UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

YEDA RESEARCH AND DEVELOPMENT CO., LTD.,	)	
Plaintiff,	)	
v.	)	**Civil Action No. 10-1836 (RMC)**
ABBOTT GMBH & CO. KG,	)	
Defendant.	)	

OPINION

What does it take to disclose a protein sufficiently so that it can be patented? After 20 years of litigation, the parties are still arguing about it. Abbott GMBH & Co. KG and Yeda Research and Development Co. Ltd. claim competing U.S. patent applications, each based on an earlier-filed foreign patent application. Abbott's application to patent the TBP-II protein was filed in Germany on May 9, 1989. Yeda filed its application to patent the TBP-II protein nine days later, on May 18, 1989 in Israel. From that few days' difference in time fortunes might be made. Yeda has been arguing since April 5, 1995 that Abbott's application was incomplete and infirm, while its own application more fully identified the TBP-II protein and is entitled to priority and U.S. patent protection for the next 17 years. Abbott's patent has since expired. Here, Yeda raises serious issues.

The current focus is a May 26, 2010 opinion by the Board of Patent Appeals and Interferences that granted Abbott the benefit of the earlier filing date of its first German application. After thorough consideration of the full administrative record,[1] the parties' briefs

[1] The administrative record (AR) before the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences in Interference No. 103,625 has been filed in five parts: Part 1 of 5,

and accompanying exhibits, and with the benefit of excellent oral argument, the Court will grant Abbott's motion for summary judgment and deny Yeda's motions for summary judgment.

I. OVERVIEW

As stated by the Board of Patent Appeals and Interferences (Board)[2] in 2010, "This is an old interference," *i.e.*, a claim by one inventor that another has interfered with his invention and the claimant was the first to invent. Administrative Record (AR) [Dkt 89-4] (5/26/10 Board Decision[3]) at 5961.[4] The interference in this case resulted when Yeda asserted that its inventors were the first to disclose a protein[5] called the Tumor Necrosis Factor Binding

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Dkt. 89, includes documents #4541-5088; Part 2 of 5, Dkt. 89-1, includes documents #5089-5358; Part 3 of 5, Dkt. 89-2, includes documents #5359-5633; Part 4 of 5, Dkt. 89-3, includes documents #5634-5931; Part 5 of 5, Dkt. 89-4, includes documents #5932-6196. The interference record was deemed admitted into evidence upon filing. *See* Minute Entry Order dated 10/02/2013.

[2] Effective September 16, 2011, the Leahy–Smith America Invents Act (AIA) changed the name of this entity from the "Board of Patent Appeals and Interferences" to the "Patent Trial and Appeal Board." Pub. L. No. 112–29, 125 Stat. 284. This litigation precedes the AIA.

[3] The entire 5/26/10 Board Decision is located at AR 5960-6005.

[4] The complex facts of this case and its procedural history are set forth in detail in prior opinions of this Court and the United States Court of Appeals for the Federal Circuit. *See Abbott GmbH & Co., KG v. Yeda Research & Dev. Co.* (*Abbott I*), Civ. No. 00-1720 (RMU), Mem. Op. (D.D.C., filed June 13, 2005) (denying Yeda's motion for summary judgment); *Abbott GmbH & Co., KG v. Yeda Research & Dev. Co.* (*Abbott II*), 516 F. Supp. 2d 1 (D.D.C. 2007) (construing U.S. Patent 5,344,915 ('915 Patent"); *Abbott GmbH & Co., KG v. Yeda Research & Dev. Co.* (*Abbott III*), 576 F. Supp. 2d 44 (D.D.C. 2008) (granting Abbott's motion for summary judgment); *Abbott GmbH & Co., KG v. Yeda Research & Dev. Co.* (*Abbott IV*), 333 F. App'x 524 (Fed. Cir. 2009) (dismissing Yeda's appeal for lack of jurisdiction); *Abbott GmbH & Co., KG v. Yeda Research & Dev. Co.*, (*Abbott V*), 415 F. App'x 257 (Fed. Cir. 2011) (dismissing Yeda's second appeal for lack of jurisdiction); *Yeda Research & Dev. Co. v. Abbott GmbH & Co.. KG* (*Yeda I*); Civ. No. 10-1836 (RMC), Op. (D.D.C., filed June 7, 2013 (Sealed Version) & June 18, 2013 (Redacted Version) (granting, in part, Abbott's motion to compel documents from Yeda's expert).

[5] "[P]roteins are long chains of amino acids like beads on a string. . . . The chain begins at the N-terminus, the location of an amino group to which all other amino acids are sequentially

Protein-II[6] (TBP-II) claimed by Abbott in U.S. Patent No. 5,344,915 (the '915 Patent"). TBP-II was "isolated from the urine of individuals with a fever and from the ascites fluid of individuals with ovarian carcinomas." *Abbott III*, 576 F. Supp. 2d at 46. TBP-II "binds to, and thereby neutralizes, potentially harmful polypeptides." *Id.* at 45.

To prove its priority before the Board and this Court, Abbott relies on application P39 15 072 ('072 Application) to patent TBP-II in Germany, filed on May 9, 1989 by Hans-George LeMaire and three co-inventors, Abbott's predecessors.[7] Thereafter, on July 15, 1989, Abbott filed application P39 22 089 ('089 Application) in Germany covering the same protein. On May 4, 1990, Abbott filed an International Patent Application (later designated as a U.S. patent application) claiming the benefit of the filing date of the '072 Application. On September 6, 1994, the U.S. application matured into the '915 Patent. As described by the Board:

> This proceeding had its genesis when Yeda requested an interference with Abbott's ['915] patent. Application 07/930,443, Miscellaneous Incoming Letter, filed April 5, 1995. An examiner requested Yeda to make a claim for the purpose of interference. Miscellaneous Office Action, mailed May 15, 1995. Yeda responded by submitting its Claim 67. Application 07/930,443, Amendment filed May 24, 1995. After some additional prosecution,

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attached. . . . Because a protein can be made up of a very long sequence of amino acids, scientists identify each protein by listing the sequence of amino acids beginning at the N-terminus. . . . [T]he [915 P]atent describes the TBP-II protein by listing 22 of the amino acids located at the N-terminus." *Abbott III*, 576 F. Supp. 2d at 46 (citing *In re O'Farrell*, 853 F.2d 894, 895–99 (Fed. Cir. 1988)).

[6] Tumor necrosis factor "is a known protein which has a broad spectrum of biological activities. It influences various malignant and non-malignant cell types, plays a part in septic shock and tissue injuries and in kidney rejections, transplantations, shock lung and cerebral malaria." Abbott Mot. for Summ. J., Ex. M [Dkt. 70-16] ('072 Application).

[7] The patent applications discussed here were filed by groups of scientists and predecessor companies that owned the rights to the patents. Because none of these facts is in dispute or material to the instant matter, the Court will refer to the patent applications and patents as having been filed by or granted to Yeda or Abbott.

the examiner recommended that an interference be declared. Form 850, attachment to Paper 1.

This interference was declared with Yeda designated as the senior party. Paper 2, p.1. Yeda was accorded the benefit of the filing dates of four earlier applications. The earliest was an Israeli application filed May 18, 1989. Paper 1, Appendix, numbered p.1. Abbott was accorded the benefit of the May 4, 1990, filing date of [the International Patent Application].

During the interference, Yeda filed a . . . motion asserting that all of Abbott's claims were unpatentable over certain prior art. Paper 21. Abbott opposed the motion arguing that its claimed subject matter was entitled to the benefit of the filing dates of two German applications under 35 U.S.C. § 119 – Applications P 39 22 089 (089) and P 39 15 072 (072). The filing dates of both applications preceded the date of [the prior art] reference. Abbott argued that because it was entitled to benefit [from the application dates for the '072 Application and the '089 Application], the reference was not prior art to its claims.

A panel of the Board held that Abbott had not established entitlement to the filing dates of the German applications and that its claims were unpatentable over the prior art. In particular, the panel held that the German applications do not have written descriptive support for the subject matter claimed. Since Abbott did not have any patentable claims, the panel entered judgment against Abbott. Paper 105. The other preliminary motions filed by the parties were considered moot and left undecided.

On July 21, 2000, Abbott sought judicial review of the board's decision under 35 U.S.C. § 146. Paper 107. Abbott reasserted entitlement to the filing date of the 089 application. Entitlement to the filing date of the 072 application was apparently not asserted in the district court.

On September 15, 2008, the district court held that Abbott's claimed subject matter was described in the 089 application, vacated the panel's decision of unpatentability, and remanded the interference to the board. Paper 110. Yeda's appeal to the Court of Appeals for the Federal Circuit was dismissed for lack of jurisdiction on May 29, 2009. Paper 115.

See 5/26/10 Board Decision [Dkt. 89-4] AR at 5961-62. After remand in 2008, the Board granted Abbott the benefit of the May 9, 1989 filing date of German Application P 39 15 072 ('072 Application), giving it priority over Yeda. *Id.* at 5963.

This appeal followed. It has its own intricate history, which need not be detailed. During the course of the immediate proceedings, the parties have engaged in discovery, which has amplified the record from that before the Board. In the interim, the Federal Circuit determined that parties can introduce new evidence before the district court in a § 146 interference action, regardless of whether the issue or evidence was presented to the Board. *See Troy v. Samson Mfg'g Corp.*, 758 F.3d 1322, 1325 (Fed. Cir. 2014) (*reh'g denied*) ("We conclude that the Supreme Court's decision in [*Kappos v. Hyatt*, 132 S.Ct. 1690, 1694, 1700 (2012)] permits new evidence to be admitted without regard to whether the issue was raised before the Board. The Supreme Court held, without qualification, that 'there are no evidentiary restrictions beyond those already imposed by the Federal Rules of Evidence and the Federal Rules of Civil Procedure.'") Yeda seeks to introduce evidence produced from Abbott in discovery in this case and to obtain a claim construction on a new term. With some legitimacy, Abbott argues that the Federal Rules of Procedure bar Yeda's late evidence. Nonetheless, to provide a complete record for appeal, this Court has considered all of the evidence and arguments submitted by both parties.

II. PATENT AND INTERFERENCE BACKGROUND

Under long-standing U.S. patent law, the "*first person to conceive the invention is the first inventor*, . . . provided that when the first to conceive the invention is the last to reduce it to practice, the person who was first to conceive must have exercised reasonable diligence to his own actual or constructive reduction to practice, 'from a time prior to conception by the other.'"

Hyatt v. Boone, 146 F.3d 1348, 1351 (Fed. Cir. 1998) (quoting 35 U.S.C. § 102(g) prior to 2011 amendment; other citations omitted) (emphasis added).

As a consequence of the principle that the first to invent is granted the patent, "there must be a mechanism for determining who among multiple patent applicants . . . was the first to invent the claimed subject matter." *Cytologic, Inc. v. Biopheresis GmbH*, 682 F. Supp. 2d 1, 4 (D.D.C. 2010). For this purpose, 35 U.S.C. § 135 specifically provided for "Interferences," a "proceeding [] principally declared to permit a determination of priority." *Minnesota Mining and Mfg. Co. v. Norton Co.*, 929 F.2d 670, 674 (Fed. Cir. 1991). As is the case here, a patent applicant may suggest an interference. *See* 37 C.F.R. § 41.203. If the Director of the United States Patent and Trademark Office (USPTO) decides that an interference is warranted, *i.e.*, that "an application is made for a patent which . . . would interfere with any pending application, or with any unexpired patent," he may declare an interference. 35 U.S.C. § 135. The Board "determine[d] questions of priority of the inventions." *Id*.

In 2013, the United States moved to a "first to file" system. *See* 35 U.S.C. § 102; *see also* Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011). While not applicable to this long-standing dispute, the critical change to the rules of priority must be noted. The AIA obviated patent interferences. *See* AIA § 3(i). Pursuant to AIA § 3(n)(2)(A), this interference remains governed by the laws in effect at the relevant time.

III. FACTS

Plaintiff Yeda Research & Development Co., Ltd. (Yeda) is an Israeli company; Abbott GmbH & Co. KG (Abbott) is a German subsidiary of Abbott Laboratories, Inc., which is based in Illinois. Compl. [Dkt. 1] ¶¶ 3, 6–7.

A. Abbott's German Patent Applications and the '915 Patent

Abbott filed application P39 15 072 on May 9, 1989 ('072 Application) in Germany to cover a "novel protein found in certain biological fluids." Abbott Mot. for Summ. J. [Dkt. 70] (Abbott Mot.) at 5; *id.*, Ex. M [Dkt. 70-16] ('072 Application).[8] Abbott filed a second patent application in Germany, P39 22 089 ('089 Application) on July 15, 1989. *See id.*, Ex. K [Dkt. 70-14] ('089 Application). On May 4, 1990, Abbott filed an International Patent Application, "claiming the benefit of the filing date of [the '072 Application];" the International Patent Application was eventually designated as a U.S. Patent Application, and the USPTO issued U.S. Patent No. 5,344,915 ('915 Patent) to Abbott on September 6, 1994. Compl. ¶¶ 8–10; *see also* Abbott Mot., Ex. A [Dkt. 70-4] ('915 Patent).

1. '072 Application

The '072 Application described a novel protein as having the following characteristics: (1) a molecular weight of about 42 kilodaltons (kDa); (2) the specific biological property of inhibiting the cytotoxicity of TNF[9] alpha; (3) found in the urine of febrile patients; and (4) not digestible by trypsin. *See* '072 Application at 2. The '072 Application identified the following partial amino acid sequence at the N-terminus of the claimed protein: "XTX^{1}YX^{2}X^{3}EX^{4}GSX^{5}X^{6}RLR where X is oxygen, a phenylalanine radical (Phe) or the amino acid sequence X^{7}X^{8}PheQX^{9}X^{10}." *Id.* Each of X^1-X^{10} "denote[s] not yet determined amino acids." *Id.* at 3. The '072 Application identified three main sequences; Sequence 1: F T X^1 Y X^2 X^3 E X^4 G S X^5 X^6 R L R; Sequence 2: X^7 X^8 F Q W^9 X^{10} F T X^1 Y X^2 X^3 E X^4 G S X^5 X^6 R L R; and Sequence 3: T X^1 Y X^2 X^3 E X^4 G S X^5 X^6 R L R. *Id.* at 8. The '072 Application suggested

[8] The application has been translated from German.

[9] TNF and TNFα are abbreviations for the protein Tumor Necrosis Factor. *See* Abbott Mot. at 6. When produced in excess by the body, TNFα causes numerous immunological diseases. *Id.*

probable identities for several of the amino acids that had not been definitely identified at the time of filing. *Id*.

Example 2 of the ’072 Application described a protocol for isolating the protein from the urine of patients with fever, which included the following elements: (1) collecting 40 liters of urine from patients with fever by (a) filtering the urine through a “Hemoflow F60” cartridge, and then (b) subjecting the “retentate” (what was retained on and then collected from the cartridge) to the following multi-step column-chromatography protocol: (i) “S-Sepharose” column chromatography; (ii) “TNF-affinity” column chromatography; and (iii) “Mono-Q” column chromatography. *Id*. at 4-5.

2. ’915 Patent

The ’915 Patent described a novel protein having the following characteristics: (1) a molecular weight of about 42 kilodaltons (kDa); (2) the specific biological property of inhibiting the cytotoxicity of TNF alpha; (3) found in the urine of febrile patients; and (4) digestible by trypsin with difficulty or not at all. *See* ’915 Patent at 2. Example 2 of the ’915 Patent discloses the same protocol to isolate the protein as the ’072 Application. *Compare* ’915 Patent at 2-3 [Dkt. 70-4] *with* ’072 Application at 4-5 [Dkt. 70-16].

The ’915 Patent identified the following amino acid sequence at the N-terminus of the claimed protein:

’915 PATENT (COUNT 2)

Seq. 1								Thr	Pro	Tyr	Ala	Pro	Glu	Pro	Gly	Ser	Thr	Cys	Arg	Leu	Arg	Glu
Seq. 2							Phe	Thr	Pro	Tyr	Ala	Pro	Glu	Pro	Gly	Ser	Thr	Cys	Arg	Leu	Arg	Glu
Seq. 3						Ala	Phe	Thr	Pro	Tyr	Ala	Pro	Glu	Pro	Gly	Ser	Thr	Cys	Arg	Leu	Arg	Glu
Seq. 4					Val	Ala	Phe	Thr	Pro	Tyr	Ala	Pro	Glu	Pro	Gly	Ser	Thr	Cys	Arg	Leu	Arg	Glu
Seq. 5				Gln	Val	Ala	Phe	Thr	Pro	Tyr	Ala	Pro	Glu	Pro	Gly	Ser	Thr	Cys	Arg	Leu	Arg	Glu
Seq. 6			Ala	Gln	Val	Ala	Phe	Thr	Pro	Tyr	Ala	Pro	Glu	Pro	Gly	Ser	Thr	Cys	Arg	Leu	Arg	Glu
Seq. 7		Pro	Ala	Gln	Val	Ala	Phe	Thr	Pro	Tyr	Ala	Pro	Glu	Pro	Gly	Ser	Thr	Cys	Arg	Leu	Arg	Glu
Seq. 8	Leu	Pro	Ala	Gln	Val	Ala	Phe	Thr	Pro	Tyr	Ala	Pro	Glu	Pro	Gly	Ser	Thr	Cys	Arg	Leu	Arg	Glu

Abbott Mot., Appendix I.

Below is a comparison of Sequence 1 of the ’072 Application with Sequence 2 of the ’915 Patent:

	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
’072	Phe	Thr	X^1	Tyr	X^2	X^3	Glu	X^4	Gly	Ser	X^5	X^6	Arg	Leu	Arg	
’915	Phe	Thr	Pro	Tyr	Ala	Pro	Glu	Pro	Gly	Ser	Thr	Cys	Arg	Leu	Arg	Glu

Abbott Mot. at 18; *see also id*., Appendix I.

B. Yeda’s Patent Applications

On May 18, 1989, Yeda filed application No. 90,339 (’339 Application) in Israel for a patent covering the TBP-II protein.[10] *See* Abbott Mot., Ex. AA [Dkt. 70-30] (’339 Application). Yeda disclosed an N-terminal sequence consisting of 13 amino acids in its longest sequence. *See* Abbott Mot. at 10. Below is a comparison of the longest sequence disclosed in Yeda’s ’339 Application with the nine amino acids disclosed in Abbott’s ’072 Application:

	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
’339	Val	Ala	Phe	Thr	Pro	Tyr	Ala	Pro	Glu	Pro	Gly	Ser	Thr				
’072			Phe	Thr	X^1	Tyr	X^2	X^3	Glu	X^4	Gly	Ser	X^5	X^6	Arg	Leu	Arg

Abbott Mot. at 10. Asserting the benefit of the ’339 Application, Yeda filed U.S. Patent Application No. 07/930,443 (’443 Application) on August 19, 1992 to claim the TBP-II protein. Compl. ¶ 12; *see also* Abbott Mot., Ex. B [Dkt. 70-5] (’443 Application).

[10] Yeda filed two additional applications in Israel (91229 on August 6, 1989 and 94039 on April 6, 1990).

C. Engelmann Paper

On January 16, 1990, the *Journal of Biological Chemistry* published a paper by Dr. Hartmut Engelmann *et al*. titled, "Two Tumor Necrosis Factor-Binding Proteins Purified from Human Urine." *See* Abbott Mot., Ex. C [Dkt. 70-6] (Engelmann Reference). Dr. Engelmann is one of the named inventors on Yeda's '443 Application. The Engelmann Reference described the identification of the TBP-II protein, including the identification of an N-terminal sequence consisting of five amino acids. *Id*. at 1. The authors relied on that short amino acid sequence along with other characteristics and data to identify the TBP-II protein. *Id*. 1, 4-6. There was agreement in the scientific community that the data cited in the Engelmann Reference showing that the scientists had identified a new TNFα-binding protein. *See, e.g*., Heller *et al.*, Proc. Natl. Acad. Sci. USA 87, 6151-6155 (1990) ("The result is compatible with the sequence Val-Ala-Phe-Thr-Pro found in the recently published urinary TNF-binding protein II, which was also reported to be variable at the amino terminus."); Loetscher *et al.*, J. Bio. Chem. 265:33, 20131, 20137 (1990) (". . . a short amino acid sequence of a second TNF inhibitory protein has recently been reported"); Lewis *et al.*, Proc. Natl. Acad. Sci. USA. 88: 2830-2834 (April 1991) ("Recently two immunologically distinct cell-surface-associated TNF-binding proteins of 55-kDa and 75-kDa were identified.").

Below is a comparison of the five amino acid sequence disclosed in the Engelmann Reference compared with the nine amino acid sequence disclosed in the '072 Application and the fifteen amino acid sequence disclosed in the '915 Patent:

	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
Engelmann	Val	Ala	Phe	Thr	Pro													
'072			Phe	Thr	X^1	Tyr	X^2	X^3	Glu	X^4	Gly	Ser	X^5	X^6	Arg	Leu	Arg	
'915			Phe	Thr	Pro	Tyr	Ala	Pro	Glu	Pro	Gly	Ser	Thr	Cys	Arg	Leu	Arg	Glu

Abbott Mot. at 11; *see also id*., Appendix III.

D. The 2003 Abbott Experiments

In response to Yeda's claims, Abbott conducted a set of experiments in 2003 to demonstrate the validity of the protocol in the '072 Application (2003 Experiments). *See* Abbott Mot., Ex. F [Dkt. 70-9] (Bradshaw Report) ¶¶ 40-52. There were two stages to the 2003 Experiments. The first took place in Ludwigshafen, Germany, and the second took place in Abbott Park, Illinois. During the 2003 Experiments, Abbott scientists repeated the protocol in Example 2 of the '072 Application to demonstrate "that Abbott's first patent application describes and enables the subject matter of the Count." Abbott Mot. at 3. Yeda retained Dr. Engelmann to observe the first phase in Germany, and it retained Dr. Menachem Rubinstein (another of the inventors named on Yeda's '443 Application) to observe the second phase in the United States. Bradshaw Report ¶¶ 41, 45.

During the first stage, in a laboratory in Germany on February 3 through 7, 2003, Andreas Striebinger, one of Abbott's scientists, performed the protocol from Example 2 in the '072 Application. *Id*. ¶ 41. Present and observing the first phase were Dr. Bradshaw for Abbott and Dr. Engelmann for Yeda. *Id*. The first phase yielded two fractions of "essentially homogenous protein," which Abbott then sent to Abbott Park "for an analysis of the N-terminal amino acid sequence using automated Edman sequencing techniques." Bradshaw Report. ¶¶ 42, 44. In lay terms, in Germany Abbott attempted to isolate the TBP-II protein; in the United States it sought to determine the composition of the sample.

The second stage of the 2003 Experiments took place on March 3 through 5, 2003, in Abbott Park, Illinois. Abbott scientist Dr. Thomas Holzman and his assistant, Sally Dorwin, performed the Edman degradation. *Id*. ¶ 45. Also present for the second phase were Dr. Bradshaw for Abbott and Dr. Rubinstein for Yeda. *Id*.

The parties characterize the results of the two phases differently. Abbott states that "the 2003 experiments resulted in a purified and isolated protein that could be definitively identified as the TBP-II protein based on (among other characteristics) its molecular weight, its method of purification, its biological activity, and its N-terminal sequence." Abbott Mot. at 14. Yeda states that the 2003 Experiments "did not result in a purified and isolated TBP-II protein as defined by the Count . . . [because] the data does not permit the identification of anything close to one of the complete amino-acid sequences recited in the Count." Yeda Response to Abbott Statement of Undisputed Facts [Dkt. 81-2] (Response to Abbott Facts) at 36.

IV. PROCEDURAL HISTORY

A. Interference before the Board

On October 1, 1996, the Board declared Interference No. 103,625 ('625 Interference) between Abbott's '915 Patent and Yeda's '443 Application. Compl. ¶ 14. The subject matter of the Interference was set forth in subsections (b) and (c) of the re-declared Count 2 (Count), which correspond to claims in the '915 Patent:

> (b) A purified and isolated TNFα-binding protein which has a molecular weight of about 42,000 daltons and has at the N terminus the amino acid sequence
> Xaa-Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr-Cys-Arg-Leu-Arg-Glu
> where Xaa is hydrogen, a phenylalanine residue (Phe) or
> the amino acid sequences
> Ala Phe,
> Val Ala Phe,
> Gln Val Ala Phe,
> Ala Gln Val Ala Phe,
> Pro Ala Gln Val Ala Phe or
> Leu Pro Ala Gln Val Ala Phe.
>
> or
>
> (c) A process for the preparation of a protein which has a molecular weight of about 42,000 daltons and has at the N terminus the amino acid sequence

> Xaa Thr Pro Tyr Ala Pro Glu Pro Gly Set Thr Cys Arg Leu Arg Glu
> where Xaa is hydrogen, a phenylalanine residue (Phe) or
> the amino acid sequences
> Ala-Phe,
> Val-Al a-Phe,
> Gln-Val-Ala-Phe,
> Ala-Gln-Val-Ala-Phe,
> Pro-Ala-Gln-Val-Ala-Phe or
> Leu-Pro-Ala-GlnVal-Ala-Phe
> which comprises concentration of the urine of patients with fever and subsequent purification of the retentate obtained in this way by ion exchange and affinity chromatography.

AR at 6007-08 (Board Redeclaration).[11] Parts (b) and (c) of the Count, which correspond to claims in Abbott's '915 Patent, require that the protein contain one of the following N-terminal amino acid sequences:

Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr-Cys-Arg-Leu-Arg-Glu
Phe-Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr-Cys-Arg-Leu-Arg-Glu
Ala-Phe-Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr-Cys-Arg-Leu-Arg-Glu
Val-Ala-Phe-Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr-Cys-Arg-Leu-Arg-Glu
Gln-Val-Ala-Phe-Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr-Cys-Arg-Leu-Arg-Glu
Ala-Gln-Val-Ala-Phe-Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr-Cys-Arg-Leu-Arg-Glu
Pro-Ala-Gln-Val-Ala-Phe-Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr-Cys-Arg-Leu-Arg-Glu
Leu-Pro-Ala-Gln-Val-Ala-Phe-Thr-Pro-Tyr-Ala-Pro-Glu-Pro-Gly-Ser-Thr-Cys-Arg-Leu-Arg-Glu

Id.

Yeda prevailed in the '625 Interference, arguing that the Engelmann Reference was a prior art publication that invalidated the claims of the '915 Patent because Abbott had not established entitlement to the filing dates of the '072 and '089 Applications. The Board invalidated Abbott's '915 Patent and found that Abbott was not entitled to priority. *See Abbott III*, 576 F. Supp. 2d at 47. The Board reasoned that the '072 and '089 Applications did not, "as originally filed," sufficiently describe the TBP-II protein, *id.*, and that Abbott "failed to

[11] Part (a) of the Count corresponds to a claim in Yeda's '443 application and is not relevant to the instant dispute.

effectively remove Engelmann as prior art," Abbott Mot., Ex. D [Dkt. 70-7] (First '625 Interference Decision) at 19. Abbott sought review of the Board's decision in this Court under 35 U.S.C. § 146, in case Civil No. 00-1720.[12]

B. Initial District Court Litigation

The case was assigned to the Honorable Ricardo Urbina. In 2005, Judge Urbina denied Yeda's motion for summary judgment, rejecting its argument that Abbott's '089 Application did not adequately describe the '915 Patent as a matter of law. *See Abbott I* at *7. Two years later, Judge Urbina construed the '915 Patent, adopting Abbott's proposed construction, and concluding that the "['915] Patent covers only the TBP-II protein" but not its "naturally occurring muteins." *See Abbott II*, 516 F. Supp. 2d at 6. After construing the single term in the '915 Patent requested by the parties, Judge Urbina found the evidence underlying the Board's decision in the '625 Interference "wholly unsupportive" of the Board's conclusion. *See Abbott III*, 576 F. Supp. 2d at 51. He found that the Board had committed clear error in invalidating the '915 Patent. *Id*. at 46. Specifically, Judge Urbina rejected the Board's conclusions that the '089 application did not inherently disclose the TBP-II protein and that the '089 application did not provide an adequate written description because it could describe either

[12] 35 U.S.C. § 146 provides, in relevant part, that "[a]ny party to an interference dissatisfied with the decision of the [Board] on the interference, may have remedy by civil action." 35 U.S.C. § 146. An action under section 146 "may be instituted against the party in interest as shown by the records of the [USPTO] at the time of the decision complained of, but any party in interest may become a party to the action. . . . Judgment of the court in favor of the right of an applicant to a patent shall authorize the Director [of the USPTO] to issue such patent on the filing in the [USPTO] of a certified copy of the judgment and on compliance with the requirements of law." *Id*. "District court review of an interference proceeding under Section 146 is an equitable remedy of long standing," and a Section 146 action is "an authorized phase of the interference proceeding" before the USPTO. *Abbott GMBH & Co., KG v. Centocor Ortho Biotech, Inc.*, 870 F. Supp. 2d 206, 212–13 (D. Mass. 2012) (quoting *Gen. Instrument Corp. v. Scientific–Atlanta, Inc.*, 995 F.2d 209, 214 (Fed. Cir. 1993) & *Vas-Cath, Inc. v. Curators of the Univ. of Mo.*, 473 F.3d 1376, 1382 (Fed. Cir. 2007)).

the TBP-I or TBP-II protein. *Id*. at 50-51. Judge Urbina found that (a) the '089 application, '915 Patent, and Engelmann Reference "provide entirely consistent descriptions of the TBP-II protein albeit with varying levels of specificity;" and (b) the "majority of the known amino acids set forth in the 072 application match the amino acids designated in the 089 application" and '915 Patent. *Id*. at 50. Judge Urbina granted summary judgment to Abbott and remanded the case to the Board for further proceedings. *See* Order, Civ. No. 00-1720 (RMU) (D.D.C. Sept. 15, 2008) (Dkt. 117). Yeda appealed to the Federal Circuit, which dismissed the appeal. *See Abbott IV*, 333 F. App'x at 525 ("Since the district court remanded the case for the Board to determine priority, the case is not final; the issue of patentability can be reviewed on appeal from a final judgment resolving all issues.").

C. On Remand

On remand, the primary issue was whether Abbott's '072 Application was a constructive reduction to practice of the Count, which required Abbott to prove by a preponderance of the evidence that the '072 Application "describes and enables at least an embodiment meeting all the limitations of the [C]ount." 5/26/10 Board Decision at 5968-89, 5971 (citing *Frzer v. Schlegel*, 498 F.3d 1283 (Fed. Cir. 2007)). Before the Board, Abbott argued that the "N-terminal sequences are inherent in the proteins obtained as described in the '072" Application so that it did not need to identify a full sequence to recognize the TBP-II protein. *Id*. at 5965. Yeda maintained that Abbott did not submit sufficient evidence of discovery. The Board noted that Abbott's burden was to "show that it is more likely true than not that the necessary and only reasonable construction of the 072 application is that the proteins are the same." *Id*. at 5970. The Board compared the disclosures contained in the '072 Application with the '915 Patent and found that

> they describe (1) the same source of the protein—urine from patients with a fever, (2) the same method of isolating and purifying the protein from the urine—the use of a TNF affinity column, (3) the same amount of protein obtained . . . per liter of urine, (4) the use of the same technique to determine the molecular weight and purity of the protein—15% SDS gel electrophoresis, (5) obtaining a protein that has a molecular weight of about 42,000 daltons with a purity of about 90%, (6) recovered a protein that does not degrade when exposed to trypsin and (7) a protein that binds TNFα. Additionally, the N-terminal sequences of the protein of 072 [Application] are consistent with the N-terminal sequences disclosed in the 915 patent.

Id. In light of these similarities, the Board concluded that the '072 Application and the '915 Patent "describe the same proteins." *Id*.

The Board evaluated Yeda's central argument that the '072 Application did not meet the written description or enablement requirements of 35 U.S.C. § 112. *Id*. at 5971. Yeda argued that "a correct sequence, at least at the N-terminal, is critical in order to adequately identify and fingerprint the [TBP-II] protein as being something different from other proteins of about the same molecular weight and activity, and obtained from the same source." *Id*. at 5973. The Board rejected Yeda's argument because "Abbott's motion [was] not based on the disclosure of 072 [Application] alone. Abbott relies upon a comparison of the 072 and 915 disclosures to show that the proteins are the same." *Id*. The Board reiterated its prior finding that the protein described in both applications is the same. *Id*. at 5973-74.[13] The Board rejected

[13] The Board states:

> Abbott relies upon a comparison of the 072 and 915 disclosures to show that the proteins described are the same. Abbott argues that 'the protein of the count of this interference is the same as the protein disclosed in [Abbott's] priority document P 39 15 072.' As detailed above, comparison of the 072 application and 915 patent reveals many more similarities than just the source, molecular weight, and binding activity to TNFα. The comparison additionally shows the same source of the protein, the same method of isolating, purifying, and determining the molecular weight of the protein, and obtaining

Yeda's argument that an enabling disclosure would have had to enable a skilled person to "immediately ascertain the N-terminal sequence of the protein at the time the 072 application was filed." *Id*. at 5975. Because amino acid sequencing is not the only way to identify a protein, the Board was satisfied that the '072 Application provided "sufficient information to enable the protein" because it "describes the protein by partial N-terminal sequences, its source, the method of making and purifying it, its molecular weight, amount recovered, purity, degradation characteristics in trypsin and its ability to bind TNFα." *Id*. Accordingly, on May 26, 2010, the Board granted judgment in the '625 Interference to Abbott, giving Abbott the benefit of the filing date of the '072 Application. *Id*. at 5980.

D. The Instant Litigation

Yeda filed a Complaint in the Northern District of Illinois on September 8, 2010 to obtain review of the May 26, 2010 Board Decision. That Court granted Abbott's motion to transfer the case to this District, where it was docketed as Civil No. 10-1836, before Judge Urbina. While discovery was under way, Judge Urbina retired and the case was reassigned to the undersigned.

V. LEGAL STANDARDS

A. Review of Board Decision under 35 U.S.C. § 146

A district court has authority to review a decision by the Board under 35 U.S.C. § 146. Questions of law are reviewed *de novo* and the Board's underlying factual determinations are reviewed for clear error. *See Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1348 (Fed.

> the same amount of protein having the same purity. The comparison also shows that the incomplete N-terminal sequences 1-3 in [the] 072 [Application] are reasonably consistent with the complete N-terminal sequences la-3a of [the] 915 [Patent].

5/26/10 Board Decision at 5973-74 (internal citations omitted).

Cir. 2000). If a district court accepts new evidence not previously before the Board, the proceedings become "a hybrid of an appeal and a trial de novo." *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 592 (Fed. Cir. 1997). In a hybrid case, the court is a *de novo* factfinder for issues on which the court accepts new evidence. *See Winner*, 202 F.3d at 1347-48.

B. Written Description, Enablement, and Best Mode under 35 U.S.C. § 112

"The filing of a patent application serves as conception and constructive reduction to practice of the subject matter described in the application." *Hyatt v. Boone,* 146 F.3d 1348. 1352 (Fed. Cir. 1998). As is argued here, "when the priority claim is based on subject matter disclosed in a foreign patent application whose filing date is properly claimed, . . . the foreign application has the same effect as if filed in the United States." *Frazer v. Schlegel*, 498 F.3d 1283, 1287 (Fed Cir. 2007) (citing 35 U.S.C. § 119(a), (e)(1)). Therefore, the invention disclosed in a foreign patent application "must be disclosed in the manner provided by the first paragraph of [35 U.S.C.] section 112." *Id.*

35 U.S.C. § 112 codifies the written description, enablement, and best mode requirements of a patent:

> [t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

A written description of the invention "is separate and distinct from the enablement requirement." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). To satisfy the written description requirement, "the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*." *Id*. (emphasis in the original).

Enablement requires that "the specification of a patent must teach those skilled in the art how to *make and use* the full scope of the claimed invention without 'undue experimentation.'" *ALZA Corp. v. Andrx Pharm. LLC*, 603 F.3d 935, 946 (Fed. Cir. 2010) (citing *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997)) (emphasis added). "Enablement is not precluded where a 'reasonable' amount of routine experimentation is required to practice a claimed invention, however, such experimentation must not be 'undue.'" *Id*. at 940 (citations omitted). "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). In *Wands*, the Federal Circuit set forth the factors that a district court may consider when determining if a disclosure requires undue experimentation:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. at 737.

The test for best mode is whether the "invention possessed a better mode than was described in the patent and . . . such better mode was intentionally concealed." *Ateliers de la Haute-Garonne v. Bruetje Automation USA, Inc.*, 717 F.3d 1351, 1356-57 (Fed. Cir. 2013). In the context of a priority claim, "one looks to the foreign application and its filing date to determine the adequacy of the best mode disclosure and not the filing date of the corresponding U.S. application." *Transco Prods. Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 558 (Fed. Cir. 1994).

C. Summary Judgment

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment shall be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *accord Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). Moreover, summary judgment is properly granted against a party who "after adequate time for discovery and upon motion . . . fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

The moving party bears the initial burden of "identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp.*, 477 U.S. at 323. In ruling on a motion for summary judgment, the court must draw all justifiable inferences in the nonmoving party's favor. *Anderson*, 477 U.S. at 255. A nonmoving party, however, must establish more than "the mere existence of a scintilla of evidence" in support of its position. *Id.* at 252. In addition, the nonmoving party may not rely solely on allegations or conclusory statements. *Greene v. Dalton*, 164 F.3d 671, 675 (D.C. Cir. 1999). If the evidence "is merely colorable, or is not significantly probative, summary judgment may be granted." *Anderson*, 477 U.S. at 249-50 (citations omitted). Summary judgment is properly granted against a party who "after adequate time for discovery and upon motion . . . fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322.

VI. ANALYSIS

Abbott filed for summary judgment, Dkt. 70, on the grounds that the Board of Patent Appeals and Interferences correctly determined that the ’072 Application met the written description and enablement requirements in 35 U.S.C. § 112. Yeda filed three separate motions for summary judgment, contending that the ’072 Application did not contain an adequate written description, Dkt. 71; that the ‘072 Application did not enable the invention defined by the Count in the ’915 Patent, Dkt 73; and that the ’072 Application did not disclose Abbott’s best mode of carrying out the invention, Dkt. 72.

Although somewhat reframed to support each of its motions for summary judgment, Yeda rests on the same alleged frailties of the ’072 Application: (1) the ’072 Application failed to disclose a complete amino acid sequence identified in the Count; (2) just before the ’072 Application was filed, Abbott scientists used different processes that were not disclosed in the ’072 Application to discover some of the TBP-II amino acids claimed in the ’072 Application; and (3) the ’072 Application failed to describe a process that would result in a “purified and isolated” TBP-II protein, as required by the Count. These arguments challenge the legitimacy of the ’072 Application as the parent of the ’915 Patent.[14]

A. Written Description in ’072 Application

Yeda has repeatedly argued that Abbott’s ’072 Application is infirm because it did not disclose any of the “complete N terminal amino acid sequences recited in the [C]ount.”

[14] The Court has jurisdiction over this case under 28 U.S.C. §§ 1331, 1338(a) and 35 U.S.C § 146 because Abbott and Yeda are parties “to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference.” 35 U.S.C § 146. Venue is proper in this district under 28 U.S.C § 1391(b)(3) because this Court has personal jurisdiction over the parties. *See* 35 U.S.C § 146 (providing that “[i]f there be adverse parties residing in a plurality of districts not embraced within the same state, or an adverse party residing in a foreign country, the United States District Court for the District of Columbia shall have jurisdiction.”).

See, e.g., Yeda Mot. for Summ. J. on Written Description [Dkt. 71] (Yeda Mot. re: Description) at 10; *see also* 5/26/10 Board Decision at 5972-73 ("Yeda argues that the 072 application neither provides a written description nor enables the subject matter of the count. Yeda's argument focuses on the failure of 072 [Application] to disclose the complete N-terminal sequences of the count."). The facts are not in contention: the '072 Application correctly identified nine[15] amino acids at the N-terminal of the TBP-II protein. Parts (b) and (c) of the Count (from the '915 Patent) disclose eight complete N-terminal amino acid sequences, the shortest of which contains 15 amino acids and the longest of which contains 22 amino acids. The real question is whether Abbott's admitted failure to identify any of the complete amino acid sequences recited in the Count is fatal.

Yeda advances three arguments concerning the amino acid sequences disclosed in the '072 Application: first, that the '072 Application does not satisfy the express limitations of the Count because it does not explicitly include at least one of the complete N-terminal amino acid sequences recited in the Count; second, that Abbott cannot rely on the doctrine of inherent disclosure because all of the amino-acid-sequence limitations in the Count are material to the patentability of Abbott's claims; and third, that a person of ordinary skill would not have

[15] Depending on the context, the parties assert that the '072 Application identified between eight and eleven amino acids of the TBP-II protein. Yeda disputes Abbott's assertion that the '072 Application identified a total of 11 unambiguous amino acids and claims that it only unambiguously identified 10 amino acids. *See* Response to Abbott Facts at 15. One of Abbott's central arguments is that "the N-terminal amino sequence of the nine amino acids specified in Sequence 1 of the '072 Application is characteristic of *one and only one normal protein*—the normal TBP-II protein." Abbott Mot. at 8. Both parties agree that a comparison of Sequence 1 of the '072 Application with Sequence 2 of the Count shows that the '072 Application unambiguously identified nine amino acids of the TBP-II protein in the first sequence. Appendix I to Response to Abbott Facts; *see also* Response to Yeda Statement of Facts re: Written Description [Dkt. 82-1] at 4. The Court will refer to the '072 Application as disclosing nine amino acids of the TBP-II protein.

understood, at the time the ’072 Application was filed, that the specification disclosed any complete amino acid sequence disclosed in the Count.

Yeda quotes *Hyatt v. Boone*, 146 F.3d 1348, 1354-55 (Fed. Cir. 1998), as its basic support: “the written description must include all of the limitations of the interference count, or the applicant must show that any absent text is necessarily comprehended in the description provided and would have been so understood at the time the patent was filed.” *Hyatt* also instructs that “when an explicit limitation in an interference count is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation.” *Id.* at 1353. *See also Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) (“Put another way, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims.”).

Yeda’s “first step” in furtherance of the *Hyatt* analysis is its contention that “you can’t really define the invention properly without [identifying] all 22 [amino acids.]” Oral Arg. Tr. I [Dkt. 94] at 18-19. In the alternative, Yeda argues that the ’072 Application is fatally flawed because it failed to identify, at the least, “the shortest [sequence] at the top, which I believe is 15 amino acids.” *Id.* at 19.

Despite Yeda’s adherence to its argument, it is clear that the identification of every amino acid in a sequence is not always necessary before it can be determined that a new protein has been identified. The Federal Circuit most recently made this point clear when it adopted the Board’s findings in *Sanofi-Aventis v. Pfizer Inc.*, 733 F.3d 1364 (Fed. Cir. 2013). *Sanofi-Aventis* was an interference in which Pfizer claimed priority of invention of a “DNA polynucleotide that encodes the protein binding chain of the IL-13 receptor.” *Id*. at 1366. The

Circuit noted the unremarkable fact that, under "applicable law [pre-AIA], the patent is awarded to the first party to conceive and reduce to practice the invention represented by the interference count." *Id.* The Board awarded priority to Pfizer because Pfizer "had established conception of the subject matter of the count when it selected, isolated, and obtained the desired IL-13bc full-length polynucleotide and verified that it was the desired product, regardless of whether the fully correct sequencing of the polynucleotide was complete." *Id.* On appeal, Sanofi continued to argue that "conception of the claimed cDNA could not be established for priority purposes until the fully correct nucleotide sequence was determined, because the interference count was directed to the isolated polynucleotide." *Id*. In sharp contrast, the Board had concluded that, "'[f]or proteins and polynucleotide species, a sequence is the gold standard for identifying a species with precision. . . . It does not, however, thereby follow that a sequence is the only way to identify the composition precisely.'" *Id.* at 1369. Because the Board's findings were based on substantial evidence and it had "applied the correct law," the Circuit sustained the award of priority to Pfizer, even though Pfizer had not identified all of the polynucleotides. *Id*.

This should come as no surprise to Yeda. Indeed, Yeda's own '339 Application disclosed an N-terminal sequence consisting of 13 amino acids in the longest sequence, and therefore did not disclose *any* of the complete amino acid sequences identified in the Count. The Engelmann Reference, written by Yeda's chief scientist, reported that an N-terminal sequence of five amino acids, together with other biological data, was sufficient to identify a novel TNFα-binding protein. *See* Engelmann Reference at 1, 4-6. When prosecuting its U.S. Patent Application No. 08/485,129 (claiming priority for Yeda's '339 Application), Yeda assured the U.S. Patent Examiner that a novel protein can be "adequately defined and *fingerprinted by a partial amino acid sequence* with disclosures of certain biological properties." Abbott Mot., Ex.

E [Dkt. 70-8] (Amendment to Yeda Application) at 16 (emphasis added). The Examiner agreed and concluded that the amino acid sequence of the TBP-II protein is an "inherent property" of that protein. *Id.*, Ex. I [Dkt. 70-12] (Examiner's Answer) at 8, 12. In fact, despite its argument before this Court, Yeda conceded at oral argument that a full recitation of all the amino acids identified in any of the sequences in the Count is *not* necessary for its identification. Oral Arg. Tr. I at 25-26 ("The Court: And it seems to me that once I have 13 of 15 [amino acids in the sequence], I got it because there's nothing else that's going to result—that we know of to date, that's going to result, except this particular protein. [Yeda Counsel]: Correct.").[16] More critically, the parties agree that "the *only* normal protein containing the N-terminal sequence set forth in the '072 Application is the normal TBP-II protein—*i.e.*, the same protein claimed in the '915 Patent and recited in the Count." Abbott Mot. at 8; Oral Arg. Tr. I at 18 (Yeda Counsel: "[I]f you look at the amino acids which were . . . identified correctly in the 072 Application at the correct positions, we don't know of a protein today, other than TBP-II, that actually has . . . those amino acids there.").

Yeda attempts to avoid this evidence and its concessions by challenging Abbott's reliance on the doctrine of inherent disclosure. That doctrine holds that the requirement of Section 112 for a written description can be satisfied by showing that the first-filed application inherently discloses a property of the later-claimed subject matter. *Kennecott Corp. v. Kyocera Int'l Inc.*, 835 F.2d 1419, 1422-23 (Fed. Cir. 1987). The doctrine stands on the recognition that a "compound and all of its properties are inseparable; they are one and the same thing." *Regents of the Univ. of New Mexico v. Knight*, 3221 F.3d 1111, 1122 (Fed. Cir. 2003). Thus, "the

[16] Counsel promptly added that it would be necessary to have a purified and isolated protein to get a contiguous amino acid sequence of 13. *Id.* at 26.

disclosure in a subsequent patent application of an inherent property does not deprive the product of the benefit of an earlier filing date. Nor does the inclusion of a description of that property in later-filed claims change this reasonable result." *Kennecott*, 835 F.2d at 1423; *see also Therma Tri Corp. v. Peachtree Doors, Inc.*, 44 F.3d 988, 993 (Fed. Cir. 1995). It is not necessary for skilled artisans to possess actual knowledge of an inherent property so long as the initial filing provides an adequate description of the claimed invention. *See Hitzeman v. Rutter*, 243 F.3d 1345, 1354 (Fed. Cir. 2001) ("Where the balance of the claim fully identifies the compound . . . and the property is inherent, we fail to see that such statements add anything to the claim definition of the named compound."); *Silvestri v. Grant*, 496 F.2d 593, 599 (Fed. Cir. 1974).

Yeda stresses that "in the context of priority determination, the allegedly inherent limitation cannot be material to the patentability of the invention." *Hitzeman*, 243 F.3d at 1355 (rejecting "conception" of invention based on later-discovered inherent property). Yeda contends that Abbott relied exclusively on amino acid sequences to distinguish prior art, *i.e.*, the Engelmann Reference, and to persuade the Patent Office to issue the '915 Patent. Yeda therefore urges the Court to disregard Abbott's reliance on inherency to prove Abbott's invention of the TBP-II protein based only on nine amino acids at the N-terminal.

Yeda, however, has misread the prosecution record. Reviewing the '915 Patent, the Patent Examiner first concluded that prior art relating to the *TBP-I* protein invalidated the claimed *TBP-II* protein. Decl. in Support of Yeda Motions for Summ. J. (Yeda Exhibits) [Dkt. 74] Ex. K (Office Action dated 6/1/93) at 5. To overcome this rejection, Abbott convinced the Patent Examiner that Dr. Engelmann conclusively distinguished TBP-II from TBP-I based on variations of five contiguous amino acids at the N-terminal. *Id.*, Ex. N [Dkt. 74-4] (Abbott

Response dated 10/7/93) at 3.[17] In response, the Patent Examiner withdrew its prior-art-based rejection because it agreed with Abbott that the "prior art protein was in fact different from the protein of the applied reference" and issued the '915 Patent. *Id*., Ex. O [Dkt. 74-4] (Office Action dated 10/22/93) at 2-3.[18] Thus, Abbott demonstrated that TBP-II was different from TBP-I and patentable based, in part, on Dr. Engelmann's description of a new protein after he had identified only five amino acids. Abbott distinguished prior art (articles on TBP-I) by *embracing* (not distinguishing) the Engelmann Reference to show that a second TBP protein existed. In making its argument to the Patent Examiner, Abbott did not rely on any of the additional amino acids identified in the '915 Patent. The peculiar nature of Abbott's reliance on the Engelmann Reference to support the fact of the separate existence of the TBP-II protein undercuts Yeda's argument here. The Court concludes that Abbott can rely on the doctrine of inherent disclosure because the additional amino acids identified in the Count, but not disclosed in the '072 Application, are not material to the patentability of the TBP-II protein.

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[17] Abbott argued:

> The Engelmann et al. paper was published after the effective filing date of the present application. This paper disclosed for the first time that there exist two different specifically TNF-binding proteins (TBPs) in the human urine.
>
> TBPI: NH2-Term: ASP-SER-VAL-CYS-PRO
> TBPII: NH2-Term: VAL-ALA-PHE-THR-PRO
>
> . . . [T]he Engelmann et al. paper presents evidence that the TNF binding protein . . . is TBPI. Applicants' claimed protein is TBPII.

Id. at 3.

[18] More precisely, the Examiner agreed to withdraw its rejection after it received a certified translation of the Engelmann Reference.

Next, Yeda maintains that one of ordinary skill in the art must have been able to deduce each of the additional amino acids identified in the Count based on those disclosed in the '072 Application. *See* Yeda Mot. re: Description at 23 (citing *Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1383 (Fed. Cir. 2009) ("The very essence of inherency is that one of ordinary skill in the art would recognize that a reference unavoidably teaches the property in question.")). Yeda argues that "there is no dispute here by Abbott that one of ordinary skill, back in 1989, looking at the 072 Application could not have discerned . . . that the missing amino acids . . . are inherent, inherently disclosed or inherently described." Oral Arg. Tr. I at 31. Without doubt, the '072 Application did not disclose any of the *complete* amino acid sequences set forth in the Count; it erred in one identified amino acid, inserted an X in the sequence for amino acids not yet identified, and suggested probable amino acids (not always correctly) when uncertain. Abbott's experts acknowledge that the unknown amino acids could not have been predicted or otherwise identified as of the date of filing of the '072 Application. *See* Yeda Exhibits, Ex. G [Dkt. 74-3] (Dep. Of Dr. Heinz Hillen) at 63-64.

Nonetheless, the Court is persuaded that Yeda's test for inherent disclosure is not scientifically or legally required when the claimed subject matter is a protein and the limitation at issue is the protein's amino acid sequence. Yeda's position ignores that "'[i]nherent' properties . . . are the rare exceptions to the rule that a party must show possession of 'every feature' recited in the count and that 'every limitation' of the count must have been known to the inventor at the time of the alleged conception." *Hitzeman v. Rutter*, 243 F.3d 1345, 1354-55 (Fed. Cir. 2001). The purpose of the written description requirement of 35 U.S.C. § 112 is "to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him." *Haynes*, 146 F.3d at 1354. *Sanofi Aventis* confirms, under "*In re*

Wallach, 378 F.3d 1330, 1333 (Fed. Cir. 2004), . . . when a protein was described by a partial amino acid sequence in addition to other characteristics sufficient to identify it, the inventors were in possession of the protein."[19]

This Court has no difficulty concluding that the Board's findings here are supported by substantial evidence. The '072 Application correctly identified nine of 15 amino acids in the top line of the full N-terminal sequences recited in the Count. The '072 Application also identified certain biological characteristics of the novel protein: (1) a molecular weight of about 42 kilodaltons (kDa); (2) the specific biological property of inhibiting the cytotoxicity of TNFα; (3) found in the urine of febrile patients; and (4) not (usually) digestible trypsin. *See* '072 Application. Yeda's argument that "those other limitations . . . did not distinguish what Abbott had in its test tube" fails to read the Board's decisions or Abbott's argument correctly. Oral Arg. Tr. I at 24. As the Board held and Abbott argues, a partial amino acid sequence *and* the other biologic characteristics distinguished the TBP-II protein in the '072 Application. Yeda argued:

> What distinguished TBP-II, in fact, when Yeda scientists actually purified and isolated it and actually got the entire N-terminal sequence correct, was the sequence. So the – that's why the sequence is so critical here is because it's that sequence that, in combination with the other characteristics, distinguished what had come before. And so once you have the complete sequence here, you can distinguish what came before, in combination with the other limitations in the count, of course.

Id. Yeda is incorrect that the entire sequence for TBP-II is necessary to distinguish it from TBP-I. Yeda's own reliance in multiple fora on fewer than 15 amino acids to identify the TBP-II protein imposes judicial estoppel against its contrary position here. *See, e.g., Comcast Corp. v.*

[19] Yeda does not actually dispute this. *See* Response to Abbott Notice of Suppl. Authority [Dkt. 91] at 3 (agreeing that "under certain circumstances, a partial amino-acid sequence, combined with other characteristics sufficient to identify a protein, can indicate that the inventors isolated and thus physically possessed the protein.") (internal quotation marks omitted).

FCC, 600 F.3d 642, 647 (D.C. Cir. 2010). Even if judicial estoppel did not bar Yeda's argument, it is without merit. With identification of other biologic characteristics, a partial amino acid sequence for a protein may be sufficient to distinguish the novel protein from a known protein. The Engelmann Reference relied on biologic characteristics, in addition to only *five* identified amino acids. *See* Engelmann Reference at 1, 4-6 ("TBPII can be clearly differentiated from TBPI by its lack of immunological cross-reactivity, different NH2-terminal amino sequences, and a difference in chromatographic properties . . . ."). Yeda itself argued to the Patent Examiner that biologic references with an incomplete amino acid sequence were sufficient to identify the novel TBP-II protein. *See* Amendment to Yeda Application at 16 (stating that a novel protein can be "adequately defined and fingerprinted by a partial amino acid sequence with disclosures of certain biological properties"); Abbott Mot., Ex. BB [Dkt. 70-31] (Technical Paper Explaining [Yeda]'s Invention to the Board) at 8 ("The claims of [Yeda] which have been designated as corresponding to the count in the declaration of [the '625 Interference] are drawn to the substantially purified TBP-II protein identified by a partial amino acid sequence of 10 amino acid residues and by the functional property of being able to inhibit the cytotoxic effect of TNF and/or to maintain the prolonged benefit effects of TNF."). The Board's reliance on biologic characteristics in addition to specified amino acids adopted the very same approach. *See* 5/26/10 Board Decision at 5970.

Having found that the '072 Application adequately described the invention of the TBP-II protein, the Court agrees with Abbott that the additional amino acids of the TBP-II protein disclosed in the '915 Patent are inherent properties of the TBP-II protein. Abbott cites *Wallach* for the proposition that "a protein's amino acid sequence is an inherent property of that protein." *Wallach*, 378 F.3d at 1134. Yeda objects, pointing out that the Federal Circuit adds

that "the fact that Appellants may have isolated and thus physically possessed TBP-II does not amount to knowledge of that protein's sequence or possession of any of its other descriptive properties." *Id*. at 1334-35. The Federal Circuit, however, has previously said that an applicant need not demonstrate knowledge of an inherent property at the time of filing. *See Hitzeman*, 243 F.3d at 1354. The additional amino acids "add[] nothing to the count beyond the other recited limitations and [are] redundant to the count." *Id*.

Yeda's argument that the '072 Application was required to identify all 22 amino acids, or alternatively, the 15 amino acids in the first sequence, contradicts its own application, its own admissions and Federal Circuit law. The full record demonstrates that the '072 Application satisfies the written description requirements of 35 U.S.C. § 112. A complete sequence of 15 amino acids in the first sequence is not needed to identify and distinguish the TBP-II protein. Yeda's argument that one of ordinary skill would not have understood the '072 Application to disclose a full sequence of amino acids is merely a variant of the argument that the '072 Application was infirm because it did not identify a full sequence of amino acids. It fares no better on the second try. For the foregoing reasons, the Court will grant summary judgment to Abbott on the issue of written description.

B. Enablement: Claim Construction and Practicing the '072 Application and the 2003 Experiments

Yeda's argument on enablement has two parts: First, Yeda argues that Abbott "failed to successfully practice its 072 Application protocol in 1989" because the procedure that is reported in the '072 Application did not yield a sample that was "purified and isolated" when practiced just before the '072 Application was submitted. Oral Arg. Tr. I. at 32, 35. Second, Yeda argues that to obtain the sample reported in the '072 Application, Abbott "worked out a materially different protocol that involved different column chromatography methods," which

"they didn't disclose in the 072 Application." Oral arg. Tr. I. at 35. Yeda asks this Court, years after Judge Urbina issued his *Markman*[20] opinion,[21] to construe the term "purified and isolated" in the '915 Patent and the '072 Application. Abbott responds that Yeda failed to raise its proposed claims construction at any prior time in decades of litigation and is woefully late, after discovery in this specific lawsuit has closed, to the severe prejudice of Abbott, which had no opportunity to develop opposing evidence. However, it appears that Yeda proposed approximately the same construction to the Board and Abbott proposes a competing construction. Therefore, the Court will address the argument.

1. Construction of "Purified and Isolated"

The Court begins with Yeda's request that the Court construe "purified and isolated" to mean "sufficiently purified and isolated to permit identification of one of the complete amino-acid sequences in the Count." Yeda Mot. for Summ. J. on Enablement [Dkt. 73] (Yeda Mot. re: Enablement) at 13. Yeda argues that the need for a purified and isolated sample is the

> principle [that] is at the heart of what Yeda's experts have explained in this case, which is that the sample is dirty, it's contaminated, and . . . one can't discern anything that even comes close to a complete 15 to 22 amino acid sequence, and if the sample had been purified and isolated, then that would be clear from the sequence data, but it's just not.

Oral Arg. Tr. II [Dkt. 96] at 9. Abbott opposes on the grounds that Yeda's proposed construction is the product of attorney argument and that a person of ordinary skill in the art in 1989 would not know that "purified and isolated" required the specification of either 22 *or* 15 amino acids in

[20] *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 385 (1996).

[21] *See Abbott II*, 516 F. Supp. 2d 1 (D.D.C. 2007).

sequence. *See id*. at 39-40. Abbott proposes that a protein is "purified and isolated" when "you're able to make a definitive identification of the protein." Oral Arg. Tr. II at 40.[22]

The words of a patent claim "are generally given their ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*) (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, *i.e.*, as of the effective filing date of the patent application." *Id*. at 1313. "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id*. "[I]n interpreting an asserted claim, the court should look first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history. Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (internal citation omitted). "In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term." *Id*. at 1583. "In some cases, however, the district court will need to look beyond the patent's intrinsic evidence and to 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 Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015).

[22] Abbott notes that the '072 Application discloses a protein having a purity of greater than 90% as a result of the protocol described in Example 2, which it argues helps to discern the meaning of "purified." *See* '072 Application at 5.

In arguing that it proposed a construction of "purified and isolated" to the Board, Yeda adopts and re-argues points made on enablement in its earlier brief. *See* Yeda Reply [Dkt. 85] at 21-21. As now, Yeda argued:

> Furthermore, the enablement requirement of 35 U.S.C. § 112 is not satisfied by the '072 Application as there is no evidence of record that those of ordinary skill in the art repeating Example 2 of this application would be able to obtain *a protein of sufficient purity to allow an unambiguous N-terminal amino acid sequence to be determined*. . . . Accordingly, the only conclusion that could be reached by one of ordinary skill . . . is that there is *no guarantee* that the process for obtaining the protein from urine as disclosed in Example 2 of the '072 Application would ever yield *an unambiguous protein pure enough to obtain an unambiguous N-terminal amino acid sequence*.

Abbott Opp'n, Ex. PP [Dkt. 82-5] (Wallach Opp. to LeMaire Preliminary Mot. No. 1) at 21-23 (emphasis added). Before this Court, Yeda asks that "purified and isolated" be defined as "sufficiently purified and isolated to permit identification of one of the complete amino-acid sequences in the Count." Yeda Mot. re: Enablement at 13. Yeda claims that the language of the Count, the specification of the '915 Patent, and the prosecution history of the '915 Patent support this construction. *Id*. at 13-16.

Yeda's proposed definition of "purified and isolated" is merely a lawyer's repeat of the failed argument that a full sequence of the TBP-II amino acids must have been "unambiguous[ly]" revealed. Given the long history of this litigation and Yeda's own repeated admissions, the argument is a non-starter. In other fora, as well as before this Court, Yeda has admitted that it is not necessary to identify a complete amino acid sequence, and the Court has rejected this argument as unsound. *See Sanofi-Aventis*, 733 F.3d at 1369 (a protein can be adequately described based on a partial amino acid sequence and other biological data). It is now clear, as a matter of law, that identification of a full amino acid sequence is not required when a patent applicant has additionally disclosed sufficient biological characteristics of a

protein to "distinguish it from other materials, and to define how to obtain it." *Id.* (quoting *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991)).

Furthermore, the intrinsic evidence does not support Yeda's proposed construction. First, Yeda admits that the '915 specification "does not define or indicate that any special meaning was meant for 'purified and isolated.'" Yeda Mot. re: Enablement at 15. The specification of the '915 Patent identifies characteristics of the TBP-II protein in addition to amino acid sequences, *i.e.*, the protein's molecular weight, its ability to inhibit the cytotoxicity of TNFα, its source, and its digestibility by trypsin. The specification uses "purified" and "isolated" in reference to sources and techniques used to obtain the protein. For example, the specification states that "[t]he novel proteins can be isolated . . . from the urine of patients with fever," "[t]he proteins can be purified by conventional methods such as affinity or ion exchange chromatography" and "the protein obtained [by the protocol in Example 2] had a purity of > 90% by gel electrophoresis." *See* '915 Patent at 2, 3. Without explanation, none of these characteristics, sources or techniques is incorporated into Yeda's proposed construction. Some combination of these factors, along with identification of a certain number of amino acid sequences, could also be used to define the term "purified and isolated."

Part (b) of the Count describes the "purified and isolated TNFα-binding protein" as having one of eight amino acid sequences. *See supra* p. 12. Yet, defining "purified and isolated" to mean "sufficiently purified and isolated to permit identification of one of the complete amino-acid sequences in the Count" would conflate these limitations. Yeda has advanced the most stringent restriction from the Count and specification to form a narrow construction of the term in furtherance of its legal position here.

Yeda's reliance on the prosecution history of the '915 Patent fares no better. Yeda points to Abbott's attempts to distinguish TBP-II from prior art based on amino acid sequences as evidence that identification of a complete amino acid sequence is key to the definition of "purified and isolated." *See* Yeda Mot. re: Enablement at 16. Granted, explanation of the unique amino acid sequences of the TBP-II and TBP-I proteins was necessary for Abbott to convince the Patent Examiner that they are separate proteins: Abbott distinguished the TBP-II protein from the TBP-I protein based, in part, on Dr. Engelmann's description of a new protein after he had identified only five amino acids. The five amino acids identified by Dr. Engelmann were critical because they were sufficient—along with other biologic characteristics—to differentiate the novel protein from the known protein. Here, as before, Yeda ignores the significant role the other characteristics of the TBP-II protein played in the prosecution history of the '915 Patent. The intrinsic evidence reveals that the term "purified and isolated" does not have the narrow meaning that Yeda's lawyers now ascribe to it. The Court therefore rejects Yeda's proposed definition of the term "purified and isolated."

Because the intrinsic evidence alone could arguably render several variations of the definition of "purified and isolated," the Court finds the intrinsic evidence insufficient to define the term. Therefore, the Court turns to the parties' experts to identify "the meaning of a term in the relevant art during the relevant time period." *Teva Pharmaceuticals*, 135 S. Ct. at 841. First, the Court notes that Yeda's proposed construction is unaccepted by its own experts. Both Dr. Shively and Dr. Capra acknowledged that different meanings could be imputed to the term:

> When I refer to "purified and isolated" and "purification" in this statement, I have in mind various meanings that I can imagine the parties might contend apply to those terms, e.g., purified and isolated or a purification so as to permit the identification of an N-

> terminal amino acid sequence recited in the Count; purified and isolated or a purification so as to ensure that TBP-I was either absent from a sample or did not significantly contribute to the activity detected for a protein sample; and at least 90% pure.

Yeda Exhibits, Expert Statement of John E. Shively, PH.D [Dkt. 74-10] (Shively Report) ¶ 68; *id*., Expert Statement of J. Donald Capra, M.D. [Dkt. 74-8] (Capra Report) ¶ 70. Abbott's experts, Drs. Bradshaw and Baldwin, provided opinions directly on the question of how one skilled in the art at the time of invention would have understand the term "purified and isolated:"

> In 1989, protein chemists recognized that the meaning of the term "purified and isolated" differed with the context and purpose of its use. In the case of the purification and characterization of novel proteins, protein chemists did not use the term "purified and isolated" to require absolute homogeneity. Rather, protein chemists considered a protein sample to be "purified" if it had sufficient purity to permit a definitive identification and characterization of the protein of interest.

Abbott Mot., Ex. J [Dkt. 70-13] (Bradshaw Rebuttal) ¶ 19; *id.*, Ex. W [Dkt. 70-26] (Baldwin Rebuttal) ¶ 19. Yeda does not point to evidence to contradict or undermine the position of Abbott's experts. *See* Yeda Reply at 22. The Court therefore adopts the statements of Drs. Bradshaw and Baldwin for purposes of construing the term "purified and isolated."

The Court is persuaded by the experts. The Court finds that Abbott's proposed construction—that a protein is "purified and isolated" within the meaning of the Count if it results in a definitive identification of the protein—more accurately reflects the intrinsic evidence and the expert opinions. It therefore adopts Abbott's proposed construction and construes "purified and isolated," as used in the '072 Application (and therefore in the '915 Patent) to mean "purified and isolated enough to definitely identify the TBP-II protein."[23]

[23] Yeda's objection that "definitely" is too vague a term is rejected. *See* Yeda Reply at 23. Both parties acknowledge that the nine amino acids and other characteristics identified in the '072 Application belong only to the TBP-II protein and no other. *See* Oral Arg. Tr. I at 18; Abbott Mot., Ex. MM (Capra Dep.) at 49; Bradshaw Report ¶ 16. "Definitely" is the appropriate

2. Enablement: Practicing the '072 Application and the 2003 Experiments

Yeda discovered Abbott's 1989 lab notebooks after this § 146 suit was filed in September 2010.[24] Abbott's lab notebooks show that when it tried to repeat the '072 protocol shortly before it submitted the '072 Application, "[a]n attempt was made to assign the strongest sequence, but it was not entirely unambiguous" and the sample's ability to neutralize TNFα was "very weak." Yeda Exhibits, Ex. S at A5521, A5522 (Abbott Lab Notebooks); *id.*, Ex. X (Verified English Translation). Thereafter, Yeda contends, Abbott "abandoned the '072 protocol before it filed the '072 [A]pplication, and used a materially-different protocol to obtain the protein sample reported in the '072 [A]pplication." Yeda Mot. re: Enablement at 19.[25] From this history, Yeda cries foul and asserts that Abbott cannot rely on the '072 Application to support the '915 Patent because the '072 protocol neither resulted in a purified and isolated protein nor was the actual basis for the amino acids identified in the '072 Application.

The Patent Act requires a specification to "contain a written description . . . of the manner and process of making and using [the claimed invention] in such full, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same . . . ." 35 U.S.C. § 112, ¶ 1. "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'"

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adverb, as it comports with the experts' statements and follows *Sanofi Aventis* which requires definition of a new protein "so as to distinguish it." *Sanofi Aventis*, 733 F.3d at 1369.

[24] Yeda did not ask earlier for Abbott's lab notebooks. Interestingly, Yeda's own lab notebooks have not been found and Dr. Engelmann's notes from the 2003 Experiment have been lost since he last reviewed them prior to a deposition in this matter.

[25] Abbott challenges Yeda's interpretation that it "failed" and "abandoned" the '072 protocol. It insists that its goal was not to obtain immediately the complete amino acid sequences recited in the Count, but to try to acquire different kinds of information about the protein, including potential therapeutic properties. *See* Abbott Opp'n at 34-35 (quoting Dr. Heinz Hillen).

ALZA Corp. v. Andrx Pharmaceuticals, LLC, 603 F.3d 935, 940 (Fed. Cir. 2010) (internal citation omitted). "That some experimentation is necessary" to practice the invention does not constitute a lack of enablement. *Atlas Powder Co. v. E.I. DuPont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984). "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1998). A court need not consider all of the *Wands* factors, but only those that pertain to the facts of the case. *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991).

A. Practice of the '072 Application in 1989

The protocol in Example 2 of the '915 Patent repeats the protocol from Example 2 of the '072 Application in relevant part. *Compare* '915 Patent at 2-3 *with* '072 Application at 4-5. Yeda claims, and Abbott does not effectively dispute, that the Abbott scientists attempted to duplicate the '072 protocol just before the '072 Application was filed and got weak results. Yeda's new evidence shows that "[t]he sample that Abbott actually obtained when they practiced the 072 protocol—the protocol reported in the application—[] resulted in a sample that was more contaminated and less purified and isolated than the sample they actually reported." Oral Arg. Tr. I at 34-35. Therefore, Abbott scientists "worked out a materially different protocol that involved different column chromatography methods. That's the procedure, that's the protocol which they didn't disclose in the 072 Application, and they actually used that to obtain the sample reported in the 072 Application." *Id.* at 35. More precisely Dr. Capra, one of Yeda's experts, states:

> 291. In the '072 Application, the applicants said that the purification and isolation protocol that they followed was, in general: filtering urine using a Hemoflow F60 filter; passing the subsequent retentate through a S-Sepharose column; loading a fraction from that column onto a TNF-affinity column; and then loading the eluate from that

> TNF-affinity column onto a Mono-Q anion-exchange column. A2923-A2924.
>
> 292. The purification and isolation protocol that the '072 applicants actually used to obtain and identify the disclosed protein was materially different from the protocol that they disclosed in the' '072 Application. Instead of using a chromatographic procedure including an S-Sepharose column, a TNF affinity column, and then a Mono-Q column, the applicants used a TNF affinity column, and then a Mono-S column, and then a Mono-Q column. Thus, the '072 Application incorrectly states that the protocol disclosed in that application was used to obtain the disclosed proteins (and the amino acid sequence information therein), and the sequences that were reported in the '072 Application were actually obtained using a procedure different that that disclosed in the '072 Application. The '072 applicants did this after they practiced the '072 protocol and obtained a contaminated protein sample . . . .
>
> . . .
>
> 297. . . . [U]sing a Mono-S column instead of an S-Sepharose column, and using a TNF affinity column, a Mono-S column, and then a Mono-Q column, were materially different from the protocol disclosed in the '072 Application, were not disclosed or suggested by the '072 Application, and likely had a significant difference on the quality of Abbott's results (although the sample they obtained remained contaminated).

Yeda Exhibits, Expert Statement of J. Donald Capra, M.D. [Dkt. 74-8] (Capra Report) ¶¶ 291, 292, 297. Yeda asserts that this history reveals that the '072 Application did not specify a protocol that would enable a person of ordinary skill in the art to duplicate the invention.[26]

[26] This is a new argument, not presented to the Board, based on new evidence. The Court therefore is a *de novo* factfinder. *See Winner*, 202 F.3d at 1347-48. When last before the Board, Yeda attacked the use of a Hemoflow F60 filter made by Fresenius AG because it allegedly "could not retain the protein of the [C]ount." 5/26/10 Board Decision at 5975. Thereby, "Yeda, in effect, challenge[d] the operativeness of Example 2 [of the '072 protocol] to concentrate the proteins from urine," relying on experts not before the Court here. *Id.* at 5976. The Board found the evidence insufficient, in part because the filter used by Yeda scientists years after the '072 Application and '915 Patent were filed was not the same filter used by Abbott scientists, and because Yeda's attempts to duplicate Example 2 of the '072 Application were of little value inasmuch as Abbott scientists were neither invited to, nor did, observe. *Id.* at 5979. Yeda no longer relies on this argument.

Abbott responds that it is "[u]ndisputed that Abbott used sources and methods in addition to the protocol in the '072 Application, but disputed that the '072 protocol did not yield a protein containing the sequences recited in the Count." Response to Yeda Facts re: Enablement [Dkt. 82-2] at 6. Abbott does not dispute that its lab notebooks show use of different chromatographic procedures and equipment prior to submission of the '072 Application, but disputes that these differences were material. *Id*. at 4-5. Abbott also acknowledges that, after the '072 Application was filed, it continued its research and used additional sources and methods to identify the complete 22 amino acids identified in the '915 Patent. *Id.* at 6-7; *see* '089 Application [Dkt. 70-14]. Abbott points to the 2003 Experiments to prove that the '072 protocol successfully resulted in sufficient biological evidence and amino acids of the TBP-II protein to prove its discovery.

The Court finds that Abbott's pre-filing modifications to the '072 protocol do not bear on the question of enablement, which concerns the specification of a patent. The real inquiry, then, is whether the '072 protocol, as written and disclosed in the '072 Application, "teach[es] those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *ALZA Corp.*, 603 F.3d at 940. The legitimacy and outcome of the 2003 Experiments are the proper focus of this inquiry.

B. 2003 Experiments

Abbott cites to the 2003 Experiments,[27] fully observed by Yeda scientists, which followed the '072 protocol and resulted in an identifiable TBP-II protein, as support for its

[27] Because Yeda's experts observed both stages of the 2003 Experiments, the Court has considered all evidence regarding them. *See Carnegie Steel Co. v. Cambria Iron Co.*, 185 U.S. 403, 420-21 (1902) (evidence of testing without opportunity afforded the opponent[] to inspect the plant or witness its operation likely inadmissible); *Wagoner v. Barger*, 463 F.2d 1377, 1382 (CCPA 1972) ("the results of tests made by one party . . . without notice to, and in the absence

position that the ’072 protocol satisfies the enablement requirements. *See* Oral. Arg. Tr. II. at 35 (“The 2003 experiment took Example 2 [of the ’072 Application and the ’915 Patent] and it replicated Example 2, and it did so in the presence of experts from the opposing party.”); Bradshaw Report ¶¶ 40-52. Yeda challenges the results of the 2003 Experiments because “Abbott didn’t follow the precise protocol” and “the amino acid sequence data that was generated in those experiments shows contamination. . . . [I]t does not reveal a purified and isolated protein.” Oral Arg. Tr. I at 10, 40-41.

i. The 2003 Experiments Materially Followed the ’072 Protocol

Yeda does not argue about the chromatography techniques performed during the 2003 Experiments. *See* Oral Arg. Tr. II at 10 (Yeda: “[A]s far as the count chromatography that’s reported in the ’072 Application, we’re not taking the position that they didn’t do what the ’072 Application said to do” in the 2003 Experiments.). Instead, Yeda objects that during the 2003 Experiments Abbott scientists “actually put a lot less protein on the gel” compared to the ’072 protocol. Oral Arg. Tr. II at 16-17. Yeda asserts that less protein would produce stronger evidence of the TBP-II protein. *Id*. at 17 (Yeda: “Why does that matter? When you’re putting less protein on the gel, . . . the contaminants are less likely to be visible.”). Although Dr. Bradshaw stated that 2 micrograms is the “normal amount that’s used in experiments of that type” and noted that smaller amounts of protein were loaded onto certain lanes of the gel in the 2003 Experiments, he was not asked about the significance of using less gel. *See* Abbott Mot., Ex. KK (Bradshaw Dep.) at 80-84; 170-174. Yeda’s experts, Dr. Shively and Dr. Capra, do not cite this alleged deficiency in their review of the 2003 Experiments. *See* Shively Report ¶¶ 302-

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of, the other party . . . [are] for that reason alone entitled to little or no weight”), *superseded on other grounds*, *Kubota v. Shibuya*, 999 F.2d 517 (Fed. Cir. 1993).

314; Capra Report ¶¶ 304-316. The Court does not accept or rely on a lawyer's late invention of a scientific argument.

Yeda also argues that Abbott did not perform an amino assay in 2003 as it did in 1989, which, Yeda contends, would have shown evidence of contamination with TBP-1. Oral Arg. Tr. II at 19; *see also* Shively Report ¶ 308 ("Abbott's 2003 experiments did not include any immunoassay with antibodies to TBP-I to rule out the existence of TBP-I in Abbott's protein fractions . . . ."). Abbott does not address the point, and the Court deems it conceded. Whether it matters is a different question. Yeda's attack on the 2003 Experiments is ultimately dependent on its proffered definition of "purified and isolated" which the Court has already rejected.

Yeda does not otherwise dispute that Abbott followed the '072 protocol during the 2003 Experiments. On the record as a whole, the Court concludes that the 2003 Experiments materially followed the '072 protocol.

ii. The 2003 Experiments Demonstrated that the '072 Protocol Produced the TBP-II Protein

Yeda neatly describes its central objection to Abbott's 2003 Experiments:

> So that principle is at the heart of what Yeda's experts have explained in this case, which is that the *sample is dirty*, it's *contaminated*, and part of the evidence of that is looking at the data, one can't discern anything that even *comes close to a complete 15 to 22 amino acid sequence*, and if the sample had been purified and isolated, then that would be clear from the sequence data, but it's just not.

Oral Arg. Tr. II at 9 (emphasis added). The presence of contaminants in the samples produced by the 2003 Experiments are "the heart" of Yeda's case but ultimately fails to prove its point. The relevant question is whether the '072 protocol results in a sample from which TBP-II can be definitively distinguished from TBP-I. The answer to that question is certainly yes, contamination and all.

Abbott concedes that contaminants may have been present in the samples, but insists that "it cannot be denied that whatever contaminants may have been present, the Abbott scientists were able to identify a protein that has each of the amino acids specified in the count." Oral Arg. Tr. II (Abbott) at 43. Based on their review of the sequencing results, both of Abbott's experts conclude that a person skilled in the art who followed the '072 protocol would have obtained a protein with one of the amino acid sequences identified in the Count. *See* Bradshaw Rebuttal ¶¶ 47-52; Baldwin Rebuttal ¶¶ 69-71.

Yeda asserts that the Board failed to apprehend that the "gemish"[28] resulting from Abbott's '072 protocol inevitably means that a scientist of ordinary skill in the art could not have identified an unambiguous sequence of amino acids. Oral Arg. Tr. II (Yeda) at 3, 7, 9. Yeda notes that Dr. Baldwin, Abbott's expert, admitted that the protocol in the '072 Application could lead to "anywhere from 35 to 60 percent of the amino acids that were detected in any given cycle could be from a contaminant." *Id.* at 13. Dr. Baldwin explained that the unaccounted-for amino acids "could come from internal sequences in TBP-II." Abbott Mot., Ex. OO (Baldwin Dep.) at 183. Dr. Capra, Yeda's expert, opines that "the data suggests that the percentage of contaminants in the sample could have been as high as 15 to 20%." Capra Report ¶ 313. Although Dr. Capra and Dr. Shively, Yeda's experts, declare that "the amino acid sequence data that Abbott obtained from its 2003 experiments does not permit one of ordinary skill to identify any of the eight N-terminal amino acid sequences recited in the Count," they both admit that one could identify the sequences if one knew what to look for, despite any contamination. Capra Report ¶¶ 310, 315; Shively Report ¶¶ 308, 313. Specifically, when asked whether the results of

[28] "Gemish" is Yiddish for "mixture." *See* Gemish definition, Yiddish Dictionary Online, http://www.yiddishdictionaryonline.com/ (last visited April 9, 2015).

the purification procedure demonstrated that Abbott obtained a sample containing TBP-II, Dr. Shively answered that he "would conclude that the sample [from the 2003 Experiments] had some TBP-II in it based on hindsight, based on the knowledge of the sequence of TBP-II." Yeda Opp'n, Ex. II [Dkt. 81-10] (Shively Dep.) at 109. He also confirmed that "[t]he multiple sequences that were obtained by Abbott in 2003 to the best of my knowledge do not correspond to TBP-I." *Id*. at 110. In light of Dr. Shively's testimony, the Court finds that there is no material dispute that the '072 protocol resulted in samples containing TBP-II that could be discerned by one of ordinary skill in the art.

Yeda contends that one of ordinary skill in the art in 1989 would not have used Coomassie Blue, a dye used by Abbott scientists in 1989 and 2003 to provide evidence of purification. *Id.* At oral argument, Yeda asserted that "[i]t hasn't been rebutted that one of ordinary skill in the art typically does not rely on Coomassie Blue . . . [instead of] silver stain." *Id.* Yeda's expert, Dr. Shively, stated that "Coomassie Blue stain . . . was well-known to be not nearly as sensitive as other stains (such as silver stain) for detecting small amounts of protein. One of ordinary skill in the art would have expected Abbott to use a more sensitive stain." Shively Report ¶ 118. Dr. Baldwin, Abbott's expert, admitted that proteins do not show up with the same intensity in stains other than silver stained gel. *See* Baldwin Dep. at 99. Dr. Bradshaw, Abbott's expert, testified that "if there was a contaminant present to the extent of 10 percent, it would have been visible in the Coomassie stain. The absence of any such bands suggest to one skilled in the art at that time that the protein band would have been in the order of 90 percent pure." Bradshaw Dep. at 143. Dr. Bradshaw also stated that "[i]n 1989, as today, protein chemists routinely used Coomassie blue stain in SDS-PAGE analysis to measure the purity of isolated proteins, including TNF-α binding proteins." Bradshaw Rebuttal ¶ 45. The Court finds

the issue of the Coomassie Blue stain is not material to the legitimacy of the '072 protocol as practiced in 1989 and 2003. The point may be one of contention among scientists about the best way to demonstrate a sample's purification—Coomassie Blue or silver stain—but the selection of one rather than the other does not invalidate the '072 protocol. No expert suggests that one or the other hue was fatal or necessary.

Yeda challenges the identification of amino acids from the contaminated samples produced from the 2003 Experiments. Oral Arg. Tr. II at 13-14 (Yeda) ("[I]f you already know the sequences to look for, which Abbott's experts did, then you can see the sequences, but you can also see other sequences in the data. That's not a genuine demonstration of entitlement . . . . [W]e submit that it biased their opinions in this case."). However, a later scientist, seeking to reproduce the protocol taught by the '072 Application, would inevitably "know the sequences to look for:" the results specified in the patent. And, as Abbott points out, this is the central question of an enablement case: whether a skilled person, using *all* of the information in the challenged specification, could practice the claimed invention. *See* Abbott Opp'n [Dkt. 82] at 36-37. Yeda responds that the sufficiency of an application must be judged as of the filing date, *see Vas-Cath Inc.*, 935 F.2d at 1566, and one skilled in the art would not have had the benefit of the complete sequences disclosed in the '915 Patent. However, this objection again rests on the rejected premise that one skilled in the art must have been able to identify a full sequence of 15 or 22 amino acids of the TBP-II protein disclosed in the Count. Yeda cannot escape the fact that the amino acids identified by the '072 Application are found only in the TBP-II protein and that the amino acids of the TPB-II protein were found in the contaminated sample produced by the 2003 Experiments after adhering to the '072 protocol.

Lastly, Yeda questions how it could be that the '072 protocol failed when attempted in late May 1989 and "just magically work[ed] in 2003." Oral Arg. Tr. II at 10. This is a purely speculative question and is rejected as neither factual nor legal argument.

Nonetheless, the Court recognizes that Yeda's argument on enablement rests on the alleged "failure" of Abbott scientists to duplicate the '072 protocol in 1989 when it discovered TBP-II and some of its amino acids. Abbott's defense rests on its initial success in 1989 (uncontested by Yeda), albeit in a "contaminated" sample, and the success of the same protocol in 2003 to produce a "contaminated" sample following the '072 protocol from which TBI-II amino acids were discerned. Inasmuch as Yeda's scientists were immediately present and observant at the 2003 Experiments, while an unobserved scientist reproducing the '072 protocol in 1989 may have erred in some unknown way, the Court credits Abbott and the scientists for both parties that the '072 protocol resulted in the presence of TBP-II amino acids during the 2003 Experiments, albeit in a "contaminated" sample. This real-life reproduction of the '072 protocol, under the wary view of Yeda's own scientists and inventors, establishes that the '072 Application enabled the TBP-II protein. The Court will grant summary judgment to Abbott on the issue of enablement.

C. Best Mode

Finally, Yeda argues that the '072 Application does not comply with 35 U.S.C. § 112 because it does not set forth the best mode practiced by Abbott for obtaining the TBP-II protein. Specifically, the '072 Application does not disclose the modified protocol that Abbott relied upon to obtain the protein and an unspecified number of amino acids immediately before

filing the '072 Application. *See* Yeda Mot. for Summ. J. on Best Mode [Dkt. 72] (Yeda Mot. re: Best Mode) at 9-11.[29]

Section 112 requires that the specification of a patent "set forth the best mode contemplated by the inventor or joint inventory of carrying out his invention." 35 U.S.C. § 112. Courts engage in a two-pronged inquiry to determine compliance with the best-mode requirement. "First, the court must determine whether the inventor possessed a best mode of

[29] Abbott first argues that Yeda waived its best-mode defense by failing to present it to the Board. *See* Abbott Opp'n at 38. In light of the Federal Circuit's decision in *Troy v. Samson Mfg'g Corp.*, this argument does not have merit. *See Troy*, 758 F.3d at 1325 ("[W]e conclude that new evidence on new issues is admissible" in Section 146 proceedings). Abbott also contends that it need not comply with the best mode requirement of 35 U.S.C. § 112 to receive the priority date of its earlier-filed German application. *See* Abbott Opp'n at 38. It cites *Cromlish v. D.Y.*, 57 U.S.P.Q.2d 1318 (B.P.A.I. 2000) for the Board's statement that "it is not apparent why it should be necessary for a priority benefit application to satisfy all the requirements [of § 112] for the patentability of a claim as long as it is sufficient to show prior invention by another." The Board later explained in *Scripps Research Inst. v. Genentech, Inc.*, 2005 Pat. App. LEXIS 19, *37-38 (B.P.A.I. February 28, 2005), that *Cromlish* "did not hold that there is no best mode requirement for constructive reduction to practice . . . ." While this Court shares the *Cromlish* Board's skepticism that the best-mode requirement bears on the underlying issue of invention, the Federal Circuit has explained that

> Section 119 provides that a foreign application "shall have the same effect" as if it had been filed in the United States. 35 U.S.C. § 119. Accordingly, if the effective filing date of what is claimed in a United States application is at issue, to preserve symmetry of treatment between sections 120 and 119, the foreign priority application must be examined to ascertain if it supports, within the meaning of section 112, ¶ 1, what is claimed in the United States application.

In re Gosteli, 872 F.2d 1008, 1011 (Fed. Cir. 1989); s*ee also Bigham v. Godtfredsen*, 857 F.2d 1415, 1418 (Fed. Cir. 1988) (noting that for priority claim under 35 U.S.C. § 119, disclosure of subject matter of the count must meet the requirements of 35 U.S.C. § 112, first paragraph); *Frazer*, 498 F.3d at 1287 ("Constructive reduction to practice does not invoke different standards whether the priority document is foreign or domestic."). When Congress amended 35 U.S.C. § 120 in 2011, it repealed the best mode requirement so that an earlier filed application need only comply with the written description and enablement requirements of Section 112. *See* 35 U.S.C. § 120 (2011). The amendment does not have retroactive effect, however. Best mode was plainly a requirement of 35 U.S.C. § 112, paragraph 1, and, therefore, the Court entertains Yeda's best mode argument.

practicing the claimed invention at the time of filing the patent application. This first step is subjective and focuses on the inventor's preference for a best mode of practicing the invention at the time of the application's filing date. The second step is an objective inquiry to determine whether the inventor concealed from the public the best mode of practicing the invention." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1373 (Fed. Cir. 2011) (internal citations omitted). "If the inventor in fact contemplated such a preferred mode, the second part of the analysis compares what he knew with what he disclosed—is the disclosure adequate to enable one skilled in the art to practice the best mode or, in other words, has the inventor 'concealed' his preferred mode from the 'public'?" *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 928 (Fed. Cir. 1990). "Violation requires intentional concealment; innocent or inadvertent failure of disclosure does not of itself invalidate the patent." *Ateliers*, 717 F.3d at 1357.

Yeda concedes that it has presented no evidence showing that Abbott intentionally concealed its best mode. Yeda argued only that Abbott did not disclose its preferred mode in the '072 Application. *See* Yeda Mot. re: Best Mode at 11-12. In response to Abbott's defense that Yeda had presented no evidence of intentional concealment, Yeda only suggests that "if the Court does not grant one of Yeda's other motions for summary judgment, Yeda may seek leave to take additional discovery regarding Abbott's failure to disclose its best mode." Yeda Reply at 30.[30] Notwithstanding Yeda's position that *Ateliers* should be reversed, *Ateliers* is binding precedent on this Court and, as plaintiff, Yeda must establish intentional concealment to support its best mode theory. Moreover, as the party seeking summary judgment, Yeda "always bears the initial responsibility for . . . identifying those portions of 'the

[30] This case is twenty years old. Discovery is closed.

pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex*, 477 U.S. at 323. Because Yeda concedes its failure to present any evidence of intentional concealment, Yeda cannot meet this initial responsibility and its best mode argument fails. *See also Bigham*, 857 F.2d at 1418 (rejecting argument on best mode in appeal from Board decision in interference proceeding where there is no claim that defendant concealed information in patent application). The Court will deny Yeda's motion for summary judgment on best mode.

VII. CONCLUSION

The Court finds that there are no true disagreements of fact between the parties. While the experts disagree, in part, those disagreements that are relevant are resolved on the record. Thus, as both parties' motions for summary judgment suggest, the Court agrees that this matter can be decided without an evidentiary hearing.

Having so concluded, the Court affirms the May 26, 2010 decision of the Board of Patent Appeals and Interferences and finds that Abbott is entitled to the benefit of the May 9, 1989 application date of the '072 Application in Germany. The Court will grant Abbott's motion for summary judgment, Dkt. 70, and will deny Yeda's motions for summary judgment, Dkts. 71, 72, and 73. Judgment will be entered in favor of Abbott. A memorializing Order accompanies this Opinion.

Date: April 15, 2015

/s/
ROSEMARY M. COLLYER
United States District Judge