

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

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|-------------------------|---|-------------------|---------------|
| ABBOTT GMBH & CO. KG,   | : |                   |               |
|                         | : |                   |               |
| Plaintiff,              | : | Civil Action No.: | 00-1720 (RMU) |
|                         | : |                   |               |
| v.                      | : | Document Nos.:    | 107, 108, 109 |
|                         | : |                   |               |
| YEDA RESEARCH &         | : |                   |               |
| DEVELOPMENT, CO., LTD., | : |                   |               |
|                         | : |                   |               |
| Defendant.              | : |                   |               |

**MEMORANDUM OPINION**

**GRANTING THE PLAINTIFF’S MOTION FOR SUMMARY JUDGMENT;  
DENYING THE DEFENDANT’S MOTION FOR SUMMARY JUDGMENT;  
DENYING THE DEFENDANT’S MOTION TO EXCLUDE EVIDENCE AND ARGUMENTS**

**I. INTRODUCTION**

This case comes before the court on the parties’ cross motions for summary judgment and the defendant’s motion to exclude evidence. The plaintiff, Abbott GmbH & Co. KG, is the owner of U.S. Patent No. 5,344,915, also known as the “LeMaire patent.” The patent describes a protein called TBP-II, which is found in the urine of patients with a fever and binds to, and thereby neutralizes, potentially harmful polypeptides. The plaintiff requests that the court set aside the final decision made by the Board of Patent Appeals and Interferences of the United States Trademark Office (the “Board”) holding that the claims in the LeMaire patent are unpatentable for failing to remove an article, the Engelmann reference,<sup>1</sup> as prior art. Specifically, the plaintiff contends that the Board’s reasoning is flawed and that new evidence resoundingly favors removal of the article as prior art. The defendant disagrees on both accounts, submitting expert testimony of its own to rebut the plaintiff’s evidence and also filing a

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<sup>1</sup> The article, written by Helmut Engelmann, is titled *Two Tumor Necrosis Factor-Binding Proteins Purified from Human Urine*. Mem. Op. (June 13, 2005) at 2.

motion to exclude the new evidence altogether. Because the defendant failed to comply with Local Civil Rule 7(m), the court denies its motion to exclude evidence. And because the Board's determination is clearly erroneous, the court vacates its decision and remands for further proceedings.

## **II. BACKGROUND**

### **A. Proteins**

Generally speaking, proteins are long chains of amino acids like beads on a string. *See In re O'Farrell*, 853 F.2d 894, 895-99 (Fed. Cir. 1980). "Any sequence of amino acids of a significant length within a given protein will be unique to that protein." Pl.'s Claim Construction Br. ("Pl.'s Br." at 4). The chain begins at the N-terminus, the location of an amino group to which all other amino acids are sequentially attached. *Id.* The long chains of amino acids fold on themselves to form an often complex shape determined by the interplay of the amino acids in the chain. Both the sequence of amino acids and the folded structure are unique to each protein. 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. *Id.* The number of amino acids necessary to uniquely identify a protein varies. *Id.* (stating that amino acid sequences of varying lengths can be characteristic of a single protein). For example, the LeMaire patent describes the TBP-II protein by listing 22 of the amino acids located at the N-terminus.<sup>2</sup> *Id.* at 7. The sole requirement in identifying a protein by a sequence of amino acids in a patent is that "one skilled in the art" be able to recreate the protein without experimentation.

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<sup>2</sup> The TBP-II protein is also described in the patent by listing seven additional truncated forms. That is, the plaintiff described the TBP-II protein by listing the amino acids in the first 22 positions of the chain, as well as by listing the amino acids in positions 2-22, 3-22, 4-22, 5-22, 6-22, 7-22, and 8-22. Pl.'s Claim Construction Br. ("Pl.'s Br.") at 7.

*In re Fisher*, 427 F.2d 833, 836 (C.C.P.A. 1970); *see generally In re O'Farrell*, 853 F.2d at 895-99.

### **B. The LeMaire Patent**

On May 4, 1990, Hans-Georg LeMaire, Heinz Hillen, Achim Moeller, Lothar Daum, Thomas Doerper and Thomas Subkowski filed an international patent application, PCT/EP90/00719, for a protein, called the TBP-II protein, that is isolated from the urine of individuals with a fever and from the ascites fluid of individuals with ovarian carcinomas. Mem. Op. (June 13, 2005) at 1. After the patent application entered the United States, on September 6, 1994, the Patent and Trademark Office (“the PTO”) issued the LeMaire patent to BASF, a previous owner of the patent. *Id.* at 2. The plaintiff is now the owner of this patent.

### **C. The Board’s Decision**

Seeking to patent the same protein, the defendant, Yeda Research and Development, challenged the plaintiff’s patent in an interference proceeding before the Board. *Id.* During the interference proceeding, the defendant argued that the LeMaire patent was in violation of 35 U.S.C. § 102(b)<sup>3</sup> and, therefore, invalid because it was described in the Engelmann reference. *Id.* The plaintiff conceded that the Engelmann reference constituted prior art, Pl.’s Mot., Ex. D (“Bd. Dec.”) at 8, but argued that it had patented the protein before the article was published through its ‘072 and ‘089 applications in Germany, Mem. Op. (June 13, 2005) at 2. Therefore, the plaintiff insisted that it was entitled to the benefit of the earlier filing dates of the ‘072 and

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<sup>3</sup> 35 U.S.C. § 102(b) states that “[a] person shall be entitled to a patent unless the invention was . . . described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States.”

‘089 applications under 35 U.S.C. § 119.<sup>4</sup> *Id.* The Board held that the LeMaire claims were unpatentable because “the party LeMaire [did] not sustain[] its burden of establishing, by a preponderance of the evidence, that their earlier filed German applications satisf[ied] the first paragraph description requirement of 35 U.S.C. § 112.” Bd. Dec. at 8. Noting the omission of three amino acids in positions 20-22 in the ‘089 application, the Board rejected the plaintiff’s argument that these three amino acids are an inherent characteristic of the truncated sequence. *Id.* at 15-18. The Board reasoned that the “N terminal sequence analysis indicates the inhomogeneity of the amino acid sequences found,” and “[t]herefore, the N terminus sequences of the proteins are unpredictable.” *Id.* at 18. The Board also noted that the sequences described in the ‘089 application may describe either the TBP-I or the TBP-II protein. *Id.* at 19. Because “inherency may not be established by probabilities or possibilities,” the Board ruled that the ‘089 application did not sufficiently describe the TBP-II protein, and therefore, the plaintiff’s patent was invalid.

#### **D. Procedural Background**

The plaintiff now appeals the Board’s decision to this court under 35 U.S.C. § 146.<sup>5</sup> In 2005, the defendant filed a preliminary motion for summary judgment, agreeing for purposes of that motion to adopt the plaintiff’s interpretation of the LeMaire patent. Mem. Op. (June 13, 2005) at 3. After clarifying that the plaintiff’s interpretation limits the scope of the LeMaire patent to the TBP-II protein (as opposed to the TBP-II protein and a partial amino acid

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<sup>4</sup> 35 U.S.C. § 119 states that “[a]n application for patent for an invention filed in this country by any person who has . . . previously regularly filed an application for a patent for the same invention in a foreign country . . . shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country.”

<sup>5</sup> 35 U.S.C. § 146 states that “[a]ny party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference, may have remedy by civil action.”

sequence), the court denied the defendant's motion because the defendant conceded in its reply that the '089 application adequately describes the TBP-II protein. *Id.* at 7.

Both parties then filed claim construction briefs to propose how the court should interpret the claims of the LeMaire patent. On June 28, 2007, the court concluded that the LeMaire patent covers a single protein, TBP-II, rejecting the defendant's argument that the patent includes man-made and naturally occurring muteins. Mem. Op. (June 28, 2007) at 1. Several months later the parties filed motions for summary judgment, oppositions and replies. In addition, the defendant filed a motion to exclude evidence on which the plaintiff relied in its motion for summary judgment. Briefing complete, the court now turns to the parties' motions.

### **III. ANALYSIS**

#### **A. The Court Denies Defendant's Motion to Exclude Evidence and Arguments**

The plaintiff argues that the defendant's motion should be denied *ab initio* because the defendant failed to comply with Local Civil Rule 7(m). Pl.'s Opp'n to Def.'s Mot. to Exclude Evidence ("Pl.'s Evid. Opp'n") at 4. The plaintiff recounts that the defendant merely sent "an e-mail announcing [its] intention to file a motion . . . to exclude certain unspecified evidence . . . ." *Id.* In an e-mail the following day, the plaintiff responded that it would oppose the motion, and the defendant then replied that it would file a motion "if and when [the plaintiff] advances such argument or evidence in its motion for summary judgment." *Id.*, Ex. A. The defendant submits that in addition to the three e-mails exchanged, the defendant placed two telephone calls to the plaintiff's counsel on the day the motion was filed. Def.'s Evid. Reply at 4. Failing to reach the plaintiff on both attempts, the defendant left one message that the plaintiff did not return. *Id.*

Local Civil Rule 7(m) requires counsel to “discuss the anticipated motion . . . *either in person or by telephone*, in a good-faith effort to determine whether there is any opposition to the relief sought and, if there is opposition, *to narrow the areas of disagreement*.” LCvR 7(m) (emphasis added). Thus, the defendant failed to satisfy Rule 7(m) on two accounts. First, the defendant did not discuss the anticipated motion “either in person or by telephone.” *Ellipso, Inc. v. Mann*, 460 F. Supp. 2d 99, 102 (D.D.C. 2006) (denying discovery motions absent “any hint that [the parties] discussed the motion in person or by phone”). The defendant telephoned the plaintiff twice the day it filed the motion, but was unsuccessful in reaching the plaintiff. Def.’s Evid. Reply at 4. Although a party need not “wait in vain on an evasive party,” *United States ex rel. K&R Ltd. P’ship v. Mass. Hous. Fin. Agency*, 456 F. Supp. 2d 46, 52 (D.D.C. 2006), after years of disputing the merits of a claim, calling the day of a filing hardly represents a “good-faith effort” to discuss the anticipated motion, as Rule 7(m) requires.

Second, the defendant’s e-mails and phone calls failed to address one of the stated purposes of Rule 7(m) – “to narrow the areas of disagreement.” LCvR 7(m). The defendant acknowledges this purpose and summarily concludes that it “satisfied its obligation to make a good-faith effort to narrow the issues that might be presented to the Court.” Def.’s Evid. Reply at 4-5. But the record belies the defendant’s assertion. In the brief e-mail exchange the defendant merely notifies the plaintiff that it “intends to file a motion in limine requesting the Court to exclude evidence and argument that Abbott offers in this action, but did not put before the Board.” Pl.’s Evid. Opp’n, Ex. A. The defendant provides no more detail and no opportunity to narrow the issues. In fact, the defendant sent the e-mail on October 4, 2007 – before the plaintiff had filed its motion for summary judgment. *Id.* At that time, the defendant was not aware what evidence it would be asking the court to exclude, making it difficult, if not

impossible, for the parties to engage in fruitful discussions. Even after the plaintiff filed its motion for summary judgment on October 31, 2007, the defendant's perfunctory two phone calls the day of the filing did not constitute a good-faith effort. *Poque*, 235 F.R.D. at 529 (holding that "[t]he obligation to confer may not be satisfied by perfunctory action, but requires a good faith effort to resolve the nondispositive disputes that occur in the course of litigation").

The defendant adds that it contacted the plaintiff after briefing had commenced to discuss whether it might narrow the issues. Def.'s Evid. Reply at 5. Specifically, the defendant avers that it contacted the plaintiff for this purpose "well before briefing was complete." *Id.* The defendant fails to mention that the plaintiff had already filed its opposition to the defendant's motion at the time of the contact. *Compare* Pl.'s Evid. Opp'n (Dec. 7, 2007) *with* Def.'s Evid. Reply, Ex. 4 (stating in an e-mail dated December 13, 2007 that "it is still possible to narrow those issues"). By that time, the plaintiff had spent time and resources opposing the defendant's motion, and the feeble attempts to reach an agreement at that stage were not sufficient to satisfy Rule 7(m). *See Poque*, 235 F.R.D. at 529. The defendant also cites *Hagar v. Bluefield Regional Medical Center* in asserting that the plaintiff's "argument is moot, as it can't point to any prejudice." Def.'s Evid. Reply at 5. In *Hagar*, the court explained in a footnote that "[a]lthough [the defendant] did not timely comply with [Rule 7(m)], it eventually conferred with plaintiff who advised it that it would be opposing the motion[, and] it is clear from the record that [the plaintiff] was not going to voluntarily produce the memoranda." *Hagar v. Bluefield Reg'l Med. Ctr.*, 170 F.R.D. 70, 75 n.4 (D.D.C. 1997). Although prejudice *vel non* may indeed weigh on a court in determining whether to dismiss a motion for failing to comply with Rule 7(m), the court cannot, on the current record, determine the likelihood that an agreement may have been reached. Def.'s Evid. Reply, Ex. 4 (responding to the defendant's late request to narrow the

issues, the plaintiff's counsel relays that he will first have to confer with the client).

Consequently, the court denies the defendant's motion to exclude evidence.<sup>6</sup>

## **B. The Board's Decision is Clearly Erroneous**

### **1. Legal Standard for Review of Board Decision under 35 U.S.C. § 146**

Congress provides for district court review of a decision by the Board of Patent Appeals and Interferences of the United States Trademark Office Patent and Trademark Office. 35 U.S.C. § 146. Questions of law are reviewed *de novo*, but the underlying factual determinations made by the Board are reviewed for clear error. *See Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1348 (Fed. Cir. 2000). If, however, the 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 these hybrid cases the court becomes a *de novo* factfinder for issues on which the court accepts new evidence. *Winner*, 202 F.3d at 1347-48. (holding that "live testimony admitted on all matters that were before the Board triggers a *de novo* trial").

### **2. Legal Standard for a "Written Description" Under 35 U.S.C. § 112**

Congress requires patents to provide a "written description" of the invention. 35 U.S.C. § 112. Compliance with the "written description" requirement in 35 U.S.C. § 112 is a question of fact that must be determined on a case-by-case basis. *Vas-Cath v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991); *In re Wilder*, 736 F.2d 1516, 1520 (Fed. Cir. 1984). The description is "separate and distinct from the enablement requirement," *Vas-Cath*, 935 F.2d at 1563, and detailing the use or function of an invention is insufficient, *Holland Furniture Co. v. Perkins*

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<sup>6</sup> The court notes, however, that a party "may not . . . advance new legal theories [and therefore evidence substantiating these new legal theories] at the trial court level, even if the overarching legal issue was presented below." *Boston Sci. Scimed v. Medtronic Vascular, Inc.*, 497 F.3d 1293, 1298 (Fed. Cir. 2007) (recognizing that "permitting a party to raise [] theories for the first time before the trial court would be both inefficient and 'wasteful of administrative resources'").



*Glue Co.*, 277 U.S. 245, 257-58 (1928). “[T]he applicant must [] 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*.” *Vas-Cath*, 935 F.2d at 1563-64. The description “must be in such full, clear, and exact terms as to enable one skilled in the art to which it appertains to compound and use the invention . . . without making any experiments . . . .” *Wood v. Underhill*, 46 U.S. 1, 4 (1846).

### **3. The Evidence Does Not Support the Board’s Conclusion**

The parties raised, and the Board addressed, whether the ‘089 application satisfies the written description requirement by inherently disclosing the TBP-II protein. Def.’s Mot., Ex. F (“LeMaire Br.”) at 12; Bd. Dec. at 18-19 (concluding that neither the “‘072 [n]or ‘089 application, when given its necessary and only reasonable construction, inherently satisfies the limitations of the LeMaire claims”). Echoing the Board’s reasoning, the defendant contends that the ‘089 application’s description (omitting three amino acids added to the LeMaire patent) could describe more than one protein and, therefore, the three omitted amino acids were not inherently described. Def.’s Mot. at 16-17. The plaintiff counters that the ‘089 application only describes one protein and that naming the three additional amino acids in the LeMaire patent adds nothing to the validity of the identification. Pl.’s Opp’n at 10, 16.

Before the Board, the plaintiff “submitted no testimony as to what the . . . ‘089 application[] would reasonably convey to one of the ordinary skill in the art at the time of filing . . . vis-à-vis the N terminus amino sequences now claimed by the LeMaire involved patent.” Bd. Dec. at 17-18. Although the court is sympathetic to the Board’s position – analyzing complex protein structures with insufficient expert testimony – the evidence does not support the Board’s conclusion that the description in the ‘089 application was insufficient. The Board channeled two rationales to support its decision. First, it reasoned that the N-terminus sequences of the

TBP-II protein are unpredictable because of the “inhomogeneity of the amino acid sequences found.” Bd. Dec. at 18. The Board cited to the ‘072 and ‘089 applications and the LeMaire patent description to support its conclusion, but did not cite the Engelmann reference although well aware of its relevance. *Id.*; LeMaire Br. at 6; Def.’s Evid. Reply, Ex. 2 (“Wallach Opening Br.”) at 7 (attaching the Engelmann reference as exhibit 1 to the brief). When compared, the ‘089 application, LeMaire patent and Engelmann reference provide entirely consistent descriptions of the TBP-II protein albeit with varying levels of specificity.<sup>7</sup> Def.’s Mot. at 13-14; Pl.’s Opp’n at 22. Even the majority of the known amino acids set forth in the ‘072 application match the amino acids designated in the ‘089 application and LeMaire patent. Def.’s Mot. at 13-14. And the Engelmann reference further clarifies that the inhomogeneity of N-terminus sequences “was not due to coexistence of different proteins in the TBPII preparation, but rather reflected truncation in the same protein to varying degrees at its NH<sub>2</sub> terminus.” Pl.’s Opp’n, Ex. C (“Engelmann Reference”) at 1532. Accordingly, the evidence cuts against the Board’s determination that the N-terminus sequences of the TBP-II protein are unpredictable.

Second, the Board explained that the ‘089 application does not provide an adequate description because it may describe either the TBP-I or the TBP-II protein. Bd. Dec. at 19. In its decision the Board cited an article and two patent applications to support its conclusion, but did not extrapolate any relevant information from these sources. *Id.* In its motion, the defendant, reciting the Board’s own language, fails to substantiate the Board’s reasoning. Def.’s Mot. at 16-17. The plaintiff protests that the TBP-II protein, as described in the ‘089 application, Pl.’s Opp’n, Ex. A at col. 5, and the TBP-I protein “do not have any amino acids in common at any of the first 16 positions,” *id.*, Ex. GG at 39 & Ex. HH at 3. After reviewing the record, the court

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<sup>7</sup> The ‘089 application does not disclose the amino acids in positions 20-22, and the Engelmann reference provides, at most, 5 of the 22 amino acids described in the LeMaire patent. Def.’s Mot. at 13-14; Pl.’s Opp’n at 22.

agrees and vacates the Board's decision because the evidence is wholly unresponsive. *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948) (opining that "[a] finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed").

#### **IV. CONCLUSION**

For the foregoing reasons the court grants the plaintiff's motion for summary judgment and denies the defendant's motion for summary judgment and motion to exclude evidence and arguments. Therefore, the court vacates the Board's decision, and remands the case for further proceedings. An order consistent with this Memorandum Opinion is separately and contemporaneously issued this 15th day of September, 2008.

RICARDO M. URBINA  
United States District Judge