UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

BRISTOL-MYERS SQUIBB COMPANY, Plaintiff, v. GENENTECH, INC., and CITY OF HOPE, Defendants.	Case No. 2:13-cv-05400-MRP-JEMx **CLAIM CONSTRUCTION ORDER**
ELI LILLY AND COMPANY, and IMCLONE SYSTEMS LLC, Plaintiffs, v. GENENTECH, INC., and CITY OF HOPE, Defendants.	Case No. 2:13-cv-07248-MRP-JEMx

I. Introduction

Plaintiff Bristol-Myers Squibb Company ("BMS") and Plaintiffs Eli Lilly and Company and ImClone Systems LLC (collectively "Lilly," and together with BMS "Plaintiffs") have filed for declaratory judgments of noninfringement and invalidity of U.S. Patent Nos. 6,331,415 (the "Cabilly II Patent") and 7,923,221 (the "Cabilly III Patent") (collectively "Cabilly Patents") against Genentech, Inc. and City of Hope (collectively "Genentech"). In this Order, the Court construes certain claim terms in dispute.

II. Technical Background

The Cabilly Patents relate to methods, host cells, and vectors for making genetically engineered immunoglobulins. The Cabilly III Patent is a continuation of the Cabilly II Patent, and the Cabilly Patents share the same specification, which discloses recombinant DNA techniques for producing immunoglobulins. Immunoglobulins are proteins normally produced by cells of the immune system in response to an infection. Antibodies[1] have a Y-shape and are made up of two heavy chains and two light chains, linked together by disulfide bonds. Antibodies are able to bind with very high specificity to targets called antigens, such as bacteria or viruses. When an antibody binds to an antigen, the body's immune system is activated and can destroy the antigen.

The Cabilly Patents claim methods of producing antibodies by inserting DNA that codes for the heavy and light immunoglobulin chains into a host cell through the use of one or two vectors. These host cells then produce, or "express," antibodies. The Cabilly Patents claim a process called "coexpression," where DNA coding for the heavy and light chains could be inserted into the same host cell and expressed at the same time.

[1] The parties dispute the claim construction of the terms "immunoglobulin" and "antibody." The Court takes no position on the claim construction of these terms in this Order. For the purposes of this section, "antibody" means an immunoreactive immunoglobulin molecule.

The accused products in the two related cases are Yervoy and Erbitux. Yervoy, manufactured by BMS, contains a recombinant, fully human antibody that binds to cytotoxic T-lymphocyte antigen 4. Yervoy is used to treat patients with unresectable or metastatic melanoma. The Yervoy antibody is made in Chinese hamster ovary host cells that were transformed with the DNA encoding the antibody heavy and light chains before the issue dates of either of the Cabilly Patents.

Erbitux, developed by Lilly and manufactured by BMS, is the trade name for cetximab, a recombinant, chimeric mouse/human antibody that binds to the human epidermal growth factor receptor. Erbitux is used to treat patients with head and neck cancer. The Erbitux antibody is made in mouse myeloma host cells that, like Yervoy, were transformed with the DNA encoding the antibody heavy and light chains before the issue dates of either of the Cabilly Patents.

III. Procedural History

The Cabilly II Patent has been litigated before this Court several times. Beginning with *MedImmune Inc. v. Genentech, Inc.* in 2003, this Court presided over discovery and claim construction for the Cabilly II Patent. Case No. 2:03-cv-02567 (C.D. Cal. filed Apr. 11, 2003) (issuing claim construction order at Dkt. No. 243). In *Centocor, Inc. v. Genentech, Inc.*, the Court again presided over claim construction of the Cabilly II Patent. Case No. 2:08-cv-03573-MRP (C.D. Cal. filed May 30, 2008). The Court also presided over the *Glaxo Group Ltd. v. Genentech, Inc.* ("*Glaxo I*") litigation over infringement of the Cabilly II Patent by the Arzerra antibody product. Case No. 2:10-cv-02764-MRP (C.D. Cal. filed Feb. 17, 2010). The Glaxo Group filed a second declaratory judgment suit concerning the Benlysta antibody product. *Glaxo Group Ltd. v. Genentech, Inc.*, Case No. 2:11-cv-03065-MRP (C.D. Cal. filed Apr. 12, 2011) ("*Glaxo II*"). In *Centocor* and *Glaxo I*, the Court issued rulings on claim construction. *See Centocor* at Dkt. No. 93; *Glaxo I* at Dkt. No. 96. In *Glaxo II*, as well as in two related cases brought by

Human Genome Sciences, Inc., the Court received claim construction briefing concerning claim terms of both the Cabilly II and the Cabilly III Patents. *Human Genome Sciences Inc. v. Genentech Inc.*, Case No. 2:11-cv-06519-MRP (C.D. Cal. filed Aug. 9, 2011); *Human Genome Sciences Inc. v. Genentech Inc.*, Case No. 2:11-cv-06594 (C.D. Cal. filed Aug. 11, 2011). The parties stipulated to dismissal prior to the claim construction hearing in all three cases.

Plaintiffs filed the two instant cases separately in 2013. Both cases were transferred to this Court and ordered related. On January 21, 2014, the parties filed a stipulation agreeing to the construction of two claim terms from the Cabilly II Patent and two claim terms from the Cabilly III Patent as follows:

Cabilly II Patent	
Claim Term	**Stipulated Construction**
"different insertion sites"	"in the vector, the DNA sequence encoding for at least the variable domain of the heavy chain is not contiguous to the DNA sequence encoding for at least the variable domain of the light chain, the former being separated from the latter by sufficient DNA sequence to ensure independent expression"
"transformed host cell"	"a cell whose heritable DNA has been altered by the inclusion of foreign DNA; the term includes the progeny of the originally transformed cell"
Cabilly III Patent	
Claim Term	**Stipulated Construction**
"recombinant host cell"	"a cell whose heritable DNA has been altered by the inclusion of foreign DNA; the term includes the progeny of the originally transformed cell"
"heavy chain or fragment thereof and the light chain or fragment thereof"	"independently expressing the heavy chain or fragment thereof and the light chain or fragment thereof in the same host cell"

In the stipulation, the parties stated that disagreements remained on the claim construction of nine claim terms in the Cabilly II Patent and six claim terms in the Cabilly III Patent.

Genentech opened the claim construction briefing by arguing its proposed constructions for ten claim terms. BMS and Lilly each provided separate responses to Genentech's opening brief.

Lilly reached agreement with Genentech on the construction of all claim terms except "immunoglobulin"/immunoglobulin molecule," "antibody," "host cell," and "transformed." BMS withdrew its opposition to Genentech's proposed constructions for the claim terms "vector," "host cell culture," and "replicable expression vector."[2] In addition, BMS declined to argue against Genentech's proposed constructions for the claim terms "immunoglobulin"/"immunoglobulin molecule," "first DNA sequence," "second DNA sequence," "said immunoglobulin heavy and light chains are produced as separate molecules in said transformed single host cell," "antibody," and "DNA encoding." Instead, BMS "preserve[d] the issue for appeal" by "incorporat[ing] by reference the facts, law, and argument set out in" claim construction briefs filed by other parties in the prior *Glaxo I* and *Glaxo II* litigations.

[2] The parties agreed to the following constructions of these claim terms used in the Cabilly II and Cabilly III Patents:

Claim Term	Stipulated Construction
"host cell culture"	No construction necessary; plain and ordinary meaning.
"vector"	"a DNA construct comprising DNA foreign to the DNA host cell, which DNA construct is capable of effecting the expression of the foreign DNA"
"replicable expression vector"	"a DNA construct comprising DNA foreign to the DNA host cell, which DNA construct is capable of effecting the expression of the foreign DNA"

Finally, at the claim construction hearing, Genentech and Lilly agreed to postpone argument on the terms "immunoglobulin"/"immunoglobulin molecule" and "antibody" until the case progressed to motions on invalidity issues. As a result, only the claim terms "host cell," "transformed," and "recovering the heavy chain or fragment thereof and light chain or fragment thereof" were argued at the claim construction hearing.

IV. Principles of Claim Construction

The purpose of claim construction is to determine the meaning and scope of the patent claims alleged to be infringed. *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008). Claim construction is a pure question of law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 384 (1996); *see generally Lighting Ballast Control LLC v. Philips Electronics N. Am. Corp.*, 744 F.3d 1272 (Fed. Cir. 2014). For purposes of claim construction, the Court reviews both intrinsic and extrinsic evidence, placing emphasis on the former.

A. Intrinsic Evidence.

i. Claim Language

"[T]he words of a claim 'are generally given their ordinary and customary meaning.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (citation omitted). "[T]he ordinary and customary meaning of a claim term 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." *Id.* at 1313. "The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." *Id.*

The claims themselves provide insight into proper claim construction. "[A] court must presume that the terms in the claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms." *Gart v. Logitech*, 254 F.3d 1334, 1341 (Fed. Cir. 2001) (quotation

and citation omitted); *see also Becton, Dickinson and Co. v. Tyco Healthcare Grp.*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) ("Claim construction begins and ends in all cases with the actual words of the claim.") (quotation and citation omitted). Claims "must be construed in light of the appropriate context in which the claim term is used." *Aventis Pharms. Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013). Claim language is paramount. The other intrinsic and extrinsic evidence, though valuable, cannot "be used to rewrite[] the chosen claim language." *SuperGuide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). "Specifications teach. Claims claim." *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1985) (en banc).

ii. Specification

The specification is "always highly relevant to the claim construction analysis." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (Fed. Cir. 1995). As Judge Rich wrote shortly after the creation of the Federal Circuit, "the specification . . . is the primary basis for construing the claims." *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985). "[T]he 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. "In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id*. In such cases, the inventor's intention as expressed in the specification "is regarded as dispositive." *Id.*

iii. Prosecution History

The Court may also consider the patent's prosecution history. "The prosecution history, which we have designated as part of the "intrinsic evidence," consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent." *Id.* The patentee created the prosecution history much like the specification in an attempt to explain and obtain

the patent, and thus the prosecution history provides evidence about how the PTO and the inventor understood the patent. *Id.* "Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* "Nonetheless, the 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.*

Statements in the prosecution history may give rise to a disclaimer of the scope of the claims of the patent. In particular, "an applicant's statements to the PTO characterizing its invention," including statements made in response to a rejection over prior art, may exclude matter from the scope of the claims as finally granted. *Uship Intellectual Properties, LLC v. United States*, 714 F.3d 1311, 1315 (Fed. Cir. 2013); *see also Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 994 (Fed. Cir. 2003) (holding the patentee "to the restrictive claim construction that was argued during prosecution").

B. Extrinsic Evidence

In addition to using intrinsic evidence, this Court may also use extrinsic evidence in claim construction. *Phillips*, 415 F.3d at 1317 ("[W]e have . . . authorized district courts to rely on extrinsic evidence . . . ."). Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Id*. While extrinsic evidence can shed light on claim meaning, it is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Id*. (citation omitted). Extrinsic evidence is "unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1319.

V. Claim Construction

As a preliminary matter, legal arguments are not properly raised before the district court by inclusion in declarations and exhibits. *See* Local Rule 7-5 (requiring "[a] brief but complete memorandum in support thereof and the points and authorities upon which the moving party will rely"); Local Rule 7-7 ("Declarations shall contain only factual, evidentiary matter . . . ."); *cf. Graphic Controls Corp. v. Utah Med. Prods.*, 149 F.3d 1382, 1385 (Fed. Cir. 1998) (declining to consider argument presented in footnotes and appendices in light of a rule requiring that the litigants' briefs contain the contentions and reasoning of the parties). The Court therefore does not consider the arguments incorporated by reference by BMS in its briefing and considers only the arguments made by the parties in their filed papers. The Court also does not construe claim terms listed in the parties' joint statement but not argued on the papers.

The Court therefore construes only the claim terms "host cell," "transformed," and "recovering the heavy chain or fragment thereof and light chain or fragment thereof" in this Order. The Court reserves judgment on arguments presented by Genentech and Lilly on the claim terms "immunoglobulin"/"immunoglobulin molecule" and "antibody." The Court will address the claim construction of those terms when the Court considers issues of invalidity.

A. "host cell"

The Court finds that the term "host cell" means "a cell whose heritable DNA has been or will be altered by the inclusion of foreign DNA; the term includes the progeny of the originally transformed cell."

Claim 33 of the Cabilly II Patent requires a "process for producing an immunoglobulin molecule or . . . fragment . . . in a single host cell, comprising: independently expressing . . . DNA sequence[s] . . . so that said immunoglobulin heavy and light chains are produced as separate molecules in said single host cell transformed with said . . . DNA sequences." The preamble describes the process

as occurring in a single host cell, and the single step of the process further describes the single host cell as transformed with certain DNA sequences. These two uses of the claim term "host cell" make clear that the first use of the term "host cell" describes a cell that is prepared to undergo the transformation process of taking up foreign DNA.[3]

Because the term "host cell" clearly includes cells that are prepared to but have not yet undergone the transformation process, the remaining relevant question is whether a host cell remains a "host cell" after it has undergone the transformation process. Said differently, is a "host cell transformed" still a "host cell"?

From the perspective of ordinary English, the answer is yes. As used in the claims of the Cabilly II Patent, the term "transformed" is a past participle used as an adjective to describe the noun "host cell." Adding a descriptive term to a noun does not generally change the definition of the noun; instead, it provides description that specifies a certain class or type of noun with additional particularity. The phrase "host cell transformed" is a more specific category of host cells, including only host cells that have undergone the transformation process.

From the perspective of the claim language, the answer is also yes. The Court's construction of the term "host cell" is consistent with the fact that the claim term "host cell" is used both alone and with the past-participial adjective "transformed." "[A] claim term should be construed consistently with its appearance in other places in the same claim or in other claims of the same patent." *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001). Since the patentee chose to use the phrase "host cell" as part of the term "host cell transformed," it is more consistent to interpret the term "host cell" to include both untransformed and

[3] The parties have agreed to the language "heritable DNA has been altered by the inclusion of foreign DNA; the term includes the progeny of the originally transformed cell" to describe the result of the transformation process for creating recombinant DNA. For consistency, the Court adopts the same language to describe the transformation process for the term "host cell" as well.

transformed host cells, thereby giving the term "host cell" the same construction every time the term is used in the claims.

BMS is correct that the term "host cell" as used in the preamble of Claim 33 provides the antecedent basis for the later term "said host cell transformed." This argument does more to support the Court's construction than it does to undermine it; the broader term used in the preamble provides a basis for the more specific condition in the claimed step.

The specification is in accord. The invention "includes the host cells and cell cultures which result from transformation with these vectors." Cabilly II Patent at 5:34–35; *see also* Cabilly II at 4:29–32 ("The resulting product may be obtained by lysis, if necessary, of the host cell and recovery of the product by appropriate purifications from other proteins."). If host cells can result from the transformation process, then the term "host cell" must include transformed host cells. The specification also describes host cells that have not yet undergone transformation,[4] indicating that the term "host cell" is broader than the term "host cell transformed" and therefore also includes cells that are the target of the transformation process before the process has occurred.

Lilly argues that the prosecution history of the patent precludes the argument that host cells include transformed host cells. Lilly relies on a statement by the patentee in its October 30, 2006 response to the P.T.O. during reexamination: "According to the '415 patent, a host cell is a cell that has the capacity to be transformed with DNA sequences encoding the heavy and light chains of an immunoglobulin and to pass on to its progeny the genetic material that has been introduced into it." The patentee's statement is merely another example of a discussion of a host cell prior to transformation and is not sufficient to disclaim transformed cells from the construction of "host cell." Furthermore, the next

[4] *See, e.g.*, *id*. at 4:17–24, 4:27–32, 4:54–55, 5:30–35, 8:26–32, 8:40–43, 8:57–59, 9:28–31, 9:56–66, 11:51–54, 27:3–5.)

sentence in the October 30, 2006 response following states "it [the host cell] and its progeny also have the ability to express the introduced DNA sequences." Since a cell must be transformed in order to express introduced DNA sequences, this usage indicates that a host cell can be a transformed host cell, consistent with the Court's construction.

Not only does the prosecution history not preclude the argument that host cells include transformed host cells, it supports that argument. In a response to the P.T.O. dated November 25, 2005 in reexamination 90/007,542, the patentee stated "that claim 33 of the '415 patent—considered in its entirety—requires additional steps [not in the parent patent,] . . . [s]pecifically: . . . a single host cell that has been transformed to include DNA sequences." Declaration of Susanne Flanders in Support of Lilly's Responsive Brief on Claim Construction ("Flanders Decl."), Ex. E at 25 (Dkt. No. 142). A host cell remains a host cell, even after undergoing the transformation process.

B. "transformed"

The Court finds that the term "transformed" needs no construction in light of this Court's construction of "host cell" and the parties' agreed construction of "host cell transformed." The term "transformed" does not require a separate step of transformation.

The term "transformed" alone does not require the act of transformation as a step in the claimed process. BMS correctly asserts that a host cell cannot be transformed without undergoing the transformation process. But a claim may describe a condition without reciting, and therefore claiming, "each and every step necessary to obtain that condition." *In re Alul*, 468 F.2d 939, 943 (C.C.P.A. 1972); *see also Rambus Inc. v. Infineon Techs. AG*, 318 F.3d 1081, 1093 (Fed. Cir. 2003) ("[C]laims need not recite every component necessary to enable operation of a working device."). Here, Claim 33 requires the condition of a host cell

transformed; it does not require the step of transformation necessary to obtain the transformed host cell.

In particular, the difference in claim terminology between independent Claims 1 and 33 indicates that the term "transformed" does not require a transformation step. *See Ancora Technologies, Inc. v. Apple, Inc.*, 744 F.3d 732, 735 (Fed. Cir. 2014) (finding that use of a broad term in one independent claim and related, more specific term in another independent claim "tend[ed] to reinforce, rather than undermine" construing the first term more broadly). Claims 1 and 33 are similar, but not identical, as shown below:

Claim 1	Claim 33
A process for producing an immunoglobulin molecule or an immunologically functional immunoglobulin fragment comprising at least the variable domains of the immunoglobulin heavy and light chains, in a single host cell, comprising the steps of:	A process for producing an immunoglobulin molecule or an immunologically functional immunoglobulin fragment comprising at least the variable domains of the immunoglobulin heavy and light chains, in a single host cell, comprising:
(i) transforming said single host cell with a first DNA sequence encoding at least the variable domain of the immunoglobulin heavy chain and a second DNA sequence encoding at least the variable domain of the immunoglobulin light chain, and	independently expressing a first DNA sequence encoding at least the variable domain of the immunoglobulin heavy chain and a second DNA sequence encoding at least the variable domain of the immunoglobulin light chain
(ii) independently expressing said first DNA sequence and said second DNA sequence	so that said immunoglobulin heavy and light chains are produced as separate molecules
so that said immunoglobulin heavy and light chains are produced as separate molecules	in said single host cell transformed with said first and second DNA sequences.
in said transformed single host cell.	

Claim 1 explicitly lists a process comprised of multiple steps including a transformation step and an expression step. Claim 33 includes only one step, reinforcing this Court's interpretation that Claim 33 in fact requires only one step.

Lilly argues that the prosecution history of the patent precludes the argument that Claim 33 and Claim 1 are patentably distinct and that all of Cabilly II's claims must be read to include at least three steps: transformation, expression, and assembly. Lilly relies on several portions of the prosecution history.

The November 25, 2005 Reexamination Response. In a response to the P.T.O. dated November 25, 2005 in reexamination 90/007,542, the patentee compared Claim 1 of the parent patent to Claim 1 of the Cabilly II Patent and stated that Claim 1 of the Cabilly II Patent required additional limitations that implicated "additional steps" that "the host cell be transformed," that the host cell independently express two immunoglobulin polypeptides, and that "steps be taken" to assemble an immunoglobulin or functional fragment. Flanders Decl., Ex. E at 25. The patentee also stated that Claim 33 included the same additional limitations, but did not describe any additional steps. *Id*. at 29–30. The patentee's choice to address Claims 1 and 33 separately indicates that the additional steps included in the argument with respect to Claim 1 were not generally applicable to all the claims. In particular, Claim 1 explicitly includes a transformation step, consistent with the patentee's statement. Claim 33 does not explicitly include a transformation step, consistent with the patentee's refusal to describe Claim 33 as requiring an "additional step" of transformation. The patentee's language is in no way inconsistent with the Court's construction.

The October 30, 2006 Reexamination Response. In a response to the P.T.O. dated October 30, 2006 in merged reexaminations 90/007,542 and 90/007,859, the patentee stated that, unlike its parent patent, the Cabilly II Patent required "the host cell to be transformed with [] DNA sequences" as well as production of separate polypeptide molecules assembled into an immunoglobulin or functional fragment.

Flanders Decl., Ex. A at 16–17. This language is consistent with the requirement of a transformed host cell in the same way that the Cabilly II Patent claims require an assembled molecule rather than a separate step of assembly. Nothing in the patentee's statement addressed the issue of requiring a separate transformation step.

The May 21, 2007 Reexamination Response. In a response to the P.T.O. dated May 21, 2007, the patentee discussed claim elements in the Cabilly II Patent not found in the parent patent, including the transformation step. Declaration of Joseph M. Lipner in Support of Genentech's Request for Leave to Respond to New Citations ("Lipner Decl."), Ex. 3 at 31 (Dkt. No. 115). The patentee noted that "claim 1 of the '415 patent and claim 1 of the '567 patent [were used] for an illustrative comparison of the claims of the two patents. Distinctions exist between these claims and other independent claims in the two patents, which owners have previously discussed." *Id.*, Ex. 3 at 29 n.7. First, the initial statement only implies that at least one of the Cabilly II Patent claims includes a transformation step, not that all the claims do. Second, the patentee clearly disclaimed any attempt to limit Claim 33 based on the statements made about Claim 1 in the May 21, 2007 response.

The June 6, 2008 Reexamination Response. In a response to the P.T.O. dated June 6, 2008, the patentee stated that an expert declaration submitted with the response characterized the claims as requiring "three separate steps: (i) a host cell must be transformed with immunoglobulin heavy chain and light chain DNA sequences; (ii) the DNA sequences must be independently expressed (transcribed and translated) by the host cell to produce polypeptides, and (iii) the polypeptides must be assembled to form an immunoglobulin molecule or an immunologically functional immunoglobulin fragment ("fragment")." The expert declaration stated that in order for the invention of the Cabilly II Patent to function, "all of the following things must happen: . . . host cells must have been successfully

transformed with DNA sequences . . . ; the transformed host cell must independently express both sequences . . . ; and the polypeptides must be assembled . . . . *Id*., Ex. 2 at ¶ 4.

Although the patentee's summary of the expert declaration is not so direct, the expert clearly describes the transformation as having occurred at some point in the past. Read in its entirety, patentee's argument in the June 6, 2008 response is not sufficient to require that the term "transformed" import the step of transformation into the claim. The patentee neither clearly disavowed claim scope nor argued for the inclusion of a transformation step in a manner sufficient to give rise to an argument of estoppel.

None of the citations to the prosecution history of the Cabilly II Patent indicate that the Court should read a separate transformation step into the claim term "transformed."

C. "recovering the heavy chain or fragment thereof and light chain or fragment thereof"

The Court finds that the term "recovering the heavy chain or fragment thereof and light chain or fragment thereof" should be construed according to its plain and ordinary meaning.

BMS proposes to add the words "separately" and "each of" to the claim term so that the claim would not include a heavy chain and a light chain recovered together. The meaning and uses of the term "and" are well known. "The word 'and' has multiple dictionary definitions. Webster's Third New International Dictionary defines 'and' to mean, inter alia: 'along with or together with' or 'as a function word to express . . . reference to either or both of two alternatives.'" *Ortho-McNeil Pharm. Inc. v. Mylan Labs., Inc.*, No. 04-cv-1689-SRC, 2005 WL 1683644, at *7 (D.N.J. July 18, 2005), aff'd, 520 F.3d 1358 (Fed. Cir. 2008) (quoting WEBSTER'S 3D NEW INTERNATIONAL DICTIONARY at 80 (Merriam-Webster 1993)). As a matter of plain English, the use of the term "and" is

therefore broad enough to encompass recovery of the chains both separately and together. No plain meaning of the term "and" would exclude recovery of the chains together.

BMS argues that, when read in the context of the specification and claims, the recovery of the chains must occur separately unless the claim specifies recovery of an assembled antibody. According to BMS, an antibody is not a heavy chain or a light chain, and therefore recovery of an antibody could neither be recovery of a heavy chain nor recovery of a light chain. Since the patentee knew how to claim an antibody as shown in Claims 38 and 39, BMS believes that claims describing recovery of a heavy and light chain must exclude recovery of antibodies. Furthermore, BMS argues that the overarching purpose of the invention was to allow novel assemblies of individual chains, which could not be done with recovered, assembled antibodies. *See* Cabilly III Patent at 12:58–63, 14:1–3, 14:24–36.

BMS's proposed construction is simply an attempt at reading in to the Cabilly III Patent a requirement that assembly of the antibody occur outside the cell (*in vitro*), and not inside the cell (*in vivo*). Limitations may not be read into the claim terms from the specification and prosecution history lightly. "Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of the claim language." *Home Diagnostics, Inc. v. Lifescan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004). The specification describes recovery of separate chains for *in vitro* assembly, but it also describes assembly of the chains *in vivo*. *See, e.g.*, Cabilly III Patent at 12:33–46. The fact that the specification contains only an embodiment for *in vitro* assembly does allow the Court to limit the claims to only that embodiment. *See Phillips*, 415 F.3d at 1323 ("In particular, we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.").

The comparison of claims directed to recovery of assembled antibodies and to recovery of the chains is inapt. Different claims are drafted to encompass different scopes, and the use of a more narrow term, "antibodies," does not preclude the term "the heavy chain or fragment thereof and light chain or fragment thereof" from encompassing both chains recovered separately and chains recovered together as part of a single assembly. Claim 33 says nothing about how or where the chains are recovered, and it is, therefore, broad enough to cover antibodies assembled *in vitro* and antibodies assembled *in vivo*.[5]

Consequently, the Court finds that the plain and ordinary meaning of this expression suffices for claim construction purposes.

VI. Conclusion

Claim Term	Claim Construction
"host cell"	"a cell whose heritable DNA has been or will be altered by the inclusion of foreign DNA; the term includes the progeny of the originally transformed cell"
"transformed"	plain and ordinary meaning; does not require a separate step of transforming
"recovering the heavy chain or fragment thereof and light chain or fragment thereof"	plain and ordinary meaning; no construction necessary

[5] Genentech deftly points out the difficulty inherent in BMS's argument: an antibody is a molecule composed of a heavy chain and a light chain, and recovering an antibody therefore encompasses recovery of the heavy and light chains that make up the antibody. BMS acknowledged in its briefing that an antibody "is an assemblage of heavy chains and light chains (two of each) in a specific, Y-shaped configuration" and admitted that Yervoy's and Erbitux's "respective heavy and light chains are recovered after they are assembled into an antibody." *See* BMS's Response to Genentech's Opening Brief on Claim Construction, 12–13 (Dkt. No. 106).

IT IS SO ORDERED.

DATED: April 18, 2014

Hon. Mariana R. Pfaelzer
United States District Judge