).

[FF 14] The '839 Application was published as U.S. Patent Application Publication No. 2019/0338045 on November 7, 2019, approximately 6 weeks before the FDA first approved Enhertu®. (DX-1208 at 1; DX-1209 ¶¶ 41, 47, 65; DX-1212 at 117:14–20).

[FF 15] Seagen did not submit any nonpublication requests during prosecution of the '039 Patent family and did not withhold any allowed claims from issuance. (DX-1209 ¶ 66; DX-1212 at 104:04–105:09).

[FF 16] Seagen has licensed patents and applications in the '039 Patent family to collaborators and licensees, including DSC, and has not hidden the existence of the family or any patent in the family from a collaborator or licensee. (DX-1209 ¶ 78).

[FF 17] Seagen has disclosed all members of the '039 Patent family, including all abandoned applications, to the public. (DX-1209 ¶¶ 78, 80, 106).

[FF 18] Seagen made no attempts to keep its invention disclosure secret from the public or from its prior licensees, including DSC. (DX-1209 ¶¶ 66, 78, 80, 106).

[FF 19] Seagen did not delay publication or issuance of any application or patent during prosecution of the '039 Patent family. (DX-1209 ¶¶ 66–67).

[FF 20] Seagen abandoned U.S. Patent Application No. 14/194,106 (the "'106 Application") on August 25, 2016 in favor of U.S. Patent Application No. 15/188,843 (the "'843 Application") after receiving a third office action from the examiner rejecting all pending claims of the '106 Application. (DX-0011 at 832–33; DX-1209 ¶ 62). Seagen subsequently abandoned the '843 Application on January 17, 2018 in favor of U.S. Patent Application No. 15/811,190, which issued on September 17, 2019 as U.S. Patent No. 10,414,826 (the "'826 Patent"). (DX-0012 at 502–03; PX-0037 at 1; DX-1209 ¶ 64).

[FF 21] DSC's expert acknowledges that Seagen's prosecution of the '039 Patent was typical until January 17, 2018. (DX-1212 at 91:13–21).

C. Seagen/DSC Collaboration and DSC's Knowledge of the '039 Patent Family

[FF 22] DSC and Seagen entered into a Collaboration Agreement on July 2, 2008 to jointly develop an ADC product. (DX-1209 ¶ 69).

[FF 23] DSC and Seagen's Collaboration Agreement provided DSC a license to all applications and patents issuing from those applications in the family of the '039 Patent. (DX-1209 ¶ 69).

[FF 24] As a prior collaborator and former licensee to the '039 Patent family, DSC was already aware by 2008 that the Seagen patent portfolio could include all inventions and their embodiments enabled and adequately disclosed in the published specification shared by all members of the '039 Patent family. (DX-1209 ¶ 95).

[FF 25] On April 8, 2022, the jury in this case returned a verdict that DSC willfully infringed the '039 Patent. (Dkt. 369 at 6).

II. CONCLUSIONS OF LAW

[CL 1] "In an action tried on the facts without a jury . . . , the court must find the facts specially and state its conclusions of law separately." Fed. R. Civ. P. 52(a)(1). "If a party has been fully heard on an issue during a nonjury trial and the court finds against the party on that issue, the court may enter judgment against the party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue." Fed. R. Civ. P. 52(c).

[CL 2] The purpose of these findings is to "afford[] . . . a clear understanding of the ground or basis of the decision of the trial court." *S. S. Silberblatt, Inc. v. U.S. for Use & Benefit of Lambert Corp.*, 353 F.2d 545, 549 (5th Cir. 1965) (internal quotation marks omitted); *see also Schlesinger v. Herzog*, 2 F.3d 135, 139 (5th Cir. 1993) (explaining that trial courts need not "recite every piece of evidence" or "sort through the testimony of . . . dozen[s] [of] witnesses").

[CL 3] In making a particular finding, the district court "does not . . . draw any inferences in favor of the non-moving party and . . . [instead] make[s] a determination in accordance with its own view of the evidence." *Fairchild v. All Am. Check Cashing, Inc.*, 815 F.3d 959, 964 n.1 (5th Cir. 2016) (internal quotation marks omitted). However, a district court still must arrive at each of its factual determinations based on the applicable burden of proof. *In re Medrano*, 956 F.2d 101, 102 (5th Cir. 1992) (reversing the district court because it applied the

preponderance of the evidence standard rather than the clear and convincing standard in making its factual determinations under Rule 52).

A. Prosecution Laches

[CL 4] Prosecution laches is an equitable affirmative defense to patent infringement. *Hyatt v. Hirshfeld*, 998 F.3d at 1347, 1359–60 (Fed. Cir. 2021); *Cancer Rsch. Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 729 (Fed. Cir. 2010). If found, prosecution laches may "render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution that constitutes an egregious misuse of the statutory patent system under a totality of the circumstances." *Hyatt*, 998 F.3d at 1360 (quoting *Cancer Rsch.*, 625 F.3d at 728).

[CL 5] The Federal Circuit has explained that "the doctrine of prosecution laches places an additional, equitable restriction on patent prosecution conduct beyond those imposed by statute or PTO regulation." *Hyatt*, 998 F.3d at 1366. "An applicant must therefore not only comply with the statutory requirements and PTO regulations but must also prosecute its applications in an equitable way that avoids unreasonable, unexplained delay that prejudices others." *Id.*

[CL 6] Prosecution laches as a defense to infringement requires proof of two elements: (a) that the patentee's delay in prosecution was unreasonable and inexcusable under the totality of the circumstances; and (b) that the accused infringer or the public suffered prejudice attributable to the delay. *Hyatt*, 998 F.3d at 1362 (citing *Cancer Rsch.*, 625 F.3d at 728–29).

[CL 7] To establish prejudice, an accused infringer must show evidence of intervening rights, in the sense that "either the accused infringer or others invested in, worked on, or used the claimed technology during the period of delay." *Cancer Rsch.*, 625 F.3d at 731.

[CL 8] This Court has previously applied the clear and convincing evidence standard when the enforceability of an issued patent is challenged for prosecution laches. *Personalized Media Commc'ns, LLC v. Apple, Inc.*, 552 F. Supp. 3d 664, 685–86 (E.D. Tex. 2021) ("*PMC*");

SynQor, Inc. v. Artesyn Techs., Inc., No. 2:07-cv-497, 2011 WL 2729214, at *8 (E.D. Tex. July 11, 2011); *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 669 F. Supp. 2d 756, 771 (E.D. Tex. 2009), *rev'd on other grounds*, 636 F.3d 1341, 1353 (Fed. Cir. 2011). This is consistent with the presumption of validity, and with the application of the clear and convincing evidence standard to other invalidity and unenforceability defenses. *See* 35 U.S.C. § 282(a) (presumption of validity), § 282(b)(1) (unenforceability is a defense to patent infringement); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1358–59 (Fed. Cir. 1984) (the burden under § 282 "is constant and never changes and is to convince the court of invalidity by clear evidence"), *abrogated on other grounds*, *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290–91 (Fed. Cir. 2011) (abrogating the "sliding scale" approach to inequitable conduct but nonetheless maintaining the clear and convincing evidence standard); *see also Radio Corp. of Am. v. Radio Eng'g Labs.*, 293 U.S. 1, 8 (1934) (Cardozo, J.) ("[O]ne otherwise an infringer who assails the validity of a patent fair upon its face bears a heavy burden of persuasion, and fails unless his evidence has more than a dubious preponderance."); *contra Hyatt*, 998 F.3d at 1370–71 (applying a preponderance of the evidence standard in a *de novo* civil action to obtain a patent under § 145). The Federal Circuit has also confirmed that the PTO may issue laches rejections during prosecution. *In re Bogese*, 303 F.3d 1362, 1367–68 (Fed. Cir. 2002). Where the PTO has not, it is presumed to have acted correctly. Consistent with these principles, and its prior practice, the Court applies the clear and convincing evidence standard to prosecution laches when raised as a complete defense to patent infringement.

[CL 9] As discussed below, the Court finds that DSC has failed to meet its burden on at least the first element: "that the patentee's delay in prosecution was unreasonable and inexcusable under the totality of the circumstances."

B. Prosecution Laches: Seagen Did Not Engage in Unreasonable Delay

[CL 10] Whether an applicant's delay is unreasonable is a fact-intensive inquiry that depends on the specific circumstances. *Hyatt*, 998 F.3d at 1366–67. Determinations of unreasonable delay are not limited to the specific patent application in question; rather, "an examination of the totality of the circumstances, including the prosecution history of all of a series of related patents and overall delay in issuing claims, may trigger laches." *Id.* at 1362; *Symbol Techs., Inc. v. Lemelson Med., Educ. & Rsch. Found., LP*, 422 F.3d 1378, 1385 (Fed. Cir. 2005) ("*Symbol II*").

[CL 11] In *Symbol II*, the Federal Circuit gave non-exclusive examples of reasonable and unreasonable delays. Examples of reasonable delays include (i) filing a divisional application in response to a restriction requirement—even immediately before issuance of the parent application; (ii) refiling an application to present new evidence of an invention's unexpected advantages; and (iii) refiling an application to add subject matter to attempt to support broader claims as the development of an invention progresses. *Symbol II*, 422 F.3d at 1385; *Hyatt*, 998 F.3d at 1361–62. The Federal Circuit noted that an applicant may refile an application for other reasons, "provided that such refiling is not unduly successive or repetitive." *Symbol II*, 422 F.3d at 1385. In contrast, the court in *Symbol II* stated, "refiling an application solely containing previously-allowed claims for the business purpose of delaying their issuance can be considered an abuse of the patent system." *Symbol II*, 422 F.3d at 1385.

[CL 12] There are no "firm guidelines" for when laches is triggered, and the determination is left to the district court's careful consideration as a matter of equity. *Symbol II*, 422 F.3d at 1385. Yet, the Federal Circuit has found instructive two prior Supreme Court cases finding "patents unenforceable based on eight- and nine-year prosecution delays." *Hyatt*, 998 F.3d at 1367 (citing *Woodbridge v. U.S.*, 263 U.S. 50, 53 (1923) (nine-and-a-half-year delay); *Webster*

Elec. Co. v. Splitdorf Elec. Co., 264 U.S. 463. 465 (1924) (eight-year delay)); *see also Bogese*, 303 F.3d at 1369 (eight-year delay); *Symbol II*, 422 F.3d at 1385 (citing *Woodbridge* and *Webster*).

[CL 13] The Federal Circuit recently addressed prosecution laches in the context of a civil action to obtain a patent under 35 U.S.C. § 145. *Hyatt*, 998 F.3d at 1355–56. The Federal Circuit held that that PTO had met its burden to establish unreasonable and unexplained delay—reversing the district court's conclusion otherwise. *Id.* at 1370–71. The Federal Circuit also held that a presumption of prejudice applied in the context of a § 145 action, and remanded the case to the district court to hear additional evidence and determine whether the patentee had rebutted the presumption. *Id.* at 1371–72.

[CL 14] This Court recently found that prosecution laches applied in a case where the patentee "sought 30 to 50 years of patent protection and it obtained exactly that." *PMC*, 552 F. Supp. 3d at 689. In *PMC*, the Court noted that the asserted "claims will expire 34 years after the application was filed, 42 years after the 1987 specification, and 48 years after the 1981 parent application." *Id.* The Court concluded that "[d]elays of this magnitude did not occur by accident and do not occur when an applicant reasonably pursues prosecution." *Id.*

[CL 15] In this case, Seagen's prosecution of the '039 Patent claims—including its decision of when and how to prosecute disclosed inventions and their embodiments—does not amount to an "unreasonable and unexplained delay in prosecution that constitutes an egregious misuse of the statutory patent system under the totality of the circumstances" so as to warrant a finding of prosecution laches. *See Cancer Rsch.*, 625 F.3d at 728–29.

[CL 16] Seagen's prosecution of the '039 Patent family is distinctly different from the aforementioned cases where prosecution laches was found. Unlike the patentees in *Hyatt* and *PMC*, for example, Seagen did not bulk-file hundreds of patent applications with hundreds of

thousands of claims to "unduly increase[] the administrative burden on the PTO" in an effort to artificially inflate the life of its patents. *Hyatt*, 998 F.3d at 1370; *PMC*, 552 F. Supp. 3d at 687. The '039 Patent is not a submarine patent that has "been in the patent office for an extended period of time—intentionally or otherwise." *PMC*, 552 F. Supp. 3d at 671 (internal quotations omitted); [FF 11]–[FF 15], [FF 18]–[FF 20]. To the contrary, as DSC itself recognized, Seagen sought, and was granted, expedited prosecution for the '039 Patent, which resulted in issuance just over a year after Seagen filed its application. [FF 10].

[CL 17] The prosecution history of the '039 Patent family further indicates that Seagen has diligently prosecuted each of the patent applications that arose from the disclosure set forth in the voluminous '039 Patent family specification from the time Seagen first filed its initial application in 2004. [FF 9]–[FF 15], [FF 17]–[FF 21]. DSC does not point to any "unexplained gap" in the prosecution history of the '039 Patent family because Seagen continuously filed patent applications between 2004 to the present day—i.e., Seagen was not "sitting on its hands." *Id.*; *SynQor*, 2011 WL 2729214, at *6. DSC's work on Enhertu® reasonably related to its FDA approval process, including its clinical trials, could not infringe any Seagen U.S. patent under the safe harbor in the patent statute, whether Seagen had an earlier patent claim that could have reached Enhertu® or not. 35 U.S.C. § 271(e); [FF 13]–[FF 14].

[CL 18] DSC's position that a reasonable patent applicant would view the invention of the '039 Patent as limited to auristatin/dolastatin drug payloads runs contrary to the Court's Claim Construction Order and the jury's verdict. The Court rejected DSC's position that the claims of the '039 Patent should be limited to auristatin/dolastatin drug payloads. (Dkt. No. 155 at 9–15). Further, the jury did not accept DSC's position that the '039 Patent family specification lacks support for non-auristatin/dolastatin drug payloads. This is established by the jury's finding that

DSC failed to present clear and convincing evidence that the '039 Patent was invalid on that basis. [FF 4]. A decision in DSC's favor on prosecution laches would be in tension with the implicit and explicit findings of the jury. *HTC Corp. v. Telefonaktiebolaget LM Ericsson*, 407 F. Supp. 3d 631, 635–36 (E.D. Tex. 2019) (citing *Sanders v. City of Newport*, 657 F.3d 772, 783 (9th Cir. 2011) ("[W]here legal claims tried by the jury and equitable claims tried by the court are 'based on the same set of facts, the Seventh Amendment requires the trial judge to follow the jury's implicit and explicit factual determinations.'") (citation omitted)).

[CL 19] DSC's argument that Seagen's prosecution of the '039 Patent claims unreasonably followed DSC's disclosure of its infringing product is similarly unavailing. The Federal Circuit and courts in this District have found that "[t]here is nothing unusual or improper about drafting claims to cover a competitor's product, as long as there is a basis in the pending application," even if that claim has never appeared before in the family. *SynQor*, 2011 WL 2729214, at 7; *see also PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235, 1247 (Fed. Cir. 2002) ("[I]t is legitimate to amend claims or add claims to a patent application purposefully to encompass devices or processes of others.") Similarly, here, there was nothing atypical or unreasonable in Seagen filing claims directed towards Enhertu®. [CL 17].

[CL 20] DSC relies heavily on an alleged 15-year gap between the filing of the priority application and the issuance of the '039 Patent claims. (*E.g.*, Dkt. No. 408 at 1–3, 6–8; Dkt. No. 422 at 7:10, 8:18–19, 9:14–15, 9:24, 13:12, 14:1–2, 14:18–19, 15:6–9, 15:11–12, 16:12–18, 16:25–17:1, 17:7; Dkt. No. 427 at 4, 7, 10, 12–13, 18, 25–26, 28–29, 31–35, 37–38). However, prosecution laches is not simply a time-counting exercise. *See* [CL 10]–[CL 14]. The Court is tasked with conducting an analysis of Seagen's prosecution conduct by evaluating the totality of the circumstances. *Hyatt*, 998 F.3d at 1360. In performing that analysis, the Court declines to find

that Seagen's "delay in prosecution was unreasonable and inexcusable under the totality of the circumstances." Importantly, Seagen has done nothing to extend its patent term. [FF 9]. Use of the patent prosecution process to extend the patent term is an important commonality amongst cases finding prosecution laches. [CL 13]–[CL 14]. At the bench trial, DSC was unable to direct the Court to any case where a court has found prosecution laches when the patentee took no action to extend the term of the patent at issue. Dkt. No. 422 at 53:21–54:6. Seagen has done nothing to hide its disclosure or prosecution. [FF 15], [FF 17]–[FF 19]. Seagen even sought to expedite—not delay—the prosecution of the patent at issue. [FF 10]. Further, DSC's own expert acknowledged that Seagen's prosecution conduct was typical until 2018. [FF 21]. DSC's explanation of this testimony as "typical of prosecution if they only were going to claim the auristatin/dolastatin-type drugs that are the subject of their patent" (Dkt. No. 422 at 17:2–5) is inconsistent with this Court's prior holdings and the jury's findings. As repeatedly stated, DSC's "claims lack support" argument has been considered by both the Court and the jury and DSC did not prevail on both occasions. [FF 4].

[CL 21] The Court finds that DSC has failed to establish, by clear and convincing evidence, "that the patentee's delay in prosecution was unreasonable and inexcusable under the totality of the circumstances." Accordingly, the first element of prosecution laches is not met, so the Court need not address the second element.

C. § 112(b)[3]

[CL 22] DSC relies on the Federal Circuit's decision in *Allen Eng'g Corp. v. Bartell Indus., Inc.* to argue that §112(b) contains two requirements: "first, [the claim] must set forth what

[3] Seagen disputes whether this defense is still available after the Supreme Court's decision in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014). (Dkt. No. 426 at 14). Seagen also contends that if this defense does exist, it should have been raised at claim construction, not post-trial. (*Id.*). While the Court believes these to be reasonable positions, it does not substantively address these arguments by Seagen because it rejects DSC's § 112(b) defense on the merits.

'the applicant regards as his invention,' and second, it must do so with sufficient particularity and distinctness, i.e., the claim must be sufficiently 'definite.'" 299 F.3d 1336, 1348 (Fed. Cir. 2002). DSC raised the second requirement at claim construction (Dkt. No. 130 at 5) but raises the first requirement only now—post-trial. [FF 7]; Dkt. No. 408 at 9.

[CL 23] In *Allen*, the Federal Circuit found that a claim did not satisfy the first requirement of § 112(b). The appeal came to the Federal Circuit after a bench trial on the issue of infringement, *inter alia*. *Id.* at 1343. The district court never held a *Markman* hearing, nor did it construe the claims of the asserted patent. *Id.* Said differently, *Allen* was not a case such as this where the district court is asked to decide the first requirement of § 112(b) after a jury found the defendant failed to carry its burden with respect to written description and enablement. *Id.*

[CL 24] On appeal of the § 112(b) issue in *Allen*, the patentee argued that "one of skill in the art would understand that the term 'perpendicular' in the claim should be read to mean 'parallel.'" *Id.* at 1349. The Federal Circuit held that the patentee attempted to "stretch[] the law too far." *Id.* The Federal Circuit concluded that the claim was invalid because "perpendicular" and "parallel" were contradictory. *Id.* In doing so, the Federal Circuit noted that "[i]t is not our function to rewrite claims to preserve their validity." *Id.*

[CL 25] The Court finds that *Allen* is distinguishable from the present case. This is not a scenario where the claimed invention is clearly contrary to the specification such as "parallel" verses "perpendicular." Instead, DSC argues that the "claims are contradictory to the specification" because "the '039 patent claims (encompassing any drug moieties) reach much broader than the specification (limited to drug moieties with monomethylvaline compounds)." Dkt. No. 408 at 10. At its core, DSC's § 112(b) defense requires the Court to conclude that the

specification is limited to dolastatin/auristatin compounds. The Court, once again, declines to do so.

[CL 26] The Court has repeatedly noted the jury's finding that DSC and AstraZeneca failed to meet their burden on other § 112 issues—namely, written description and enablement. [FF 4]; [CL 20]; *see also* Dkt. No. 422 at 20:20–21:14. The Court finds that DSC's § 112(b) defense is an attempt to take at least a third bite at the same apple: whether claims directed to ADC with a glycine phenylalanine tetrapeptide linker are within the '039 Patent specification. The Court rejected DSC's attempts to narrow the patent at *Markman* (as it did above regarding prosecution laches) and the jury likewise was unpersuaded at trial. [FF 4]; [CL 18]; [CL 20]. Though undeterred, DSC has not offered any additional evidence during the equitable phase of this case that warrants a deviation from the Court's claim construction order and the jury's verdict.[4] The Court will not deviate from the implicit and explicit findings of the jury on this issue. *See HTC Corp.*, 407 F. Supp. 3d at 635–36.

[CL 27] Accordingly, DSC has not established by clear and convincing evidence that the patent is invalid under 35 U.S.C. § 112(b).

III. CONCLUSION

For the reasons stated herein, the Court finds that DSC has failed to meet its burden of clear and convincing evidence to show that the '039 Patent should be unenforceable under the equitable theory of prosecution laches. Further, the Court finds that DSC has failed to meet its burden of clear and convincing evidence to show that the '039 Patent is invalid under the first requirement of § 112(b). Judgment will be entered accordingly.

[4] DSC places outsized emphasis on inventor testimony presented at trial. (Dkt. No. 408 at 9–10). The Court has considered this same testimony, which was before the jury when it decided the issues of written description and enablement.

So ORDERED and SIGNED this 15th day of July, 2022.

RODNEY GILSTRAP
UNITED STATES DISTRICT JUDGE