

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

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HARBOUR ANTIBODIES BV, HARBOUR )  
ANTIBODIES HCAB BV, ERASMUS )  
UNIVERSITY MEDICAL CENTER )  
ROTTERDAM and DR. ROGER )  
KINGDON CRAIG, ) C.A. No. 21-1807 (MN)  
)  
Plaintiffs, )  
)  
v. )  
)  
TENEOBIO, INC. and AMGEN INC., )  
)  
Defendants. )

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TENEOBIO, INC. and AMGEN INC., )  
)  
Counterclaim- Plaintiffs, )  
)  
v. )  
)  
)  
HARBOUR ANTIBODIES BV, HARBOUR )  
ANTIBODIES HCAB BV, ERASMUS )  
UNIVERSITY MEDICAL CENTER )  
ROTTERDAM, DR. ROGER KINGDON )  
CRAIG, and HBM HOLDINGS LTD. )  
)  
Counterclaim-Defendants. )

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**MEMORANDUM ORDER**

At Wilmington, this 3rd day of June 2026:

The Court heard argument about the disputed claim terms of U.S. Patent Nos. 9,346,877 (the “877 Patent”); 9,353,179 (the “179 Patent”); 10,906,970 (the “970 Patent”); and 10,993,420 (the “420 Patent”) (collectively, “the Asserted Patents”) on September 24, 2025. (D.I. 385). IT IS HEREBY ORDERED that the claim terms of the Asserted Patents with agreed-upon constructions are construed as follows (*see* D.I. 366 at 4–5):

1. Preambles. The parties agree the preamble of each independent claim of each asserted patent is limiting.
2. “heterologous”<sup>[1]</sup> means “a nucleotide sequence or locus which is not endogenous to the mammal in which it is located” (all claims of the ’877, ’179, and ’970 Patents).
3. “V<sub>H</sub> heavy chain locus” means “a minimal micro-locus encoding a V<sub>H</sub> domain comprising one or more V gene segments, one or more D gene segments and one or more J gene segments, operationally linked to one or more heavy chain effector regions (each devoid of a CH1 domain).” (all claims of the ’877, ’179, and ’970 patents).
4. “V<sub>H</sub> heavy chain locus” means “an engineered locus encoding a V<sub>H</sub> domain comprising one or more V<sub>H</sub> genes . . . , one or more D segments and one or more J segments, operationally linked to one or more heavy chain effector regions (each devoid of a CH1 domain).” (all claims of the ’420 Patent).

Further, as announced at the September 24, 2025 hearing, IT IS HEREBY ORDERED that the disputed claim terms of the Asserted Patents are construed as follows:

1. “V<sub>H</sub> binding domain” (’877, ’179, and ’970 Patents, all asserted claims) means “a binding portion of an expression product of a V gene segment when recombined with a D gene segment and a J gene segment”;
2. “Antigen-specific heavy chain only antibody”/“said soluble, antigen-specific heavy chain only antibody” (’179 and ’970 Patents, all asserted claims) means “heavy chain-only antibody specific to an antigen”;
3. “Rodent” (’877, ’179, ’970 Patents, all asserted claims) will be given its plain and ordinary meaning;
4. “Heterologous” (’420 Patent, claims 1, 2, 3, and 13) means “a nucleotide sequence or locus which is not endogenous to the mammal in which it is located”;
5. “Isolating V<sub>H</sub> heavy chain only antibody” (’420 Patent, claims 1, 2, 3, and 13) will be given its plain and ordinary meaning; and

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<sup>1</sup> The parties dispute this term as it appears in the ’420 Patent.

6. “Functional  $C_{H1}$  domain”/“Does Not Encode a Functional  $C_{H1}$  domain” (’877, ’179, and ’970 Patents, all asserted claims) is not indefinite.<sup>2</sup>

Further, as announced at the hearing on September 24, 2025, the Court continued the *Markman* hearing for two terms. Those terms are: “soluble”<sup>3</sup> and “[a] functional  $C_{H1}$  domain with an antigen.”<sup>4</sup> The continued *Markman* hearing took place on November 10, 2025 in Courtroom 4A, and both sides’ experts testified. (D.I. 411). The Court is now prepared to rule on those terms, and, THEREFORE, IT IS HEREBY ORDERED THAT:

1. “Soluble” (’877, ’179, and ’970 Patents, all asserted claims) means “remains in solution and active in physiological media through B-cell maturation to secretion, without requiring a light chain to maintain solubility”;
2. “a functional  $C_{H1}$  domain with an antigen,” (’877 and ’179 Patents, all asserted claims) is indefinite.

The parties briefed the issues (D.I. 366) and submitted exhibits containing intrinsic and extrinsic evidence (D.I. 366). Both sides provided a tutorial describing the relevant technology. (D.I. 362, 365). After the November continued *Markman*, the parties submitted additional briefing. (D.I. 405, 406). The Court carefully reviewed all submissions in connection with the parties’ contentions regarding the disputed claim terms, heard oral argument (D.I. 385; D.I. 411) and applied the legal standards below in reaching its decision.

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<sup>2</sup> The dispute over this term was whether the phrase was indefinite. The Court found that indefiniteness had not been proven at this stage but permitted the parties to re-raise this issue in connection with summary judgment briefing. (D.I. 385 at 90:16–91:1).

<sup>3</sup> ’877, ’179, and ’970 Patents, all asserted claims.

<sup>4</sup> ’877 and ’179 Patents, all asserted claims.

## I. LEGAL STANDARDS

### A. Claim Construction

“[T]he ultimate question of the proper construction of the patent [is] a question of law,” although subsidiary fact-finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325 (2015). “[T]he words of a claim are generally given their ordinary and customary meaning [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (internal citations and quotation marks omitted). Although “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” the context of the surrounding words of the claim must also be considered. *Id.* at 1314. “[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted).

The patent specification “is always highly relevant to the claim construction analysis . . . [as] it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also possible that “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316. “Even when the specification describes only a single embodiment, [however,] the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

In addition to the specification, a court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996). The prosecution history, which is “intrinsic evidence, . . . consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

In some cases, courts “will need to look beyond the patent’s intrinsic evidence and [] consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period.” *Teva*, 574 U.S. at 331. Extrinsic evidence “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. Expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Phillips*, 415 F.3d at 1318. Nonetheless, courts must not lose sight of the fact that “expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.* Overall, although extrinsic evidence “may be useful to the court,” it is “less reliable” than intrinsic evidence, and its consideration “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope

of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

## **B. Indefiniteness**

“The primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, e.g., competitors of the patent owner, can determine whether or not they infringe.” *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28-29 (1997)). Put another way, “[a] patent holder should know what he owns, and the public should know what he does not.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002).

A patent claim is indefinite if, “viewed in light of the specification and prosecution history, [it fails to] inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). A claim may be indefinite if the patent does not convey with reasonable certainty how to measure a claimed feature. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). But “[i]f such an understanding of how to measure the claimed [feature] was within the scope of knowledge possessed by one of ordinary skill in the art, there is no requirement for the specification to identify a particular measurement technique.” *Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312, 1319 (Fed. Cir. 2015).

Like claim construction, definiteness is a question of law, but the Court must sometimes render factual findings based on extrinsic evidence to resolve the ultimate issue of definiteness. *See, e.g., Sonix Tech. Co. v. Publications Int’l, Ltd.*, 844 F.3d 1370, 1376 (Fed. Cir. 2017); *see also Teva*, 574 U.S. at 334-36. “Any fact critical to a holding on indefiniteness . . . must be proven by

the challenger by clear and convincing evidence.” *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003); *see also Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008).

## II. THE COURT’S RULING

### A. The Court’s Ruling at the September 24, 2025 *Markman* Hearing

The Court’s ruling regarding the disputed claim terms of the Asserted Patents was announced during the *Markman* hearing on September 24, 2025 as follows:

Okay. At issue, there are eight disputed claim terms in four patents.<sup>[5]</sup> Five of the disputes as briefed initially were about the meaning of a claim term and three argued indefiniteness. I am prepared to rule on all but two of the disputes.

I will not be issuing a written opinion, but I will issue an order stating my rulings. I want to emphasize before I announce my decisions that although I am not issuing a written opinion, we have followed a full and thorough process before making the decisions I am about to state. I have reviewed the patents, and all the evidence submitted by the parties, including the evidence that was just submitted yesterday by Defendants.<sup>[6]</sup> There was joint briefing on each of the disputed terms<sup>[7]</sup> and we had argument today.<sup>[8]</sup> All of that has been carefully considered.

As to my rulings, I am not going to read into the record my understanding of claim construction law and indefiniteness. I have a legal standard section that I have included in earlier opinions, including somewhat recently in *REX Computing v. Cerebras Systems, Inc.*, Civil Action No. 21-525(MN). I incorporate that law and adopt it into my ruling today and will also set it out in the order that I issue.

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<sup>5</sup> U.S. Patent Nos. 9,346,877 (the “877 Patent”); 9,353,179 (the “179 Patent”); 10,906,970 (the “970 Patent”); and 10,993,420 (the “420 Patent”).

<sup>6</sup> (D.I. 384).

<sup>7</sup> (D.I. 345, 363, 366, 367, 368). The parties also submitted technology tutorials. (D.I. 362, 365, 377).

<sup>8</sup> (D.I. 385).

The parties argued the terms today in a different order from how they were briefed, but I will address the terms in the order in which the parties briefed them because that is how I made my notes.

The first dispute involves the term “V<sub>H</sub> binding domain.”<sup>[9]</sup> Plaintiffs maintain that this term does not need construction or, in the alternative, it refers to “a binding portion of an expression product of a V gene segment when recombined with a D gene segment and a J gene segment.”<sup>[10]</sup> Defendants initially construed “V<sub>H</sub> binding domain” as “an expression product of a V gene segment combined with a D and J gene segment, which is able to bind antigen as a monomer.”<sup>[11]</sup> To moot one of Plaintiff’s arguments, Defendants altered their proposed construction to be “an expression product of a V gene segment when recombined with a D gene segment and a J gene segment, which is able to bind antigen as a monomer.”<sup>[12]</sup>

With that, the main dispute here centers on whether the entirety of the V<sub>H</sub> domain must bind or just a portion of it.

Defendants contend that the specification states that “[t]he V<sub>H</sub> domain is able to bind antigen as monomer”<sup>[13]</sup> and that when read in context, the specification teaches that “a V<sub>H</sub> domain is an antibody fragment [] and a ‘V<sub>H</sub> binding domain’ is a V<sub>H</sub> domain that can bind antigen as a monomer.”<sup>[14]</sup> In essence, Defendants argue that a V<sub>H</sub> domain and a V<sub>H</sub> binding domain are synonymous.

Plaintiffs contend that Defendants’ proposal is wrong for at least two reasons. First, Defendants’ proposed construction relies on specification language pertaining to “V<sub>H</sub> domain,” not “V<sub>H</sub> binding domain,” which it contends is improper because the specification uses those two terms differently.<sup>[15]</sup> And second, Defendants are

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<sup>9</sup> ('877, '179, '970 Patents, all asserted claims).

<sup>10</sup> (D.I. 366 at 5).

<sup>11</sup> (*Id.*).

<sup>12</sup> (*Id.* at 9).

<sup>13</sup> '877 Patent at 11:25.

<sup>14</sup> (D.I. 366 at 8–9).

<sup>15</sup> (*Id.* at 6).

trying to import a functional limitation into the meaning of the term.<sup>[16]</sup>

On this term I agree with Plaintiffs. Even though the patent<sup>[17]</sup> does not expressly define the term “V<sub>H</sub> binding domain,” it does provide sufficient disclosure for a person skilled in the art to understand the term. For example, in addition to discussing what “V<sub>H</sub> domain” is at ’877 patent, column 11, lines 14 to 16, the specification also discusses what a “binding domain” is in a later portion.<sup>[18]</sup> Moreover, I find the additional language Defendants rely on discusses “V<sub>H</sub> domain,” not “V<sub>H</sub> binding domain.”<sup>[19]</sup> The specification uses the two terms differently, so the language about binding antigen as monomer speaks to what a “V<sub>H</sub> domain” can do.<sup>[20]</sup> I also agree with Plaintiffs that Defendants’ construction would introduce a functional limitation, which the Federal Circuit has cautioned against.<sup>[21]</sup>

Given all of this, I agree with Plaintiffs that the specification provides sufficient disclosure for “V<sub>H</sub> binding domain” and I will construe it to mean “a binding portion of an expression product of a V gene segment when recombined with a D gene segment and a J gene segment.”

The second term is “antigen-specific heavy chain only antibody”/“said soluble antigen-specific heavy chain-only

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<sup>16</sup> (*Id.* at 7).

<sup>17</sup> Consistent with the parties’ briefing, the Court cites to the ’877 Patent’s specification. (D.I. 366 at 4 n.1).

<sup>18</sup> ’877 Patent 11:14–17 (“A ‘V<sub>H</sub> domain’ in the context of the present invention refers to an expression product of a V gene segment when recombined with a D gene segment and a J gene segment as defined above.”); *id.* at 17:50–52 (“The term ‘binding domain’ as used herein in respect of all the above aspects of the present invention includes any polypeptide domain that is active in a physiological medium.”).

<sup>19</sup> *Id.* at 11:25 (“The V<sub>H</sub> domain is able to bind antigen as a monomer[.]”).

<sup>20</sup> *Id.* at 7:6–8 (“V<sub>H</sub> binding domains may then be produced by identifying and isolating an antigen-specific V<sub>H</sub> domain from the cloned mRNA of step (c).”).

<sup>21</sup> *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367 (Fed. Cir. 2001) (“Where the function is not recited in the claim itself by the patentee, we do not import such a limitation.”).

antibody.”<sup>[22]</sup> Plaintiffs propose that this term does not need to be construed or that in the alternative it should be construed as “heavy chain-only antibody specific to an antigen.”<sup>[23]</sup> Defendants propose this term be construed as “the soluble antibody encoded by the V<sub>H</sub> heavy chain locus, including the variable region and a heavy chain constant (effector) region, and not a derivative thereof.”<sup>[24]</sup>

Plaintiffs argue this term does not need construction because the language is facially clear in that antecedent basis in the claim is obvious given the claim language that says, “a soluble, heavy chain-only antibody.”<sup>[25]</sup> Plaintiffs also argue that Defendants’ construction adds a lot of additional verbiage that limits the term in a way that is inconsistent with the dependent claims, particularly with respect to the “cloning” language.<sup>[26]</sup> Defendants contend their proposal follows logically from the claim language and that there is a clear disclaimer in the prosecution history.<sup>[27]</sup> In particular, Defendants point to prosecution history where the applicant traversed an objection to a claim including the phrase “or a derivative thereof” at the end, by amending the claim language.<sup>[28]</sup>

On balance, I’m not convinced Defendants’ proposal is the correct one. The plain language of the term is clear on its face to a person of skill in the art, and the prosecution history does not clearly and unequivocally disclaim the claim scope Defendants assert.<sup>[29]</sup> Moreover, Defendants’ construction appears to add in additional limitations that are not required by the claims or specification. And I do agree that Defendants’ proposal is inconsistent with the

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<sup>22</sup> ’179, ’970 Patents, all asserted claims.

<sup>23</sup> (D.I. 366 at 15).

<sup>24</sup> (*Id.*).

<sup>25</sup> (*Id.* at 16, 23).

<sup>26</sup> (*Id.* at 17–18).

<sup>27</sup> (*Id.* at 19).

<sup>28</sup> (D.I. 377, Ex. 17 (Appx-0671) (’524 Patent File History: 5/7/12 Office Action) at Appx-0674).

<sup>29</sup> *Id.*; see *Cordis Corp. v. Medtronic AVE, Inc.*, 511 F.3d 1157, 1177 (Fed. Cir. 2008) (“Such argument-based disavowals will be found, however, only if they constitute clear and unmistakable surrenders of subject matter.”).

dependent claims.<sup>[30]</sup> So, I will construe this term as “heavy chain-only antibody specific to an antigen.”

The third term is “Rodent.”<sup>[31]</sup> It was not clear to me that the dispute on this was really one of claim scope that I had to decide. But in any event, during argument, Defendants withdrew their proposal that rodent included rabbit.<sup>[32]</sup> So, I will not construe this term and will give it its plain and ordinary meaning to a person of skill in the art.

The fourth term is “heterologous.”<sup>[33]</sup> Plaintiffs’ proposed construction is “a nucleotide sequence or locus which is not endogenous to the mammal in which it is located”<sup>[34]</sup> and Defendants’ proposed construction is “a nucleotide sequence or locus which is not endogenous to the mammal in which it is located, and which excludes any endogenous constant region sequences.”<sup>[35]</sup> As an initial matter, I note that the parties have agreed to a definition of the term “heterologous” for the ‘877, ‘179, and ‘970 patents.<sup>[36]</sup> So, this dispute is only relevant to the ‘420 patent, and the real dispute here turns on whether the patentee disclaimed any scope of this term during prosecution of the ‘420 patent. Defendants point to the prosecution history where, in trying to overcome the Examiner’s § 102 rejection, the applicant stated that “heterologous locus is defined in the specification . . . to exclude endogenous nucleotide sequences.”<sup>[37]</sup> According to Defendants that amounts to an affirmative disclaimer.<sup>[38]</sup> Plaintiffs point out that the Examiner

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<sup>30</sup> *Wright Med. Tech., Inc. v. Osteonics Corp.*, 122 F.3d 1440, 1445 (Fed. Cir. 1997) (“[W]e must not interpret an independent claim in a way that is inconsistent with a claim which depends from it[.]”).

<sup>31</sup> ‘877, ‘179, ‘970 Patents, all asserted claims.

<sup>32</sup> (D.I. 385 at 62:25–63:25).

<sup>33</sup> ‘420 Patent, claims 1, 2, 3, and 13.

<sup>34</sup> (D.I. 366 at 32).

<sup>35</sup> (*Id.*).

<sup>36</sup> (*Id.* at 4).

<sup>37</sup> (D.I. 367, Ex. 5 (Appx-0423) (‘420 Patent File History: 2/1/17 Request for Reconsideration) at Appx-0427).

<sup>38</sup> (D.I. 366 at 35).

rejected the arguments Defendants rely on,<sup>[39]</sup> and that as of the August 2017 office action the applicant abandoned the argument, instead opting to overcome the Examiner’s rejection through amendment.<sup>[40]</sup>

Defendants’ principal response is that the Applicant did not abandon the argument in the August 2017 office action.<sup>[41]</sup> As support, Defendants point to office actions from November 2, 2018<sup>[42]</sup> and January 21, 2020.<sup>[43]</sup> The 2018 statement says “contrary to the Examiner’s assertion, insertion of a heterologous sequence into the endogenous locus does not make the entire locus heterologous.”<sup>[44]</sup> The 2020 statement says “Applicant has contended, and continues to contend, rather, that a modified endogenous gene is expressed in MacDonald.”<sup>[45]</sup>

On this record, I don’t agree that the prosecution history shows a clear and unequivocal disclaimer of claim scope.<sup>[46]</sup> Had Applicant

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<sup>39</sup> (D.I. 367, Ex. 6 (Appx-0431) (’420 Patent File History: 4/13/2017 Final Rejection) at Appx-0440 (“Contrary to Applicant’s assertion, this statement does not state or imply that heterologous locus excludes endogenous nucleotide sequences because [sic] rather defines the locus as a whole is not endogenous to the mammal, not just any particular sequences within it.”); (*Id.*, Ex. 8 (Appx-0457) (’420 Patent File History: 8/17/2017 Advisory Action at Appx-0459 (“Applicant’s argument has been fully considered and is not found persuasive because a transgene encoding a chimeric human/mouse sequences is still considered a ‘transgene’ and ‘heterologous’ for reasons already stated in the last office action.”))).

<sup>40</sup> (*See Id.*, Ex. 9 (Appx-0460) (’420 Patent File History: 8/14/2017 Request for Reconsideration) at Appx-0463–64).

<sup>41</sup> (D.I. 366 at 35–36).

<sup>42</sup> (D.I. 367, Ex. 22 (Appx-0761) (’420 Patent File History: 11/2/18 Request for Reconsideration) at Appx-0763).

<sup>43</sup> (*Id.*, Ex. 23 (Appx-0766) (’420 Patent File History: 1/21/20 Request for Reconsideration) at Appx-0771); *see also id.* Ex. 24 (Appx-0780) (’420 Patent File History: 3/31/20 Request for Reconsideration) at Appx-0785).

<sup>44</sup> (*Id.*, Ex. 22 (Appx-0761) (’420 Patent File History: 11/2/18 Request for Reconsideration) at Appx-0763).

<sup>45</sup> (*Id.*, Ex. 23 (Appx-0766) (’420 Patent File History: 1/21/20 Request for Reconsideration) at Appx-0771).

<sup>46</sup> *See Cordis Corp.*, 511 F.3d at 1177.

not abandoned the argument Defendants rely on, Defendants would have a stronger case; however, I agree with Plaintiffs that the Applicant abandoned the argument Defendants rely on. And far from disavowing claim scope, Applicant's abandonment of the argument Defendants now rely on shows that Applicant acquiesced to the Examiner's reading of the term "heterologous," which is consistent with how the applicant defined "heterologous" in the specification.<sup>[47]</sup>

The subsequent prosecution history statements Defendants point to do not clearly and unequivocally state that "heterologous" "excludes any endogenous constant region sequences" as required by binding case law.<sup>[48]</sup>

Moreover, there is also a practical implication here, which is that the parties agreed to the construction of heterologous that Plaintiffs are proposing for the three other Asserted Patents.<sup>[49]</sup> And that makes sense because Plaintiffs' proposed construction comes directly from the specification.<sup>[50]</sup>

Given this, I will construe "heterologous" to mean "a nucleotide sequence or locus which is not endogenous to the mammal in which it is located."

The fifth term is "Isolating V<sub>H</sub> heavy chain-only antibody."<sup>[51]</sup> For this term, as we discussed during the argument, I am not convinced that the issue is one of claim scope that I have to decide on claim construction rather than an issue of fact for infringement. After that discussion, the parties ultimately agreed that I can give this term its plain and ordinary meaning and then decide, if I must, at a later date

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<sup>47</sup> '420 Patent at 10:3–6; *see also Malvern Panalytical Inc. v. TA Instruments-Waters LLC*, 85 F.4th 1365, 1376 (Fed. Cir. 2023) ("A reasonable interpretation of this colloquy with the examiner is that by abandoning its argument [] the [] applicant acquiesced to the examiner's views regarding the scope of the [] application.").

<sup>48</sup> *See Cordis Corp.*, 511 F.3d at 1177.

<sup>49</sup> (D.I. 366 at 4).

<sup>50</sup> '420 Patent at 10:3–6.

<sup>51</sup> *Id.*, claims 1, 2, 3, and 13.

on a more fulsome record whether this actually is an O2 Micro issue or an issue of fact for infringement.<sup>[52]</sup>

The sixth term is “functional C<sub>H</sub>1 domain”/“Does not encode a functional C<sub>H</sub>1 domain.”<sup>[53]</sup> Based on the briefing, it appears Defendants initially proposed the term “Functional C<sub>H</sub>1 domain” and then shifted the term to “does not encode a functional C<sub>H</sub>1 domain” at some later point. Plaintiffs propose this term is not indefinite. Defendants contend this term is indefinite.

Defendants have the burden of proving indefiniteness by clear and convincing evidence.<sup>[54]</sup> Here, Defendants have not met that burden. As Plaintiffs pointed out, the prosecution history provides guidance as to what a C<sub>H</sub>1 domain is - namely, it is one that contains the light chain domain anchorage site.<sup>[55]</sup> Moreover, Plaintiffs have identified portions of the specification that discuss expressing heavy chain constant genes without a functional C<sub>H</sub>1 domain “so that generation of heavy chain-only antibody can occur.”<sup>[56]</sup>

I note that both sides have put forth expert testimony on either side of this issue.<sup>[57]</sup> So, given that Plaintiffs have pointed to the specification for at least some support for this term and the parties have expert testimony on both sides, ultimately there is insufficient evidence on the record before me to indicate that this term is indefinite. However, I will note, that if Defendants believe at some later point that there are no material facts in dispute and that this term is still indefinite, they may raise that argument at the appropriate time - likely in connection with summary judgment briefing.

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<sup>52</sup> (D.I. 385 at 29:8–30:24).

<sup>53</sup> ’877, ’179, and ’970 Patents, all asserted claims.

<sup>54</sup> *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017); *Intel Corp.*, 319 F.3d at 1366.

<sup>55</sup> (D.I. 366, Ex. 11 (Appx-0476) at 15:30–16:2 (“It is the lack of a CH1 domain (which in conventional antibodies possesses the anchorage site for the constant domain of the light chain) which accounts for the inability of the heavy-chain-only antibodies of the present invention to associate with light chains to form conventional antibodies.”)); *see also* (*id.* at 3:11–16).

<sup>56</sup> ’877 Patent at 12:8–12.

<sup>57</sup> (D.I. 366, Ex. 14 (Appx-0536) (Decl. of Hidde L. Ploegh, Ph.D.) ¶¶ 53–68, Ex. 32 (Appx-0851) (Reply Decl. of Marjorie A. Oettinger, Ph.D.) ¶¶ 63–76).

The seventh term is “a functional C<sub>H1</sub> domain with an antigen.”<sup>[58]</sup> Plaintiffs ask me to judicially correct this term to remove the words “with an antigen,” or, in the alternative, construe the term with its plain and ordinary meaning. Defendants contend this term is indefinite and that the Court should not judicially correct the term. Plaintiffs have conceded this term is “nonsensical” as it appears in the claims, so it does not have any “plain and ordinary meaning.” With that, I am left with two options: judicially correct the term or hold it indefinite.

For this term, I am struggling with a few issues, but one in particular is the reasonableness of Defendants’ expert’s alternative proposal from the point of view of a person of skill in the art. So on this term I am going to hear from the experts before I decide it.

The eighth and final term is “soluble.”<sup>[59]</sup> Plaintiffs contend this term is not indefinite and Defendants contend it is indefinite.<sup>[60]</sup>

Again, as I said before, Defendants need to show indefiniteness by clear and convincing evidence.<sup>[61]</sup> I don’t feel comfortable finding that that standard has been met on the current record, but I do have concerns about this term. I am having a hard time distinguishing between attorney argument and the opinions of a person of skill in the art about whether this term is definite. So as with the prior term, what I would like to do here is bring in both sides’ experts to hear from them. I think what we should do is set up a time when the experts can come in and testify about those last two terms so that I can make a determination on that.

So with that, those are the rulings that I am prepared to make today.

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<sup>58</sup> ’877 and ’179 Patents, all asserted claims.

<sup>59</sup> ’877, ’179, and ’970 Patents, all asserted claims.

<sup>60</sup> (D.I. 366 at 67).

<sup>61</sup> *BASF Corp.*, 875 F.3d at 1365; *Intel Corp.*, 319 F.3d at 1366.

**B. The Court’s Ruling on the Terms “Soluble” and “With an Antigen”**

**1. Soluble<sup>62</sup>**

The parties also dispute the term “soluble.” Plaintiffs say this term is not indefinite, and Defendants say this term is indefinite. (D.I. 366 at 67). Defendants argue that “soluble” as it is used in the patents is a spectrum determined after secretion and a person of skill in the art would not know what conditions are required to determine that. Plaintiffs disagree that it is a spectrum and assert that “soluble” means it remains in solution and active in physiological media through B-cell maturation to secretion, without requiring a light chain to maintain solubility. The Court agrees with Plaintiffs here.

Starting with the claim language, the claims claim “[a] method for the production a of soluble, antigen-specific heavy chain only V<sub>H</sub> binding domain[/antibodies]” comprising multiple steps. ’877 Pat. cl. 1; ’179 Pat. cl. 1; ’970 Pat. cl. 1. The first step requires “immunising a transgenic rodent” and creating a “V<sub>H</sub> heavy chain locus” that can form “a soluble, heavy chain-only antibody comprising a soluble, antigen-specific V<sub>H</sub> binding domain and a constant effector region devoid of a functional C<sub>H</sub>1 domain with an antigen.” ’877 Pat. cl. 1; ’179 Pat. cl. 1; ’970 Pat. cl. 1 (similar). That step occurs within the rodent, which lends support to Plaintiffs’ read of soluble, and moreover, the use of “soluble” in the claims does not indicate that the claims are using solubility as a spectrum like Defendants say. In addition, Defendants’ expert, Dr. Ploegh, seemed to understand soluble as Plaintiffs propose when he said that if a B-cell fails to secrete an antibody “this is often because it lacks the features of structure that keep it soluble.” (D.I. 367, Ex. 33 at 135:24–136:6). So it appears that those skilled in the art understand the claims’ use of “soluble” in this context. Finally, Defendant Teneobio itself understands what “soluble” means in this

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<sup>62</sup> ’877, ’179, and ’970 Patents, all asserted claims.

context because, in its own patent application, it pointed to U.S. Pat. No. 8,883,150 (the “’150 Patent”) as disclosing “[s]oluble heavy chain-only antibodies.” (D.I. 367, Ex. 39 at 3:13–15).

Given how the patents use the term soluble, the fact that Defendants’ expert appears to understand “soluble” in this context, and the fact that Defendant Teneobio’s own patent applications appear to understand “soluble” in this context, the Court finds there is no convincing evidence that this term is indefinite.

That leaves the Court with only Plaintiffs’ proposed construction, i.e., that “soluble” means it remains in solution and active in physiological media through B-cell maturation to secretion, without requiring a light chain to maintain solubility. This construction is supported by the specification. *See* ’877 Pat. at 6:48–50, 7:25–30, 7:41–43, 8:20–23, 11:18–20. Thus, the Court will adopt Plaintiffs’ construction and construe “soluble” to mean: remains in solution and active in physiological media through B-cell maturation to secretion, without requiring a light chain to maintain solubility.

## 2. With an Antigen<sup>63</sup>

The full term the parties dispute here is “a functional  $C_{H1}$  domain with an antigen,” but the dispute is whether the Court should judicially correct that term to remove the phrase “with an antigen.”

“The standard for judicial correction is a demanding one.” *Canatex Completion Sols., Inc. v. Wellmatics, LLC*, 159 F.4th 39, 46 (Fed. Cir. 2025). To start, the error must be “evident from the face of the patent.” *Pavo Sols. LLC v. Kingston Tech. Co., Inc.*, 35 F.4th 1367, 1373 (Fed. Cir. 2022) (quoting *Grp. One, Ltd. v. Hallmark Cards, Inc.*, 407 F.3d 1297, 1303 (Fed. Cir. 2005)). Even then, “[c]orrection is appropriate ‘only if (1) the correction is not subject to reasonable debate

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<sup>63</sup> This term appears in the ’877 and ’179 Patents, all asserted claims.

based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims.” *Id.* (quoting *Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1354 (Fed. Cir. 2003)). “[T]he determination ‘must be made from the point of view of one skilled in the art.’” *Id.* (quoting *Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1353 (Fed. Cir. 2009)). “In deciding whether a particular correction is appropriate, the court ‘must consider how a potential correction would impact the scope of a claim and if the inventor is entitled to the resulting claim scope based on the written description of the patent.’” *Id.* (quoting *CBT Flint Partners, LLC v. Return Path, Inc.*, 654 F.3d 1353, 1359 (Fed. Cir. 2011)). “Any correction of a claim has to be consistent with the invention ‘described in the specification and drawings of the original patent.’” *CBT Flint Partners, LLC*, 654 F.3d at 1359 (quoting *I.T.S. Rubber Co. v. Essex Rubber Co.*, 272 U.S. 429, 444 (1926)). When there are multiple “proposed reasonable interpretations” that “would result in the same claim scope,” then the correction is not subject to reasonable debate. *Id.* at 1359–60 (“Because each of the three proposed reasonable interpretations would result in the same claim scope . . . the district court was not required to guess which meaning was intended in order to make sense out of the patent claim, nor is one of skill in the art.”). Finally, the Federal Circuit recently indicated that judicial correction is limited to “obvious minor typographical and clerical errors in patents.” *Canatex Completion Sols.*, 159 F.4th at 46 (assuming this is a “necessary” requirement for judicial correction).

To start, the error here is evident from the face of the patent because everyone agrees this term is nonsensical as written.<sup>64</sup> (D.I. 366 at 60, 61 (parties agreeing the term is “not scientifically

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<sup>64</sup> Because both experts agree that this term is nonsensical as written, there is clear and convincing evidence that, absent judicial correction, it is indefinite.

meaningful”); *see also* D.I. 411 at 92:8–10 (Dr. Ploegh agreeing that “with an antigen” “scientifically, do[es]n’t make sense”); 93:5–9 (similar); 94:13–95:3 (similar), 108:8–22 (Dr. Oettinger stating that “with an antigen is meaningless”).

The next step is determining whether there is just one reasonable correction based on the claim language, specification and prosecution history. The experts agree that one way to correct this term is simply to delete “with an antigen.” (D.I. 411 at 95:4–9 (Dr. Ploegh agreeing that “strik[ing] out the words, ‘with an antigen’” is “one option”), 108:23–25 (Dr. Oettinger saying “get rid of with an antigen” to correct this phrase)). Indeed, that is how Harbour corrected other patents that contain this term. According to Dr. Ploegh, however, there are other reasonable alternatives, namely, that a POSA could replace “with an antigen” with either “which can bind an antigen” or “in complex with an antigen.” (D.I. 367, Ex. 14 (Ploegh Decl.) ¶ 71). But because he agreed that his additional alternatives have the same scope (D.I. 411 at 96:14–22, 100:9–10), the Court treats them as one alternative. *See CBT Flint Partners*, 654 F.3d at 1359–60. Although his initial claim construction declaration did not cite the claims, specification or prosecution history (D.I. 367, Ex. 14 ¶¶ 69–72; D.I. 411 at 101:7–13), at the continued *Markman* Dr. Ploegh pointed to three portions of the specification that support his proposed alternative. (Ploegh Op. Rpt. ¶ 652 (identifying ’877 Pat. 4:18–21, 5:38–46, and 5:47–52 as supporting his proposed alternatives)). Those sections indicate that one goal of the disclosed invention is to “retain maximum antigen-binding potential.” *See* ’877 Pat. at 5:47–53. According to Dr. Ploegh, it is well known in the art that the constant region of an antibody can inhibit specific binding. (D.I. 411 at 95:22–96:2). Correcting the claim term to read “forming a soluble, heavy chain-only antibody comprising a soluble, antigen-specific V<sub>H</sub> binding domain and a constant effector region devoid of a functional C<sub>H1</sub> domain *in complex* with an antigen,” would result in a different claim scope

because it excludes all antibodies “with a constant region that affects negatively the ability of that heavy chain-only antibody to bind antigen” whereas simply deleting the phrase “with an antigen” would result in broader claim scope that includes antibodies with constant regions that negatively affect the ability to bind specifically. (D.I. 411 at 97:11–18). Given that testimony, which the Court credits after having both experts testify live, there is more than one reasonable way to correct this claim term based on the claims, specification and prosecution history. That means judicial correction in this case is inappropriate. *See Pavo Sols. LLC*, 35 F.4th at 1373.

Finally, the Court is not convinced that the error here is a mere typographical or clerical error. To be sure, the parties agree that the phrase “with an antigen” does not make sense, but that alone does not mean it is a typographical or clerical error. In fact, the ’179 and ’877 patents remained in prosecution (and uncorrected) for more than a year after the patentee submitted certificates of correction for two related patents to remove the phrase “with an antigen.” (D.I. 367, Ex. 37 (Request for Certificate of Correction for U.S. Pat. No. 8,921,522), Ex. 38 (Request for Certificate of Correction for U.S. Pat. No. 8,921,524)). Then, later on, the patentee submitted a certificate of correction for the ’179 Patent, but did not seek to correct the claims to remove the phrase “with an antigen.” (D.I. 384). On this record, the Court is not convinced that including the phrase “with an antigen” is a typographical or clerical error so much as a decision. And that is reinforced by the fact that there is more than one reasonable way to correct the claim language here. With that, the Court will not correct the term because the standard for judicial correction is not met.

In addition, it is worth noting that even if the standard for judicial correction had been met, in the circumstances presented here, the Court would decline to exercise its equitable<sup>65</sup> powers to

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<sup>65</sup> The parties agreed that judicial correction is an equitable remedy. (D.I. 411 at 5:18–6:13).

correct this term. Federal Circuit cases discussing judicial correction are clear that a district court “can” or “may” judicially correct a patent when the standard for judicial correction is met, not that a district court “must” or “shall” do so. *See CBT Flint Partners*, 654 F.3d at 1358 (“It is well-settled law that, in a patent infringement suit, a district court **may** correct an obvious error in a patent claim.” (emphasis added)); *Novo Indus.*, 350 F.3d at 1357 (“A district court **can** correct a patent only if (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims.” (emphasis added)); *Grp. One*, 407 F.3d at 1303 (“[I]n some circumstances the district court **can** correct errors retroactively.”) (emphasis added); *see also KeyMe, LLC v. Hillman Grp., Inc.*, Case No. 19-1539 (LPS), 2021 WL 243252, at \*6 (D. Del. Jan. 25, 2021) (judicially correcting patent because “[t]he Court is persuaded that the claim term contains a typographical error which it can, **and should**, correct” (emphasis added)). In fact, Federal Circuit precedent indicates that a district court should not judicially correct a patent when there is “evidence of culpability or intent to deceive by delaying formal correction” or the error is not “harmless.” *In re Hoffer*, 405 F.3d 1326, 1331 (Fed. Cir. 2005). This is one such case.

Here, Harbour<sup>66</sup> has known that inclusion of “with an antigen” is an error, but delayed correction for years. **First**, Harbour sought to correct the exact same alleged error in the ’522 and ’524 patents in February 2015, just over a month after those patents issued. (D.I. 367, Ex. 37 (Request for Certificate of Correction for U.S. Pat. No. 8,921,522), Ex. 38 (Request for Certificate of Correction for U.S. Pat. No. 8,921,524)). At that time, if including the phrase “with an antigen” was such an obvious error as Harbour now contends, it could have and should have recognized the

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<sup>66</sup> The Court uses “Harbour” to refer to all plaintiffs and “Teneobio” to refer to both defendants.

error and sought correction in the '877 and '179 Patents. Instead, Harbour continued to prosecute those patents for more than a year without seeking to remove the phrase “with an antigen” from any claims. **Second**, after the '179 Patent issued, Harbour asked the patent office to correct other errors, but not to correct any claims to remove the phrase “with an antigen.” (D.I. 384). Crediting Harbour’s expert’s testimony that the phrase “with an antigen” was such a glaring error that she “glitched because it didn’t make sense,” (D.I. 411 at 108:14–22), there is no explanation for Harbour’s failure to correct the error at the latest at that point. **Third**, Harbour had another chance to catch and correct the error when it sent Teneobio a cease-and-desist letter in October 2017, which “specifically identified the '877 and '179 patents” as patents that Harbour believed Teneobio infringed. (D.I. 213 ¶ 64; D.I. 332 ¶ 64). It is not too much to expect that a party sending a cease-and-desist actually read the claims in its own patents, and had Harbour done that, it would have noticed that it sent a cease-and-desist on claims that are “not scientifically meaningful.” (D.I. 366 at 60). Instead, Harbour pressed forward with a lawsuit alleging infringement of claims that its own expert says “ha[ve] no meaning.” (D.I. 411 at 108:14–22). **Fourth**, in October 2022 Teneobio told Harbour that these claims were indefinite “because [they] didn’t make any sense,” (D.I. 385 at 18:11–14), and Harbour still chose to not correct the errors. **Fifth**, Harbour’s own expert flagged the error during this lawsuit a year before the continued *Markman* hearing. (*Id.* at 109:1–7). In response, Harbour told its expert that “it’s been corrected,” even though it had not. (*Id.*). The reality is, Harbour had chance after chance after chance to catch and correct the error, but for whatever reason did not. Equity aids the vigilant, not the willfully blind.

Then, during claim construction, Harbour took inconsistent positions in its efforts to have the Court correct what Harbour should have corrected years before this lawsuit was filed. For example, in its *Markman* briefing, Harbour asked this Court, in the alternative, to give this term

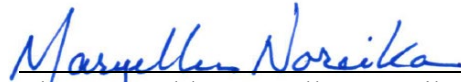
its plain and ordinary meaning. (D.I. 363 at 14; D.I. 366 at 59). But at the first *Markman*, Harbour's own counsel stood up and agreed that "it doesn't make sense as it's written." (D.I. 385 at 4:23–5:3). Then, once the Court ordered live testimony, Harbour's expert confirmed (repeatedly) that the claim as written is nonsensical. (D.I. 411 at 108:8–22, 109:1–7, 116:12–14). It is hard to see how Harbour's plain-and-ordinary position could be considered "good faith" in any meaningful sense of the phrase when its own counsel and expert agreed that the term is meaningless. Then, the Thursday before the continued *Markman*, Harbour had the attorney who prosecuted these patents (Ms. Trujillo) submit a sworn declaration that not only purports to explain away including the phrase "with an antigen" as a "copy and pasting error" (D.I. 397 ¶ 15) but also purports to explain why she did not correct the '179 and '877 Patents to remove the phrase "with an antigen." (*Id.* ¶ 14 ("Because it did not occur to me that the copy and pasting error had been duplicated in the claims of the applications that would later issue as the '877 and '179 patents, I did not take any steps to correct that error in the pending claims before those patents issued."); *id.* ¶ 17 (insinuating the alleged error was missed because "the assistant who had reviewed the issued claims of the '522 and '524 patents had been replaced by a different assistant")). The problem there, however, is that Ms. Trujillo had already been deposed in this case, and in that deposition, she testified that had no recollection about why she did not remove the phrase "with an antigen" from the '179 and '877 patents. (D.I. 400, Ex. 1 at 84:8–19 ("Q. Now, why did you not do anything to remove the words 'with an antigen' in what became the '877 Patent? A. I don't recall"); *id.* at 85:24–86:2 ("Q. Is there a reason why you did not take any action to remove the words 'with an antigen' from this part of the claim in the '179 Patent? A. Not to my recollection.")). Defendants are right: that "contradictory sworn testimony about her conduct itself bespeaks inequity." (D.I. 405 at 11).

Harbour's repeated failures to correct the error evidence culpability, and its statement to its expert that the error has "been corrected," when in fact it had not, shows an intent to deceive. (D.I. 411 at 109:1-7). Moreover, Harbour's attempt to backdoor an after-the-fact explanation of why this alleged error was not corrected indicates, at a minimum, an intent to deceive Teneobio as to the circumstances surrounding Harbour's repeated failure to correct. That harms Teneobio by depriving it of a full and accurate record and forcing it to litigate against a moving target. And it also harms Teneobio by forcing it to expend resources deposing Harbour's prosecuting attorney on this topic only to have that same prosecuting attorney provide an inconsistent declaration months after the deposition. Equity is not meant to save litigants in these situations.

But more tangibly, correcting the '179 and '877 Patents now would harm Teneobio by subjecting it to damages on claims that Harbour knew (or should have known) were "not scientifically meaningful" from the day they issued. That harm is compounded by the fact that Harbour is seeking a willfulness finding and enhanced damages based (in part) on Harbour's October 6, 2017 letter to Teneobio, which identified scientifically meaningless patents. (D.I. 213 ¶¶ 64, 78, 91). And, assuming Teneobio's representation is correct that the '179 Patent has expired (D.I. 405 at 11), it would effectively revive years' worth of damages and reward Harbour for its repeated failures. It is not "asking too much to expect a patentee to check a patent when it is issued in order to determine whether it contains any errors that require the issuance of a certificate of correction." *Sw. Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280, 1296 (Fed. Cir. 2000). Indeed, the public notice function of patent law is best served when patent owners *do* double-check their issued patents and promptly seek certificates of correction.

Ultimately, the Court finds that there is evidence of Harbour's culpability and intent to deceive by delaying formal correction and that the error is not harmless. Given that the test for

judicial correction is not met and that the facts here indicate the Court should not exercise its equitable powers, the Court will decline to judicially correct the '877 and '179 Patents. Instead, because everyone agrees that, absent judicial correction, the claims including the phrase “with an antigen” are nonsensical, the Court finds there is clear and convincing evidence that those claims are indefinite.



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The Honorable Maryellen Noreika  
United States District Judge

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

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HARBOUR ANTIBODIES BV, HARBOUR )  
ANTIBODIES HCAB BV, ERASMUS )  
UNIVERSITY MEDICAL CENTER )  
ROTTERDAM and DR. ROGER KINGDON )  
CRAIG, )

Plaintiffs, )

v. )

TENEOBIO, INC. and AMGEN INC., )

Defendants. )

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TENEOBIO, INC. and AMGEN INC., )

Counterclaim-Plaintiffs, )

v. )

HARBOUR ANTIBODIES BV, HARBOUR )  
ANTIBODIES HCAB BV, ERASMUS )  
UNIVERSITY MEDICAL CENTER )  
ROTTERDAM, DR. ROGER KINGDON )  
CRAIG, and HBM HOLDINGS LTD. )

Counterclaim-Defendants. )

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C.A. No. 21-1807 (MN)

**JURY TRIAL DEMANDED**

**ORDER AFTER PRETRIAL CONFERENCE**

AND NOW, this 3rd day of June 2026, after a Pretrial Conference and upon consideration of the Proposed Pretrial Order (D.I. 552) and the discussion at the June 1, 2026 Pretrial Conference, IT IS HEREBY ORDERED that:

1. The Proposed Pretrial Order is ADOPTED as modified by any discussion at the Pretrial Conference. (*See* D.I. 552).

2. A five-day jury trial will begin on June 8, 2026 at 9:00 a.m. with jury selection occurring on Friday, June 5 at 9:00 a.m. Subsequent trial days will begin at 9:00 a.m., with the

exception of Tuesday, June 9th when trial will begin at 11:00 a.m. Each side should be prepared to present its case until 4:45 p.m. of each trial day, although the end of the trial day may, at the discretion of the Court, be earlier or later than 4:45 p.m.

3. The trial will be timed. Each side is allowed up to twelve (12) hours for its opening statement, its direct and cross-examination of witnesses, closing arguments, and argument of evidentiary issues. Each side shall reserve at least one (1) hour of its twelve (12) hours for closing arguments. Time during the trial day that does not neatly fit into one of these categories will be attributed to one side or the other as the Court deems appropriate.

4. Issues that need to be addressed outside the presence of the jury will usually be taken up before the jury arrives, at lunch, or at the end of the day as the Court deems appropriate. Those issues – including objections to anticipated exhibits or demonstratives – must be brought to the attention of the Court’s judicial administrator by 7:00 a.m. on the day on which the evidence objected to will be adduced. There will be thirty minutes to forty-five minutes for lunch and a fifteen-minute break in the morning and in the afternoon.

5. As discussed at the Pretrial Conference, Plaintiffs’ motions for summary judgment on No Tortious Interference and No Unenforceability (D.I. 428, 432) are DENIED-AS-MOOT. (D.I. 576 at 7:16–18). Furthermore, for the reasons stated at the Pretrial Conference, Plaintiffs’ remaining summary judgment motions (D.I. 425, 435) are DENIED.

6. For the reasons stated at the Pretrial Conference, Defendants’ motions for summary judgment (D.I. 420, 422, 423) are DENIED.

7. For the reasons stated at the Pretrial Conference, Plaintiffs’ motions to exclude Dr. Meek (D.I. 413), Dr. Muyltermans (D.I. 415) and Dr. Vellturo (D.I. 421) are DENIED.

8. For the reasons stated at the Pretrial Conference, and subject to the parties' representations regarding Dr. Oettinger's testimony,<sup>1</sup> Defendants' motion to exclude Dr. Oettinger (D.I. 417) is DENIED-IN-PART. As the Court stated at the Pretrial Conference, the Court will hear live testimony from Dr. Oettinger on Friday June 5, 2026 after jury selection regarding her opinion on the number of infringing expressions and rule on Defendants' *Daubert* motion as to those opinions at that time. (D.I. 576 at 47:10–21). The parties will receive 30 minutes per side.<sup>2</sup>

9. For the reasons stated at the Pretrial Conference, the Court has taken Defendants' motion to exclude Dr. Serwin's testimony (D.I. 418) under advisement and will rule on that motion pending the Court's ruling on the Oettinger *Daubert*.

10. Defendants withdrew their motion to exclude Dr. Matal. (D.I. 419, 565).

11. For the reasons stated at the Pretrial Conference, the Court RESERVED ruling on Plaintiffs' Motion *in Limine* No. 1 (D.I. 552, Ex. 13A), pending Defendants' showing that they timely disclosed that the relevant witnesses were knowledgeable about the relevant testimony. Defendants are instructed to bring the relevant disclosures on Friday. In light of the significant argument the Court has already heard on this issue, the Court will permit the parties to briefly (no more than 5 minutes per side) argue this Motion on Friday June 5, 2026.

12. For the reasons stated at the Pretrial Conference, and subject to Defendants' representations, Plaintiffs' Motion *in Limine* No. 2 (D.I. 552 Ex. 13B) is DENIED. To the extent

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<sup>1</sup> To the extent Defendants believe Dr. Oettinger's testimony begins to go outside the bounds of what Plaintiffs' counsel represented at the Pretrial Conference, Defendants should object live.

<sup>2</sup> This time is in addition to the trial time and will not come out of either side's respective trial time.

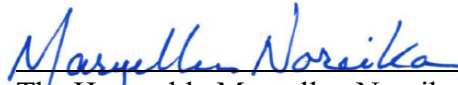
Plaintiffs believe Defendants offer testimony beyond what Defendants' counsel agreed to at the Pretrial Conference, Plaintiffs should object live.

13. For the reasons stated at the Pretrial Conference, and subject to Defendants' representations, Plaintiffs Motion *in Limine* No. 3 (D.I. 552, Ex. 13C) is DENIED. To the extent Plaintiffs believe Defendants offer testimony beyond what Defendants' counsel agreed to at the Pretrial Conference, Plaintiffs should object live.

14. For the reasons stated at the Pretrial Conference, Defendants' Motion *in Limine* No. 2 (D.I. 552, Ex. 14B) is GRANTED; Defendants' Motion *in Limine* No. 3 (D.I. 552, Ex. 14C) is DENIED.

15. As explained at the Pretrial Conference, the parties may not provide witness binders or physical copies of documents (demonstratives, deposition transcripts, etc.) to the Court, but the parties must provide witness binders to the witnesses. The parties shall provide electronic copies of ALL trial exhibits to the Courtroom Deputy by NOON on June 5, 2026. The trial exhibits must be labeled with JTX, DTX or PTX prefixes with exhibit numbers, and the trial exhibits must be organized in a single folder. Additionally, at the beginning of each trial day, the parties shall provide to the Courtroom Deputy and Judicial Administrator electronic copies of witness folders containing the exhibits and demonstratives (if any) to be used on direct examination and cross-examination<sup>3</sup> of any witnesses expected to be called that day.

16. Any trial logistics should be coordinated through the Courtroom Deputy.

  
The Honorable Maryellen Noreika  
United States District Judge

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<sup>3</sup> This includes any deposition transcripts or expert reports to be used with witnesses.