EXHIBIT B

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

THE WASHINGTON UNIVERSITY, Plaintiff, v. WISCONSIN ALUMNI RESEARCH FOUNDATION, Defendant.	)	Civ. No. 13-2091-JFB **REDACTED - PUBLIC VERSION**

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OPINION

November 26, 2018
Wilmington, Delaware

BATAILLON, Senior District Judge

I. INTRODUCTION

A. Procedural Background

On December 26, 2013, Plaintiff, Washington University ("WashU" or "Washington University") filed this action against Defendant, Wisconsin Alumni Research Foundation ("WARF") alleging breach of contract, breach of the implied covenant of good faith and fair dealing, breach of fiduciary duty, and requesting an equitable accounting. (D.I. 1.) WashU's claims arise out of a 1995 Inter-Institutional Agreement (the "IIA") between the parties. (*Id*.)

WARF answered the Complaint with a motion to dismiss that it filed on February 20, 2014. (D.I. 12.) In addition to challenging the sufficiency of the Complaint, WARF also challenged WashU's claims as time-barred by Wisconsin's relevant statutes of limitations. (D.I. 14 at ¶ 8 at 3–4, ¶ 9 at 4.) The motion to dismiss was fully briefed on April 3, 2014. (D.I. 19.) This Court deferred ruling on the motion to dismiss until summary judgment. After the close of discovery, on July 15, 2015, the parties filed cross motions for summary judgment. (D.I. 96; D.I. 99.) Summary judgment briefing was complete on September 15, 2015. (D.I. 120; D.I. 122.)

With trial scheduled for February 2016, this Court issued its Memorandum Opinion, (D.I. 130), and Order, (D.I. 131), on January 25, 2016, dismissing the motion to dismiss as moot and granting summary judgment in favor of WARF on its statute of limitations defenses, (*id.*). Specifically, this Court held that neither equitable estoppel, (D.I. 130 at 15–20), nor Wisconsin's annual payment exception applied, (*id.* at 13–14). This Court also granted partial summary judgment in favor of WashU, holding that the implied covenant of good faith and fair dealing applied to the IIA. (*Id.*) This Court then granted judgment in favor of WARF. (D.I. 131.)

On February 24, 2016, WashU appealed this Court's summary judgment decision to the United States Court of Appeals for the Third Circuit. A panel of the Third

Circuit issued its opinion on July 11, 2017, agreeing with this Court's ruling on the covenant of good faith and fair dealing and otherwise reversing this Court's issue of judgment, citing various issues of material fact that, according to the Third Circuit, made summary judgment inappropriate. *Washington Univ. v. Wisconsin Alumni Research Found.*, 703 F. App'x 106 (3d Cir. 2017).

Following the Third Circuit's reversal, on September 22, 2017, WARF filed an Answer to the Complaint. (D.I. 145.) In the Answer, WARF raises the defenses of statute of limitations, laches, and accord and satisfaction. (*Id.* at ¶¶ 59–61 at 14.) WashU argues that the accord and satisfaction defense was not disclosed by WARF during discovery, specifically in response to a contention interrogatory "on point." (D.I. 154 at 9–10.)

B. Trial

On March 5, 2018, the parties submitted a Joint Pretrial Order. D.I. 154. In the parties' Statements of Contested Issues of Fact and Law, the parties identified the following issues for resolution at trial: (1) express breach of the IIA, (D.I. 154-1, ex. 2 at ¶¶ 1–7, *id.*, ex. 3 at ¶ 4), which necessarily involves construing the IIA's "relative value" clause, (*compare*, D.I. 100 at 6–16 (proposing construction of "relative" and "value" terms in the IIA), *with* D.I. 113 at 6–14 (proposing an alternative construction under the plain meaning of these contested terms)); (2) breach of the covenant of good faith and fair dealing (implied breach of the IIA), (D.I. 154-1, ex. 2 at ¶¶ 8–14, *id.*, ex. 3 at ¶¶ 5–7), including the interpretation of the responsibilities associated with the covenant, (*compare* D.I. 100 at 16–18, D.I. 120 at 5–6 (ascribing a duty to determine relative value "in good faith and fairly"), *with* D.I. 97 at 16–17; D.I. 122 at 8–9 (arguing that the covenant required WARF to assign a relative value in accordance with [WARF's] policies)); (3) whether WashU's claims are time-barred, (D.I. 154-1, ex. 2 at ¶¶ 15–16, *id.*, ex. 3 at ¶¶ 1–3), including the subsidiary questions of: (a) whether WashU's

equitable estoppel claim prevents WARF from asserting a statute of limitations defense, (*id.*, ex. 2 at ¶ 15, *id.*, ex. 3 at ¶ 3), including findings of fact outlined by the Third Circuit, (D.I. 141-2 at 9); and (b) whether the annual payment exception applies, D.I. 154-1, ex. 2 at ¶ 16, *id.*, ex. 3 at ¶ 2), including factual questions identified by the Third Circuit, (D.I. 141-2 at 6); (4) whether WARF's laches defense applies, (D.I. 154-1, ex. 2 at ¶ 17, *id.*, ex. 3 at ¶¶ 8–9); (5) whether WARF was timely in raising its accord and satisfaction defense and, if so, whether the defense applies, (*id.*, ex. 2 at ¶¶ 18–19, *id.*, ex. 3 at ¶¶ 10–11); and (6) what remedies, including compensatory damages, are warranted, (*id.*, ex. 2 at ¶¶ 20–22, *id.*, ex. 3 at ¶¶ 12–16).

The court held a four-day bench trial.

The court's findings of fact and conclusions of law are set forth below.

II. FINDINGS OF FACT

A. Uncontested Facts

The parties have agreed to the following facts. (D.I. 154-1, ex. 1.)

1. The Parties and Jurisdiction

1. Washington University ("WashU") is a not-for-profit Missouri corporation having its principal place of business at One Brookings Drive, St. Louis, Missouri 63130. (*Id.* at ¶ 1.)

2. Wisconsin Alumni Research Foundation ("WARF") is a not-for-profit Wisconsin corporation having its principal place of business at 614 Walnut Street, Madison, Wisconsin 53726. (*Id.* at ¶ 2.)

3. WARF is the designated technology transfer organization for the University of Wisconsin-Madison. (*Id.* at ¶ 3.)

4. The amount in controversy exceeds $75,000. (*Id.* at ¶ 4.)

5. Dr. Eduardo Slatopolsky ("Dr. Slatopolsky") is and was at relevant times a professor and researcher at WashU. (*Id.* at ¶ 5.)

6. Dr. Hector DeLuca ("Dr. DeLuca") is and was at relevant times a professor and researcher at the University of Wisconsin. (*Id.* at ¶ 6.)

2. WARF's 1993 License with Abbott And The '497 and '925 Patents

7. On January 1, 1993, WARF and Abbott Laboratories ("Abbott")[1] entered into a license agreement (the "1993 License") relating generally to two Vitamin D compounds that were under research and development as a pharmaceutical drug product by Abbott—(1) "paricalcitol" (which later became known as "Zemplar" upon FDA approval in 1998) and (2) 1 alpha, 25 dihydroxy-19-nor-24, 24-dihomo-cholecalciferol ("24,24-dihomo" or the "licensed 19-nor Vitamin D_3 compound").[2] (D.I. 154-1, ex. 1 at ¶ 7.)

8. The 1993 License granted Abbott exclusive rights to WARF-owned U.S. Patent Nos. 5,587,497 ("the '497 patent") and 5,246,925 ("the '925 patent").[3] (*Id.* at ¶ 8.)

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[1] Abbott Laboratories is currently known as AbbVie, Inc. Subject to a few exceptions (e.g., when quoting from specific documents), the Court refers to both entities as "Abbott."

[2] Paricalcitol, is referred to as "1 alpha [or α], 25 dihydroxy-19-nor-ergocalciferol[,]" (JX-005, appxs. A, D), and as "1 alpha-dihydroxy-19-nor-vitamin D_2[,]" (*see* JX-003 at col. 12, l. 49; Tr. at 151:5–11 (Dr. DeLuca)). "Ergocalciferol" is another term for vitamin D_2; thus, paricalcitol is a vitamin D_2 compound. (Tr. at 120:10–16 (Dr. DeLuca).) Vitamin D_3 is also referred to as "cholecalciferol," so 24,24-dihomo-cholecalciferol is a vitamin D_3 compound. (JX-085 at ¶ 19 at 5 of 215; JX-092 at JX092.002; *see also* D.I. 163–2, ex. B at 17:6–8.) *See infra* note 21. The 1α, 25 dihydroxy-19-nor-ergocalciferol compound was not given the generic name "paricalcitol" by the FDA until some point in time between 1997 and 1998. (*See* JX-374 (noting that the generic name had been "[c]hanged from Paracalcin to Paricalcitol").) Nonetheless, in discussing events prior to 1998, the court refers to the compound as **paricalcitol**, even though the parties at the time may have employed different terms to refer to the compound.

[3] The court notes that neither of the '497 or '925 patents had issued at the time of the1993 license, (JX-002, cover page; JX-003, cover page), the '497 patent had not even been applied for (because it was filed on May 16, 1995 (JX-003, cover page)), and neither patent was specifically mentioned in the 1993 license, (JX-005, appx. B). However, "licensed patents" are defined a "those patents and patent applications listed in Appendix B . . . and any continuations, continuations-in-part, divisions, reissues, or extensions thereof and any patents which may issue from any such applications."

9. The 1993 License also granted Abbott rights to 28 other patent families, which were listed in Appendix C and called "Ancillary Patents." (*Id.* at ¶ 9.)

10. The 1993 License does not include the '815 patent, the subject matter of which had not yet been invented. (*Id.* at ¶ 10.)

11. The '497 patent is a compound or composition of matter patent that covers paricalcitol (among other vitamin D compounds). (*Id.* at ¶ 11.)

12. The '497 patent names Dr. DeLuca as an inventor. (*Id.* at ¶ 12.)

13. Under "Related U.S. Application Data," the '497 patent states that it "is a division of Ser. No. 960,241, Oct. 1992, Pat. No. 5,246,925." (*Id.* at ¶ 13.)

14. Under "Related U.S. Application Data," both the '497 and '925 patents state that they are "a continuation-in-part of Ser. No. 321,030, Mar. 9, 1989, abandoned." (*Id.* at ¶ 14.)

15. The '925 patent is a method of treatment patent that covers a method of using paricalcitol (among other vitamin D compounds) to treat secondary hyperparathyroidism ("SHPT"). (*Id.* at ¶ 15.)

16. The '925 patent names Dr. DeLuca as an inventor. (*Id.* at ¶ 16.)

17. Dr. Slatopolsky is not an inventor on the '925 and '497 patents. (*Id.* at ¶ 17.)

18. WashU does not have an ownership interest in either the '497 patent or the '925 patent. (*Id.* at ¶ 18.)

(JX-005, appx. A.) U.S. Patent Application No. 07/557,400 (the "'400 application") is listed in Appendix B. (JX-005, appx. B.) The '925 patent is a continuation of an application that is a continuation of the '400 application. (JX-002, cover page.) The '497 patent is the divisional application of a divisional application, which is a divisional application of a continuation application, which is a continuation of the '400 application. (JX-003, cover page.) Therefore, the '497 and '925 patents are included in the 1993 license.

19. The ’925 patent was granted a patent term extension of 574 days based on the regulatory approval of paricalcitol. (*Id.* at ¶ 19.)

20. The ’925 patent expired on April 6, 2012, with an extension for pediatric exclusivity until October 17, 2012. (*Id.* at ¶ 20.)

21. The ’497 patent expired on December 24, 2013, with an extension for pediatric exclusivity until June 24, 2014. (*Id.* at ¶ 21.)

3. The ’815 Patent and The Parties’ 1995 Inter-Institutional Agreement

22. On July 13, 1995, WARF filed a patent application that issued on January 28, 1997 as U.S. Patent No. 5,597,815 (“the ’815 patent.”). (*Id.* at ¶ 22.)

23. The ’815 patent names Dr. DeLuca and Dr. Slatopolsky as co-inventors. (*Id.* at ¶ 23.)

24. WARF prosecuted the patent on behalf of WARF and WashU. (*Id.* at ¶ 24.)

25. The ’815 patent expired on July 13, 2015, with an extension for pediatric exclusivity until January 13, 2016. (*Id.* at ¶ 25.)

26. In November 1995, WashU and WARF entered into an “Inter-Institutional Agreement for Prevention of Hyperphosphatemia in Kidney Disorder Patients” (the “1995 Inter-Institutional Agreement” or “IIA”) to govern the parties’ relationship with respect to the patent application that led to the ’815 patent. (*Id.* at ¶ 26.)

27. The 1995 Inter-Institutional Agreement is valid and enforceable as between the parties. (*Id.* at ¶ 27.)

4. Zemplar’s Regulatory Approval

28. Abbott submitted a New Drug Application (NDA) for paricalcitol on January 17, 1997. (*Id.* at ¶ 28.)

29. Paricalcitol was first FDA-approved for the treatment of secondary hyperparathyroidism in patients with chronic renal failure in an intravenous ("IV") form on April 17, 1998, and in capsule form on May 26, 2005. Paricalcitol was sold under the brand name Zemplar. (*Id.* at ¶ 29.)

5. WARF's 1998 License With Abbott

30. Effective July 28, 1998, WARF and Abbott entered into a new license agreement (the "1998 License") that "supersede[d] the 1993 [Abbott License] with respect to [paricalcitol/Zemplar]." (*Id.* at ¶ 30.)

31. The 1998 License added the '815 patent to the bundle of IP rights licensed by Abbott in 1993. (*Id.* at ¶ 31.)

6. Standstill Agreement

32. The parties entered into a valid and enforceable standstill agreement effective April 9, 2013, which resulted in the tolling of all applicable periods of limitation, repose, and laches relating to any claim concerning the 1995 Inter-Institutional Agreement or the '815 patent effective as of April 9, 2013. (*Id.* at ¶ 32.)

This concludes the uncontested facts agreed to by the parties. (D.I. 154-1, ex. 1 at 4.)

B. Background

33. The trial transcript is docketed at D.I. 181 (pages 1–337), D.I. 182 (pages 338–682), D.I. 183 (pages 683–1037), D.I. 184 (pages 1038–1191)—the Court refers to these docket items collectively as the trial transcript (hereinafter, "Tr.").

1. Witnesses

34. In addition to Dr. Slatopolsky and Dr. DeLuca, introduced above, the parties presented a number of witnesses at trial. The Court introduces these witnesses herein by their order of appearance at trial.

(a) Dr. Cleare

35. Michael Cleare, PhD ("Dr. Cleare") holds a doctorate in chemistry and appeared on behalf of WashU as an expert on technology transfer and patent licensing. (Tr. at 165:1–168:14.) Dr. Cleare was "asked to evaluate WARF's conduct under the [IIA]" and "to evaluate the relevance, if any, of the ancillary patents [to the 1998 WARF-Abbott License] to Zemplar." (Tr. at 168:15–169:5.)

(b) Dr. Brandt

36. Ms. E.J. Brandt, PhD ("Dr. Brandt") worked in the technology transfer office at Washington University's medical school from 1993–1997 and negotiated the 1995 Inter-Institutional Agreement with WARF. (Tr. at 343–372.) Dr. Brandt appeared by deposition. (*Id.*)

(c) Mr. Kratochivil

37. Mr. John Kratochivil ("Mr. Kratochivil") is a business development director at the Office of Technology Management at Washington University. (Tr. at 372–392.) Mr. Kratochivil had primary responsibility for the IIA at WashU and appeared by deposition. (*Id.*)

(d) Mr. Surber

38. Mr. James Surber, Esq. ("Mr. Surber") is assistant vice chancellor and associate general counsel for Washington University. (Tr. at 393–485.) He has worked at WashU since 2010. (Tr. at 394.)

(e) Mr. Stoveken

39. Mr. Mark Stoveken ("Mr. Stoveken") is a licensing manager at WARF, a position he has held since 2008. (Tr. at 486–519.) Mr. Stoveken has direct knowledge of the 1998 WARF-Abbott License and appeared by deposition. (*Id*.)

(f) Mr. Thomas

40. Mr. Vincent Thomas ("Mr. Thomas") is WashU's economic damages expert. (Tr. at 521–621.)

(g) Dr. Gulbrandsen

41. Carl E. Gulbrandsen, PhD, JD (Dr. Gulbrandsen) is the former managing director of WARF, having retired in 2016 after nearly nineteen years with WARF. (Tr. at 623–750.) Dr. Gulbrandsen arrived at WARF a few years after the IIA was signed and shortly before WARF and Abbott signed the 1998 License. (*Id*.)

(h) Mr. Lentz

42. Mr. Edward Lentz, Esq. ("Mr. Lentz") is WARF's pharmaceutical licensing expert. (Tr. at 775–915.)

(i) Dr. Severson

43. James A. Severson, PhD ("Dr. Severson") is WARF's technology transfer expert. (Tr. at 916–1036.)

(j) Ms. Mulhern

44. Ms. Carla S. Mulhern ("Ms. Mulhern") is WARF's economic damages expert. (Tr. at 1059–1129.)

2. WARF's Prior Representations to This Court

45. The parties admitted into evidence more than 500 documents, including filings by WARF and Abbott in litigation against generic pharmaceutical manufacturers. For example, the record includes various filings in *Abbott Labs. et al. v. Hospira, Inc.*, Civ. No. 1:12-cv-00234-GMS (D. Del. Feb. 27, 2012) (the "*Hospira* Litigation") throughout these Findings of Fact and Conclusions of Law. (JX-063 (Complaint); JX084 (rebuttal expert report of Dr. Vigil); JX-085 (ex. M to Joint Pretrial Order, WARF and

Abbott's proposed findings of fact and conclusions of law); JX-293 (Proposed Joint Pretrial Order).)

46. When Dr. DeLuca and Dr. Slatopolsky were deposed in the case at bar, the parties' questions focused on the deponents' prior deposition testimony in the *Hospira* litigation. (*Compare* D.I. 163-2, ex. B (March 13, 2015 deposition of Dr. DeLuca in the instant litigation); D.I. 163-8, ex. H (March 11, 2015 deposition of Dr. Slatopolsky), *with* JX-424 & JX-425 (Feb. 13–14, 2013 deposition of Dr. DeLuca in *Hospira*); JX-508 (March 8, 2013 deposition of Dr. Slatopolsky in *Hospira*).) At times, the original depositions from the *Hospira* litigation provide far more insight into the background of the research relationship between Drs. DeLuca and Slatopolsky. *See infra* ¶¶ 97–117.

47. These filings are part of the record, and thus, the Court relies on them.

3. Chronic Kidney Disease

48. Chronic kidney disease is a progressive disease defined by structural or functional abnormalities of the kidney with staging based on the level of kidney function. The most severe form of chronic kidney disease was known as chronic renal failure or end-stage renal disease ("ESRD") and is now termed chronic kidney disease ("CKD") Stage 5. (JX-085 at ¶ 8 at 3 of 215.)

49. The five stages of chronic kidney disease are based on the estimated rate of blood filtration by the kidneys, known as glomerular filtration rate ("GFR"). CKD Stage 5 involves the lowest estimated rate of blood filtration by the kidneys. Patients with CKD Stage 5 have total or nearly total permanent kidney failure and must undergo some form of renal replacement therapy (e.g., dialysis or transplantation) in order to stay alive. (JX-085 at ¶ 9 at 3 of 215.)

50. The diagnosis of chronic kidney disease has significant consequences for both patients and their doctors because the disease will affect every aspect of life and health. (JX-085 at ¶ 10 at 3 of 215.)

51. Chronic kidney disease implicates an extremely complicated system of minerals and hormones, including calcium, phosphorus, active vitamin D (calcitriol), and parathyroid hormone ("PTH"). With the progressive development of chronic kidney disease, the body attempts to maintain normal serum concentrations of calcium and phosphorus (referred to as calcium homeostasis and phosphorus homeostasis, respectively) with altered production of calcitriol, PTH, and the protein known as FGF-23. (JX-085 at ¶ 11 at 3 of 215.)

52. Eventually, the body of a chronic kidney disease patient becomes unable to maintain normal mineral homeostasis, resulting in (1) altered serum levels of calcium, phosphorus, calcitriol, PTH, and FGF-23; (2) disturbances in bone remodeling and mineralization or impaired linear growth in children; and (3) extraskeletal calcification in soft tissues and arteries, which can lead to cardiovascular disease and increased mortality. (JX-085 at ¶ 12 at 4 of 215; JX-083 at ¶ 50.)

53. Put simply, Dr. Slatopolsky testified that "the idea is to suppress parathyroid hormone. But if your calcium goes up too high, then you calcify your body. Later on, we learn[ed] that if your phosphorus goes up, [] you [also] calcify your body." (JX-508 at 30:12–15 (Dr. Slatopolsky's deposition in *Hospira*).)

(a) Secondary Hyperparathyroidism (SHPT) is part of Renal Osteodystrophy (RO), so SHPT = RO.

54. In 2006, when a consensus conference was held by KDIGO (Kidney Disease: Improving Global Outcomes), the term "chronic kidney disease-mineral bone disorder" ("CKD-MBD") was developed to describe this triad of abnormalities in biochemical measures, skeletal abnormalities, and extraskeletal calcification. (JX-083

at ¶ 50; JX-080 at ¶ 32.) However, prior to 2006, and specifically in the 1980s and 1990s, the term "renal osteodystrophy" ("RO") was used broadly in the medical and academic community to encompass a spectrum of disorders of bone, mineral, and hormonal metabolism, including secondary hyperparathyroidism ("SHPT").[4] (JX-083 at ¶ 50; JX-082 at ¶ 37; JX-080 at ¶¶ 29–33.) At the same time, it developed the CKD-MBD moniker in 2006, the KDIGO proposed redefining the term "renal osteodystrophy" to focus on just the bone disorders of chronic kidney disease. (JX-082 at ¶ 13; JX-080 at ¶¶ 29–33.)

C. Dr. DeLuca, WARF, and Abbott—Calcijex

55. In the late 1960s and early 1970s, Dr. DeLuca first identified the active form of Vitamin D in the body, which is known as "calcitriol."[5] (Tr. at 640:1–13 (Dr. Gulbrandsen); *see also* JX-085 at ¶ 22 at 7 of 215.) WARF granted one of the early calcitriol licenses "to Ross Laboratories, which was part of Abbott." (Tr. at 641:1–4 (Dr. Gulbrandsen).)

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[4] This is notable, for example, in that the '400 application, from which the '497 and '925 patents both derive, is entitled "19-nor vitamin D compounds for use in treating *renal osteodystrophy*." (*See* JX-005, appx. B at 14 of 16 (emphasis added) (listing WARF case number P90058US for "United States Div 07/557400" under this same "renal osteodystrophy" title); *see also* U.S. Patent Application No. 07/557,400. By October 13, 1992, when WARF's attorneys filed the file wrapper continuation of U.S. Patent Application No. 07/879,706, which ultimately became the '925 patent, WARF's attorneys had amended the title of the application to be "19-nor-vitamin D compounds for use in treating *hyperparathyroidism*." *See* U.S. Patent Application No. 07/960,241 (emphasis added). This common specification supports a definition in which hyperparathyroidism is a subset of renal osteodystrophy for two reasons. First, the specification explains that the 19-nor-vitamin D "compounds exhibit highly potent activity in vito [sic] or in vitro, and possess advantageous activity profiles and thus are in use, or have been proposed for use, in the treatment of a variety of diseases such as renal osteodystrophy, vitamin D-resistant rickets, osteoporosis, psoriasis, and certain malignancies[,]" (JX-002 at 1:38–43), but does not include hyperparathyroidism in the list, even though it is claimed, (*id.* at 11:64). Second, claim 1 is for "[a] method for treating hyperparathyroidism which comprises suppressing parathyroid activity by administering . . . at least one compound . . . in an amount . . . sufficient to suppress parathyroid activity *thereby treating renal osteodystrophy*." (*Id.* at 11:64–12:48 (emphasis added).) The '925 patent plainly states that, at least in the minds of the inventors, treating hyperparathyroidism by suppressing PTH has the effect of treating renal osteodystrophy.

[5] The chemical name for calcitriol is 1α,25-dihydroxy Vitamin D_3. (Tr. at 121:17–19 (Dr. Slatopolsky).)

56. In 1986, Abbott obtained FDA certification for "an intravenous solution containing the D_3 version of calcitriol as its active ingredient[]" that it marketed under the trade name Calcijex®. (Tr. at 641:10–14 (Dr. Gulbrandsen); JX-085 at ¶ 40 at 11 of 215; JX-279.) At the time, Calcijex was "the standard of care for the treatment of renal osteodystrophy [RO], and specifically secondary hyperparathyroidism [SHPT]." (JX-085 at ¶ 41 at 11 of 215.)

57. Calcijex's use and efficacy were limited in some kidney disease patients because Calcijex could lead to deleterious side effects known as "hypercalcemia" (excessive blood calcium levels) and "hyperphosphatemia" (excessive blood phosphate levels). (Tr. at 160:4–14 (Dr. DeLuca); JX-080 at ¶ 35; JX-082 at ¶ 24; JX-083 at ¶¶ 59–61; JX-085 at ¶ 41 at 11 of 215.) Hypercalcemia can result in seizures, rickets, arrhythmias, or heart failure, while hyperphosphatemia can cause mineral deposits to form in a patient's soft tissue, including cardiovascular organs, leading to serious illness or death. (JX-080 at ¶ 35; JX-082 at ¶ 23; JX-083 at ¶¶ 11, 61; JX-085 at ¶¶ 27 at 8 of 215, ¶¶ 32–33 at 9–10 of 215, ¶ 41 at 11 of 215.)

D. Replacing Calcijex—Abbott's 19-Nor Analog Program

58. As the WARF-DeLuca patents covering Calcijex neared their end of life, Abbott approached Dr. DeLuca about developing a next generation drug that would "succeed in keeping this franchise of Abbott alive and serving patients." (Tr. at 641:15–23 (Dr. Gulbrandsen).)

59. Abbott "was in search of an injectable solution that had therapeutic efficacy similar to [Calcijex] but with fewer side effects." (JX-085 at ¶¶ 53–54 at 14 of 215.)

60. During the 1980s, in collaboration with other scientists at the University of Wisconsin, Dr. DeLuca synthesized a class of 19-nor Vitamin D_2 and D_3 analogs (the

"19-nor analogs" or the "19-nor Vitamin D analogs") for potential development into a drug. (Tr. at 768:1–14 (Dr. DeLuca); Tr. at 641:24–642:21 (Dr. Gulbrandsen); JX-085 at ¶ 43 at 12 of 215.)

61. In the early to mid-1990s, Abbott referred to this project as the 19-Nor Analog program (the "19-Nor Analog Program"). (JX-086 at JX086.002 ("the 1993 Development Report for the 19-Nor Analog"); *see also* JX-364 at 1 (1994 Development Report).) The focus of this project was to develop what was to become an injectable version of paricalcitol marketed under the name Zemplar®.[6]

E. WARF & Dr. DeLuca Patent the 19-Nor Analogs

62. Beginning in 1989 and through the mid 1990s, Dr. DeLuca and his coinventors described and claimed the 19-nor analogs in a family of patents that includes the '497 patent.[7] (Tr. at 642:22–643:16 (Dr. Gulbrandsen); *see also* JX-085 at ¶ 43 at 12 of 215; JX-003, cover page (listing "Related U.S. Application Data"); *id.* at 11:17–12:50.) The '497 patent discloses and claims "many" compounds.[8] (Tr. at 150:19–151:4 (Dr. DeLuca).)

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[6] For example, by May 1996, the 1995 "Abbott Laboratories 19-nor Development Report" featured the chemical name for the Vitamin D_2 analog in its title. (JX-368 at 1 ("19-NOR-1α,25-DIHYDROXYVITAMIN D2 (19-NOR) DEVELOPMENT REPORT").) The 1996 "Abbott Laboratories Paracalcin Injection Development Report included the generic name for the Vitamin D_2 analog ("paracalcin injection") in its title. (JX-371 at 1 ("19-NOR-1α,25-DIHYDROXYVITAMIN D2 (PARACALCIN INJECTION) DEVELOPMENT REPORT"). In the 1997 "Abbott Laboratories Paricalcitol Injection Development Report[,]" Abbott noted that the generic name had "[c]hanged from Paracalcin to Paricalcitol" and included this new name in the title of the report. (JX-374 at 1 ("19-NOR-1α,25-DIHYDROXYVITAMIN D2 (PARICALCITOL INJECTION) DEVELOPMENT REPORT").) The NDA for "Zemplar (paricalcitol injection)" was approved on April 17, 1998. (JX-051 at JX051.001.)

[7] The court is aware of at least one subsequent application in which WARF was required to file a terminal disclaimer to overcome a double patenting rejection in view of the subject matter of the '497 patent. (Tr. at 237:20–238:5; JX-252, cover page (U.S. Patent No. 5,880,113 (the "'113 patent") noting "[t]he term of this patent shall not extend beyond the expiration date of Pat. Nos. 5,185,150, 5,587,497, 5,321,018, and 5,086,191.").) This terminal disclaimer suggests that at least the '113 patent claimed the same compounds in the '497 patent. (Tr. at 237:14–238:5 (Dr. Cleare).)

[8] Although not at issue in this litigation, the '497and '925 patents disclose treatment of a number of possible diseases and conditions, including: "renal osteodystrophy, vitamin D-resistant rickets, osteoporosis, psoriasis, and certain malignancies." (JX-002 at 1:41–43.)

63. The ’497 patent is entitled “19-nor vitamin D compounds.” (JX-003, cover page.)

64. The ’497 patent originated as U.S. Patent Application No. 08/442,292, which was filed by WARF on May 16, 1995. (JX-003, cover page.)

65. The ’497 patent issued on December 24, 1996. (JX-003, cover page.)

66. The ’497 patent claims “1α,25-dihydroxy-19-nor-vitamin D_2” or paricalcitol/Zemplar. (JX-003 at 12:47; *see supra* ¶ 11.)

67. The ’925 patent is entitled “19-nor vitamin D compounds for use in treating hyperparathyroidism.” (JX-002, cover page.)

68. The ’925 patent originated as U.S. Patent Application No. 07/960,241, which was filed by WARF on October 13, 1992. (JX-002, cover page.)

69. The ’925 patent issued on September 21, 1993. (JX-002, cover page.)

70. The ’925 patent is based on the same specification as the ’497 patent. (Tr. at 874:10–16 (Mr. Lentz); Tr. at 643:17–644:1 (Dr. Gulbrandsen).)

71. The ’925 patent claims “[a] method for treating hyperparathyroidism which comprises suppressing parathyroid activity by administering to a patient having such a disorder at least one [of the claimed] compound[s.]” (JX-002 at 11:64–67.)

72. Both the ’925 and ’497 patents disclose that “[t]hese [19-nor Vitamin D] compounds *should also find use in the suppression of parathyroid tissue*, as for example, in cases of secondary hyperparathyroidism found in renal disease.” (JX-002 at 8:5–8 (emphasis added) (citing “Slatopolsky et al., J. Clin Invest. 74, 2136, 1984”).)[9]

[9] Although WashU does not discuss this citation, the Court notes that the ’497 and ’925 patents cite, as the basis for claims to the suppression of parathyroid tissue, *see* 35 U.S.C. § 112(a), research by Dr. Slatopolsky, published in 1984 and focused on the intravenous effectiveness of 1α, 25-dihydroxyvitamin D_3 (calcitriol, which was approved by the FDA in 1986), (JX-508 at 47:11–48:4 (describing Dr. Slatopolsky’s mid-1980s study of intravenous calcitriol on its ability to suppress PTH in

73. Although the possibility of suppressing parathyroid tissue is discussed in the specification common to the ’925 and ’497 patents, *supra* ¶ 72, and is specifically claimed in the ’925 patent, *supra* ¶ 71, neither of the ’925 or ’497 patents discloses that any of the claimed compounds (especially paricalcitol/Zemplar) were tested and actually *will suppress PTH levels*.[10] (Tr. at 163:15–19 (Dr. DeLuca).)

74. Meanwhile, the ’925 patent discloses two assays, comparing “1α,25-dihydroxyvitamin D_3” (or calcitriol) with “1α,25-dihydroxy-19-nor-vitamin D_3” (a 19-nor Vitamin D_3 analog to calcitriol) in the “differentiation of leukemia cells” and the “calcification of bone[.]” (JX-002 at 6:45–7:46.) These two studies do not discuss results for any 19-nor Vitamin D_2 compounds (including paricalcitol/Zemplar) or the 24,24-dihomo Vitamin D_3 compound licensed to Abbott in 1993. *See infra* ¶ 87; (JX-002 at 6:45–8:62; Tr. at 879:8–14 (Mr. Lentz); *see also* JX-085 at ¶¶ 238–240 at 56 of 215; JX-083 at ¶ 100.)

1. Unanswered Questions from the ’925 and ’497 Patents

75. Even though the ’925 and ’497 patents disclose many compounds that may treat hyperparathyroidism, (*e.g.*, JX-002 at 1:37–43), commercializing a drug requires answering additional questions not answered by either of these patents. Examples of these questions are as follows:

76. First, the patents do not contain biological data showing the effect of 19-nor analogs on parathyroid hormone (PTH) suppression or associated blood

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patients with renal failure—the study was published “in a very good journal, the Journal of Clinical Investigation[.]”)). Based upon this disclosure in the specification common to these patents, the Court concludes that, in the ’925 patent, WARF and Dr. DeLuca obtained patent protection for the treatment of secondary hyperparathyroidism using paricalcitol/Zemplar and the other 19-nor Vitamin D compounds *based entirely on Dr. Slatopolsky’s prior, published research* into the effectiveness of calcitriol.

[10] Contrary to the Court’s finding, WARF argued that the ’925 patent disclosed “that paricalcitol *would* suppress” PTH levels. (D.I. 178 at ¶ 30 at 12 (emphasis added).) As is discussed herein, although Abbott and Dr. DeLuca expected that the 19-nor Vitamin D analogs would suppress PTH, when tested in Dr. Slatopolsky’s lab, at least one of the analogs, the 24,24-dihomo Vitamin D_3 compound, did not suppress PTH. *See infra* ¶¶ 120–123.

phosphorous levels. (Tr. at 163:15–24 (Dr. DeLuca); Tr. at 876:24–877:15, 880:15–19 (Mr. Lentz); *see also* JX-085 at ¶¶ 310–314 at 70–71 of 215, ¶ 431 at 107 of 215, ¶ 466 at 124 of 215.)

77. Second, neither patent includes biological data relating to 19-nor Vitamin D_2 analogs, like paricalcitol/Zemplar.[11] (JX-002 at 6:45–8:62; JX-003 at 6:35–8:40; Tr. at 879:8–14 (Mr. Lentz); *see also* JX-085 at ¶¶ 238–240 at 56 of 215; JX-083 at ¶ 100.)

78. Third, of the many different 19-nor Vitamin D_2 and D_3 compounds identified in the patents, neither patent teaches which specific compounds would actually treat hyperparathyroidism without increasing serum calcium or serum phosphorous.[12] (Tr. at 163:9–24 (Dr. DeLuca); JX-085 at ¶ 246 at 57 of 215; *see generally* JX-083 at ¶¶ 82–104.)

2. Narrowing The 19-Nor Focus

79. Despite the similarities between the many compounds identified in the '497 and '925 patents, different Vitamin D_2 and D_3 analogs have different biological effects. (*See* JX-083 at ¶ 100 (discussing the bone ash testing performed with a Vitamin D_3 analog that was disclosed in the '925 patent and distinguishing this testing from tests performed with paricalcitol, which is a D_2 analog).) Thus, "[k]nowledge of the biological effects of one [19-nor Vitamin D] analog would not necessarily [] translate[] into knowledge of the biological effects of another[analog,]" (JX-085 at ¶ 42 at 12 of 215), such as with respect to a compound's effect on a patient's serum phosphorous levels, (Tr. at 878:19–879:1 (Mr. Lentz); Tr. at 227:16–228:21 (Dr. Cleare)).

[11] WARF's patent attorney made this observation during prosecution of the '815 patent application, "[t]he ['925 patent] disclosure . . . clearly does not state that 19-nor vitamin D_2 compounds have been used, or suggested for use, in the treatment of renal osteodystrophy." (JX-324 at JX324.099.)

[12] Again, this point was not lost on WARF's patent attorney, who argued during prosecution of the '288 patent application that "[i]t should be further noted that the specification of the '925 patent never even mentions serum phosphorus. In addition, there is no data presented in the specification of the '925 patent relating to serum phosphorus." (JX-324 at JX324.099.)

80. The record is not clear about how, in the 19-Nor Analog Program, Abbott narrowed the number of Calcijex-replacement compounds it was considering.

81. Nonetheless, the record shows that between 1991 and 1993, Abbott was evaluating paricalcitol and at least two different Vitamin D_3 analogs. (JX-206 at JX206.002 (identifying "19-NOR-Bis-Homo-1, 25-Dihydroxyvitamin D_3" (the "first 19-nor Vitamin D_3 compound") as a subject of Dr. DeLuca's 1991 study on biological activity); JX-005, appx. A at 12 of 26 (including "1 alpha, 25 dihydroxy-10-nor-24, 24-dihomo-cholecalciferol" in the 1993 License).)

82. In September 1991, Abbott contracted with Dr. DeLuca to perform "Study #91030 –'Biological Evaluation of Two 19-NOR Vitamin D Analogs for Use in Renal Osteodystrophy.'" (JX-206; Tr. at 760:7–763:17 (Dr. DeLuca).) This was a study of "biological activity in vitamin D deficient rats[,]" of two compounds: paricalcitol and the first 19-nor vitamin D_3 analog. (Tr. at 764:2–5 (Dr. DeLuca); *see also* Tr. at 761:12–762:6 (Dr. DeLuca); JX-206.) The objective of the study was "[t]o determine if the two 19-NOR-Vitamin D Analogs . . . have biological activity[.]" (JX-206 at JX206.002.)

83. According to Dr. DeLuca, at the time, his lab was able to measure "[s]erum calcium, bone calcium mobilization, [and] mineralization," but not parathyroid hormone ("PTH"), a logical addition to this study.[13] (Tr. at 764:2–765:21 (Dr. DeLuca); *see also* JX-424 at 165:15–166:19 (explaining that Dr. DeLuca's lab was not set up to study parathyroid glands in culture until "the late '90s").)

84. Therefore, in this 1991 study, Dr. DeLuca was able to test the calcemic effects of paricalcitol and the first 19-nor Vitamin D_3 compound but not whether either of these compounds suppressed PTH.

[13] The Court notes that Dr. DeLuca did not mention measuring phosphorous, the idea of which is attributed to Dr. Slatopolsky. *See infra* ¶¶ 114–115.

85. Given the lack of PTH-measurement capability in Dr. DeLuca's lab and the PTH-focused research that Dr. Slatopolsky eventually performed for Abbott, there is sufficient evidence that Dr. DeLuca and Abbott identified Dr. Slatopolsky as the investigator who could measure the *in vivo* PTH suppression characteristics of the 19-nor analogs. (Tr. at 149:10–150:3 (Dr. DeLuca); JX-005, appx. F at 26 of 26 (outlining Abbott's "Development Plan" in the 1993 License).)

F. The 1993 License

86. WARF and Abbott signed the 1993 License on January 1, 1993. *See supra* ¶ 7.

87. The 1993 License was to two compounds: paricalcitol and the 19-nor-24, 24-dihomo-Vitamin D_3 compound. *See supra* ¶ 7; (*see also* JX-005, appx. A at 12 of 26).

88. The 1993 License was limited to use of these two compounds in the field of the "treatment of renal osteodystrophy and suppression of hyperparathyroidism." (JX-005, appx. A at 13 of 26.)

89. As consideration for the 1993 License, Abbott paid WARF a one-time license fee and agreed to pay earned royalties that were capped at seven percent (7%) of any resulting net sales "calculated as a percentage of the Selling Price of Products whenever manufacture, use or sale of Compounds or Products, absent this license, would amount to infringement of any claim of Licensed Patents or Ancillary Patents" included in the License.[14] (JX-005, § 3.C. at 4 of 26; Tr. at 652:6–23 (Dr. Gulbrandsen).)

[14] This included a seven percent (7%) royalty on any resulting net sales on a product based on the exclusively licensed patents (which included but were not limited to the '497 and '925 patents) and a five percent (5%) royalty on the nonexclusively licensed patents. (Tr. at 651:23–652:14 (Dr. Gulbrandsen); Tr. at 1109:11–1110:16 (Ms. Mulhern).)

90. In the 1993 license, Abbott agreed to the following:

> Abbott warrants that it will diligently pursue commercialization of the inventions of the Licensed Patents. Abbott agrees to and warrants that it will establish and actively pursue the Development Plan. Abbott agrees that within one month following each annual period ending on December 31 and until the Date of NDA[15] Approval in the United States, it will supply WARF with a written Development Report. All development activities and strategies and all aspects of Products design and the like are entirely at the discretion of Abbott, and Abbott shall rely entirely on its own expertise with respect thereto. WARF's review of Abbott's Development Plan is solely to verify the existence of Abbott's activity and to assure compliance with Abbott's obligations to commercialize the inventions of the Licensed Patents, as set forth above.

(JX-005, § 3.A. at 4 of 26.)

91. WARF's expert, Mr. Lentz, explained that "[t]here's always a risk that a company will [] license something exclusively in order to shelve it and thereby bury competition. That's what the university's worried about." (Tr. at 806:13–17.) Thus, in the Development Plan[16] and the annual Development Report, WARF "want[ed] to get enough information to make sure that . . . [Abbott was] diligently pursuing the invention." (Tr. at 806:17–19.)

92. The Development Plan, which was appended to the 1993 License, outlined a number of studies that Abbott needed to perform before submitting a New Drug Application ("NDA") for one of the licensed 19-nor Vitamin D analogs. (JX-005, appx. F at 26 of 26.)

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[15] "NDA" stands for the FDA "New Drug Application" process. *See, e.g.*, 21 C.F.R. § 314 ("Applications for FDA Approval to Market a New Drug").

[16] The "Development Plan," is found in "Appendix F" of the 1993 License. (JX-005, appx. F at 26 of 26.)

93. The very first "Action" item in this Development Plan referred to animal research to be performed by Dr. Slatopolsky in 1993 on the two licensed compounds to "[e]valuate PTH suppression and calcemia in uremic rat model." (JX-005, appx. F at 26 of 26.)

94. At the time, it was not yet known which of the two licensed compounds (paricalcitol, which is a Vitamin D_2 analog, or the 24,24-dihomo Vitamin D_3 analog) would suppress PTH without elevating blood calcium levels. (*See supra* ¶¶ 75–78; Tr. at 136:17–137:12 (Dr. Slatopolsky); Tr. at 154:5–155:13 (Dr. DeLuca); Tr. at 188:1–189:1 (Dr. Cleare).)

95. Based upon subsequent statements in Abbott's 1993 Development Report, which Abbott produced for WARF as part of its obligations under the 1993 License, it is clear that the 1993 License was integral to Abbott's 19-Nor Analog Program (the "19-Nor Analog Program"). (*See* JX086 at JX086.002 (describing, in the 1993 Development Report, the program by the name "19-NOR ANALOG[.]").)

96. By virtue of the Development Plan, WARF had knowledge, at the time it signed the 1993 License, of Dr. Slatopolsky's role in selecting paricalcitol over the 24,24-dihomo Vitamin D_3 analog. (JX-005, appx. F at 26 of 26.)

G. Involving Dr. Slatopolsky

97. According to Dr. DeLuca, the need to "do parathyroid"—to study the PTH effects of the 19-nor analogs *in vivo*—was the reason why "Dr. Slatopolsky came into the picture." (JX-424 at 170:5–11.) For several reasons, Dr. Slatopolsky was an ideal choice to carry out the studies that Abbott needed in connection with its anticipated NDA.

98. First, Dr. Slatopolsky had lab capabilities that Dr. DeLuca did not have, including the ability to "study[] parathyroid glands in culture" and to conduct an animal

model for chronic kidney disease called "the 5/6 nephrectomy model." (Tr. at 149:10–150:3 (Dr. DeLuca).) In fact, Dr. Slatopolsky was one of the first researchers to develop "an immunoassay to measure parathyroid hormone." (JX-508 at 49:22–24.)

99. Dr. DeLuca's laboratory at the time, by contrast, was not studying parathyroid glands in culture, did not have the antibodies needed to study PTH in the blood, and was not performing 5/6 nephrectomy model studies. (D.I. 163–2, ex. B at 27:20–28:11, 56:9–22 (Dr. DeLuca).)

100. Second, Dr. Slatopolsky had extensive clinical experience, having been director of WashU's dialysis clinic for nearly thirty years. (JX-508 at 38:1–20.) Dr. DeLuca described Dr. Slatopolsky as "a nephrologist with a fairly astute knowledge of biochemistry." (JX-424 at 165:17–166:1.)

101. Third, Dr. Slatopolsky and Dr. DeLuca had worked with each other for approximately twenty years, were good friends, and talked on the phone regularly. (JX-508 at 46:24–47:2; 50:17–24 (Dr. Slatopolsky); JX-424 at 164:19–165:14 (Dr. DeLuca); *see also* D.I. 163-8, ex. H at 17:9–12.)

102. Fourth, Abbott had already funded Dr. Slatopolsky's research—a relationship that began in 1982 when Dr. Slatopolsky met with Abbott and discussed the possibility of performing a study on the potential to use an injectable form of calcitriol to treat hyperparathyroidism. (JX-508 at 45:21–23; 47:11–48:4.) In that research, Dr. Slatopolsky and his research team showed "that calcitriol will suppress PTH even before the calcium goes up. Then when you continue with calcitriol, unfortunately your calcium and your phosphorus starts to go up." (JX-508 at 48:1–4.)

103. Fifth, Dr. Slatopolsky's intravenous calcitriol research was published in a journal in 1984 and subsequently formed the basis for WARF's claim eight years later,[17] in the '925 patent, to uses of the 19-nor analogs to calcitriol to treat hyperparathyroidism. *See supra* ¶ 72.

104. Sixth, Abbott's relationship with Dr. Slatopolsky was ongoing. Starting in the late 1980s, Dr. Slatopolsky began traveling around the world, giving lectures for Abbott on treating kidney disease approximately "5 to 10 times a year." (JX-508 at 161:3–9.)

105. However, despite the prior relationship with Abbott, there is no evidence in the record that Abbott ever approached Dr. Slatopolsky about studying the 19-nor Vitamin D analogs. Rather, according to Dr. Slatopolsky, at some point in time between September, 1991[18] and 1993, he and Dr. DeLuca had the idea to research the 19-nor analogs. (Tr. at 140:20–23 (Dr. Slatopolsky).)

106. For Dr. Slatopolsky, the research project was a logical fit for his laboratory:

> I . . . don't remember if [Dr. DeLuca] called me or I called [him]. Because he knew that I knew phosphorus. . . . [and] can work with uremic rats. He knew that I can measure PTH. I was one of the first person that developed an immunoassay to measure parathyroid hormone. [At the time] I ha[d] a facility to measure parathyroid hormone.
>
> . . . .
>
> He knew my background and I knew his background. He can make the products. I cannot – I'm not a biochemist. . . . he can produce hundreds of analogs. I cannot produce one. He provide[d] it to us.

(JX-508 at 49:17–50:6.)

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[17] This research was published in 1984. (JX-002 at 8:5–9.) The '925 patent was filed on October 13, 1992. *See supra* ¶ 68; (*see also* JX-002, cover page).

[18] According to the 1993 Development Report, Abbott's 19-Nor Analog Program began on September 19, 1991. (JX086 at JX086.002.)

107. Prior to this time, Dr. Slatopolsky was unaware of paricalcitol and had not worked with it before—he relied on Dr. DeLuca to provide him with paricalcitol and the other 19-nor Vitamin D analogs he tested in his research. (Tr. at 141:13–142:5.)

1. The Relationship Between Dr. Deluca And Dr. Slatopolsky

108. The dynamic between Drs. DeLuca and Slatopolsky is worth noting. At the time the two researchers were studying the effects of the 19-nor Vitamin D compounds on parathyroid hormone, Dr. Slatopolsky was essentially a part-time researcher who ran a laboratory *in addition to* teaching medical students and running WashU's dialysis clinic, which he had been doing for close to thirty years at that point. (JX-508 at 38:1–20 (Dr. Slatopolsky testifying that he started the dialysis unit in 1965 and resigned from his clinical work in 1997, at which point the clinic had some 700 patients).)

109. At a personal level, Dr. Slatopolsky appears to have preferred to work in his laboratory and to leave the administrative details to others. (JX-508 at 24:23–25:8 (describing Jane Finch as Dr. Slatopolsky's "right hand" for over forty years); *id*. at 59:6–63:12 (testifying that Dr. DeLuca handled the patent attorneys and that Dr. Slatopolsky had no contact at all with them during patent preparation and prosecution).) Within the WashU community, Dr. Slatopolsky was one of many researchers, and key staff in the technology transfer office did not know him personally. (D.I. 163-4, ex. D at 43:6–45:13 (Dr. Brandt) ("I wouldn't know [Dr. Slatopolsky] if he walked in the door."); D.I. 163-6, ex. F at 51:9–19 (Laurie Lockman) ("I do not know [Dr. Slatopolsky]. I have heard his name.").)

110. By contrast, Dr. DeLuca was well known at the University of Wisconsin—WARF staff knew him well and worked with him extensively. (Tr. at 626:5–19 (Dr. Gulbrandsen stating that while he was in private practice, he "got to know WARF quite well . . . [and] got to know [Dr.] DeLuca very well, . . . and became friends with [him].").)

For example, Dr. DeLuca was so well versed in WARF processes, that he could approach WARF's patent attorneys to file patent applications, well before following the administrative processes for invention disclosure and the like. *See infra* ¶¶ 146–147 (documenting that Dr. DeLuca took the lead on working with the WARF patent attorneys to file the '288 patent application); (*see also* JX-042 at 1 (explaining that WARF filed the '288 patent application "at the suggestion of [Dr.] DeLuca[.]").)[19]

2. Dr. Slatopolsky's 19-Nor Analog Work Plan

111. Dr. Slatopolsky's 19-nor analog research proceeded in two stages.

112. First, Dr. DeLuca provided him with several 19-nor Vitamin D analogs, including paricalcitol. Dr. Slatopolsky and his team were then "able to discriminate between these compounds and [find] after preliminary work that paricalcitol was the best compound." (Tr. at 136:17–137:1; *see also id.* at 137:13–142:14.)

113. Second, after the "preliminary results showed the paricalcitol was the best" at suppressing PTH, Dr. Slatopolsky then "dedicate[d] an entire lab, entire budget, a year of work in one single comparative study between calcit[ri]ol [Calcijex] and paricalcitol [Zemplar]." (Tr. at 142:15–143:2; *see also* D.I. 157-4, ex. D at 15 of 15.)

3. Dr. Slatopolsky's Idea To Study The Effect Of The 19-Nor Vitamin D Analogs And Calcitriol On Serum Phosphorus

114. Dr. Slatopolsky had the idea to compare Dr. DeLuca's 19-nor Vitamin D analog with calcitriol and to measure the effects of the compounds on serum phosphorus levels. (Tr. at 155:14–156:7 (Dr. DeLuca) ("it would be logical for Doctor Slatopolsky to insist on it because serum phosphorous is a major concern in dialysis

[19] Dr. DeLuca essentially took credit for Dr. Slatopolsky's research by having himself listed as the first named inventor for what was to become the '815 patent. This was after Dr. DeLuca had been listed *last* on the journal article. Moreover, despite the fact that several researchers from Dr. Slatopolsky's laboratory were identified in the journal article, based upon Dr. DeLuca's communications with WARF's patent attorneys, these individuals were not included as inventors on the resulting patent. *See infra* ¶¶ 146–151.

patients and the control of it is very important."); JX-508 at 26:21–27:4 (Dr. Slatopolsky) ("I'm the first author, the primary investigator, . . . because this was mainly my idea."); *see also* JX-188 at 852 (listing Dr. Slatopolsky first in the November 1995 article in the *American Journal of Kidney Diseases*).)

115. In fact, Dr. Slatopolsky had been researching phosphorous for thirty years:

> I have been working in the field of phosphorus -- phosphorus is my field of research. . . . I have close to 200 papers on phosphorus. I started in 1963, and I was the one who show[ed] for the first time that phosphorus, per se, independent of anything else, can increase parathyroid hormone.
>
> It took a long time. People did not believe me, and I had to publish 20 papers to convince the world. Finally in 1996 categorically we demonstrated in the best journal, Journal of Clinical Investigation, that phosphorus, per se, independent of calcium, independent of Vitamin D, also has an effect. All are important. Calcium is important. Vitamin D is important. But phosphorus is important, too.

(JX-508 at 31:25–32:18 (Dr. Slatopolsky).)

4. Funding Dr. Slatopolsky's 19-Nor Research

116. Dr. Slatopolsky funded the research through several sources: WashU funds, NIH, and Abbott. *See infra* ¶ 127. As to Abbott's involvement, in the *Hospira* litigation, Dr. Slatopolsky explained that he and his laboratory "submit[ted] a protocol to [Abbott], and they agree[d]" to fund part of the research. (JX-508 at 39:8–13.)

117. When asked about what Abbott did to support the work, Dr. Slatopolsky rejected the premise that Abbott was involved beyond partially funding it: "They look[ed] at [the] protocol and [did] nothing [else]. This is investigator-initiated research. This is not Abbott research. This is our research. . . . [and Abbott] fund[ed] the research, *part, part, part*." (JX-508 at 39:16–22 (emphasis added).)

118. It is unclear from the record exactly *which aspects* of Dr. Slatopolsky's research were funded by Abbott. As is discussed herein, Abbott was clearly involved in Dr. Slatopolsky's preliminary research.[20] *See infra* ¶¶ 119–124.

5. Dr. Slatopolsky's Preliminary Research—Selecting Paricalcitol

119. In 1993, Dr. Slatopolsky completed "pilot studies" of the two licensed Vitamin D compounds using *in vitro* parathyroid cell cultures and a small-scale *in vivo* animal model. (Tr. at 136:17–137:12, 141:18–143:2 (Dr. Slatopolsky).)

120. As reflected in Abbott's 1993 Development Report, which Abbott shared with WARF in February 1994, Dr. Slatopolsky determined that "neither of the two analogs induced hypercalcemia," but only one of them—paricalcitol—was effective in suppressing PTH. (JX-086 at JX086.004.) Dr. Slatopolsky described these tests as "preliminary studies" that he performed to select the best analog for use in "the full long demanding expensive study" that led to the '815 patent. (Tr. at 141:18–143:2 (Dr. Slatopolsky).)

121. In the *Hospira* litigation, Dr. DeLuca testified that Abbott evaluated paricalcitol and the 24,24-dihomo Vitamin D_3 compound licensed by Abbott in the 1993 License but did not proceed with the D_3 analog, because "Dr. Slatopolsky found that the 19-Nor-D_2 [compound, or paricalcitol,] suppressed [PTH]; whereas, at the doses tried, the 24,24-Dihomo did not." (JX-424 at 163:18–164:10.)

122. In the 1993 Development Report, the "planned future studies" section, which describes projects in 1994 and beyond, only mentions paricalcitol ("the D_2

[20] Dr. Slatopolsky may have been involved with other research related to the 19-Nor Analog Program. For example, the 1993 Development Report also discusses, under "Third party development[,]" a "[d]ose range study to determine the systemic effect of the D2 analog on PTH and serum calcium. Study initiated in 9/93 and completed in 12/93. Results showed 73% PTH suppression with insignificant rise in calcium for D_2 analog dose of 75ng." (JX-086 at JX086.004.) This dosage is consistent with the dosages studied, and disclosed, in the research that led to the '815 patent. (JX-188 at 852.)

analog") and does not include any future studies involving the D_3 analog.[21] (JX-086 at JX086.003.)

123. Therefore, the Court concludes that Dr. Slatopolsky performed his preliminary 19-nor analog research in 1993 and completed that research no later than September of that year.

124. Following Dr. Slatopolsky's preliminary study, Abbott focused its 19-Nor Analog Program, under the 1993 License, on the commercialization of the vitamin D_2 analog—paricalcitol.[22]

H. Dr. Slatopolsky's Second Study That Led to the '815 Patent

125. As with the preliminary 19-nor research, Dr. Slatopolsky—not Dr. DeLuca—designed and carried out the study that led to the '815 patent at the Washington University School of Medicine. (Tr. at 120:3–122:10 (Dr. Slatopolsky); Tr. at 148:14–18 (Dr. DeLuca); *see also* D.I. 163–2, ex. B at 26:20–25, 32:11–33:7, 34:22–41:13 (Dr. DeLuca).) Dr. DeLuca's role was limited to supplying the compound,

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[21] Abbott terminated the 1993 License to the 24,24-dihomo compound in October, 2004. *See infra* ¶ 396.

[22] WARF's expert, Mr. Lentz, testified that Dr. Slatopolsky's research "concluded that neither of the compounds [(paricalcitol and 24,24-dihomo Vitamin D3)] induced hypercalcemia, so they did not have calcemic activity and the D_3 analog was less infective [sic] here in expressing parathyroid hormone in this model." (Tr. at 807:20–808:8.) The 1993 Development Report described the 24,24-dihomo Vitamin D_3 compound as "ineffective in suppressing PTH[,]" (JX-086 at JX086.004), as in it *could not* suppress PTH—which is a very different statement than saying it was *less effective* than paricalcitol at suppressing PTH.

Mr. Lentz testified that Dr. DeLuca had "found these results back on the bench years earlier[.]" (Tr. at 808:9–13.) Mr. Lentz's testimony in this regard lacks credibility. As discussed above, Dr. DeLuca could not measure PTH in 1991, *see supra* ¶¶ 82–85, and, therefore, could not have performed studies of PTH several years earlier for disclosure in a 1989 patent application, (*see* JX-002, cover page ('925 patent claiming priority to "Ser. No. 321,030, Mar. 9, 1989, abandoned.")). Moreover, while the '925 patent discloses two assays, comparing "1α,25-dihydroxyvitamin D_3" (or calcitriol) with "1α,25-dihydroxy-19-nor-vitamin D_3" (a 19-nor Vitamin D_3 analog to calcitriol) in the "differentiation of leukemia cells" and the "calcification of bone[,]" (JX-002 at 6:45–7:46.), the studies do not discuss results for any 19-nor Vitamin D_2 compounds (*i.e.,* paricalcitol) or the 24,24-dihomo Vitamin D_3 compound, (JX-002 at 6:45–7:46); *see supra* ¶ 77. And, the only disclosure in the '925 patent suggesting that the 19-nor analogs could be used to suppress parathyroid tissue is actually based on Dr. Slatopolsky's 1984 research into the performance of intravenous calcitriol. *See supra* ¶ 72 & n.9.

formulation, and dosage information for the compounds that Dr. Slatopolsky used in the study that led to the '815 patent.[23] (Tr. at 122:11–20 (Dr. Slatopolsky); D.I. 163–2, ex. B at 32:11–33:7 (Dr. DeLuca).)

126. Dr. Slatopolsky "dedicate[d] an entire lab, entire budget, a year of work in one single comparative study between calcitriol and paricalcitol." (Tr. at 142:24–143:2 (Dr. Slatopolsky); *see also* Tr. at 120:23–122:10 (Dr. Slatopolsky); Tr. at 148:14–18 (Dr. DeLuca).)

127. Dr. Slatopolsky paid for the study in part with WashU's own research funds, in part with funds from the NIH, and in part with funds from Abbott. (D.I. 163–8, ex. H at 30:9–31:2 (Dr. Slatopolsky); JX-508 at 39:5–22 (Dr. Slatopolsky); JX-188 at 852 ("Supported in part by National Institute of Diabetes and Digestive and Kidney Disease, Bethesda, MD . . . and by a grant provided by Abbott Laboratories, Abbott Park, IL.").)

128. In designing the study that led to the '815 patent, Dr. Slatopolsky came up with the idea to study the effects of calcitriol and paricalcitol on serum phosphorus levels. *See supra* ¶ 114; (*see also* Tr. at 128:1–20 (Dr. Slatopolsky); Tr. at 155:14–156:7 (Dr. DeLuca).)

129. When the results came in, Dr. Slatopolsky realized that paricalcitol could be administered in a manner to minimize blood phosphorous levels and avoid hyperphosphatemia. (Tr. at 128:1–20 (Dr. Slatopolsky); *see also* JX-508 at 69:19–22 (Dr. Slatopolsky) ("I discovered the properties of the drug as far as hyperphosphatemia.").)

[23] Dr. Slatopolsky talked with Dr. DeLuca "[m]any times" on the telephone about the study. (JX-508 at 50:17–19.)

130. Specifically, in comparison to calcitriol, which was the "gold standard" for suppressing PTH, Dr. Slatopolsky "found that paricalcitol is better than the gold standard." (JX-508 at 69:23–70:20 (Dr. Slatopolsky).) In addition, he found that paricalcitol is "less hyperphosphatemic than calcitriol. It's not zero. It's less, much less. 15 times less. 10 to 15 times less." (JX-508 at 70:21–71:17 (Dr. Slatopolsky).)

131. Dr. Slatopolsky was the first scientist to make this discovery. (Tr. at 128:1–20 (Dr. Slatopolsky); *see also* Tr. at 164:7–11 (Dr. DeLuca).)

132. Dr. DeLuca described Dr. Slatopolsky's finding as "important" because "rising serum phosphorous is of concern to nephrologists," "so it's important if you have a drug that doesn't raise serum phosphorous to the same degree as previously used drugs [like calcitriol]." (Tr. at 157:24–158:4 (Dr. DeLuca).)

1. Publishing the Study Results

(a) Abstract

133. In May 1994, Dr. Slatopolsky drafted an abstract of his research for publication in relation to the American Society of Nephrology's October 1994 conference. Dr. Slatoposky faxed a draft of the abstract to Dr. DeLuca. (JX-190.)

134. At the time, Dr. Slatopolsky focused the abstract on the PTH suppression and calcemic effects of paricalcitol in comparison to calcitriol, (JX-322 at JX322.006), and not the avoidance of hyperphosphatemia, because at "that particular time people were talking more about calcium and calcium, and that's why we wrote only the calcium part[,]" (JX-508 at 31:2–24 (Dr. Slatopolsky)).

135. The research abstract was published in September 1994. (JX-322.)

(b) Journal Article

136. In January, 1995, Dr. Slatopolsky sent Dr. DeLuca a draft of a journal article discussing his research into the compound that was to become paricalcitol. (JX-191.)

137. At the time, Dr. Slatopolsky sought specific input from Dr. DeLuca related to "statements . . . on Page 13 regarding studies performed in [Dr. DeLuca's] laboratory. They may not be accurate!" (JX-191 at JX191.001.) These studies appear to have been bench studies comparing paricalcitol to calcitriol in binding to "intestinal vitamin D receptor[s.]" (JX-191 at 13.)

138. According to Dr. Slatopolsky, Dr. DeLuca "made just two minor English correction[s] and one biochemical correction [to the article]." (JX-508 at 21:14–22:4.)

139. The draft journal article lists seven investigators: "Eduardo Slatopolsky, Jane Finch,[24] Cindy Ritter,[25] Masashi Denda,[26] Jeremiah Morrissey,[27] Alex Brown[28] & Hector DeLuca[.]" (JX-191 at JX191.002.)

140. Dr. Slatopolsky submitted this article to *American Journal of Kidney Diseases* on February 27, 1995. (JX-188 at JX188.001.) He edited the article and submitted a revised version on April 25, 1995. (*Id.*) The article was published in the November issue of *American Journal of Kidney Diseases*. (JX-188.)

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[24] "Jane Finch . . . was with me for 40 years, and she was my right hand." (JX-508 at 24:24–25.)

[25] "Cindy Ritter [] is a scientist who can design, write, and present the papers. . . . She present[s] papers herself in international meetings . . . She's outstanding, outstanding." (JX-508 at 24:21–28:13.)

[26] "Masashi Denda was a fellow from Japan who spent 2 years and he did minimum work." (JX-508 at 27:14–15.)

[27] "Dr. Morrissey is a Ph.D., an expert with parathyroid cells, because we had to test the compound first in vitro, which is much easier to get results, and then you go in vivo." (JX-508 at 27:16–19.)

[28] "Alex Brown [] is a Ph.D. who was trained by Hector DeLuca, is an expert in vitamin D, married to Cindy Ritter. They both work together." (JX-508 at 27:20–22.)

I. Spring 1995: WARF & Abbott Closing in On Paricalcitol

141. Unbeknownst to Dr. Slatopolsky and WashU, by the spring of 1995, WARF was busily seeking patent protection for the 19-nor compounds and their methods of use.

142. The first of two WARF patents related to paricalcitol and the treatment of conditions related to kidney disease, the '925 patent, had issued on September 21, 1993, shortly after Dr. Slatopolsky completed his preliminary research into paricalcitol. *See supra* ¶ 123; (JX-002, cover page). The '925 patent is a method of treatment patent that covers a process for using paricalcitol (among other vitamin D compounds) to treat secondary hyperparathyroidism. *See supra* ¶ 15.

143. On March 31, 1995, Abbott filed its Investigational New Drug ("IND") submission for paricalcitol with the FDA. (JX-085 at ¶ 64 at 17 of 215.)

144. On April 14, 1995, while Dr. Slatopolsky was drafting the journal article discussing his research comparing calcitriol and paricalcitol, *see supra* ¶ 140, Abbott sent WARF its annual "19-Nor Analog 1994 Development Report[,]" which documented the progress Abbott was making in commercializing paricalcitol, (JX-364). In this document, Abbott informed WARF about the "[f]irst clinical study" into paricalcitol, which was to begin in May 1995, as well as Abbott's IND submission with the FDA. (JX-364 at 2.)

145. A month later, on May 16, 1995, WARF filed U.S. Patent Application No. 08/442,492, which would become the '497 patent. *See supra* ¶ 64. The '497 patent is a compound patent that covers various compositions of matter based on 19-nor Vitamin D compounds, including paricalcitol. *See supra* ¶ 11. Claim 9 of the '497 patent is to "1α,25-dihydroxy-19-nor-vitamin D_2" (or paricalcitol). *See supra* ¶ 66.

J. Patenting Dr. Slatopolsky's Results—The '288 Patent Application

146. At some point between January and July 13, 1995,[29] Dr. DeLuca spoke with Dr. Slatopolsky and told him that he would like Dr. Slatopolsky to be a "co-inventor" with him on a patent application involving Dr. Slatopolsky's paricalcitol research. (Tr. at 127:11–128:15.)

147. Dr. DeLuca then took Dr. Slatopolsky's draft journal article to a WARF patent attorney and pursued a patent on the parties' co-invention. (Tr. at 164:1–6 (Dr. DeLuca); *see also* D.I. 163–2, ex. B at 115:1–14 (Dr. DeLuca).)

148. On July 13, 1995, WARF's patent attorneys filed U.S. Patent Application No. 08/552,288 ("the '288 patent application"). (JX-004.)

149. In the '288 patent application, Dr. DeLuca is the first listed inventor.[30] (JX-324 at JX324.007; JX324.048.)

150. The '288 patent application became the '815 patent. (JX-324 at JX324.001.)

151. WARF's patent attorney did not list any of the other investigators in Dr. Slatopolsky's laboratory as inventors on the '288 patent application. (*Compare* JX-191 at JX191.002 (listing seven researchers as authoring a journal article, with Dr. DeLuca listed last), *with* JX-324 at JX324.007 (listing two inventors, with Dr. DeLuca listed first).)

152. There is no evidence in the record that WARF, WARF's patent attorney, or Dr. DeLuca investigated the inventorship of the '288 patent application. Nor is there any

[29] WARF's patent attorney filed the patent application on July 13, 1995. *See supra* ¶ 68.

[30] When asked about whether he would consider Dr. DeLuca the "main inventor" of the '815 patent, Dr. Slatopolsky explained that Dr. DeLuca is "the inventor as far as inventing the drug. But you have the drug but you don't know what the drug is doing. Then he passes the drug to me, and I show what the drug is doing." (JX-508 at 69:9–18.) The Court notes that the '497 patent already covers the compound now known as paricalcitol/Zemplar. (*See generally* JX-003.)

evidence in the record that anyone at WARF ever discussed the inventorship aspect of the ’288 patent application with WashU.[31]

153. Other than informing Dr. Slatopolsky about his co-inventorship role in the ’288 patent application, Dr. DeLuca did not involve Dr. Slatopolsky in any patenting discussions. (D.I. 163–2, ex. B at 116:3–22 (Dr. DeLuca).)

154. Dr. Slatopolsky had no prior experience with patenting inventions, and the ’815 patent is the only one, to his knowledge, on which he is listed as an inventor. (JX-508 at 54:17–21.)

155. In addition, as is discussed below in Section II.Y.1, the assignment of the ’288 application (and subsequently the ’815 patent) was defective and did not list Washington University as a co-owner of the patent. *See infra* ¶¶ 427–436.

K. The 1995 Inter-Institutional Agreement (“IIA”)

156. In July, 1995, eight days after filing the ’288 patent application, WARF approached WashU about entering into an inter-institutional agreement to govern their relationship with respect to their joint invention. (JX-039.) At the time, WARF shared the ’288 patent application with WashU. (*Id*.)

157. An inter-institutional agreement is a common type of agreement in the university technology transfer industry that frames how universities will work together to commercialize a joint invention. (Tr. at 173:20–174:12 (Dr. Cleare); Tr. at 356:2–12 (Dr. Brandt).)

158. Mr. Howard Bremer (“Mr. Bremer”) of WARF (a lawyer) prepared the IIA. (JX-039 at 1; D.I. 163-3, ex. C at 18:24–25 (Dr. Gulbrandsen).) Over the next few months, Dr. E.J. Brandt (“Dr. Brandt”) of WashU (a non-lawyer) reviewed it, proposed a

[31] WARF contends that “[w]ithout the IIA, each party would have been free to license its one-half share ownership.” (D.I. 178 at ¶ 15 at 7.) Were the other WashU investigators listed on the ’288 patent applications, WARF would have had a one seventh interest in the ’815 patent, not one half.

handful of minor revisions, and signed the agreement on behalf of WashU. (JX-040 at 1; JX-041 at 1; JX-170 at 1; JX-171 at 1; JX-001 at 8; D.I. 163-4, ex. D at 95:5–96:4 (Dr. Brandt).)

159. While the parties were negotiating the IIA, WARF sent WashU copies of the letters it had sent to "the National Cancer Research Foundation and the National Institutes of Health" concerning the '288 patent application. (JX-169.) These are obligations WARF would formally undertake in the IIA. *See infra* ¶ 178.

160. However, WARF did not share "the entire disclosure" with WashU at the time. (JX-169.) WashU requested these materials, but it is unclear whether WARF ever complied. (*Id*.)

161. The IIA became effective November 1, 1995 and is valid and enforceable as between the parties. *See supra* ¶¶ 26–27.

1. The "Sharing Income" Recital

162. As the IIA evidences, the purpose of the agreement was to facilitate commercialization of the parties' joint invention embodied in the '288 patent application while ensuring that both WashU and WARF fairly shared the resulting revenue.

163. To this end, the IIA states that WashU and WARF "wish to enter into this Agreement to establish a means for filing and prosecuting the Patent Rights, for administering and licensing the Patent Rights and/or Property Rights, and *for sharing income* derived from licensing of the Patent and/or Property Rights[]" (the "Sharing Income Recital"). (JX-001 at 1 of 8 (emphasis added) (third "Whereas" clause).)

164. At the time, the relevant property right was the '288 patent application. *See supra* ¶¶ 146–150; (*see also* JX-001, § 1.A.)

(a) Administrative and other fees

165. WashU agreed to pay a 15% administration fee to WARF, to be taken off the top of any "Income" attributable to what finally became the '815 patent. The express purpose of the administration fee was to provide WARF, as the senior party, "consideration for securing and administering" any license agreements relating to the parties' joint invention. (JX-001, §§ 1.G., 2.B.(iv).)

166. Over the course of the parties' dealings, the '815 patent earned $4,132,798 in "Income," and WARF collected $619,920 in administration fees from this income.[32] (Tr. at 317:19–21 (Dr. Cleare); JX-476A at 1.)

167. Also, WashU agreed to pay WARF $5,000 for prosecuting the patents in the United States, 33 1/3 percent of certain additional foreign filing-fee estimates. (JX-001, § 3.B.) All told, Washington University paid over $117,000 in such expenses to WARF. (Tr. 567:23-568:20 (Mr. Thomas); JX-476A at 1 (documenting $27,221 in "Patent Expense Reimbursement" and $90,195 in "Patent Expense").)

(b) Splitting income

168. Under the IIA, after deducting the administration and patent expenses, WashU was to receive 33 1/3 percent of the revenues from licensing the '815 patent, with WARF keeping the remaining 66 2/3 percent. (JX-001, § 3.A.(i); *see also* Tr. at 451:13–24 (Dr. Cleare); Tr. at 620:7–14 (Mr. Thomas).)

169. The IIA is silent on the parties' reasons for this split of income associated with the '815 patent. (JX-001.)

[32] WashU sought to characterize this as "[WashU] paid nearly $620,000 in administration fees to WARF[,]" (D.I. 175 at ¶ 33 at 18), but this is an exaggeration of how the IIA works, and Mr. Thomas's royalty report shows that *both WashU and WARF* paid the administration fees, (JX-476A, schedule 1 at 1 of 2 (showing "'Income' less Admin Fee, i.e. 'Net Revenues' [C] = [A] – [B]" and calculating WashU's 1/3 share from that number); Tr. at 566:16–567:14 (Mr. Thomas)). Nonetheless, under the IIA, WashU still paid a significant amount of money to WARF—$206,640 in administration fees. (JX-476A, schedule 1 at 1 of 2 ($\$619{,}920 \times 1/3 = \$206{,}640$).)

170. The ’815 patent claims “[a] method of treating . . . renal osteodystrophy while avoiding hyperphosphatemia [using paricalcitol.]” *See infra* ¶ 230.

171. The record is clear that this invention is attributable to Dr. Slatopolsky and his investigators at WashU. *See supra* ¶¶ 125–132.

172. WARF’s former Managing Director reasoned that the “one-third two-thirds split” in WARF’s favor reflected the fact that Dr. DeLuca “is the compound owner, and it’s his overall project.”[33] (D.I. 163-3, ex. C at 62:14–63:4 (Dr. Gulbrandsen).)

173. Based upon extrinsic evidence, the Court concludes that, in the IIA, WARF and WashU agreed that WARF would take the lion’s share of any licensing revenue generated by the parties’ joint invention, because WARF owned the compounds disclosed in the ’288 patent application. *See supra* ¶ 148 & n.30, ¶ 172

(c) Records and Reports

174. The IIA requires WARF to “pay to [WashU] its share of Net Revenue due under this Agreement every 12 months by August 31 for the preceding 12-month period beginning July 1 and ending June 30.” (JX-001, § 5.B.)

2. The Senior Party–Junior Party Framework

175. Although the IIA does not specifically employ the terms “senior party” and “junior party,” at trial the parties’ expert witnesses agreed that, in the IIA, WARF took the lead as the “senior party” pursuant to a common practice in the university technology transfer industry in which one party—the “senior party”—agrees to take on larger responsibilities than the “junior party,” such as responsibility for patenting and commercializing the invention. (Tr. at 175:1–18 (Dr. Cleare); Tr. at 933:22–934:4, 981:9–14 (Dr. Severson).)

[33] Although Dr. Slatopolsky was not involved in negotiating the IIA, (Tr. at 130:12–15), he reflected a similar sentiment about the significance of Dr. DeLuca’s invention of the compound, (JX-508 at 68:15–69:18 (“[Dr. DeLuca is] the inventor as far as inventing the drug.”)).

176. WARF, as the senior party, assumed the responsibility to act on behalf of both parties in order to: (1) ”prepare, file, prosecute, and maintain” patent rights arising from the invention; (2) “negotiate, execute, administer, and enforce” any license agreements; and (3) ”determine whether or not the parties hereto shall engage in and prosecute any legal actions” involving those patent rights.[34] (JX-001, §§ 2.A.(i), 2.B.(i), 9.A.) WARF had the “exclusive right” to engage in all three activities; it had “sole discretion” to make decisions relating to the first two—patent prosecution and licensing; and it had “exclusive control” of any legal actions on the patents. (JX-001, §§ 2.A.(i), 2.B.(i), 9.A.)

177. In its role as the senior party, WARF promised to act on behalf of and for the benefit of WashU under the IIA. (JX-001, §§ 1.D. (Mutual Benefit Clause, *see infra* ¶ 194), 2.A.(iii), 2.A.(iv), 2.B.(ii); *see also* Tr. at 180:6–181:1 (Dr. Cleare).)

178. Under the “Government Reporting Clause,” WARF agreed to “comply with all reporting requirements” to government agencies “on behalf of” Washington University. (JX-001, § 2(A)(iv); Tr. 276:11-15 (Dr. Cleare); Tr. 938:21-939:20 (Dr. Severson).) These provisions demonstrate WARF’s formal commitment to act on behalf of Washington University’s joint interests in the parties’ co-owned ’815 patent when exercising WARF’s delegated powers and responsibilities under the IIA.

179. As the junior party, WashU retained its ownership interest in the ’288 patent application but gave up its right to commercialize the claimed invention, license the ’288 patent application to others, or enforce the subsequent patent (the ’815 patent) in legal actions. (JX-001 at 1, Preamble; *id*. §§ 2.B.(i), 9.A.)

[34] In addition, under the “Government Reporting Clause,” WARF agreed to “comply with all reporting requirements” to government agencies “on behalf of” WashU. (JX-001 § 2.A.(iv); Tr. at 276:11–15 (Dr. Cleare); Tr. at 938:21–939:20 (Dr. Severson).)

(a) Extrinsic Evidence of The Senior Party–Junior Party Framework

(i) Trust Between the Parties

180. The "senior party–junior party" relationship is characterized by a high degree of trust and collaboration, reflecting the public benefit function that universities play when commercializing inventions that result from federally funded research. (Tr. at 172:3–173:14, 175:19–177:2 (Dr. Cleare); Tr. at 982:8–12 (Dr. Severson); Tr. at 380:15–381:6, 382:10–383:6, 391:12–21 (Mr. Kratochvil); Tr. at 364:5–13 (Dr. Brandt); *see also* D.I. 163-4, ex. D at 49:3–50:8 (Dr. Brandt).)

(ii) The Senior Party Keeps the Junior Party Informed

181. Under the "senior party–junior party" framework, the senior party is expected to keep the junior party informed of key events and decisions relating to the parties' joint IP. (Tr. at 177:3–20, 178:12–179:19 (Dr. Cleare);; Tr. at 391:12–21 (Mr. Kratochvil) ("We are the junior party, we shouldn't be reaching out to the senior party to find information that should be provided to us."); *see also* Tr. at 990:16–20 (Dr. Severson).)

182. Thus, WashU reasonably expected that WARF, as the senior party, would inform WashU about decisions affecting WashU's interests in the parties' co-owned patent, including information reflecting the value of the parties' joint invention to potential licensing partners. (Tr. at 175:19–176:5 (Dr. Cleare); Tr. at 353:19–355:7 (Dr. Brandt); Tr. at 381:20–382:9, 384:17–21, 391:12–21 (Mr. Kratochvil).)

(iii) The Senior Party Treats The Junior Party With Fairness

183. Mr. Kratochvil expressed that WashU believed "[t]hat WARF would act on [WashU's] behalf, equitably on our behalf, to fairly market and license the technology that we had." (Tr. at 380:5–12 (Mr. Kratochvil).)

184. With respect to patent valuations, Dr. Brandt articulated the expectation that "in the tech transfer business that we were in, and at the time, and I think it's still that way, I guess [valuations are] done in a fair way. You don't – universities aren't out to do a job on each other or anything like that, so they try to be fair on both sides and work things out." (Tr. at 364:5–13 (Dr. Brandt).)

(iv) The Junior Party Has No Duty to Police the Senior Party

185. Other than cooperating with WARF with respect to patent prosecution, licensing, and assignment activities, WashU owed no further duties to WARF under the IIA, (JX-001; Tr. at 934:5–9 (Dr. Severson).)

186. WARF's tech transfer expert acknowledged that WashU, as the junior party, had no responsibility to be distrustful of, exercise oversight over, or otherwise police WARF's performance under the IIA. (Tr. at 1003:17–20 (Dr. Severson); *see also* Tr. at 229:22–230:23 (Dr. Cleare); Tr. at 384:17–21 (Mr. Kratochvil).)

3. The "Cooperation Clause"

187. Section 2.A. describes "patent prosecution and protection" and states as follows:

> (i) [WashU] grants to WARF the exclusive right to prepare, file, prosecute, and maintain Patent Rights and related Property Rights, and WARF shall have sole discretion to make decisions with respect thereto.
>
> (ii) During the term of this Agreement, neither party will assign its undivided interest in the Patent Rights or Property Rights without the consent of the other party.
>
> (iii) WARF and [WashU] *will use all reasonable efforts to cooperate with each other* with respect to patent application preparation, filing, prosecution, maintenance, licensing, and execution of assignments of Patent Rights contemplated under this Agreement.
>
> . . . .

> (v) WARF agrees that it will supply to Washington University a copy of all issued patents within the scope of this Agreement naming Dr. Eduardo Slatopolsky as co-inventor.

(*Id.* at § 2.A. (emphasis added).) Of note here is the requirement that the parties cooperate with each other as found in Section 2.A.(iii) (the "Cooperation Clause"). In addition, in Section 2.A.(i), the IIA grants WARF the "exclusive right" to perform these tasks and "sole discretion" to make decisions about these tasks.

(a) Extrinsic evidence

188. The IIA does not define what the parties mean in the Cooperation Clause to "use all reasonable efforts to cooperate with each other[.]" This term is ambiguous, *see infra* Section III.B.5; therefore, the Court considers extrinsic evidence and makes findings of fact to construe the Cooperation Clause, *see Town Bank v. City Real Estate Dev., LLC*, 793 N.W.2d 476, 483-84 (Wis. 2010) (citation omitted) ("[W]hen a contract is ambiguous and consequently is properly construed by use of extrinsic evidence, the contract's interpretation presents a question of fact for the [trier of fact].").

189. Dr. Cleare testified that "cooperation includes communication and I would think they would work together in the preparation of patent applications and the prosecution, maintenance and licensing of the final patent." (Tr. at 179:9–13.)

190. This translates, according to Dr. Cleare, into a duty for the senior party to make certain that "the [junior] party has a reasonable level of information as to what's going on" with WARF's licensing efforts. (Tr. at 178:12–179:19 (Dr. Cleare); JX-001, § 2.A.(iii).)

191. In addition, Dr. Cleare testified that the senior party should share information about valuation of the '815 patent. (Tr. at 179:20–180:5.)

192. Dr. Severson was asked about the Cooperation Clause: he explained that "[i]t relates broadly to activities that will be necessary in order to secure patent

protection for the invention."[35] (Tr. at 944:13–18.) Dr. Severson did not discuss the obligations with respect to licensing, patent prosecution, or maintenance under the Cooperation Clause.[36]

193. Based upon the extrinsic evidence, the Court concludes that with regard to licensing, the Cooperation Clause imposes on WARF, the senior party, the duty to keep WashU reasonably informed of key events affecting their shared mission of obtaining a patent, maintaining that patent, commercializing the parties' joint invention, and equitably sharing any resulting licensing revenues.[37]

4. The "Mutual Benefit Clause"

194. In order to facilitate licensing, Section 2.B. of the IIA defines a series of rights and responsibilities:

> (i) [WashU] grants to WARF the exclusive right to negotiate, execute, administer, and enforce License Agreement(s), and WARF shall have sole discretion to make decisions with respect thereto. [WashU] shall neither use nor license Patent Rights or Property Rights for commercial purposes but shall be free to use such Rights for academic research and teaching purposes.
>
> (ii) WARF will seek a Licensee(s) for the commercial development of Patent Rights and/or Property Rights and will administer all License Agreement(s) for the *mutual benefit* of the parties of this Agreement.
>
> (iii) WARF will have the final authority to enter into negotiations and execute License Agreement(s).

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[35] WARF's counsel then asked Dr. Severson "[a]nd is this cooperation provision ever customarily relied on by technology transfer offices to require obligations not expressly included in an IIA, in your experience?" to which he replied "[n]o, it's not." (Tr. at 944:19–24.)

[36] Dr. Severson's opinion largely appears to be about what the Cooperation Clause *is not*. This is not helpful to the Court in ascertaining what the Cooperation Clause means and why WARF chose to include it in the IIA in the first place. Absent any reference to the licensing and patent prosecution aspects of the Cooperation Clause, the Court finds it difficult to credit Dr. Severson's opinions about the Cooperation Clause.

[37] *See supra* ¶ 184 ("[U]niversities aren't out to do a job on each other.").

> (iv) WARF shall be entitled to retain from any Income generated an Administration Fee as set forth in Section 1G.

(JX-001, § 2.B. (emphasis added).) In addition to the Sharing Income Recital discussed above, *see supra* ¶ 163, Section 2.B.(ii) adds the requirement that WARF administer any license for the "mutual benefit" of the parties (the "Mutual Benefit Clause").[38]

5. The "Relative Value Clause"

195. With regard to sharing "consideration" in the form of "net revenues from license fees[,]" Section 3.A. of the IIA contains the following provision, which describes the potential for licensing the '815 patent as part of a portfolio.

> (iii) In licensing Patent Rights and/or Property Rights, WARF may include rights under other patents and/or other proprietary rights to which WARF owns a part of or all right title and interest, or include in other licenses certain Patent Rights or Property Rights, which licenses may be directed primarily to other invention subject matter or technology than that contemplated in this Agreement. In such event *WARF shall have the authority to assign relative values* to Patent Rights and/or Property Rights, and other patent and/or other proprietary rights as are included in any such license and the portion of the gross receipts from royalties and other fees received by WARF under any such license, which shall be Income hereunder to be divided with [WashU] as provided in Section 3A(i), shall be determined in accordance with such relative values assigned to Patent Rights and/or Property Rights in proportion to the total value represented by all patent rights and/or proprietary rights which are included within such license.

(JX-001, § 3.A (emphasis added) (the "Relative Value Clause").) The IIA does not define "relative value."[39] (*Id.*)

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[38] This term is not ambiguous, *see infra* Section III.B.6, therefore, the Court does not consider extrinsic evidence.

[39] Despite asserting that "[t]he parties agree that the terms of the IIA are clear and unambiguous," (D.I. 178 at ¶ 3 at 1), WARF bases its Proposed Findings of Fact as to the IIA largely on extrinsic evidence, (*id*. at ¶ 24 at 10–¶ 30 at 11-12), which the Court would only need to consider if terms of the IIA are ambiguous, *Town Bank v. City Real Estate Dev., LLC*, 793 N.W.2d at 484. For example, absent any corresponding language in the IIA, WARF nonetheless argues that the "relative values" term is set once and never revisited, because "WashU's share of licensing income *in all future years* would be governed

(a) Duty to Revalue[40]

196. Dr. Cleare demonstrated that the relevant professional standards governing the level of trust and cooperation between senior parties and junior parties to an IIA, and the assignment of relative value were prevalent in the industry and known to the parties at the time of the IIA. (Tr. at 178:12–182:15, 184:22–185:19 (Dr. Cleare).)

197. WARF's tech transfer expert, Dr. Severson, acknowledged that WARF's professional obligations included duties of fairness, collegiality, and honesty within the "senior party – junior party" framework. (Tr. at 982:4–12, 983:7–18, 990:16–20, 1000:6–1001:22, 1009:2–4, 1028:4–1029:24 (Dr. Severson).)

198. The experts largely agreed that, in technology transfer situations, it is uncommon to place specific limitations on when, and how often, the senior party revalues patents in an interinstitutional agreement. (Tr. at 318:5–13 (Dr. Cleare testifying that he had never "put reevaluations" into the 50 IIAs that he has handled in his career); *see also* Tr. at 694:7–13 (Dr. Gulbrandsen); Tr. at 949:11–950:3 (Dr. Severson).)[41]

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by the assigned relative value." (D.I. 178 at ¶ 24 at 10 (emphasis added) (citing extrinsic evidence for this construction); *see also id.* at ¶ 25 at 10–11 (citing parol evidence in the form of correspondence between the parties prior to the signing of the IIA).)

Although WashU provides detailed construction of the "relative value" term within the four corners of the IIA, (D.I. 175 at ¶ 44 n.4), WashU also seeks to introduce additional color to the term through extrinsic evidence, (D.I. 175 at ¶¶ 44–50).

The Court is aware of these facts but declines to make Findings of Fact as to the parol evidence and other extrinsic evidence identified by the parties. As is discussed in Section III.B.7, below, the Court construes the "authority," "value," and "relative value" terms according to the plain meaning, as bolstered by dictionary definitions, and within the confines of the four corners of the IIA.

[40] Consistent with the Third Circuit's prior decision, *Washington Univ. v. Wisconsin Alumni Research Found.*, 703 F. App'x 106, 109 (3d Cir. 2017), the Court conducts its Findings of Fact related to a duty to revalue under the IIA. *See infra* Section III.B.7(c). As is discussed in the construction of the relative value term, the Court is able to determine the intent of the parties as to a duty to revalue from within the four corners of the IIA. *Id.*

[41] WARF proposed facts related to "WARF's 'standard practice'" but did not explain how or why these practices are relevant to construing the Relative Value Clause. (D.I. 178 at ¶ 32 at 12–13.) The IIA makes no reference to applying WARF policies or WARF's "standard practice" to the Relative Value Clause (JX-001.) Moreover, nothing in the record suggests that WARF's actions under its IIA with

199. However, there is no evidence in the record that the lack of specific language in an inter-institutional agreement prevents revaluation by the senior party. And Dr. Cleare testified that revaluation would be necessary to avoid injustice. (Tr. at 318:21–319:20.) For example, Dr. Cleare discussed a situation where the senior party had revalued patents during the course of an IIA covering "two series of compounds" after FDA approval of only one of the compounds had rendered some of the patents to the other compounds "loser[s]" and thus the senior party transferred the incoming money "just to the group where the patent actually bore [on] the product[.]" (Tr. at 318:14–319:20.) Another situation where a senior party would revalue a patent is when patents in the portfolio expire, because, as Dr. Cleare testified, "university patent policies are usually such that they're weary of paying out money on patents that . . . they don't want to get involved in patent misuse like paying out money on expired patents."[42] (Tr. at 319:21–320:3.) Finally, Dr. Cleare explained that the revenues associated with a license are also a factor in whether a senior party revalues a patent, "I'm not saying that if it's a couple of million bucks that's involved you probably wouldn't [revalue a patent] . . . , [but] if it's tens of millions, I think you have a responsibility to try to do it." (Tr. at 320:4–10.)

200. In addition, both Dr. Severson and Dr. Cleare agreed that there would be a duty to revalue if the junior party challenged the senior party over a valuation, (Tr. at 1028:22–1029:3 (Dr. Severson)), or if an inventor brought up the issue of valuation with his or her university's technology transfer office, (Tr. at 327:10–328:15 (Dr. Cleare)).

201. When asked whether WARF would have a duty to revalue in a hypothetical scenario "where WARF assigns a relative value to the '815 patent based

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WashU, or whatever its "standard practice" was at the time, constituted standard technology transfer industry practice.

[42] *See Brulotte v. Thys Co.*, 379 U.S. 29 (1964) (defining the doctrine of patent misuse); *see generally Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401 (2015) (upholding *Brulotte*).

on its belief that the ’815 patent doesn’t read on the FDA approved indication, but then later learns that that was mistaken, [and] that the ’815 patent does read on the approved indication[,]” Dr. Severson agreed that WARF “had a duty to revalue.” (Tr. at 1028:4–17.)

202. Therefore, the Court concludes that, according to the extrinsic evidence, an inter-institutional agreement includes a duty for the senior party to revalue the patents that are the subject of the agreement: (1) when patents in the portfolio expire, (2) when total license revenues range above $10 million or more, (3) when the junior party challenges the senior party’s valuation of a patent, (4) when an inventor challenges the valuation of a patent, (5) when the senior party discovers that the valuation of a patent is based upon a mistaken assumption, such as whether a patent reads on an FDA-approved indication for a patented compound, or (6) to avoid injustice.

6. Integration Clause

203. The parties, primarily WARF, discuss parol evidence in relation to the IIA. *See, e.g.*, *supra* ¶ 195 n.39. In this regard, it is worth noting that the IIA contains an integration clause:

> It is understood, as between WARF and [WashU], that this Agreement constitutes their entire agreement, both written and oral, and that all prior agreements respecting the subject matter of this Agreement, either written or oral, express or implied, are canceled. No amendment or modification of this Agreement will be binding upon the parties unless made in writing and signed on behalf of each party.

(JX-001, § 13 (“Integration”).)

L. Information WARF did not share with WashU at the time of the IIA

204. During negotiations about the IIA and in the years following, WARF did not share the following information with WashU.[43]

205. WARF did not tell WashU that the 1993 License existed. (Tr. 371:11-372:7 (Dr. Brandt).) Specifically, in 1995, WARF did not tell WashU that it had already licensed paricalcitol to Abbott in the field of "treatment of renal osteodystrophy and suppression of hyperparathyroidism." *See supra* ¶ 88.

206. In 1995, WARF did not tell WashU that, based on Dr. Slatopolsky's research, Abbott had already filed its IND submission and was actively pursuing FDA approval of paricalcitol (through the New Drug Application process) in this precise field of treatment. *See supra* ¶¶ 92–96, 120, 144.

207. In 1995, WARF did not tell WashU that it had obtained the '925 patent (which had already issued) for a method of treatment for secondary hyperparathyroidism using paricalcitol/Zemplar based primarily on Dr. Slatopolsky's earlier 1984 research into calcitriol. *See supra* ¶ 72 & n.9.

208. Also, in 1995, WARF did not tell WashU that, two months prior to filing the '288 patent application (that would become the '815 patent), WARF had filed a patent application (that would become the '497 patent) claiming the paricalcitol/Zemplar compound.

M. 1996

209. In the context of paricalcitol, 1996 was a busy year. Abbott was continuing to perform various clinical studies in preparation to submit its FDA New Drug Application for paricalcitol at the end of January 1997. (JX-368 at 13; JX-372.)

[43] Given the documentary record of extensive communications between WARF and WashU, the absence of evidence of a communication (in the form of documents or testimony of individuals with first-hand knowledge) supports the inference that no such communication took place. However, the Court declines to draw similar inferences about communications between WARF or WashU and third parties.

Meanwhile, WARF was securing domestic and foreign patent protection for paricalcitol in the form of the '497 patent as well as the '288 patent application.

210. However, as discussed below, WashU's awareness of these activities was extremely limited. *See infra* ¶¶ 211–224.

1. WARF Asked Dr. Slatopolsky To File an Invention Disclosure

211. Just three months after the parties signed the IIA, in January and February 1996, Dr. DeLuca and Dr. Slatopolsky filed an invention disclosure with WARF for "Prevention of hyperphosphatemia in kidney disorder patients," based upon the research Dr. Slatopolsky did in his lab at WashU. (JX-366.) In this invention disclosure, Dr. Slatopolsky represented that he was "associated with the University of Wisconsin-Madison" at the time of the creation of the invention.[44] (JX-366.)

212. This invention disclosure does not identify the other five WashU investigators listed on the published research.[45] (*Compare* JX-366, *with* JX-188 at 852.)

2. WARF Made Decisions During Prosecution of the '288 Patent Application

213. The claims, as originally filed in the '288 patent application, were directed to "a method of avoiding hyperphosphatemia while treating a patient having a kidney

[44] It is unclear why Dr. Slatopolsky filed a disclosure with WARF (instead of WashU), why WARF required it, or why WARF's management even signed it. At the time, the '288 patent application had already been filed, the assignments had been notarized and filed, and the IIA had already been signed.

[45] It is unclear why Dr. DeLuca and WARF's patent attorneys did not include these individuals as inventors on the '288 patent application. Given the number of researchers at WashU and the fact that Dr. Slatopolsky's laboratory performed almost all of the research that led to the '815 patent, it is puzzling that only Drs. DeLuca and Slatopolsky signed the invention disclosure that was filed with WARF and that the patent application was also filed by WARF. Dr. Slatopolsky verified that he left the patent application and other details to Dr. DeLuca—"[h]e did all the work." (JX-508 at 59:6–63:9.) The relationship between these two researchers is best described in Dr. Slatopolsky's testimony that "I've been an investigator. I work in the lab. The legal part I'm [sic] stay out." (JX-508 at 59:10–11.) With regard to patent filings, it was usual practice for patent counsel to work directly with the inventors, and Dr. E.J. Brandt, Director of WashU's Office of Technology Management for the Medical School, had no problem with WARF's patent attorneys contacting Dr. Slatopolsky directly. (Tr. at 1042:2–21 (Dr. Brandt).) And yet, WARF's patent counsel does not even appear to have contacted Dr. Slatopolsky.

disorder comprising administering to said patient a compound that has minimal effect on serum phosphorous of said patient." (Tr. at 127:11–24 (Dr. Slatopolsky); D.I. 163–8, ex. H at 78:5–21 (Dr. Slatopolsky); JX-324 at JX324.026.)

214. During patent prosecution, on March 29, 1996, facing prior art in the form of the "Lee" reference and the '925 patent to Dr. DeLuca, WARF's patent attorneys amended the application's claims to replace "kidney disorder" with "renal osteodystrophy."[46] (JX-324 at JX324.095–100.)

3. Abbott Continued to Share Paricalcitol Development Reports With WARF

215. On June 6, 1996, as part of its obligations under the 1993 License, Abbott sent WARF the 1995 19-Nor Development Report that detailed Abbott's continuing efforts to commercialize paricalcitol in the field of "treatment of renal osteodystrophy and suppression of hyperparathyroidism." (JX-368); *See supra* ¶ 88.

4. Notice of Allowability

216. On June 17, 1996, the USPTO mailed a Notice of Allowability to WARF concerning the '288 patent application. (JX-324 at JX324.110–113.) This communication stated that, based on the March 29 amendments, the examiner was allowing all the pending claims. (*Id*.) The examiner withdrew the prior obviousness rejection and stated that Dr. DeLuca's '925 patent "does not teach or suggest an effect on phosphorous levels and the clear use of 19-nor Vitamin D_2 to treat renal osteodystrophy." (JX-324 at JX324.112; Tr. at 885:13–886:15 (Mr. Lentz).)

[46] WARF now argues that Abbott never pursued approval of an indication for the treatment for renal osteodystrophy and that the only FDA-approved indication is claimed in the '925 patent, which is treatment of secondary hyperparathyroidism. (D.I. 178 at ¶¶ 45–48.) In light of that argument, WARF's decision in patent prosecution to shift the focus of the claims of the '815 patent is especially poignant, if not prejudicial to WashU.

217. On August 29, 1996, WARF paid the $1250 issue fee for the ’288 patent application. (JX-324 at JX324.114–116.)

5. Foreign Filing

218. Two weeks later, on September 13, 1996, WARF sent a letter to WashU, asking it if it wanted to participate in foreign filing for the ’288 patent application. (JX-172; *see also* JX-001, § 3.B.(ii) (giving WashU, in a section named “Foreign Rights[,]” the ability to opt-into foreign patent prosecution and to, therefore, participate in foreign license revenues).)

219. At the time, WARF did not inform WashU about the Notice of Allowability, WARF’s decision to pay the issue fee, the fact that the ’288 patent application would pass to issue as the ’815 patent in the next few months, the existence of the ’925 patent, or the claim amendments WARF had chosen in light of the ’925 patent. (JX-172); *see supra* ¶ 204 n.43.

220. Nonetheless, despite the lack of information from WARF, WashU sent WARF a letter on September 26, 1996, announcing its “wish to participate in foreign patent filings as specified under Section 3B(ii) of our [IIA].” (JX-173.)

6. WARF’s “Additional Protection” Letter to Abbott

221. While WashU was responding to WARF’s foreign filing inquiry, on September 19, 1996, Mr. Kenneth Johnson (“Mr. Johnson”), who was the WARF Licensing Associate responsible for the portfolios of Dr. DeLuca’s patents, wrote a letter (the “Additional Protection Letter”) to Abbott’s General Manager (Loreen Mershimer) highlighting the value of the ’288 patent application to paricalcitol. The letter states:

> Dear Loreen:
>
> Enclosed for your reference is a copy of the patent application with claims entitled “Prevention of Hyperphosphatemia in Kidney Disorder Patients” by Professor DeLuca and Dr. Slatopolsky.

> I'm pleased to say that the U.S. Patent Office has allowed the claims to this [the '288] patent application. This was done at the suggestion of Professor DeLuca, and *I believe it will provide additional protection for Abbott with their new 19-nor product on the marketplace*.
>
> We need to do two items with this patent application.
>
> 1. I will prepare an amendment adding this patent application and the resulting allowed claims to the [1993] Abbott License Agreement. WARF (at their expense) has prosecuted the patent and has filed a patent application under the Patent Cooperation Treating (PCT) reserving rights to file foreign equivalents to this patent application in all foreign countries.
>
> 2. Therefore, we need to discuss what countries Abbott would like WARF to file foreign equivalents, and how these costs should be handled between Abbott and WARF.
>
> I would like to note that WARF has taken the initiative and entered an agreement with Washington University, representing Dr. Eduardo Slatopolsky. *Income that WARF receives from this patent application and its foreign equivalents will be shared with Washington University and Dr. Slatopolsky.* I believe that Dr. Slatopolsky will be pleased with this being added to the Abbott License as it will provide an avenue for him to share in the benefits of the success of the 19-Nor compound. I look forward to your comments.

(JX-042 at 1 (emphasis added).) Mr. Johnson had a chemical engineering background and worked closely with Dr. DeLuca. (Tr. at 728:5–19 (Dr. Gulbrandsen).) Of note in this letter are two aspects: (1) Mr. Johnson expresses the opinion that the '288 patent application "will provide additional protection" for paricalcitol—namely that prescribing physicians will practice the amended claims of the '288 patent application, and (2) Mr. Johnson appears to believe that WARF's offer to share royalties with Dr. Slatopolsky under the 1993 License will motivate Abbott to amend that license agreement to add the '288 patent application. (JX-042 at 1.)[47]

[47] WARF argues that, based solely on this letter and testimony by Dr. Cleare on cross examination, the Court should draw the conclusion that "WARF received no response from Abbott on the

7. '497 Patent Issues

222. The '497 patent issued on December 24, 1996. *See supra* ¶ 65.

8. Amendments to the 1993 License

223. On December 31, 1996, WARF and Abbott agreed to two amendments to the 1993 License. Amendment "A" to the 1993 License expanded the licensed field of use to include "renal osteodystrophy, suppression of the hyperparathyroidism, treatment of psoriasis and the treatment of cancers as specified in the cancer development plan." (JX-006 at 3 of 17.) Amendment "B" focused on the "treatment of multiple sclerosis" (JX-007 at 4 of 5.)

9. What WashU Didn't Know In 1996

224. By the end of 1996, the extent of WashU's knowledge under the IIA was that WARF intended to file foreign patent applications. *See supra* ¶¶ 218–219. The documentary record from 1996 shows details about: (1) the invention disclosure; (2) prosecution of the '288 patent application; (3) WARF's paricalcitol activities with Abbott; (4) the 1993 License, including amendments; and (5) the '497 patent. *See supra* ¶¶ 211–215, 221–223. However, there is no evidence in the record that WARF shared any of this information with WashU at the time. *See supra* ¶ 204 n.43. Moreover, WashU did not appear to know that the '815 patent was to issue in January 1997. *See supra* ¶¶ 216–217.

'815 patent for 21 months." (D.I. 178 at ¶ 45 at 16 (citing Tr.at 267:7–268:4, 269:21–270:5 (Dr. Cleare)).) When asked whether he "s[aw] any response from Abbott about whether it wanted to license the '815 Patent . . . [in] response to the '96 letter[,]" Dr. Cleare explained that he had not "seen much from Abbott because the discovery didn't seem to have covered Abbott in any case." (Tr. at 267:13–23.) Presently, the thrust of WARF's position is that the '815 patent was of little value to Abbott, as evidenced by the fact that there is no documentary evidence that Abbott responded to Johnson's letter. Absent testimony by individuals with direct knowledge of the events in question, the Court declines to draw any inferences.

N. 1997

225. In 1997, Abbott continued to make progress towards commercializing paricalcitol/Zemplar. Meanwhile, WARF further developed the licenses surrounding paricalcitol.

1. 1996 Development Report

226. On January 7, 1997, Abbott sent its 1996 Development Report for the period from May 15 through December 31, 1996. (JX-371; *see also* JX-372 (sending the same report on January 21, 1997).) This report informed WARF that Abbott was planning on submitting the New Drug Application for paricalcitol at the end of the month. (JX-371 at 19.)

2. The New Drug Application (NDA) For Paricalcitol

227. On January 17, 1997, Abbott submitted an NDA number 20-819, "under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zemplar (paricalcitol injection)." (JX-051 at 1.)

228. According to papers that WARF and Abbott filed in the *Hospira* litigation, Abbott originally proposed that the FDA approve Zemplar for "the prevention and treatment of renal osteodystrophy and secondary hyperparathyroidism encountered with chronic renal failure." (JX-085 at ¶ 69 at 18–19 of 215.)

3. WARF–New Licensing Consultant (Mr. Kosterman)

229. On January 21, 1997, a licensing consultant at WARF, Mr. Neil Kosterman ("Mr. Kosterman"), sent a letter to Dr. Brandt at WashU introducing himself as the replacement for Mr. Johnson and sharing "a definitive foreign patent cost estimate of $259.393[,]" of which, WashU's "share . . . would be $86.464." (JX-043 at 1.)

4. '815 Patent Issues

230. The '288 patent application issued as U.S. Patent No. 5,597,815 on January 28, 1997. *See supra* ¶ 150.

231. The '815 patent claims a process and is a "method of treatment" patent. Claim 4 recites "[a] method of treating a patient having renal osteodystrophy while avoiding hyperphosphatemia comprising administering to said patient [paricalcitol] that has minimal effect on blood serum phosphorous of said patient[.]" (JX-004 at 10:38–11:17.)

232. The '815 patent expired on July 13, 2015. *See supra* ¶ 25. Therefore, WARF paid maintenance fees for the '815 patent for the life of the patents. 35 U.S.C. § 154(a)(2) ("Subject to the payment of fees under this title, [the] grant [of a utility patent] shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States[.]"); 35 U.S.C. § 41(b)(1)(A)–(C) (requiring payment of a maintenance fee at three years and six months, seven years and six months, and eleven years and six months after grant); *see also USPTO Fee Processing – Maintenance Fee Details*, U.S. PATENT & TRADEMARK OFFICE, https://fees.uspto.gov/MaintenanceFees/fees/details?applicationNumber=08502288&patentNumber=5597815 (last visited Apr. 25, 2018) (showing due dates for the '815 patent and payment information for the 11.5 year fee).

5. Income Division Memos for the 1993 License Amendments

233. On February 21 and 25, 1997, Mr. Kosterman created two Income Division Memorandums ("IDM") defining how WARF would split license royalties between individual patent portfolios under Amendments "A" and "B" to the 1993 License. (JX-014; JX-015.)

234. In these IDMs, WARF performed separate relative value allocations to apply to anticipated new indications (or FDA-approved methods of treatment for specific conditions) for paricalcitol/Zemplar. (JX-015 at 2.) For example, "for royalty payments deriving from the Multiple Sclerosis field[]" under Amendment "B," WARF assigned 29% relative value to a WARF-owned "ancillary" method of treatment patent. (JX-015 at JX015.002, JX015.014–015; JX-007, appx. C at 5 of 5 (listing reference number P95215US as an "Ancillary Patent"); Tr. at 994:23–996:16 (Dr. Severson).) This method of treatment patent supported a multiple sclerosis indication that Abbott was pursuing at the time.[48] (Tr. at 256:5–11 (Dr. Cleare) (affirming that Abbott "actually went to WARF and asked to license the multiple sclerosis patent").)

(a) WARF's Assignment Of 29% Relative Value to the MS Patent Was Consistent with WARF's Valuation Policy

235. WARF maintains a written Valuation Policy for managing the distribution of income between inventors. *See infra* ¶¶ 438–444.

236. There is no evidence in the record that, prior to the instant litigation, WARF ever communicated this Valuation Policy to WashU. *See infra* ¶ 444.

237. WARF's expert, Dr. Severson, testified that WARF's 1997 allocation of 29% relative value to the multiple sclerosis method of treatment patent located in the "Ancillary Patents" group was consistent with WARF's written Valuation Policy, which grants discretion to the Licensing Manager to assign value to patents according to the specific license. (Tr. at 996:17–998:13 (Dr. Severson); *see also* JX-010 at 3 of 4.)

6. WARF–New Licensing Associate (Ms. Kirkpatrick)

238. On September 19, 1997, Ms. Gayle Kirkpatrick ("Ms. Kirkpatrick"), a licensing associate at WARF sent WashU's Dr. Brandt the following letter:

[48] WARF's Multiple Sclerosis patent (U.S. Patent No. 5,716,946) recites a method of treating multiple sclerosis symptoms by administering a Vitamin D analog. (JX-248, 12:40–14:65.)

> Dear Dr. Brandt:
>
> I have assumed responsibility for managing the Deluca portfolio of technologies at the Wisconsin Alumni Research Foundation (WARF) replacing Mr. Neil Kosterman. The objective of this letter is to update you on the progress to date regarding our agreement. I'll run the risk of being redundant on some of the items you may already be aware of, to ensure that you have this information:
>
> • The US patent, 5,597,815, for the Deluca, Slatopolsky invention, "Prevention of Hyperphosphatemia in Kidney Disorder Patients", which is the subject of our agreement, issued on January 28, 1997. A copy of this patent is enclosed. This patent will have an expiration date of July 13, 2015.
>
> • The PCT Application was filed on July 9, 1996 and a Request for Examination was filed on March 5, 1997. I will keep you informed of status as we enter the national phase.
>
> • I am actively pursuing several leads in licensing this technology and will provide you periodic updates on my progress.
>
> If you have any questions or comments, feel free to contact me. My email address and phone number are noted on my enclosed business card.

(JX-044 at 1.) This communication, some nine months after the issue of the '815 patent, was the first notice that WashU had that the '288 patent application had passed to issue.

239. WARF's managing director at the time, Carl Gulbrandsen, PhD ("Dr. Gulbrandsen") explained that Ms. Kirkpatrick had come to WARF from Abbott. (Tr. at 712:14–16 (Dr. Gulbrandsen).) After she arrived at WARF, she undertook a diligent and careful review of the Vitamin D patent portfolio, including the '815 patent, searching for patents to include in Abbott's license agreement for paricalcitol/Zemplar. (Tr. at 712:17–22, 715:7–11 (Dr. Gulbrandsen).)

O. 1998

240. On January 8, 1998, Abbott sent WARF the 1997 Development Report for paricalcitol. (JX-374.) This was to be the last development report under the 1993 License, and in it, Abbott summarized its NDA activities and additional studies in anticipation of "FDA approval [of Zemplar in] 2Q 1998." (JX-374 at 11.) If anything, this document was a summary of the busy year ahead for paricalcitol.

241. At some point in March 1998, Ms. Kirkpatrick met with representatives from Abbott to discuss a license for the '815 patent. (JX-047 at 7.)

1. FDA Approval and Launch of Zemplar

242. On March 20, 1998, the FDA issued a written report of its medical review of Zemplar. (JX-052 at 1.) WARF maintained a copy of the FDA's medical review in its files. (*Id*. (showing a handwritten notation for "Hector," or Dr. DeLuca)) Under a section entitled, "Pharmacology Studies in Relation to Proposed Therapeutic Indication," the FDA cited Dr. Slatopolsky's '815 patent study (along with a follow-up study by Dr. Slatopolsky) as demonstrating not only the safety and efficacy of Zemplar, but also the advantages of Zemplar over Calcijex, including Zemplar's ability to suppress PTH as well as or better than Calcijex without causing an "increase in serum phosphorous." (JX-052 at 5–6; *see also* Tr. at 190:23–193:6 (Dr. Cleare).)

243. Four days later, on March 24, 1998, Abbott and representatives of the FDA met via a "video conference to discuss the insert labeling for th[e Zemplar] NDA." (JX-260 at JX260.011; *see also* Tr. at 191:3–193:6 (Dr. Cleare).) Dr. Slatopolsky participated in this video conference. (JX-260 at JX260.011; JX-508 at 127:17–22 (recounting that "there was a very large meeting that Abbott organized with FDA and many physicians. And Dr. Sobel was the director for FDA, . . . And when I try to say something, he says, Your work is on rat. I don't want to hear about you. I want to hear about patients. He shoved me off.").)

244. After this March 1998 video conference, Abbott agreed to delete the words "renal osteodystrophy"—the indication recited in the '815 patent—from Zemplar's proposed label. (JX-085 at ¶ 69 at 18–19 of 215) According to WARF and Abbott's litigation papers in the *Hospira* lawsuit, Abbott decided not to submit additional studies requested by the FDA to obtain a "renal osteodystrophy" indication on Zemplar's label "because (1) even without such data, treating physicians recognized the beneficial effect of reducing elevated parathyroid hormone levels in treating renal osteodystrophy because secondary hyperparathyroidism is encompassed by the broad term; and (2) [Abbott] did not want to delay approval of Zemplar in order to conduct such studies." (JX-085 at ¶ 71 at 19 of 215.)

245. Thus, in March 1998, Abbott recognized that even without the FDA's formal approval of an RO indication on Zemplar's label, "[t]he FDA-approved label for Zemplar demonstrates that Zemplar is safe and effective for the treatment of renal osteodystrophy while avoiding hyperphosphatemia as claimed in the '815 patent." (JX-085 at ¶ 72 at 19–20 of 215.) When presented with these papers at trial, WARF's tech transfer expert, Dr. Severson, admitted that they showed that "Abbott decided not to pursue the renal osteodystrophy indication at the time *because it knew treating physicians would recognize that they could use Zemplar to treat RO*[,]" the indication directly recited in the '815 patent. (Tr. at 1027:4–9 (Dr. Severson) (emphasis added).)

246. FDA records reflect a similar pattern of events. In a memorandum to the file for NDA 20-819 on April 13, 1998, the FDA's Solomon Sobel, M.D., director of the Division of Metabolic and Endocrine Drug Products, summarized the NDA review meeting as follows:

> The Division recommended that the indication be limited at this time to the "prevention and treatment of secondary hyperparathyroidism encountered with chronic renal failure". *The sponsor had initially asked for wording in the indication which included the treatment of osteodystrophy. However,*

> *we believe that bone biopsy data are necessary for granting this indication.* Although we recognized that a beneficial effect on bone would be the probable outcome of the effective suppression of hyperparathyroidism, we would like a direct histomorphometric demonstration of this. This analog of vitamin D is a new molecular entity and its actions on bone (both indirect and direct) remain to be verified. There is some evidence that in addition to parathyroid suppression, vitamin D and its analogs may have a direct bone effect.

(JX-262 at JX262.019 (emphasis added).) From this, it is apparent that the FDA had taken a literal interpretation of "Renal Osteodystrophy" and was not employing a definition that reflected the subtlety of the relationship between SHPT and RO. *See supra* ¶¶ 48–54.

247. At the end of April 1998, the FDA approved Abbott's NDA for Zemplar. (JX-051 at 1.) The Zemplar label identified both the'497 and '925 patents. (JX-261 at 4; Tr.at 666:11–22 (Dr. Gulbrandsen).)

248. The FDA-approved indication for Zemplar is "the prevention and treatment of secondary hyperparathyroidism encountered with chronic renal failure." (JX-051; Tr. at 575:18–22 (Mr. Thomas).) It is undisputed that the '925 patent covers a method of using paricalcitol to treat secondary hyperparathyroidism. *See supra* ¶ 15; (*see also* Tr. at 575:11–17 (Mr. Thomas); Tr. at 788:11–789:18 (Mr. Lentz)).[49]

249. Abbott launched Zemplar in the early part of May 1998. (Tr. at 716:6–8 (Dr. Gulbrandsen).) According to WARF's Dr. Gulbrandsen, he attended the May 1998 Zemplar launch event and training session with Dr. DeLuca and Ms. Kirkpatrick. (Tr. at 715:21–716:5; JX-207 at 1.) After the Zemplar launch, on May 8, 1998, Dr. DeLuca

[49] WARF proposed that the Court make a series of factual findings about Abbott's purported, 1998, Orange Book listing for Zemplar (paricalcitol), identifying the '497 and '925 patents. (*E.g.*, D.I. 178 at ¶ 62 at 21–¶ 67 at 22.) However, the only documentary evidence of Orange Book listings for Zemplar are from 2015, (JX-093), and 2001, (JX-093A). WARF does not identify any evidence that Abbott listed the '497 and '925 patents in the Orange Book in 1998. Therefore, the Court declines to make the proposed factual findings.

sent Dr. Slatopolsky a cork from a bottle of "Dom Perignon 1990 champagne that [he and others] drank in honor of the launch [of Zemplar]" with a note expressing regret that Dr. Slatopolsky had not attended. (JX-207 at 1.)

250. Since Zemplar's launch in 1998, Zemplar has generated approximately $6.1 billion in total sales revenues for Abbott. (JX-085 at ¶ 82 at 22–23 of 215–¶ 85 at 23–24 of 215; JX-476A, Schedule 1 at 1 of 2.) Sales of Zemplar in the United States grew rapidly from about $58 million in 1999, its first full year on the market, to its peak of about $501.1 million in 2009, representing a compound annual growth rate of about 23.9 percent. (JX-085 at ¶ 82 at 22–23 of 215.)

251. WARF did not inform Washington University of the role of the '815 patent study's in helping Abbott to convince the FDA of Zemplar's advantages over Calcijex and to obtain FDA approval of Zemplar. (Tr. at 193:15–19 (Dr. Cleare).) Washington University obtained a copy of the FDA's medical review of Zemplar only during civil discovery in this lawsuit. (*Id*.)

2. May 1998—WashU Asks WARF for Information About Licensing The '815 Patent

252. Following the launch of Zemplar and Dr. DeLuca's letter to Dr. Slatopolsky, on May 13, 1998, Mary Loida ("Ms. Loida"), a licensing case coordinator at WashU, sent an e-mail to WARF's Ms. Kirkpatrick that stated:

> Gayle:
>
> . . . .
>
> Regarding our phone conversation – we might have discussed this already, but being new my head is swimming with information. You mentioned an amendment with Abbott.[50] Is there an actual license agreement, etc. that this

[50] Although WARF appears to have been unwilling to share Abbott's identity as the potential licensee for the '815 patent in May 1998, *see, e.g.*, *infra* ¶ 253, in this e-mail Ms. Loida appears to know Abbott's identity. At least within Dr. Slatopolsky's laboratory, it was known that Abbott had recently introduced Zemplar based in part on Dr. Slatopolsky's research. *See supra* ¶¶ 243, 249. Given the

> amendment refers to that we can see? Dr. Neighbor would like to see any license and/or amendment *that has either been executed or has the potential of being executed in the near future*.[51] Please fax me any sort of agreement that is available.
>
> Thanks. If you have any questions, please let me know.

(JX-046 at 1 (emphasis added).)

253. Ms. Kirkpatrick responded first with the following e-mail:

> Mary - . . . I am sending you an update to the Inter-Institutional agreement in writing, as you requested.
>
> Yes, we have an existing license agreement that, if the licensee agrees, will be amended to add this new case. I did not mention[] the name of this licensee in our phone conversation. I don't anticipate any objections from the licensee to adding this case and as required by our agreement, I will keep you informed of the licensing status of the case. As I mentioned in our phone conversation, this case is not currently licensed. As per *confidentiality provisions*, I am not at liberty to provide you copies of our license agreements with any other parties.[52] I would think that your office would have the same restrictions.
>
> Please look for a fax later today and call or email with any other questions.

(*Id*. (emphasis added).)

254. At the time, none of the relevant Abbott license agreements—including the 1993 License and the two 1996 Amendments to that agreement—contained any "confidentiality provisions" that would have prevented WARF from sharing those

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timing of Ms. Loida's inquiry, the circumstantial evidence leads the Court to infer that Dr. DeLuca's Dom Perignon cork may have sparked WashU's interest in the status of any licenses to the '815 patent.

[51] WARF argues that the 1998 License had not been signed in May 1998, so "there was *no license* . . . to give WashU" at the time. (D.I. 178 at ¶ 129 at 39.) WARF provides no explanation why the 1998 License, which was signed two months later, is not considered to be "in the near future."

[52] WARF contends that, thereafter, "WashU never asked WARF to seek permission from Abbott for WashU to see the license. Nor did it ever raise the issue again. Since WashU never raised the issue again, WARF had no reason to take further action." (D.I. 178 at ¶ 131 at 39.)

agreements with Washington University. (JX-005–JX-009; Tr. at 194:20–195:18 (Dr. Cleare).)[53] WARF's tech transfer expert, Dr. Severson, agreed that these agreements lack confidentiality provisions. (Tr. at 988:21–989:5 (Dr. Severson).) Importantly, Dr. Severson acknowledged that, at the time, "Washington University had no reason to think WARF wasn't being straightforward with them[.]" (Tr. at 990:6–10 (Dr. Severson).)

255. Later in the day, on May 13, 1998, Ms. Kirkpatrick sent a facsimile to Ms. Loida at WashU that stated:

> Dear Mary:
>
> As per our conversation yesterday, I am working on incorporating the DeLuca/Slatopolsky technology, which is the subject of the above referenced Inter-Institutional Agreement, as an amendment to an existing License Agreement. *It is unclear why this was not included in the original agreement and at present, this technology is not currently licensed.* In addition, although our licensee has recently obtained approval for their product, they have advised us that they have not yet obtained [Medicare] reimbursement approval through HCFA. They noted that this process can take up to a year and that reimbursement will definitely affect the take up of this new product and consequently, any royalty revenue stream.
>
> I will keep you updated on my progress and suggest that if you have any questions or comments, please do not hesitate to contact me.

(JX-045 (emphasis added).) Of note in this communication is Ms. Kirkpatrick's statement (as she expressed to Abbott on other occasions, *see supra* ¶ 241, *infra* ¶ 256) that the '815 patent should have been licensed to Abbott but was not licensed at the time.

[53] Moreover, none of the subsequent agreements between WARF and Abbott contained confidentiality provisions. (*See* JX-047 at JX047.002 (proposing, on June 12, 1998, an amendment to the 1993 License that would add the '815 patent as an "Ancillary Patent"); JX-008 (the 1998 Abbott Agreement).)

3. The ’815 Patent “Directly Supports” Zemplar

256. A month later, on June 12, 1998, Ms. Kirkpatrick wrote a letter to Abbott’s General Manager, Loreen Mershimer, highlighting the ’815 patent and advocating that “[w]e recognize this technology *directly supports* the Abbott Zemplar™ product[]” (the “Directly Supports Letter”). (JX-047 at 1 (emphasis added).) Ms. Kirkpatrick also acknowledged to Abbott that Dr. Slatopolsky would be entitled to a portion of the royalties that Abbott paid to WARF for Zemplar, were the ’815 patent included in the license. (*Id*.)

257. Accompanying this letter was a draft amendment to the 1993 License and 1996 Amendments. (*Id*.) Attached to the draft amendment was “Appendix A,” which enumerated the different national stage applications encompassed by the ’815 patent. (*Id*.)

258. By June 24, 1998, representatives from WARF and Abbott had met in person and were negotiating an amendment to the 1993 License. (JX-376 (discussing “copies of the amendment to the current 19-nor Agreement and a draft copy of a new License Agreement for 19-nor.”).)

259. Discussions appear to have continued through July. (JX-259 (documenting a July 15, 1998 letter from Ms. Kirkpatrick to Loreen Mershimer at Abbott attaching a draft of the 1998 License).)

(a) WARF Could Sue Abbott For Infringement of the ’815 Patent

260. The significance of the Directly Supports Letter discussed above is the source of much dispute between the parties. For example, WARF elicited testimony at trial and has proposed factual findings about whether or not Abbott “used” the ’815 patent. (D.I. 178 at ¶ 52 at 18–¶ 56 at 20 (“Abbott Did Not Use the ’815 Patent Until

Late 2011.").) However, whether Abbott "used" the '815 patent does not change WARF's legal rights against Abbott.

261. In the *Hospira* litigation, Abbott admitted that it knew, at some point in time around Zemplar's FDA approval in 1998, that, based upon the labeled approved indications, physicians would prescribe Zemplar in a manner that would infringe the '815 patent.[54] (JX-085 at ¶¶ 70–71 at 19 of 215.) In other words, Abbott admitted that it knew at roughly the time of Ms. Kirkpatrick's "directly supports" letter that it could be held liable for infringement of the '815 patent.

262. And when Ms. Kirkpatrick sent the Directly Supports Letter, WARF clearly knew that it could hold Abbott liable for induced infringement of the '815 patent. *See* 35 U.S.C. § 271(b). Therefore, so long as the 1993 License did not include the '815 patent, WARF could sue Abbott for infringement.

P. The 1998 License

263. Ms. Kirkpatrick's efforts appear to have been effective—on July 28, 1998, WARF and Abbott signed the 1998 License for paricalcitol,[55] which superseded the 1993 License. *See supra* ¶ 30. The 1998 License added the '815 patent to the bundle of IP rights licensed by Abbott in 1993, *supra* ¶ 31, and expanded the licensed field of use for paricalcitol to include all human therapeutics.[56] (JX-008, appx. A at 11 of 31; JX-376; Tr. at 653:15–654:21 (Dr. Gulbrandsen).)

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[54] Moreover, some years later in the *Hospira* litigation, WARF and Abbott alleged that generic Zemplar, sold in accordance with its FDA-approved label, would infringe claim 4 of the '815 patent. *See infra* ¶ 289.

[55] "'Compound' shall mean: 1 alpha, 25 dihydroxy-19-nor ergocalciferol[,]" (JX-008, appx. A at 11 of 31), which is paricalcitol, *see supra* ¶ 7 n.2.

[56] Dr. Gulbrandsen testified that Abbott and Dr. DeLuca were particularly excited at this time about the possibility that paricalcitol could also be used to treat multiple sclerosis. (Tr.at 655:3–17 (Dr. Gulbrandsen).)

264. To be sure, the 1998 License is specifically a license for Abbott to make, use, and sell paricalcitol/Zemplar, *see supra* ¶ 263, and not (as WARF has sought to characterize it) a license to Abbott of "a suite of patents for [WARF's] Vitamin D portfolio[,]" (JX-049 at JX049.001).[57]

1. Patent Groupings

265. The 1998 License organized patents into two groups: "Licensed Patents" and "Ancillary Patents." (JX-008, appx. B ("Licensed Patents and Patent Applications"), appx. C ("Ancillary Patents and Patent Applications").)

266. The '497 patent, which claims the compound paricalcitol, *see supra* ¶ 11, was listed in the 1998 License as both a Licensed Patent, *see infra* ¶ 268, and as an Ancillary Patent, *see infra* ¶ 275.

267. Also, the 1998 License included numerous patents that had nothing to do with paricalcitol/Zemplar, its use, or the manufacture of it or any other Vitamin D_2 compounds. *See infra* ¶¶ 276–280. At trial, WARF's Dr. Gulbrandsen testified that this was because WARF followed its "blended approach," which included early inventors at the University of Wisconsin in later stage royalties associated with other inventors at the University of Wisconsin. (Tr. at 672:10-673:10.)

(a) Licensed Patents

268. Appendix B lists the '497 and '925 patents as the only two U.S. patents in the Licensed Patents group. (JX-008, appx. B at 12 of 31.)

[57] By characterizing the 1998 License as a license to a "suite of patents" in WARF's Vitamin D portfolio, WARF seems to suggest that it was Abbott's idea to throw the kitchen sink into the 1998 License and to include numerous patents that had nothing to do with paricalcitol/Zemplar, its use, or the manufacture of Vitamin D_2 compounds. *See infra* ¶¶ 276–280. As WARF has argued extensively, by including these wholly irrelevant patents in the 1998 License and assigning some relative value to these irrelevant patents—a valuation method that WARF affectionately calls the "blended approach"—WARF was able to spread licensing income among investigators at the University of Wisconsin, even though those investigators may have done no research and made no inventions relevant to the licensed compound. *See infra* ¶¶ 325–329.

269. The ’497 patent is identified under reference number P95121US. (*Id.*)

270. The ’925 patent is identified under reference number P92168US. (*Id.*)

271. The ’925 patent claims a process, namely a method of treatment using paricalcitol, *see supra* ¶ 15.

(b) Ancillary Patents

272. The Ancillary Patents group consisted of thirty (30) patent and patent application families. (JX-008, appx. C. at 13–26.)

273. The ’815 patent was included in the 1998 License as an Ancillary Patent under reference number P95011US. (JX-008, appx. C at 24 of 31.)

274. The ’815 patent claims a process, namely a method of treatment using paricalcitol. *See supra* ¶ 231.

275. The ’497 patent, which claimed the compound paricalcitol and was identified as a “Licensed Patent” in Appendix B of the 1998 License, was also identified as an “Ancillary Patent” in Appendix C of the 1998 License. (JX-008, appx. C at 24 of 31 (identifying a patent family for “19-Nor-Vitamin D Compounds” that included seven U.S. patents, including “P95121US” for the ’497 patent).)

276. The Ancillary Patent group also included reference number P89130US, which is associated with U.S. Patent No. 5,237,110 (“the ’110 patent”). (JX-008, appx C at 24 of 31.) The ’110 patent claims various 19-nor Vitamin D compounds, (JX-228, 11:54–12:55), and is a parent of both the ’925 and ’497 patents, (*e.g.* JX-003, cover page).

277. Of the 30 patents in the Ancillary Patent group, Dr. Cleare testified that, in addition to the ’815 patent, another four were “low value” and may potentially relate to

processes and/or intermediates for the manufacture of 19-nor Vitamin D compounds like paricalcitol. (Tr. at 238:8–239:2; *see also* JX-225; JX-232; JX-229; JX-230.)

278. Also, in addition to the '815 patent, Dr. Cleare testified that the Ancillary Patent group included six other method of treatment patents "that have no relevance . . . to Zemplar's approved use."[58] (Tr. at 235:24–236:2.) Dr. Cleare testified, (Tr. at 235:13-237:1), that these six other patents and patent applications included: (1) a patent for treating symptoms of multiple sclerosis, (JX-248 at 12:40–16:65; JX-008, appx. C at 25); (2) a patent for treating skin conditions, (JX-238 at 22:2–63; JX-008, appx. C at 24); (3) a patent for the treatment of immune deficiency, (JX-251 at 14:55–18:9; JX-008, appx. C at 26); (4) a patent application for treating arthritic disease (JX-008, appx. C at 25; JX-253 at 11:16–12:54;); and (5) two patent applications for preventing transplant rejection, (JX-008, appx. C at 25 of 31 (identifying U.S. Patent Applications 08/870,337 (reference number P97063US) and 08/870,569 (reference number P97064US) as separate licensed cases); JX-254, cover page (explaining, in U.S. Patent No. 6,071,897, that the '337 and '569 applications were abandoned and combined into a single application); *id.* at 11:49–14:58 (claiming methods of transplant rejection)).

279. Dr. Cleare also presented unrebutted testimony[59] that another eighteen of the "Ancillary Patents" disclosed methods of manufacturing Vitamin D compounds other

[58] Dr. Cleare's testimony in this regard was unrebutted. (Tr. at 908:2–18 (Mr. Lentz); Tr. at 1031:1–12 (Dr. Severson); Tr. at 1108:21–1109:4 (Ms. Mulhern); Tr. at 162:11–163:6 (Dr. DeLuca).) Mr. Stoveken, who analyzed each patent in the Abbott portfolio in 2007 and 2008 with an eye to determining which ones supported Zemplar, admitted in his deposition that the six other method of treatment patents and patent applications included in the Ancillary Patent group did not relate to Zemplar's approved use. (D.I. 163–9, ex. I at 51:22–66:19.)

[59] No WARF witness disputed Dr. Cleare's analysis that these 18 Ancillary Patents do not relate to making 19-nor Vitamin D compounds like paricalcitol. (*See* Tr. at 907:17–908:1 (Mr. Lentz "neither disputing nor confirming" Dr. Cleare's testimony); Tr. at 1030:17–24 (Dr. Severson testifying that "I did not conduct that analysis. I had no basis to either confirm or refute what [Dr. Cleare] said."); Tr. at 1108:21–1109:4 (Ms. Mulhern confirming "ex-post" that only the '497 and '815 patents "drove any revenue" under the 1998 License).)

than the class of 19-nor Vitamin D compounds to which paricalcitol belongs. (Tr. at 232:24–235:12 (Dr. Cleare); JX-209, JX-210, JX-211, JX-212, JX-213, JX-214, JX-215, JX-216, JX-217, JX-219, JX-220, JX-221, JX-222, JX-223, JX-224, JX-226, JX-227, JX-249.) Because paricalcitol is a 19-nor Vitamin D compound, the methods disclosed in those eighteen Ancillary Patents do not disclose processes for manufacturing paricalcitol. (*e.g.*, Tr. at 233:17–234:10 (Dr. Cleare).) In addition, Dr. Cleare testified many of those patents were filed in the 1980s—nearly a decade before Dr. DeLuca synthesized the class of 19-nor Vitamin D analogs claimed in the ’497 and ’925 patents—and therefore expired in the first three years after the execution of the 1998 Abbott License. (JX-008, appx. C at 14–15, 19–20 (showing eight case numbers identifying U.S. patents with expiration dates prior to 2002); Tr. at 233:14–235:1 (Dr. Cleare); Tr. at 548:24–549:12 (Mr. Thomas).)

280. Finally, in the Ancillary Patent group, Dr. Cleare testified that one of the WARF-owned Ancillary Patents was entirely duplicative of the ’497 patent and was subject to a “terminal disclaimer” as a result. (Tr. at 237:14–238:7 (Dr. Cleare); *see also* JX-008, appx. C at 22 (identifying case number P96050US arising from application number 08/626,431); JX-252, cover page (identifying U.S. Patent No. 5,880,113 (“the ’113 patent”) as arising from “Appl. No.: 626,431” and stating that “[t]he term of this patent shall not extend beyond the expiration date of” several patents, including the ’497 patent); JX-377 (documenting the terminal disclaimer filed with the USPTO during patent prosecution).)

2. License Types

281. The 1998 License identified two types of licenses: an “exclusive license” and a “nonexclusive license.” (JX-008, § 2.A.)

(a) Exclusive License

282. In the 1998 License, WARF granted "to Abbott an exclusive license under the Licensed Patents to make, have made, import, and use the Compound the preparation of Products and to make, have made, use, import and sell Products in the Licensed Field and Licensed Territory." (JX-008, § 2.A.(i).)

(b) Nonexclusive License

283. In the 1998 License, WARF granted Abbott "a nonexclusive license to practice Processes of Licensed Patents and Ancillary Patents and to make and use Ancillary Compounds, *but only for the purpose of making the Compound and Products*."[60] (JX-008, § 2.A.(ii) (emphasis added).)

284. According to the 1998 License, "'Processes' shall mean the processes described and claimed in Licensed Patents and Ancillary Patents[.]" (JX-008, appx. A; *see also* 35 U.S.C. § 101 (defining the four statutory classes of invention as "process[es], machine[s], [articles of] manufacture, or composition[s] of matter").)

285. In addition, the 1998 License defines "'Ancillary Compounds' . . . [as] those compounds described and claimed in Licensed Patents and Ancillary Patents which are intermediates in Processes." (JX-008, appx. A.)

286. Based upon the language of Section 2.A.(ii) of the 1998 License, the Court concludes that the Nonexclusive License provision grants Abbott nonexclusive rights to the four patents that Dr. Cleare identified as potentially relating to processes and/or

[60] In its proposed Findings of Fact, WARF contended that "[t]he 1998 [] License [] granted Abbott nonexclusive rights to the '815 patent . . . , which [was] listed in Appendix C and referred to as the 'Ancillary Patents.'" (D.I. 178 at ¶ 51 at 18 (footnote omitted).) Essentially, WARF argues, any patent listed as an "Ancillary Patent" cannot be exclusively licensed. In support of its position, WARF presented attorney argument challenging Dr. Cleare's testimony on re-cross, (id. n.5), and citation to testimony by Dr. Gulbrandsen, who affirmed, without explanation, that "the ancillary group patents [were] still nonexclusively licensed [in 1998,]" (Tr. at 652:24–653:14). *However, the '497 patent, which specifically claims the compound paricalcitol, is listed in both groups, as a Licensed Patent and an Ancillary Patent at the same time*, *see supra* ¶ 266, and WARF does not argue that *that patent* was nonexclusively licensed. Based upon the facts in the record, the Court concludes otherwise. *See infra* Section II.P.5.

intermediates for the manufacture of 19-nor Vitamin D compounds like paricalcitol. *See supra* ¶ 277.

287. Moreover, the Court finds no evidence that the parties intended for the Nonexclusive License provision to encompass the '815 patent and the six other method of treatment patents and patent applications included in Appendix C. *See supra* ¶ 278 (identifying the method of treatment patents). Even WARF's expert expressed the opinion that the "Processes" identified in Section 2.A.(ii) did not include method of treatment patents like the '925 (and '815) patents. (Tr. at 1008:3–1009:1 (Dr. Severson) ("[M]y opinion is that [in the 1998 License] a method of use is different than a process.").) And Dr. Cleare expressed a similar opinion. (Tr. at 334:16–18 ("[T]he terms of 1998 license certainly say [that] you can't fit [the '815 patent] into the nonexclusive grant.").)

3. Royalties

288. Under the 1998 License, Abbott agreed to pay "earned royalties" to WARF "whenever manufacture, use or sale of the Compound or Products, absent this license, would amount to an infringement of any claim of Licensed Patents or Ancillary Patents[.]" (JX-008, § 3.D.) Abbott agreed to pay a 7% royalty "[u]nder Exclusive License(s)," and a 5% royalty "[u]nder Nonexclusive License(s)," subject to an overall 7% royalty cap. (*Id*.)

289. In the case at bar, WARF stated that Abbott paid 7% royalties on the '815 patent as the exclusive licensee to that patent in at least the United States and Spain. (JX-466 at 4.) These royalties were "earned royalties" under the 1998 License, because, as alleged by WARF and Abbott in the *Hospira* litigation, the sale of paricalcitol (by Hospira in that case) and its use according to its approved labeling "by ultimate purchasers and users" would infringe at least claim 4 of the '815 patent. (JX-063 at ¶ 23 at 6–¶ 38 at 10.)

4. Evidence of One Amendment to the 1998 License

290. The record is replete with documentary evidence of the original 1993 License, (JX-005), the two 1996 amendments to that license, (JX-006; JX-007), communications between WARF and Abbott about subsequent amendments, *see supra* ¶¶ 221, 256–259, and the 1998 License itself, (JX-008).

291. Within the documentary record, there is evidence of one amendment to the 1998 License—on November 20, 2008, WARF and Abbott amended the 1998 License "to add a procedure in the event of an infringement action brought under the Hatch-Waxman Act or similar law[.]" *See infra* ¶ 404.

292. In addition, neither party deposed a representative from Abbott in the case at bar, "discovery didn't seem to have covered Abbott[,]" (Tr. at 267:13–23), and Abbott's position as to the nature of the 1998 License is not part of the record.

5. The 1998 License Granted Abbott Exclusive Rights to the '815 Patent

293. Based upon the evidence in the record, for the reasons discussed herein, the Court concludes that, in the 1998 License, WARF granted Abbott exclusive rights to the '815 patent.

294. In the instant litigation, WARF has taken the position that the 1998 License granted Abbott a nonexclusive license to the '815 patent but that, at some point around 2012, through a course of dealing and without an accompanying writing, WARF and Abbott modified the 1998 License to grant Abbott an exclusive license to the '815 patent.[61] (JX-466 at 2–3 ("[WARF's] Fourth Supplemental Response to [WashU's] Second Set of Interrogatories No. 15[,]" dated June 18, 2015).)

[61] In addition, WARF admits that "[s]tarting in or around 2012," Abbott and WARF represented in complaints and [redacted] "that [Abbott's] license to the '815 patent was exclusive." (JX-466 at 3 (WARF's response to Interrogatory No. 15); *see also* D.I. 175 at ¶ 176 at 80–81 (WashU's proposed

(a) A reasonable interpretation of the 1998 License grants Abbott exclusive rights to the '815 patent

295. Absent clear language defining the rights to the '815 patent that WARF granted to Abbott in the 1998 License,[62] the Court follows the guidance of Dr. Cleare, who summarized his opinion on the exclusivity of the '815 patent as follows:

> I understand that WARF has asserted [] that it granted Abbott an exclusive license at some stage. It granted Abbott exclusive license to the '815 Patent, but has taken inconsistent positions whether the original grant to Abbott in 1998 was exclusive. The position now seems, they claim that it was nonexclusive and somehow turned exclusive *without any evidence of [an] amendment* or anything whatsoever. My reading -- my reading of the original license is that you can read that quite comfortably as it being exclusive. . . . [63]

(Tr. at 330:24–331:18 (emphasis added).)

296. At trial, counsel for WashU asked Dr. Cleare questions about his expert report, but the report itself is not in the record. (Tr. at 330:20–332:3.) The Court is able, nonetheless, to contemplate a reading whereby the grant "to Abbott [of] an exclusive license under the Licensed Patents to . . . make, have made, use, import and sell Products in the Licensed Field and Licensed Territory[,]" (JX-008, § 2.A.(i)), would include an exclusive license to the '815 patent, which claims a method of treatment in the Licensed Field (of all human therapeutics). There are two primary reasons for this.

Findings of Fact).) The facts related to WARF's and Abbott's representations after 2012 are not in dispute.

[62] The experts agreed that the 1998 License is "not a particularly well-worded license," (Tr. at 332:18–23 (Dr. Cleare)), and that the Nonexclusive License terms are "less than perfect[,]" (*id.* at 796:19–20 (Mr. Lentz)).

[63] At the same time, WARF has encouraged a reading of the 1998 License that equates the Ancillary Patents solely with the Nonexclusive License provision in Section 2.A. For example, in his cross examination of Dr. Cleare, WARF's counsel asked, "Sir, you understand that . . . it says that the ancillary group are nonexclusively licensed, correct?" (*Id.* at 334:19–22.) Dr. Cleare declined to affirm this question. (*Id.* at 334:23–335:13.) *See supra* note 60.

297. First, although the ’815 patent and six other method of use patents and patent applications were listed in the Ancillary Patent group in Appendix C to the 1998 License, *see supra* ¶ 278, as discussed above, the ’815 patent (and the other method of use patents) were not licensed according to the Nonexclusive License provisions of the 1998 License, *see supra* ¶ 287.

298. Second, any party selling paricalcitol to be prescribed according to its labeled approved indications would infringe the ’815 patent. *See supra* ¶ 261. Therefore, since the 1998 License grants Abbott an exclusive license to make, use, and sell “Products” (*i.e.,* Zemplar) in the licensed field of human therapeutics and licensed territories, it is reasonable, as Dr. Cleare testified, to read the 1998 License as granting Abbott exclusive rights to the method of use patents, including the ’815 patent.[64] (Tr. at 333:7–22.) In the *Hospira* litigation, WARF’s Rule 30(b)(6) witness, Mr. Stoveken, expressed a similar position. (JX-426 at 105:22–109:14.)

(b) Abbott would have wanted an exclusive license to the ’815 patent

299. The Court finds it persuasive that, in order to maintain Zemplar’s market exclusivity, a reasonable licensee in Abbott’s position would have expected to receive an exclusive license to the ’815 patent. (Tr. at 329:8–332:3 (Dr. Cleare) (“I would have thought the conservative nature of the pharmaceutical industry is they would have wanted it to be exclusive rather than nonexclusive.”).)[65] Indeed, Abbott took an exclusive license to the ’925 patent, which also covers the approved use of Zemplar, and WARF ultimately considered the ’815 license to be licensed exclusively in at least

[64] Dr. Cleare was consistent in his position, explaining that the other method of treatment patents in the Ancillary Patents group were also licensed exclusively to Abbott. (Tr. at 332:10–333:22.) None of these six other method of treatment patents claimed FDA-approved uses of paricalcitol/Zemplar.

[65] The lack of a written amendment to the 1998 License raises the issue of the Statute of Frauds, because the term of the asserted 2011 or 2012 amendment would have lasted until the expiration of the ’815 patent in 2015—or for a term of more than a year. This is an issue that a corporation of a “conservative nature” would necessarily seek to avoid.

the United States and Spain.[66] (*See* Tr. at 253:19–24 (Dr. Cleare); Tr. at 891:20–24 (Mr. Lentz); JX-466 at 3.)

(c) Consistent with An Exclusive License, in 2010, WARF Told WashU That Abbott Had an Exclusive License to the '815 Patent.

300. In April 2010 Beth Werner, PhD ("Dr. Werner"), a licensing manager at WARF, sent an e-mail to Jon Kratochvil ("Mr. Kratochvil"), a business development director at Washington University, responding to Mr. Kratochvil's questions about the IIA. In this e-mail, Dr. Werner stated that the '815 "patent *is licensed exclusively* to Abbott Labs as part of a package of patents from WARF around the drug Zemplar."[67] (JX-410 at 2 (emphasis added).) The only "package of patents" that WARF licensed to Abbott that included the '815 patent was the 1998 License.[68] (JX-410 at 2; Tr. at 620:17–621:18 (Mr. Thomas).)

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[66] WARF did not identify any testimony to answer the question of why Abbott would have agreed to a nonexclusive license to the '815 patent in 1998 and would have subsequently modified the license some 13 or 14 years later without a writing.

[67] The Court notes that a "licensing manager" at a major research university would likely know the difference between exclusive and nonexclusive licenses. (*See, e.g.,* DX-001 at DX001.007 (discussing "exclusive or nonexclusive licenses" in a treatise chapter on "Managing Joint Inventions between Universities").)

[68] WARF has argued in the case at bar that its "attempts to license the '815 patent to third parties (other than Abbott) demonstrate that WARF did not consider the '815 patent to be exclusively licensed to Abbott in 1998[.]" (D.I. 154-1, ex. 12 at ¶¶ 124–26 at 30 of 92 (citing JX-016, license to Tetrionics).) But neither of the licenses to Tetrionics or Quatrx supports WARF's assertion. In those licenses, WARF granted those companies only the right to "make and use" a single Vitamin D_3 compound—not paricalcitol, which is a Vitamin D_2 compound. (JX-016, § 2.A.(i); *id.* appx. A at C ("'Compound' shall mean 19-nor-1,25 dihydroxycholecalciferol"); JX-017, §§ 1(D) ("'Compound' shall mean . . . 19-nor-1α,25-D-dihydroxyvitamin D3"); *id.*, 2(A)(ii).) WARF then granted Tetrionics non-exclusive rights to practice "Processes of . . . Ancillary Patents . . . only for the purpose of making" the licensed D_3 compound. (JX016, § 2.A.(i).) Because the '815 patent relates only to treatment methods for Vitamin D_2 compounds, and does not disclose any "Processes" for making Vitamin D_3 compounds, these licenses did not convey any rights to the '815 patent at all. WARF recognized this point in 2002 when it wrote a letter to Quatrx, pointing out that it had "inadvertently included" the '815 patent in the license agreement, and proposed an amendment to remove it. (*Compare* JX-208, appx. B, *with* JX-017, appx. B at JX017.025.) Similarly, WARF recognized in the Tetrionics Income Division Memo the '815 patent had been inadvertently included because WARF assigned a *0% relative value* to that patent. (*See* JX-016 at JX016.031 (identifying the reference numbers for Groups 1 & 2, but not including P95011, the reference number for the '815 patent).) The only thing that the Tetrionics License proves is that WARF did not, as it claimed, "always" assign equal value to the "Ancillary Patents" regardless of their use, (D.I. 154-1, ex. 12 at ¶ 72 at

(d) An Exclusive License to the ’815 Patent Is Consistent with Representations WARF and Abbott Made to This Court and to Others

301. Between 2012 and 2014, WARF and Abbott represented in complaints filed in this Court against Aurobindo Pharma, Agila Specialties, Sandoz, Banner Pharmacaps, Dr. Reddy’s Laboratories, and Hikma Pharmaceutical (collectively, “the generic Zemplar litigants”), that Abbott was the exclusive licensee of the ’815 patent. (JX-058 at ¶ 9; JX-059 at ¶ 9; JX-064 at ¶ 16; JX-065 at ¶ 14; JX-066 at ¶ 18; JX-416 at ¶ 11.)

302. [redacted]

303. WARF and Abbott also represented in its Proposed Findings of Fact and Conclusions of Law in the *Hospira* litigation, filed under seal in this Court, that Abbott was the exclusive licensee of the ’815 patent. (JX-085 at ¶ 1.)

(e) WARF’s 30(b)(6) Witness in the *Hospira* Litigation Testified That the Unamended 1998 License Granted Abbott An Exclusive License to the ’815 Patent

304. Mr. Stoveken’s Rule 30(b)(6) testimony in the *Hospira* litigation corroborates Dr. Werner’s e-mail. At his February 28, 2013 deposition in that litigation, Mr. Stoveken testified that the 1998 License conveyed an exclusive license to the ’815 patent to Abbott. (JX-426 at 109:6–14 (answering “yes” to the question “it’s plaintiff’s

78 of 92; *see also* JX-049), as WARF assigned *no* relative value to the ’815 patent after recognizing that it did not contribute to the development or commercialization of the licensed Vitamin D3 compound.

position that [in the 1998 License,] WARF has granted Abbott an exclusive license to ancillary patents that relate to methods of treatment"); *see also id.* at 98:6–100:11, 102:2–14, 105:7–109:14.)

(f) WARF's Amendment Theory Is Unpersuasive

305. In the case at bar, WARF's evidence contradicting its earlier statements is unpersuasive.

306. The earliest evidence in the record of WARF's position as to this purported 2011 or 2012 amendment to the 1998 License is from March 17, 2015, when WashU deposed Mr. Stoveken in the instant litigation.[69] In his deposition, Mr. Stoveken repudiated his sworn testimony from two years prior in the *Hospira* litigation. (Tr. at 489:4–490:15 (affirming that his "prior testimony under oath in the Hospira litigation . . . [about the exclusivity of the '815 patent license] was inaccurate[.]").) The Court finds Mr. Stoveken's present testimony to lack credibility. For example, Mr. Stoveken realized "within the next few days" after his deposition in the *Hospira* litigation that his testimony was incorrect, but he did not submit a correction to either Hospira or the Court. (Tr. at 517:19–518:1.) In addition, Mr. Stoveken could not recall having a chance to review his deposition transcript to "mark any places where . . . [he] felt there was an inaccuracy[.]" (D.I. 163-9, ex. I at 22:2–21.) Moreover, when presented with the actual language of the Nonexclusive License provision in the 1998 License, (JX-008, § 2.A.(ii)), Mr. Stoveken could not explain how a method of treatment patent like the

[69] WashU filed the complaint in the case at bar on Dec. 26, 2013. There is *no evidence in the record*, from prior to 2015, to support WARF's assertion that—without a writing—WARF and Abbott agreed to amend a license that ultimately generated $427.6 million in earned royalties for WARF. (*E.g.*, Tr. at 561:19–21 (Mr. Thomas).)

'815 patent related to the defined term "Processes,"[70] (Tr. at 496:16–497:22 (Mr. Stoveken)).

307. At trial, Dr. Gulbrandsen, who was at the helm of WARF until his retirement in 2016, testified that "[s]ometime around late 2011 or early 2012[,]" Abbott and WARF changed the license to grant Abbott exclusive rights to the '815 patent. (Tr. at 703:3–16.) And WARF's damages expert, Ms. Mulhern, explained further that the royalties paid on the 1998 License are "consistent with my understanding of WARF's position in this case that in the United States the '815 patent had exclusive license status . . . [in 2015.]" (Tr. at 1078:6-1080:14.) According to Ms. Mulhern, in 2015, Abbott had an exclusive license to the '815 patent in the U.S. and Spain, with a non-exclusive license in other countries. (*Id.*)

308. Nonetheless, WARF's experts were unable to explain the discrepancy between Mr. Stoveken's *Hospira* testimony and their expert reports in the instant litigation. Dr. Severson and Mr. Lentz testified that the 1998 Abbott License conveyed a nonexclusive license to the '815 patent because the '815 patent was an "Ancillary Patent" rather than a "Licensed Patent."[71] (Tr. at 1006:9–13, 1007:11–14 (Dr. Severson); Tr. at 795:9–17, 892:19–23 (Mr. Lentz).) Dr. Severson, however, had no explanation for why this was so when he admitted that the defined term "Processes" excluded method of treatment patents, like the '815 patent. (Tr. at 1008:3–1009:1 (Dr. Severson).) Mr. Lentz also implicitly conceded that the '815 patented treatment method did not fall within the defined term "Processes." (Tr. at 795:18–797:1 (Mr. Lentz).) Both experts agreed, without any additional explanation, that their opinions about the alleged

[70] Of course, Mr. Stoveken's conclusory deposition testimony also contradicts the testimony of WARF's licensing expert, Dr. Severson, who testified that the "Processes" of Section 2.A.(ii) of the 1998 License do not encompass method of treatment patents. *See supra* ¶ 287.

[71] As discussed above, the Court declines to follow a reading of the 1998 License whereby the Licensed Patents are exclusively licensed and the Ancillary Patents are nonexclusively licensed. *See supra* note 63.

nonexclusive nature of the ’815 patent’s license to Abbott contradicted Mr. Stoveken’s Rule 30(b)(6) testimony in the *Hospira* lawsuit. (Tr. at 895:4–12 (Mr. Lentz); Tr. at 1012:6–10 (Dr. Severson).)

(g) Conclusion–Exclusivity of the ’815 Patent

309. For the above reasons, the Court concludes that the 1998 License granted Abbott an exclusive license to the ’815 patent and the other method of treatment patents listed in Appendix C.

6. Internal Memorandum on WARF’s Financial Obligations Under The IIA

310. On October 16, 1998, with the 1998 License between WARF and Abbott signed, Ms. Kirkpatrick at WARF drafted an internal memorandum concerning “WARF’s financial obligations” under the 1995 IIA. (JX-205 at JX205.001.) Ms. Kirkpatrick wrote, “[i]t should be noted that this [memorandum] involves the distribution of royalties received for the 19 nor compound which is licensed to Abbott under [the IIA] . . . . Approval by FDA was received on April 23, 1998 and the product was launched in May 1998 under the tradename Zemplar™.” (*Id.*) Of note, the memo stated the following:

> Per Section 3.A.(i)(1) [of the IIA], WU is entitled to 33 1/3% of Net Revenues and per Section 3.A.(i)(3)(iii) “WARF shall have the authority to assign relative values to Patent Rights . . .” and the distribution of income “. . . shall be determined in accordance with such relative values. . .”. There is only one patent case, *“Prevention of Hyperphosphatemia in Kidney Disorder Patients”,* WARF reference P95011, which pertains to the WU Agreement. *This case has been assigned a relative value as described in the Income Distribution Memo.* As per the License Agreement, the Licensed Patents, which include the compound and the primary indication, will receive a relative value of 70%. The Ancillary Patents, which include process, intermediate and other indications, will receive a relative value of 30%. Within these two categories, each parent case within a patent family will receive an equal proportionate relative value. The patent case associated

> with the WU Agreement, is part of the Ancillary Patents category.
>
> Jan Burch will provide the IDM calculations which will detail the proportionate relative value for this patent case. As per the Agreement, WU is entitled to 33 1/3% of the relative value of this patent case. This value can then be used to calculate WU's share of Net Revenues.

(*Id.* at JX205.002 (emphasis added).) It is unclear which "License Agreement" required this 70%/30% revenue distribution, as the Court is unable to find any language in either the IIA or the 1998 License discussing such an apportionment. (JX-001; JX-008.) Dr. Cleare testified that he reviewed WARF's internal policy on allocating licensing income to inventors, "but [] saw nothing about that 70/30 split as being some sort of standard policy[.]" (Tr. at 208:3–11 (discussing JX-010).)

311. Citing an unidentified "License Agreement," Ms. Kirkpatrick assigned relative values to the patents in the 1998 License, including the '815 patent, based solely on their inclusion in the Licensed Patent or Ancillary Patent group and equally between "parent case[s]" within those groups. (JX-205 at JX205.002.)

7. October 26, 1998–WARF Informs WashU About the 1998 License to Abbott But Not the Relative Value of the '815 Patent

312. Ten days after WARF's relative valuation under the IIA, on October 26, 1998, Ms. Kirkpatrick sent a facsimile about the IIA to Ms. Loida at WashU, stating the following:

> Dear Mary:
>
> The objective of this letter is to give you an update regarding our above-referenced agreement. The Deluca/Slatopolsky patent case associated with our inter-institutional (WARF Ref. P95011 US) was added to the Abbott License Agreement this summer.
>
> Abbott Laboratories received approval of Zemplar® in April 1998 and they subsequently launched this product in late May 1998. Abbott is currently in the ramp-up stage of

> converting sales to Zemplar® and sales to date have been relatively small.
>
> The first royalties for the Zemplar® product were received from Abbott on September 21st, 1998. As per Section 5 of our agreement, "WARF will pay to Institution its share of net revenue due under this agreement every 12 months by August 31st for the proceeding 12-month period beginning July 1st and ending July 30th".[72] Since the first distribution was not received until after June 30th, we will proceed to pay Washington University by August 31st, 1999. *At that time, we will provide full details regarding the calculation used to determine Washington University's distribution.*
>
> In the interim, if you have any questions or comments, do not hesitate to contact me.

(JX-048 (emphasis added).) Even though Ms. Kirkpatrick knew WARF had already assigned a very low (<1%) relative value to the '815 patent, Ms. Kirkpatrick did not tell Washington University that WARF had completed its relative valuation. (*See id*.; Tr. at 202:19–204:5 (Dr. Cleare).)

313. In this letter, Ms. Kirkpatrick did not disclose any information about the '815 patent's relative value to Washington University, including her statement to Abbott a few months earlier that the '815 patent "directly supports" Zemplar. *See supra* ¶ 256.

8. November 5, 1998–First IDM Calculation

314. On November 5, 1998, WARF prepared an Income Division Memo ("IDM") for the 1998 License with Abbott, which WARF referred to as "98-0141."[73] (JX-011 (the "First IDM").) Ms. Kirkpatrick, Dr. Gulbrandsen, and Richard H. Leazer signed the IDM on November 10, 1995. (*Id.* at JX011.001.) The IDM organized the patents into two groups: Group 1 consisted of a single case identified as "P89130US" to which WARF

[72] This should say "June 30." (*See* JX-001, § 5.B.)

[73] In its proposed Findings of Fact, WARF contends that it "exercised [its] authority [to assign a relative value to the '815 patent] based on its standard licensing and technology transfer practice, and assigned a relative value to all patents within the Abbott portfolio in November 1998." (D.I. 178 at ¶ 75 at 24 (citing JX-011).)

assigned 70% of the license revenues, and Group 2 consisted of 31 cases assigned 30% of license revenues, including "P95011US," which identifies the '815 patent. (*Id.* at JX011.011.)

315. In the IDM, contrary to Ms. Kirkpatrick's memorandum assigning 70% of license revenues to the "Licensed Patents," *see supra* ¶ 310, WARF assigned 70% of the license revenues to the '110 patent, which is identified as an "Ancillary Patent" in the 1998 License, *see supra* ¶ 276.[74]

316. Under a section entitled "Special Instructions," the IDM stated, "For the purpose of royalty distribution; the following cases which are exceptions, have been included in the automatic calculations; P77027US (Expired), P89057US (Abandoned), P89128US (Abandoned), and P95011US (Non-UW Inventor)." (JX-011 at JX011.001.) Apart from P95011US, which reflected the '815 patent, these other cases included foreign patent assets for which the U.S. patent had expired, (*e.g.*, JX-008, appx. C at 14 of 31 (showing foreign patents under the "P77027" reference number)), or the U.S. patent application had been abandoned, (*e.g.*, *id.* at 18 of 31 (listing foreign patents for "P89057")).

317. Of the thirty-one patents identified by reference number in Group 2 of the November 1998 IDM, one was P96050US, for the '113 patent, which was duplicative of the '497 patent. (JX-011 at JX011.011); *see supra* ¶ 280.

318. Two of the thirty-one patents identified by reference number in Group 2 of the November 1998 IDM were for P97063US and P97064US, which were two U.S. patent applications that were both abandoned and consolidated into reference number

[74] As discussed, above, *supra* ¶ 276, the '110 patent is a parent of the '925 and '497 patents, and Ms. Kirkpatrick's memo discussed assigning revenues to the "parent case" in the group, *supra* ¶ 311. However, there is no evidence in the record that the case reference number P89130US is the "parent case" reference number for P92168 (the '925 patent) or P95121US (the '497 patent). Also, it is wholly confusing that both the '110 and '497 patents are listed as Ancillary Patents in the 1998 License. *See supra* ¶¶ 275–276.

(as annotated by hand on the document in evidence) P98272US. (JX-011 at JX011.011); *see supra* ¶ 278.

319. Each of the patents in Group 2 was assigned to receive 0.968% of the license revenues. (*E.g.* JX-011 at JX011.002.)

320. Therefore, under the November 5 IDM calculation, WARF assigned a "relative value" to the '815 patent—it was to receive 0.968% of WARF's Zemplar royalties under the 1998 License.

9. November 25, 1998–First Check to WashU

321. One month later, on November 25, 1998, Ms. Kirkpatrick sent another letter to Washington University, attaching a check for $131.69, stating: "Contrary to my previous letter, enclosed please find a disbursement based on the first royalty revenue received from Abbott Laboratories for their product Zemplar®."[75] (JX-021 at 1.) By way of explanation for why "the royalties received are relatively low," Ms. Kirkpatrick explained that Abbott had "launched this product in late May and are still in the ramp-up phase in converting sales from their Calcijex® product"—while never mentioning WARF's 0.968% relative valuation performed one month earlier. (*Id.*)

322. Although Ms. Kirkpatrick included some "calculations for the disbursed amount" by listing the "Royalty Income" ($929.66) and WARF's deductions under the IIA, Ms. Kirkpatrick did not explain: (1) how WARF had calculated the top-line "Royalty

[75] It is puzzling that, after assigning a relative value to the '815 patent, *supra* ¶¶ 310–311, and telling WashU that no money would be forthcoming for another year, *supra* ¶ 312, WARF decided to send WashU a royalty check. This is especially confusing, because the "July 30" deadline cited in the October letter was, in fact, a mistake, *supra* ¶ 312 & n.72, and WARF only owed WashU royalties through June 30, 1998. However, in light of the undisputed documentary evidence, it is clearly evident that, as of June 30, 1998, there were no royalties attributable to the '815 patent (and hence payable to WashU under the IIA), because WARF and Abbott did not sign the 1998 License (which added the '815 patent) until July 28, some four weeks later. (JX-008.) Therefore, WARF paid WashU its first royalty check under the IIA nearly a year before it was contractually obligated to.

Income" number, or (2) that it represented less than 1% of the royalties WARF had received from Abbott. (*Id*.)

323. At trial, the parties' experts testified about the standard practices in the technology transfer industry—the experts largely agreed that, in 1998, WashU reasonably expected WARF to share the information that it possessed about the '815 patent. (Tr. at 982:8–12, 983:15–18 (Dr. Severson); Tr. at 175:19–182:15 (Dr. Cleare); Tr. at 351:3–355:7, 371:22–372:7 (Dr. Brandt); Tr. at 380:5–381:6 (Mr. Kratochvil); Tr. at 423:4–424:6 (Mr. Surber).) Therefore, WARF's lack of disclosure, and candor, in its October 26 and November 25 letters represented a significant departure from common practices in the university tech transfer industry.

Q. 1998: What WARF Knew and What WARF Did

1. WARF Did Not Value the '815 Patent in 1998

324. In its proposed Findings of Fact and Conclusions of Law, WARF readily admits that, "[a]side from its practice of classifying its patents into compound and ancillary patent groups, *WARF did not as a matter of practice make patent-specific valuations or conduct any infringement analyses for its ancillary patents*." (D.I. 178 at ¶ 81 at 26 (emphasis added) (citing Tr.at 651:6–22, 663:11–664:6 (Dr. Gulbrandsen; JX-039[76]).)

[76] The parties signed the IIA in November 1995. *See supra* ¶ 26. WARF repeatedly relies on parol evidence, namely a July 21, 1995 letter from WARF's Dr. Bremer to WashU's Dr. Brandt, (JX-039), to explain that WARF did not breach the IIA, because, contrary to WARF's written policy, (JX-010), the "blended approach" was standard practice at WARF, and that, based upon this July 1995 letter sent prior to the parties signing the IIA, which is a fully-integrated contract, (*see* JX-001, § 13 ("Integration")), WashU must have known that the Relative Value Clause meant that WARF would not actually assign a "relative value" to the '815 patent. WARF's argument in this regard is a back-door attempt at inserting parol evidence into the construction of an unambiguous contract term, which is something that Wisconsin law says that the Court is not to do. *See infra* Section III.B.

(a) WARF Employed the "Blended Approach" Instead

325. Dr. Gulbrandsen testified that, when WARF assigned a relative value to the '815 patent in 1998, it was not the practice at WARF to perform patent-specific valuations—WARF instead followed a revenue-sharing model that it calls the "Blended Approach." (D.I. 178 at ¶¶ 81–82 at 26; Tr. at 671:21–673:24 (Dr. Gulbrandsen) ("[T]he license agreements [like the 1998 License] included a large number of patents, and WARF with these types of agreements used the blended approach.").)

326. WARF explained in its briefing that, rather than performing a relative valuation of the patents, WARF "assign[ed] equal value to the Ancillary Patents, [according to] WARF's 'blended' approach[, which] recognizes that the value of a patent may change over the patent's life based on how WARF's licensees decide to use a licensed patent in future years." (D.I. 178 at ¶ 82 at 26 (citations omitted).) Essentially, WARF admits that it included several patents, that were of low value, no value, or were about to expire, in the Ancillary Patents group of the 1998 License, because that was its policy with inventors at the University of Wisconsin. (*Id.*; Tr. at 673:7–10.)

327. Dr. Gulbrandsen testified why WARF adopted the Blended Approach in agreements like the 1998 License:

> It was – it was because the inventors, you know, particularly with [Dr.] DeLuca, he understood that everybody was involved in this [Vitamin D] project. And he wanted them to feel good about being involved in the project and not feel that they were left out when the best royalties were coming in. So it was something that was well-known among his researchers that worked with him and collaborators they worked with, and it's worked very well for WARF.

(Tr. at 673:11–24.) In other words, the Blended Approach is an informal agreement among researchers at the University of Wisconsin to share revenues between investigators working in the same laboratory, even if the inventions associated with some of the investigators are of little to no value to a license with a third party. This is

consistent with the portfolio of "Ancillary Patents" in the 1998 License as described by Dr. Cleare in his unrebutted testimony. *See supra* ¶¶ 276–280.

(b) The Blended Approach Was an Unwritten Policy At WARF

328. Accordingly, there is no documentary evidence of the Blended Approach as a formal WARF policy. As a matter of fact, WARF's Valuation Policy does not mention the Blended Approach and instead defines an automated process for income distribution as well as exceptions to that process. *See infra* ¶¶ 438–443; (*see also* JX-010.) Moreover, WARF's stated Valuation Policy contradicts the Blended Approach—"The Licensing Manager may assign a percentage to each Licensed Patent[77] to reflect the disproportionate value of the Patent Families in the development and commercialization of product(s) under the agreement." (JX-010 at 3 of 4); *see infra* ¶ 440.

(c) Under the Blended Approach, WARF Knew That Some Patents Had No Value to the 1998 License but Was Willfully Blind to This Fact

329. Dr. Gulbrandsen admitted that the Blended Approach included adding low-value (about to expire) and no-value (already expired) patents to a license. (Tr. at 673:7–10.) As for no-value patents that may not have been expired but that had no relation to the licensed product, *e.g.*, *supra* ¶ 279 (identifying eighteen patents for manufacturing Vitamin D compounds wholly unrelated to paricalcitol/Zemplar, which is a 19-nor Vitamin D_3 compound), WARF was willfully blind to the question of value—Dr. Gulbrandsen claimed not to know "what the value are of the patents in the ancillary group [of the 1998 License]" but then explained that it is WARF's "philosophy and []

[77] According to the WARF Valuation Policy, "'Licensed Patents' (or 'Optioned Patents'), as defined in an agreement, refers to those patents and patent applications included in the license in countries in the Licensed Territory." (JX-010 at 2 of 4.) As it relates to the 1998 License, this term would include both the "Licensed Patents" and "Ancillary Patents" groups. (JX-008, appx. A at 11 of 31.)

belief [] that they all provide some value. [Even though w]e don't know what that value is." (Tr. at 690:22–691:15.) Essentially, WARF does not know the value of all the patents it places in licenses, and under the Blended Approach, it does not want to know.[78]

2. In 1998, WARF Concealed Information That WashU Needed in Order to Determine That It Had A Valid Claim

330. In 1998, WARF actively concealed, and refused to share, the very information that WashU needed to determine that it had a valid claim for breach of contract.

331. First, in May 1998, WashU asked to see a copy of the license for paricalcitol. *See supra* ¶ 252. WARF cited "confidentiality provisions" that did not exist in either the 1993 License or the 1996 amendments to that license and refused to share these agreements with WashU. *See supra* ¶¶ 252–255.

332. Second, in the May 1998 correspondence, WashU had asked to see "any license and/or amendment *that has either been executed or has the potential of being executed in the near future*." *See supra* ¶ 252. Two months later, in July 1998, WARF and Abbott signed the 1998 License, which included the '815 patent that was co-owned by WARF and WashU, but WARF did not share the 1998 License with WashU.

333. Absent critical information from the 1998 License, namely that the '815 patent was exclusively licensed, *see supra* ¶¶ 293–309, and that the '815 patent was included in a group of "Ancillary Patents," most of which had *nothing to do* with the FDA-approved indication for paricalcitol/Zemplar, *see supra* ¶¶ 265–280, WashU lacked the ability to determine for itself whether it had a valid claim against WARF for breach of contract. (Tr. at 989:12–22 (Dr. Severson agreeing that "without knowing the identities

[78] For example, as discussed above, WARF offered no testimony to explain why the Ancillary Patents group of the 1998 License included a large number of patents that had nothing to do with paricalcitol/Zemplar. *See supra* ¶¶ 276–280.

of the patents included in the 1998 Abbott license, Washington University couldn't determine or couldn't evaluate whether WARF had assigned a fair relative value to the '815 patent in proportion to the other patents in the portfolio.").)

334. Washington University did not have a copy of the 1998 License in 1998 and did not obtain a copy until civil discovery in the case at bar. (Tr. at 371:11–372:7 (Dr. Brandt); Tr. at 389:6–11 (Mr. Kratochvil).)

3. In 1998, WARF Had Sufficient Information to Determine A Patent-Specific Relative Value of the '815 Patent

335. In the fall of 1998, when WARF assigned a relative value to the '815 patent, *see supra* ¶¶ 310–311, 314–320, WARF had ample information to determine a patent-specific relative value for the '815 patent using industry-standard principles.

(a) Patent Valuation Principles

336. In pharmaceutical licenses, technology-transfer professionals measure a patent's relative value (that is, in comparison with other licensed patents) using several factors that include: (1) whether the patent covers the drug or an approved indication of the drug, (2) whether the patent is valid and would be infringed by the licensed product in the absence of a license, (3) the duration of the remaining patent term at the time of licensing, (4) whether the patent confers exclusivity over the licensed product, and (5) whether the patent has been exclusively or nonexclusively licensed. *See infra* ¶ 437. The Court discusses these principles below.

(b) Whether the Patent Covers the Drug or An Approved Indication of the Drug

337. By July 1998, both WARF and Abbott had concluded that, as a method of use patent, the '815 patent covers an approved indication of paricalcitol/Zemplar. *See supra* ¶ 256 (WARF's Directly Supports Letter); ¶¶ 244–245 (Abbott's conclusion).

(c) Whether the Patent Is Valid and Would Be Infringed by the Licensed Product in the Absence of a License

338. It was apparent to WARF and Abbott that the ’815 patent would be infringed by doctors prescribing paricalcitol/Zemplar according to its approved indication and that Abbott could be liable for induced infringement in the absence of a license. *See supra* ¶¶ 260–262 (discussing the representations that WARF and Abbott made in the *Hospira* litigation).

339. In addition, Abbott certified this precise fact when it listed the ’815 patent in the FDA Orange Book in November 2011. *See infra* ¶¶ 405–412 (discussing the legal significance of the representations Abbott made to the FDA when it listed the ’815 patent in the Orange Book as covering paricalcitol/Zemplar).

(d) The Duration of the Remaining Patent Term at the Time of Licensing

340. At the time of licensing (on July 28, 1998), the ’815 patent had issued (exactly) eighteen months prior, on January 28, 1997, and was slated to expire seventeen years later, on July 13, 2015, with an extension for pediatric exclusivity until January 13, 2016. *See supra* ¶¶ 22, 25.

(e) Whether the Patent Confers Exclusivity Over the Licensed Product

341. When WARF licensed the ’815 patent to Abbott, it was known that the ’815 patent could provide exclusive coverage for eighteen months after the expiration of the ’497 patent, which claimed the compound, paricalcitol/Zemplar, and which expired on June 24, 2014.[79] *Compare supra* ¶ 25, *with supra* ¶ 20 (documenting that the ’925

[79] WARF presented evidence at trial and has argued that the ’815 patent did not confer a single day of exclusivity to paricalcitol/Zemplar. (*E.g.*, D.I. 178 at ¶ 73 at 23.) This argument is based upon hindsight–namely what we know today and not what WARF knew in 1998. (*Id.*) Moreover, whether the ’815 patent actually provided exclusivity is in large part based upon Abbott’s decision to “late list” the ’815 patent in the Orange Book. (*Cf. id.* at ¶ 7 at 3 (characterizing WashU’s argument as “that WARF should have known in 1998 when it set the relative value . . . about Abbott’s late listing of the ’815 patent in . . . .2011”).) WARF’s expert, Mr. Lentz, testified (confusingly) that the late-listed ’815 patent could not give

patent expired on April 6, 2012) *and supra* ¶ 21 (documenting that the '497 patent expired on December 24, 2013 with a six month extension for pediatric exclusivity until June 24, 2014).

(f) Whether the Patent Has Been Exclusively or Nonexclusively Licensed

342. As discussed, above, in the 1998 License, WARF granted Abbott an exclusive license to the '815 patent. *See supra* ¶¶ 293–309.

(g) Conclusion–Valuation

343. As is discussed herein in Section III.E.2(a), the information known to WARF in 1998 was sufficient for WARF to perform a patent-specific valuation of the '815 patent and to determine an appropriate relative value for it in comparison to the other patents licensed to Abbott in the 1998 License.

R. 1999

1. January 1999–Second IDM Calculation

344. On January 21, 1999, WARF prepared a second calculation of its Income Division Memo for the 1998 License to "replace[] the Memo printed on 11/05/98. . . [, because s]everal of the case codes have changed." (JX-012 at JX012.001 (the "Second IDM")). Ms. Kirkpatrick, Dr. Gulbrandsen, and Mr. Leazer signed this Second IDM. (*Id.*)

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rise to the thirty-month stay in the *Hospira* litigation, but he *failed to mention that three other patents listed in the Orange Book that were the subject of Hospira's Paragraph IV certifications already provided the 30-month stay in that litigation. See infra* ¶ 414 & n.92. In 1998, few could have anticipated what Abbott's litigation strategy would be in 2011 and what factors would influence Abbott's decision over whether, and when, to list the '815 patent in the Orange Book. Nonetheless, based upon the evidence in the record, *even in 1998, WARF and Abbott both knew that they could list the '815 patent in the Orange Book at the time*. *See supra* ¶¶ 244–245, 256, 260–262.

345. The Second IDM was similar to the First IDM in that Group 1 consisted of case number P89130US, to which WARF had assigned 70% of license royalties. (JX-012 at JX012.011.)

346. In the Second IDM, WARF reduced Group 2 to 30 reference numbers by combining the two transplant rejection patent applications under a single number, P98272US. (*Compare id.* (listing 29 reference numbers plus P98272US at the end), *with* JX-011 at JX011.011 (listing the same 29 reference numbers plus P97063US and P97064US with a hand annotation bracketing the two under P98272US).) In other documents in the record, U.S. Patent No. 6,071,987, which is a continuation in part of each of the two applications associated with the P97063US and P97064US reference numbers, *see supra* ¶ 278, is associated with P98272US, (*e.g.*, JX-382, appx. C at 13 of 15).

347. In the Second IDM, patents in Group 2, including the '815 patent, were slated to each receive 1.0% of WARF's Zemplar royalties. (*E.g.*, JX-012 at JX012.002.)

348. Despite the recalculated 1% royalty rate for the Group 2 patents, for the life of the 1998 License, WARF allocated royalties to the '815 patent *for the next sixteen years* according to the 0.968% rate from three months earlier. (*E.g.*, Tr. at 548:7–23 (Mr. Thomas).)

349. There is no evidence in the record that, prior to the instant litigation, WARF shared the information in either the First or Second IDM Calculation with WashU.

2. September 3, 1999–Second Check to WashU

350. On September 3, 1999, Ms. Kirkpatrick sent a check for $1603.07 to Ms. Loida at WashU. (JX-022.) Accompanying this check was a short letter mirroring the first letter accompanying the first check, explaining that the payment reflected royalties from "the fourth quarter of 1998 and first quarter of 1999." (*Id.* at JX022.001.) The letter

also identified $11,316.92 in "Royalty Income" and summarized the royalty calculation but did not explain the details. (*Id.*)

S. 2000

1. July 2000–WARF Pays 3.5 Year Maintenance Fee on the '815 Patent

351. There is little information in the record from 2000. However, at some point on or before July 28, 2000, WARF paid the 3.5-year maintenance fee on the '815 patent. *See supra* ¶ 232.

T. 2001

1. WARF's April 2001 Valuation Letter to WashU About Royalty Calculation

352. On April 4, 2001, in response to a specific request by WashU, WARF provided details about how WARF calculated the top line "Revenue" number based upon the relative value WARF had assigned to the '815 patent. (JX-049 at 1; Tr. at 203:15–204:13 (Dr. Cleare).) WARF's Jodie Armstrong sent the April 4, 2001 letter (the "Valuation Letter" or "2001 Valuation Letter") to an account administrator at Washington University, Kay Jinkerson, copying WARF's General Counsel Elizabeth Donley. (JX-049 at 1.)

353. The 2001 Valuation Letter stated as follows:

> Dear Kay:
>
> You had asked for some additional information regarding how [WARF] decides on the percentage of total royalties it pays to [WashU] under the above-referenced Agreement. As you know, we provide an accounting of the calculation of royalties with each check that we send you; however, your question relates more specifically to the percentage of the total royalty dollars received by WARF that is shared with [WashU] under the [IIA].
>
> The License Agreement from which royalties are generated has a portfolio of patents relating to the Vitamin D compound

> that is licensed. The compound patents are allocated seventy percent (70%) of the total royalty income in accordance with WARF's regular practice in licensing and allocating royalties in a suite of patents for its Vitamin D portfolio. In addition, there are thirty[-]one (31) ancillary patents included in the license agreement, including the patent that is the subject of the [1995 IIA]. Each of the patents in the ancillary patent portfolio is allocated an equal share of the remaining thirty percent (30%) of the royalties generated by the License Agreement. It is WARF's policy to allocate evenly among these patents regardless of whether or not the patent is actually currently being used by the Licensee. This is because, in many cases, it is difficult if not impossible for WARF to determine whether or not the patent is being used by the Licensee at this time. However, WARF believes that the patent adds some value to the entire portfolio and that, since the license runs to the last of the patents to expire there should be some blending over the lifetime of the License so that all patents in the License benefit from having been licensed.
>
> Under the terms of the Interinstitutional Agreement, pursuant to Section 3A(i), Washington University is to receive one third of all the net revenues where net revenues are defined as income less a fifteen percent (15%) administrative fee retained by WARF in consideration for administering the licenses. *Therefore, under the terms of the Interinstitutional Agreement [WashU] receives one third of .968 percent of the total royalties generated under the license agreement WARF has with its licensee.*
>
> You also requested information on the total royalties paid to WARF under its license agreement(s) involving Washington University patent. WARF considers this information to be proprietary and confidential information of its licensee(s), however, obviously it is possible to reverse the calculation provided to arrive at that royalty amount paid to WARF.
>
> I hope that this clarifies for you the exact percentage on which Washington University is being paid under the Interinstitutional Agreement. Should you have any further questions, please free to give me a call . . .

(JX-049 at JX049.001–002 (emphasis added).)

354. The 2001 Valuation Letter provided WashU with some basic information about the distribution of Zemplar revenues from the 1998 License, namely that WashU receives 1/3 of 0.968% of the total Zemplar royalties WARF receives. (*Id.*)

355. Dr. Severson, WARF's tech transfer expert, testified that WARF had an obligation to provide Washington University with "honest and accurate information" in this April 4, 2001 letter. (Tr. at 990:16–20 (Dr. Severson).)

356. However, even though the letter enabled WashU to calculate the top line revenues (to WARF) under the 1998 License by "revers[ing] the calculation[,]" WashU had no insight into the reasonableness of the relative value calculation, because WashU did not know which patents were in the portfolio.

2. The 2001 Valuation Letter Was Misleading and Inaccurate

357. For the reasons discussed herein, WARF's 2001 Valuation Letter is full of inaccurate and misleading statements.[80] (JX-049 at 1–2; Tr. at 990:11–1003:16, 1009:2–4 (Dr. Severson); Tr. at 203:2–204:13, 208:13–212:4, 216:19–217:16 (Dr. Cleare); Tr. at 476:5–483:14 (Mr. Surber).)

[80] WARF argues that its "statements in 1995 and 2001 to WashU that it didn't know how its licensee would use a given patent in the future were not misleading[] but were truthful." (D.I. 178 at ¶ 84 at 27 (citing Tr.at 670:13–671:7, 691:16–692:16 (Dr. Gulbrandsen); Tr.at 971:12–14 (Dr. Severson)).) The basis for this, according to WARF, is that "pharmaceutical companies 'value their confidential information' and limit the information shared with universities[.]" (*Id.* (citing Tr. at 780:9–781:15 (Mr. Lentz)).) This is a point that WashU's expert, Dr. Cleare, conceded when he testified that he found four patents, of the thirty in the ancillary group of the 1998 License, that *may* be involved in the manufacture of paricalcitol/Zemplar, qualifying his testimony with the statement that "I'm not privy to how Zemplar is made, but I believe that they – the claims, et cetera, gave me the impression that they were contributory to making 19-nor compounds[.]" (Tr. at 238:8–239:2); *see supra* ¶ 277. Nonetheless, even if it was not possible for someone outside of Abbott to determine whether these specific four patents read on Abbott's manufacture of Zemplar at the time, Dr. Cleare was able to identify numerous other patents that had nothing to do with the manufacture of paricalcitol/Zemplar or its approved use or were duplicative of the '425 patent. *See supra* ¶¶ 272–280. WARF presented no testimony to rebut this aspect of Dr. Cleare's opinion, *id.*, and instead continues to argue that it is *simply not possible to know* which patents read on the licensed application, (D.I. 178 at ¶ 84 at 27.) And yet, there is plenty of evidence that WARF clearly knew, when its representatives wrote to Abbott that the '815 patent provides "additional protection" and "directly supports" paricalcitol/Zemplar, whether the '815 patent read on WARF's licensed use. *See supra* ¶¶ 221, 256–259.

(a) The Portfolio Contained Many Patents That Did Not Relate to Paricalcitol At All

358. WARF stated that "[t]he License Agreement from which royalties are generated has a portfolio of patents relating to the Vitamin D compound that is licensed." (JX-049 at 1.) The 1998 License generated "earned royalties" from the sale of Zemplar based upon rights to the 19-nor Vitamin D_2 analog "paricalcitol." (JX-008 at 11; Tr. at 782:15–20 (Mr. Lentz); Tr. at 324:7–325:12 (Mr. Cleare).) However, many of those patents were unrelated to paricalcitol. *See supra* ¶¶ 277–280.

359. Because the letter did not disclose the identity of the patents in the "portfolio," the information in the letter was insufficient for WashU to evaluate for itself whether WARF had assigned a patent-specific relative value to the '815 patent in proportion to the other patents in the portfolio. (Tr. at 989:12–22 (Dr. Severson).)

(b) The Reference to "Compound Patents" Was Misleading

360. In the 2001 Valuation Letter, WARF stated that "[t]he compound patents are allocated seventy percent (70%) of the total royalty income[.]" (JX-049 at 1.) This statement was misleading for two primary reasons.

(i) Ms. Kirkpatrick's Memorandum Allocated the 70% Of License Revenues to the '497 and '925 Patents

361. First, the reference to "compound patents" was misleading because Ms. Kirkpatrick's memorandum prescribed that "the Licensed Patents, which include *the ['497] compound and the ['925] primary indication*, will receive a value of 70%." (JX-205 at JX205.002 (emphasis added).) Under this interpretation of the IDM documents, there is only *one* licensed *compound patent*, with the other "Licensed Patent," the '925 patent relating to a method of treatment. (Tr. at 991:11–23 (Dr. Severson) (agreeing that "[t]here was only one compound patent in the 70 percent group of the 1998 Abbott License[,]" the '497 patent, and "[t]he other patent in the group was the '925 patent, which was a method of treatment patent[.]").)

362. By including the ’925 patent in the 70% royalty group, WARF had allocated a full 35% relative value to that patent alone. (Tr. at 992:6–993:2 (Dr. Severson); *see also* JX-010 at 3 of 4 (“Under WARF’s process, the original U.S. patent filing of each Patent Family in an agreement, as well as any CIPs, are treated individually and equally, unless unequal percentages are assigned by the Licensing Manager.”).)

363. WARF’s statement about the “compound patents” receiving 70% created the false impression that WARF had a practice of assigning substantial relative value only the compound patents, not method of treatment patents like the ’925 and ’815 patents.[81] (Tr. at 477:9–478:4 (Mr. Surber).) Therefore, in light of Ms. Kirkpatrick’s memorandum, this April 2001 statement about “compound patents” is misleading.

(ii) Under the IDM Calculation, WARF Had Assigned More Than 70% Of Income to the Compound Patents

364. Second, WARF had actually assigned *more than 70%* to the compound patents by listing a member of the compound patent family in the ancillary group and including it in the IDM calculation. As discussed above, there were other compound patents in the same family as the ’497 patent listed in the Ancillary Patents group of the 1998 License, including the ’113 patent, *see supra* ¶ 276, the ’110 patent, *see supra* ¶ 280, as well as U.S. Patent Nos. 5,342,975 (“the ’975 patent”), 5,618,805, 5,561,123,

[81] At trial, WARF attempted to excuse its misrepresentation on the ground that WARF used the internal moniker “compound patents” to refer to the ’497 and ’925 patents. Yet WARF had no trouble explaining internally in its October 16, 1998 valuation memorandum that “the compound *and the primary indication[]* will receive a relative value of 70%.” (JX-012 at 16 (emphasis added).) Notably, the recipient of that internal memorandum, Jodie Armstrong, was the same person who authored the April 4, 2001 letter to Washington University, and WARF’s General Counsel Beth Donley was copied on both documents. (JX-012 at JX012.015; JX-049 at JX049.002.) WARF provided no explanation why it failed to convey this same level of information to Washington University. In any event, as WARF’s tech transfer expert admitted, WARF never told Washington University about its alleged use of the term “compound patents” as an internal moniker to refer to a compound patent and a method of treatment that directly related to the primary indication. (Tr. at 991:15–992:5, 993:15–23 (Dr. Severson).)

5,633,241, 5,710,294, (JX-008, appx. C at 24 of 31 ("19-Nor-Vitamin D Compounds")). This is further complicated by the fact that the '497 patent was listed as both a Licensed Patent and an Ancillary Patent in the 1998 License. *See supra* ¶ 266.

365. Of course, when it came time to calculate the division of income, WARF attached Ms. Kirkpatrick's memorandum but placed the '110 patent (an Ancillary Patent) in Group 1 and assigned all 70% to the case number for the '110 patent.[82] *See supra* ¶ 315. In the IDM calculation, WARF did not include the '110 patent and the other compound patents in that family grouping in Group 2. (JX-011 at JX011.011.) Oddly, WARF did include another compound patent, the '113 patent (P96050US), in Group 2, where it received 0.968% of Zemplar revenues, (*e.g.*, JX-011 at JX011.004), despite the fact that the '113 patent claimed priority to the '110, '497, and '925 patents, (*see* JX-252, cover page (naming the '497, '925, '975, and '110 patents as parents)) and should have been grouped with the '110 patent, (JX-010 at 3 of 4).

366. Therefore, following the IDM calculation, in its accounting system, WARF was assigning 70.968% of all Zemplar royalty revenues to the "compound patents." Therefore, the statement in the 2001 Valuation Letter was misleading, because it failed to represent the actual distribution of license revenues and because it failed to mention that WARF was giving itself additional revenues by double-counting a member of the '497 patent family in the ancillary group.

(c) WARF Had No "Regular Practice" of Allocating 70% Relative Value to Compound Patents

367. In the 2001 Valuation Letter, WARF represented that "[t]he compound patents are allocated seventy percent (70%) of the total royalty income in *accordance*

[82] Although this would be consistent with Ms. Kirkpatrick's memorandum prescribing that "each parent case within a patent family will receive an equal proportionate relative value[]" to define the "compound patents" term in the letter this way would run contrary to her memorandum in the first place, which only attributed revenue to the '497 and '925 patents, and not the other patents listed. (JX-205.)

with WARF's regular practice in licensing and allocating royalties in a suite of patents for its Vitamin D portfolio." (JX-049 at 1 (emphasis added).) There is no evidence in the record that WARF had a "regular practice" of allocating 70% relative value only to "compound patents." (*See, e.g.*, Tr. at 213:18–215:12 (Dr. Cleare); Tr. at 996:17–999:9 (Dr. Severson).) WARF's relative value assignments in other Vitamin D portfolio licenses did not adhere to this 70%/30% split. For example, in connection with Vitamin D portfolio licenses to Tetrionics, Deltanoid, Quatrx, and Buyske, WARF sometimes allocated 60% and sometimes 80% to the Licensed Patents group. (JX-016; JX-017; JX-018; JX-019; JX-020; *see also* Tr. at 214:19–215:12 (Dr. Cleare).) And, in connection with WARF's Multiple Sclerosis IDM, WARF assigned only 42% relative value to the Licensed Patents group. (JX-015 at JX015.014; Tr. at 994:23–995:22 (Dr. Severson).) In that IDM, WARF assigned 29% to a single multiple sclerosis patent in the Ancillary Patents group and allocated 29% to all remaining Ancillary Patents. (JX-015 at JX015.014–015; Tr. at 995:23–996:16 (Dr. Severson).)

368. Therefore, WARF's assertion in the 2001 Valuation Letter, that WARF had merely followed its routine practices when assigning value to the '815 patent, was misleading, because WARF had not followed its routine practices. (Tr. at 478:5–22 (Mr. Surber).)

(d) It Was Not WARF's "Policy" To Allocate Evenly Among Patents Within A Group.

369. Also, in the 2001 Valuation Letter, WARF stated that "[i]t is WARF's policy to allocate evenly among [the Ancillary Patents] regardless of whether or not the patent is actually currently being used by the Licensee." (JX-00 49 at 1.) WARF's tech transfer expert, Dr. Severson, admitted that he had never seen any WARF policy embodying that statement. (Tr. at 994:8–17 (Dr. Severson).)

370. Moreover, WARF's statement did not align with WARF's general practices for allocating value among Ancillary Patents in the Vitamin D portfolio, as evidenced by WARF's preferential treatment of its multiple sclerosis ancillary patent in the Multiple Sclerosis IDM. (JX-015 at 14–15; Tr. at 994:23–996:16 (Dr. Severson).) When asked to reconcile WARF's unequal allocation of relative value to the multiple sclerosis ancillary patent with WARF's assertion that it had a policy (or practice) of assigning equal value to all ancillary patents, Dr. Severson could not do so. (Tr. at 996:17–998:13 (Dr. Severson).) Instead, he admitted that WARF's written policy gave WARF discretion to assign unequal relative value to *any* patent based on its disproportionate "contribution to the development and commercialization" to the licensed drug and that WARF's written policy made no distinction between "Licensed Patents" and "Ancillary Patents." (Tr. at 996:17–998:13 (Dr. Severson); JX-010 at 3.)

371. WARF's assertion misleadingly conveyed that WARF had a regular practice of assigning equal value to all ancillary patents regardless of use, when in fact it did not.[83] (Tr. at 481:11–482:5 (Mr. Surber).)

(e) WARF Was Able to Determine Whether A Licensee Was Using A Patent

372. WARF explained in the 2001 Valuation Letter that its reason for assigning equal value to all Ancillary Patents regardless of their use was that "*it is difficult if not impossible for WARF to determine whether or not the patent is being used* by the Licensee at this time[.]" (JX-049 at JX049.001 (emphasis added).) This statement created the false impression that WARF was unable to determine whether any of the Ancillary Patents, including the '815 patent, supported the development and commercialization of paricalcitol/Zemplar.

[83] WashU learned the truth only through civil discovery when it received WARF's actual valuation policy and learned of WARF's actual valuation practices. (Tr. at 993:15–994:22, 998:22–999:9 (Dr. Severson).)

373. As of April 2001, WARF knew otherwise. For example, WARF had previously determined, but had not told WashU, that the '815 patent "directly support[ed]" Zemplar. *See supra* ¶¶ 256–262. WARF knew that eight of the patents were slated to expire within the first four years of the 1998 License. *See supra* ¶ 279. And WARF knew that one of the patent applications included in the ancillary group (a method of use patent covering transplant rejection) could not be used by Abbott, because WARF had abandoned it some two years prior, in January 1999. (JX-008, appx. C at 13 of 31–20 of 31; Tr. at 1002:19–1003:16 (Dr. Severson).)

374. Moreover, absent access to the 1998 License, WashU was unaware that both WARF and Abbott knew that the '815 patent would give rise to "earned royalties," which were an obligation by Abbott to pay WARF royalties based on Zemplar's sales. (JX-008 at 4.) For example, the 1998 Abbott License provided that Abbott would pay "earned royalties" to WARF "whenever manufacture, use or sale of the Compound or Products, absent this license, would amount to an infringement of any claim of Licensed Patents or Ancillary Patents[.]" (JX-008 at 3.) Abbott agreed to pay a 7% royalty for any *exclusively* licensed patents, and a 5% royalty for any *nonexclusively* licensed patents, subject to an overall 7% royalty cap. (*Id*.) As discovery revealed to Washington University in this lawsuit, Abbott paid 7% earned royalties on the '815 patent because the '815 patent (1) would have been infringed by Zemplar but for a license and (2) Abbott was the exclusive licensee of that patent. (*See, e.g.*, JX-466 at 4.)

(f) Conclusion–WARF's 2001 Valuation Letter Concealed Significant Information from WashU

375. WARF's 2001 Valuation Letter was full of misstatements, half-truths, and misdirection. (*See generally* JX-049 at 1–2; Tr. at 990:11–1003:16, 1009:2–4 (Dr. Severson); Tr. at 203:2–204:13, 208:13–212:4, 216:19–217:16 (Dr. Cleare); Tr. at 476:5–483:14 (Mr. Surber).) As such, in the 2001 Valuation Letter WARF concealed

numerous facts that WARF knew at the time, including: (1) that the '815 patent had been exclusively licensed to Abbott in 1998, *supra* ¶¶ 293–309; (2) that WARF could, and did, know whether the '815 patent read on Zemplar, *supra* ¶¶ 244–245, 256, 260–262; (3) that the "compound patents" included the '925 method of treatment patent, which (like the '815 patent) did not claim the compound paricalcitol/Zemplar, *supra* ¶ 361; (4) that WARF had assigned a 35% relative value to the '925 patent, which was the only other method-of-treatment patent that read on an FDA-approved use for paricalcitol/Zemplar, *supra* ¶ 362; (5) that many of the patents licensed to Abbott and assigned a value equal to the '815 patent were irrelevant to paricalcitol and its FDA-approved use, *supra* ¶¶ 265–280; (6) that many of the cited WARF "policies" were, in fact, not policies at WARF, *supra* ¶¶ 367–371; (7) that under WARF's written policies, the licensing manager had a great deal of discretion in assigning value to individual patents, *see infra* ¶¶ 438–444; and (8) that WARF's actual accounting calculations under the 1998 License differed from the stated relative values, *supra* ¶¶ 364–366.

3. Dr. Deluca's 2001 "Dear Nephrology Professional" Letter

376. In July 2001, Dr. DeLuca drafted a letter at Abbott's request to "put down my reasons why I think Zemplar should be used for treatment of these patients." (Tr. at 159:5–12 (Dr. DeLuca; JX-087.) In his letter, Dr. DeLuca highlighted the health benefits of using Zemplar over Calcijex, and specifically cited Dr. Slatopolsky's research that led to the '815 patent as demonstrating that Zemplar represented "a major improvement" over Calcijex. (Tr. at 159:13–16 (Dr. DeLuca); Tr. at 539:19–541:17 (Mr. Thomas); JX-087 at 1.)

377. Dr. DeLuca pointed out that Zemplar "has the important characteristic of being almost equal to Calcijex in suppressing the parathyroid hormone, while having a much less dangerous profile in terms of raising blood calcium and phosphorous." (JX-087 at 1; Tr. at 160:4–161:11 (Dr. DeLuca).) The '815 patent claims exactly that—a

way to administer Zemplar to suppress PTH while avoiding dangerous levels of blood phosphorous. (JX-004 at 7.) As Dr. DeLuca noted in his letter, "[t]he design of Zemplar was proven very clearly by Dr. Slatopolsky who tested its activity in a model, namely the 5/6 nephrectomized rat. These animal experiments demonstrated a major improvement over Calcijex in terms of being effective with much less danger." (JX-087 at 1.)

4. In 2001, Due to WARF's Concealment, WashU Did Not Have the Information It Needed to Pursue Its Claim

378. The Third Circuit identified several factual questions for the Court to resolve about WashU's knowledge about WARF's performance under the IIA. Specifically, the Third Circuit stated:

> Genuine issues of material fact remain regarding (1) whether WARF concealed information Washington University needed to determine if it had a valid claim; (2) whether that information was necessary to pursue the claim; (3) whether Washington University reasonably relied on WARF's statements and conduct; and (4) whether Washington University had the ability to obtain that information, notwithstanding WARF's alleged concealment.

Washington Univ., 703 F. App'x at 110. Prior to 2012, the 2001 Valuation Letter is the last communication during the statute of limitations period (1998–2004) in which WARF discussed the relative value of the '815 patent in a communication with WashU. The Court addresses these questions specifically with respect to WashU's knowledge of WARF's alleged breach of the Relative Value Clause of the IIA, when WARF assigned a relative value to the '815 patent in 1998.

(a) Whether WARF Concealed Information WashU Needed to Determine If It Had A Valid Claim

379. WashU alleges that WARF breached the IIA when it assigned a relative value of less than 1% to the '815 patent in 1998. (D.I. 1 at ¶ 53.) Herein, the Court defines "relative value" as "the monetary or material worth, in light of all circumstances

relevant to such license, considered in relation to the value of the other patents licensed in the portfolio." *See infra* Section III.B.7(b). WARF admits that it did not assign a patent-specific value to the '815 patent and instead argues that it assigned a value consistent with its practices and policies. (D.I. 178 at ¶ 76 at 24); *see supra* ¶ 324. Therefore, for WashU to know it had a claim, it would need to know that the relative value WARF assigned was not "in relation to the value of the other patents licensed in the portfolio" as well as numerous subsidiary questions. *See supra* ¶¶ 336–343.

380. As discussed above, in the communications between WARF and WashU in 1998 and 2001, WARF concealed critical information from WashU, including information about the '815 patent, the nature of (and patents in) the 1998 License, and WARF's written (and unwritten) valuation methodologies. *See supra* ¶¶ 330–334, 375. WashU did not know that Abbott had an exclusive license to the '815 patent, that both WARF and Abbott had concluded that the '815 patent read on Zemplar's approved indication, or that many of the other patents assigned a 0.968% valuation had nothing to do with Zemplar or its approved use. *See supra* ¶¶ 330–334. In addition, WARF's explanation about its policies made it appear to WashU that it had simply followed a formulaic calculation to determine the relative value when, in fact, WARF had systematically diluted the relative value of the '815 patent by placing it in a group of patents that had nothing to do with Zemplar and its approved use *and* by then assigning equal value to these patents. *See supra* ¶ 375.

(b) Whether That Information Was Necessary to Pursue the Claim

381. Based on WARF's representations and refusal to provide information about the 1998 License, WashU did not know information that was necessary to pursue a claim against WARF for breach of contract. For example, absent access to the 1998 Abbott License, WashU could not evaluate for itself WARF's representation that all

patents in the Abbott portfolio related to paricalcitol.[84] *See supra* ¶ 333. Without Ms. Kirkpatrick's October 1998 memorandum, WashU could not know how WARF was dividing revenues between the Licensed Patents and the Ancillary Patents.[85] *See supra* ¶ 310. And without access to WARF's November 1998 Income Division Memo, WashU had no way of knowing if WARF was actually distributing income according to the manner prescribed by Ms. Kirkpatrick and WARF's policies (which it was not). *See supra* ¶¶ 314–320, 364–366. Finally, based on the 2001 Valuation Letter, which purported to follow all sorts of policies and standard practices, WashU did not know what WARF later admitted—that WARF never performed a patent-specific valuation of the '815 patent. *See supra* ¶¶ 324–329. For the reasons discussed herein, this information was necessary for WashU to pursue a claim for breach of contract. *See infra* ¶¶ 392–394; *see also* Section III.C below.

(c) Whether WashU Reasonably Relied on WARF's Statements and Conduct

382. It is undisputed that, after the 2001 Valuation Letter and until 2012, WashU did not seek additional information about the 1998 License or the other patents licensed therein. (Tr. at 463:20–464:2 (Mr. Surber).) Moreover, WashU's representative, Mr. Surber, testified that, based upon the Valuation Letter, WashU had no reason, from 2001 to 2012, to ask WARF about the valuation of the '815 patent. (Tr. at 463:12–16.) WARF contends that, after WARF stonewalled WashU in the May 1998 communications and the 2001 Valuation Letter, there are all sorts of things that the Court should conclude that WashU did not do, but should have done, in order to

[84] The Court is not persuaded that a simple search of the USPTO database would readily uncover which 30 other patents were in the ancillary group of the 1998 License. This would be essentially looking for a needle in a haystack. Moreover, as is discussed herein, many of the patents in this group had nothing to do with paricalcitol, so WARF's assertion that a USPTO search to uncover Dr. DeLuca's paricalcitol patents would suddenly provide WashU with the identity of these non-paricalcitol patents in the ancillary group is a logical impossibility. *See infra* ¶ 393 & n.89.

[85] Although WARF shared some of this information in the 2001 Valuation Letter, Ms. Kirkpatrick's memorandum is far more detailed and goes into expenses as well. (*Compare* JX-205, *with* JX-049.)

independently investigate WARF's conduct. (*E.g.* D.I. 178 at ¶ 111 at 34–35, ¶ 119 at 36–37.) However, this is not the question identified by the Third Circuit for the Court to address. Rather, the question before the Court is whether WashU reasonably relied on WARF's statements and conduct.

383. The Court concludes that WashU reasonably relied on WARF's statements and conduct in the May 1998 communications and the 2001 Valuation Letter for several reasons. First, under the IIA, the parties agreed to "cooperate" with each other and that WARF would act on behalf of WashU to manage licenses for the "mutual benefit" of the parties. (*See* JX-001 §§ 2(A)(iii), 2(B)(ii); Tr. at 353:19–355:7, 356:15–19, 361:20–362:6, 363:1–18, 363:19–364:13 (Dr. Brandt); Tr. at 391:12–392:12 (Mr. Kratochvil).) Second, WARF was the senior party in a senior party-junior party relationship, and the experts agreed that it was reasonable, if not expected, for the junior party to rely on the senior party in such a situation. *See supra* ¶¶ 175–186; *see also supra* ¶¶ 185–186 (determining that WashU had no obligation to exercise oversight over WARF); ¶ 355 (explaining that WashU had no reason to suspect that WARF was not being honest and forthcoming in its communications). To be sure, the Court concludes from this evidence that WashU had *no duty* to: (1) investigate the Orange Book listing for paricalcitol/Zemplar; (2) do investigatory searches of USPTO databases in an attempt to figure out which patents were included in the ancillary group; or (3) interview Dr. Slatopolsky in an effort to uncover evidence that the relative value of the '815 patent was unreasonable.[86] Third, WARF collected nearly $620,000 in administration fees for the '815 patent—in essence, WashU (and Dr. DeLuca) paid WARF to secure and maintain the '815 patent, to manage the IIA, and to manage the 1998 License for the mutual benefit of the parties, thus it was reasonable for WashU to

[86] (*Contra* D.I. 178 at ¶ 111 at 34–35 (asserting the types of independent investigation WashU should have taken); ¶ 119 at 36–37 (identifying "publicly available" information WARF contends WashU would be able to find had it investigated the public record).)

rely on WARF after paying for the service under the IIA. *See supra* ¶ 166 & n.32. Based upon these facts, the Court concludes that WashU had no reason to disbelieve WARF's representations and, therefore, had no duty to doubt these representations and to pursue an independent investigation of the facts.

(d) Whether WashU Had the Ability to Obtain That Information, Notwithstanding WARF's Alleged Concealment

384. As discussed above, the information that WashU needed to determine that it had a valid claim against WARF for breach of contract included at least: (1) the 1998 License, including the appendices describing the licensed patents,[87] (2) Ms. Kirkpatrick's October 1998 memorandum prescribing income distribution under the IIA, and (3) WARF's November 1998 Income Division Memo showing the calculation of the distribution percentages by patent and by inventor. *See supra* ¶ 381. These are internal WARF documents over which WARF had exclusive control and none of which were publicly available. There is no evidence in the record that WashU had any other way (other than for WARF to produce these documents in discovery in the case at bar) to obtain the information contained in these documents. Therefore, the Court concludes that WashU did not have the ability to obtain the information contained in these documents notwithstanding WARF's concealment of this information.

(e) Other Factors

385. The evidence of WARF's concealment of information from WashU is extensive—it goes beyond simply withholding the 1998 License and November IDM from WashU.

[87] (*See, e.g.*, Tr. at 989:12-22 (Dr. Severson).) ("Question: You agree that without knowing the identities of the patents included in the 1998 Abbott license, Washington University couldn't determine or couldn't evaluate whether WARF had assigned a fair relative value to the '815 Patent in proportion to the other patents in the portfolio, correct? Answer: that's true.").)

386. First, when the parties signed the IIA, WARF did not tell WashU about the 1993 License or the 1996 amendments to that license. *See supra* ¶ 205

387. Second, when the parties signed the IIA, WARF did not tell WashU of the role that Dr. Slatopolsky played in the selection and development of paricalcitol/Zemplar as the replacement for Calcijex. WARF knew this prior to the signing of the IIA and never discussed it with WashU. *See supra* ¶ 206.

388. Third, WARF had secured a method of treatment patent, the ’925 patent, based exclusively on Dr. Slatopolsky’s prior research, and yet WARF did not inform WashU of this, nor did WARF name him as an inventor on the ’925 patent.[88] *See supra* ¶ 207.

389. Fourth, WARF did not tell WashU that the ’815 patent covered Zemplar’s FDA-approved use. *See supra* ¶ 337.

390. Fifth, WARF did not tell WashU that it had exclusively licensed the ’815 patent to Abbott. *See supra* ¶¶ 293–309.

391. In other words, WARF did not tell WashU anything that it knew about the significance of Dr. Slatopolsky’s research to paricalcitol/Zemplar, Abbott’s reliance on his research (e.g., as found in the 19-Nor development reports), or WARF/Dr. DeLuca’s reliance on his research as well. These are facts that were exclusively controlled by WARF and Abbott and which prevented WashU from learning of its claim.

(i) No Publicly-Available Information Would Have Informed WashU of Its Claim in 2001 or

[88] Based upon the record, it is likely that WARF would have named Dr. Slatopolsky as an inventor on the ’925 patent and he would have received licensing revenues under the “blended approach,” had he been a researcher at the University of Wisconsin.

Thereafter, Until Discovery in the Instant Litigation

392. In response, WARF has argued that WashU, nonetheless, filed its Complaint in the case at bar without knowing about "the license agreement or patent numbers[.]" (Tr. at 66:16–20 (WARF's counsel's opening statement.) Of course, at that point in 2013, WashU had obtained two new pieces of information previously unavailable to it at any point prior: (1) that the '815 patent was licensed exclusively to Abbott, and (2) that WARF and Abbott believed that the '815 patent directly covered Zemplar's approved use. Absent this information, WashU had no way of knowing whether the less than 1% value that WARF assigned to the '815 patent in 1998 was reasonable. And while Zemplar's label (or the Orange Book) could have provided WashU with notice of the '497 and '925 patents, knowledge of these two patents would not have informed WashU about the exclusivity of the '815 patent license, WARF's and Abbott's beliefs about whether the '815 patent covered Zemplar's FDA-approved use, or the identity of the thirty other patents in the 1998 License.

393. In addition, WARF argues that WashU "easily could have identified [other Dr. DeLuca patents] related to paricalcitol Vitamin D from searching the patent and trademark office publicly available databases." (Tr. at 67:3–6; *see also* D.I. 178 at ¶119 at 37 (citing JX-049; Tr. at 281:15–285:24 (Dr. Cleare); Tr. at 466:15–20, 483:20–484:11 (Mr. Surber)).) It is unclear what that search would be or which patents it would uncover.[89] As far as the Court is concerned, this is attorney argument that is wholly unsupported by any evidence in the record. As a matter of fact, WARF's expert witnesses claimed that it was unknowable whether the patents in the ancillary group of the 1998 License read on paricalcitol/Zemplar's FDA-approved use or manufacture.

[89] For example, in his testimony on cross examination, which WARF cited as proving its point that "The DeLuca patents on 19-nor Vitamin D Compounds" were publicly available, (D.I. 178 at ¶ 119 at 37), Dr. Cleare explained that WashU could have done a search and "could have found fifty patents and not known which of them were" in the ancillary group of the 1998 License. (Tr. at 285:19–24.)

See supra ¶ 357 n.80. Essentially, WARF wants to have it both ways—it wants it to be unknowable to a WARF licensing manager whether various patents read on a licensed use, but at the same time, WARF wants the same facts to be readily discoverable to a WashU manager based upon a cursory search of USPTO records. The Court concludes that *both of these assertions are incorrect*. First, WARF's policies suggest that licensing managers can determine whether patents read on a licensed use, (JX-010), and the evidence in the record shows that this happens, *see supra* ¶¶ 235–237 (IDM for MS treatment patent), ¶¶ 256–259 (the '815 patent Directly Supports letter). Second, WARF has provided no evidence that a USPTO patent search for Dr. DeLuca and "paricalcitol" would readily identify the 31 patents licensed in the ancillary group. It is the obvious failure of the latter point that supports what the Court now knows—that WARF assigned equal value to numerous patents that had *nothing to do* with paricalcitol and hid this from WashU for as long as possible. No patent search for paricalcitol would uncover any of these unrelated patents; therefore, there was no public way for WashU to identify the thirty other patents in the ancillary group. Thus, WARF's argument is not credible, and no public record was available to assist WashU in determining that it had a valid claim against WARF for breach of the IIA.

(f) Conclusion

394. It is clear to the Court that: (1) WARF concealed information that WashU needed in order to determine that it had a valid claim; (2) the concealed information was necessary for WashU to pursue that claim; (3) according to the IIA and the extrinsic evidence, it was reasonable for WashU to rely on WARF's statements and conduct during the limitations period; and (4) WashU did not have the ability to obtain the information that WARF concealed from it, notwithstanding the concealment.

U. 2004

1. July 2004–WARF Pays the 7.5 Year Maintenance Fee for the ’815 Patent

395. At some point on or before July 28, 2004, WARF paid the 7.5-year maintenance fee on the ’815 patent. *See supra* ¶ 232.

2. October 2004–Abbott Terminates License to 24,24 dihomo compound

396. On October 12, 2004, Abbott terminated the 1993 License to the 24,24 dihomo compound. (JX-389.)

V. 2008

1. July 2008–WARF Pays the 11.5 Year Maintenance Fee for the ’815 Patent

397. On July 1, 2008, WARF paid $3910 for the 11.5-year maintenance fee on the ’815 patent. *See supra* ¶ 232.

2. “Good News” E-Mail

398. In 2008, a relatively new hire at WARF, Mr. Stoveken, undertook a review of all the patents in the 1998 Abbott License to determine whether any patents with a longer patent term than the ’497 patent would have been infringed by Zemplar but for the license agreement. (Tr. at 504:8–21 (Mr. Stoveken); D.I. 163–9, ex. I at 76:25–77:2 (Mr. Stoveken).) The purpose of Mr. Stoveken’s review was to determine whether there were any patents subject to the 1998 Abbott License that “would still have any value” after expiration of the ’497 patent. (Tr. at 503:17–504:7 (Mr. Stoveken).) Mr. Stoveken’s review led him to conclude that the ’815 patent was the only patent in the 1998 Abbott License with a longer patent term than the ’497 patent and that practiced Zemplar. (JX-050; Tr. at 504:22–505:10 (Mr. Stoveken).)

399. On October 14, 2008, Mr. Stoveken wrote an e-mail to WARF’s Director of Licensing, Craig Christenson, explaining his findings and conclusions:

> Hi Craig,
>
> The reason I was looking to catch up with you this afternoon was to go over a claim in one of the patents that was in the Zemplar license to Abbott. The patent was titled Prevention of Hyperphosphatemia with 19 nor Vitamin D Compounds; which based on the title, did not appear to be relevant for make, use, sell, have sold....etc. However, when I read the claims I noted that the lead claim is for use of 19 nor compounds to treat renal osteodystrophy while preventing or minimizing serum phosphorous levels in the blood. This is exactly the application and population Abbott targets and sells Zemplar for with the exception that it is indicated for reducing parathyroid hormone. Elevated levels of parathyroid hormone are the cause of renal osteodystrophy so SHPT = renal osteodystrophy because SHPT is what causes the disease. So, thinking ahead, if there is any question about the applicability of the first claim I tend to think it will most likely be resolved based on an inherency argument. In any case, the reality [is that] Abbott does market [Zemplar] to [sic] for use in patients with renal osteodystrophy.
>
> I'll have Melodie send you a PDF of the patent for you to look over and then schedule a meeting with everyone for late next week. I don't want to get everyone too excited about this until we all have a chance to challenge the thinking around this, but *I sense we have some good news here*. Have a good time in China and we'll talk more when you return.

(JX-050 (emphasis added); *see also* Tr. at 502:21–24 (Mr. Stoveken).)

400. Mr. Stoveken's statement that, at first blush, the '815 patent "did not appear to be relevant for make, use, sell, have sold," reflected the mismatch between the recitation of a renal osteodystrophy (RO) treatment method in the '815 patent claims and the FDA's approved indication of Zemplar for treating secondary hyperparathyroidism (SHPT). (JX-050; Tr. at 506:2–507:2, 508:16–21 (Mr. Stoveken).) However, as Mr. Stoveken considered his knowledge of how Abbott marketed Zemplar, Mr. Stoveken realized that the '815 patent was "exactly the application and population Abbott targets and sells Zemplar for" because "SHPT equals renal osteodystrophy" and

"the reality [is that] Abbott [] market[s Zemplar] . . . for use in patients with renal osteodystrophy." (JX-050; Tr. at 507:3–509:3 (Mr. Stoveken).)

401. Mr. Stoveken emphasized in his email that this was "good news" because it meant that the '815 patent would continue to generate royalties under the 1998 Abbott Agreement after expiration of the '497 patent. (JX-050; Tr. at 509:13–511:12 (Mr. Stoveken).)

402. Mr. Stoveken's observation was inconsistent with the improperly low value that WARF assigned to the '815 patent and with WARF's prior justification for it, namely that "it [was] difficult if not impossible for WARF to determine whether or not the patent [was] being used by [Abbott] at this time." (JX-049 at JX049.001.) At no time did WARF share with WashU the "good news" in Mr. Stoveken's email or WARF's discovery that its initial valuation had been based on a mistake. (Tr. at 511:13–512:1 (Mr. Stoveken); Tr. at 219:20–220:12 (Dr. Cleare).)

3. 2008 Amendment To 1998 License

403. At the time of Mr. Stoveken's "good news" e-mail, WARF and Abbott were anticipating generic challenges to Zemplar over the '925 and '497 patents as well as two other patents owned by Abbott. (Tr. at 699:8-700:23 (Dr. Gulbrandsen)); *see infra* ¶¶ 405–408 (discussing Hatch-Waxman litigation).

404. On November 20, 2008, WARF and Abbott amended the 1998 License "to add a procedure in the event of an infringement action brought under the Hatch-Waxman Act or similar law[.]" (JX-009 at JX009.001 ("First Amendment to License Agreement"); *see also* Tr. at 699:8–701:4 (Dr. Gulbrandsen).) This amendment addressed communications between the parties, processes for which of the parties could sue generic manufacturers for infringement, and how the parties would share legal costs, should the parties choose to have the same counsel represent both. (*Id*. at

JX009.001–002.) The amendment named the '925 and '497 patents as well as two other Zemplar-related patents owned by Abbott. (*Id.* at JX009.001.) The amendment did not name the '815 patent.[90] (*Id*.)

W. 2011

1. Abbott "Late Listed" the '815 Patent in the FDA Orange Book in 2011

405. Under the regulatory scheme established by the Hatch-Waxman Act, a patent listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book," can give rise to additional, automatic exclusivity benefits against generic competition by delaying FDA approval of the generic drug. (Tr. at 897:9–898:14, 902:17–904:1 (Mr. Lentz).)

406. A patent can be listed in the Orange Book if the pharmaceutical company offering a drug represents that the patent claims the drug or a method of using the drug and a claim of patent infringement could reasonably be asserted against an unlicensed generic competitor. (Tr. at 854:11–18 (Mr. Lentz); JX-478.)

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[90] The omission of the '815 patent from this 2008 amendment to the 1998 License was largely by design. Although there is ample evidence that Abbott *could have listed* the '815 patent in the FDA Orange Book at any time after July 1998, *e.g.*, *supra* ¶¶ 337–339, it did not do so until 2011, *infra* ¶ 412. Absent a listing in the Orange Book, there would be no generic litigation over the '815 patent. Thus, when Dr. Gulbrandsen testified at trial that it was "fair to say" that in 2008, "Abbott and WARF were not contemplating litigation over the '815 patent in generic [drug] litigation[,]" (Tr. at 700:24–701:4), he failed to mention that this was *because Abbott had not listed the '815 patent in the Orange Book* at that time.

WARF seeks to convince the Court that Abbott's decision to list, or not to list, the '815 patent in the Orange Book was something wholly outside WARF's knowledge or control. (D.I. 178 at ¶ 65 at 22 ("WARF did not decide which patents to list in the Orange Book."); *see also id.* at ¶ 11 at 5–6.) However, the record shows a long-standing, cooperative business relationship between WARF and Abbott, including the numerous Hatch-Waxman complaints the parties filed jointly in this Court. Thus, while the Court recognizes that Abbott bore the formal requirement of listing patents with the FDA in the Orange Book, the Court finds it difficult to believe that WARF was not privy to, or actively involved in, Abbott's plans with respect to generic litigation, including its plans as to the '815 patent.

Nonetheless, it is largely irrelevant when Abbott listed the '815 patent in the Orange Book. The fact remains that Abbott could have listed the '815 patent when it obtained an exclusive license to it in 1998. WARF was aware of this fact at the time. That Abbott chose (as was its prerogative) to wait until 2011 to do so does not change the Court's analysis.

(a) Paragraph III and Paragraph IV Certifications

407. If an Orange Book listed patent covers the drug in question, the generic manufacturer must submit either a "Paragraph III" certification stating that the generic manufacturer will stay off the market until the listed patent has expired, or a "Paragraph IV" certification stating that the listed patent is invalid or would not be infringed by the generic drug. (Tr. at 897:9–898:14, 902:17–904:1 (Mr. Lentz).)

408. If the generic manufacturer files a Paragraph IV certification, the patent owner may sue that entity for patent infringement within 45 days of notice of the certification. In that event, FDA approval of the ANDA application is automatically stayed for 30 months. (Tr. at 897:9–898:14, 902:17–904:1 (Mr. Lentz).)

(b) Late Listing

409. The Hatch-Waxman framework allows for the "late listing" of patents in the Orange Book. (Tr. at 838:9–18, 915:4–10 (Mr. Lentz).) WARF's patent licensing expert, Mr. Lentz, agreed that those who "late list" a patent in the Orange Book can still obtain the benefit of a 30-month stay with respect to ANDA applications filed *after* the Orange Book listing. (Tr. at 906:10–16.)

410. However, Mr. Lentz explained that the downside of late listing is that "if the patent is late listed and the [generic manufacturer's] ANDA [application] was filed before . . . the patent was listed, then there is no thirty-month stay." (Tr. at 838:19–839:8.)

(c) Abbott Late Listed the '815 Patent in The Orange Book

411. In 2011, Abbott notified WARF that it intended to list the '815 patent in the Orange Book and asked whether WARF would have any objection to that (which WARF did not). (Tr. at 721:20–722:6 (Dr. Gulbrandsen).)

412. On November 30, 2011, Abbott listed the '815 patent in the Orange Book as covering Zemplar IV. (JX-263; *see also* JX-415.)

413. This listing came after Hospira had filed an NDA for paricalcitol with the FDA in 2011 and notified Abbott of the NDA with a Paragraph IV certification on July 27, 2011. (JX-063 at ¶ 12 at 3–¶ 19 at 5.) The July 27 Paragraph IV certification stated that the '497 patent was "invalid, unenforceable, and/or will not be infringed by" Hospira's generic paricalcitol.[91] (*Id.* at ¶ 17 at 5.)

414. Therefore, the '815 patent was late-listed in the *Hospira* litigation and did not give rise to the thirty-month stay. (Tr. at 838:2–839:11 (Mr. Lentz).) However, the other patents identified in that litigation (including the '497 patent) had been listed in the Orange Book and *did* give rise to the thirty-month stay.[92] (*Id.*)

415. WARF did not convey this information to WashU. (Tr. at 722:7–10 (Dr. Gulbrandsen); Tr. at 418:3–8 (Mr. Surber).)

(d) Unknown Impact of '815 Patent on Paragraph III Certifications

416. Mr. Lentz admitted he had no way of knowing how many generic companies filed Paragraph III certifications, effectively agreeing to remain off the market until the expiration of the '815 patent. (Tr. at 898:4–10 (Mr. Lentz).)

X. 2012

1. WARF and Abbott Asserted the '815 Patent in Litigation

417. Starting in 2012, unbeknownst to WashU, WARF and Abbott began filing patent infringement lawsuits in the District of Delaware that prominently featured the '815 patent. (Tr. at 220:13–222:15 (Dr. Cleare); Tr. at 400:8–11, 418:9–22, 433:9–15,

[91] In addition, Hospira had filed Paragraph IV certifications with respect to two Abbott-owned patents as well.

[92] Mr. Lentz's testimony on direct examination is misleading, because he failed to address the three Orange Book listed patents that gave rise to the *Hospira* litigation in the first place. (*See generally* JX-063 (the Complaint in the *Hospira* litigation).)

437:14–21 (Mr. Surber); Tr. at 904:2–6 (Mr. Lentz); JX-058; JX-059; JX-060; JX-063; JX-064; JX-065; JX-066; JX-416.)

418. WARF and Abbott asserted the ’815 patent in at least eight lawsuits in this Court:

- *Abbott Labs. et al. v. Hospira, Inc.*, Case No. 1:12-cv-00234-GMS (D. Del. Feb. 27, 2012).
- *Abbott Labs. et al. v. Agila Specialties Private Ltd.*, Case No. 1:12-cv-00520-GMS (D. Del. Apr. 25, 2012).
- *Abbott Labs. et al. v. Sandoz, Inc.*, Case No. 1:12-cv-00836-GMS (D. Del. June 29, 2012).;
- *AbbVie Inc. et al. v. Banner Pharmacaps Inc.*, Case No. 1:12-cv-01228-GMS (D. Del. Sept. 28, 2012).
- *AbbVie Inc. et al. v. Sun Pharma Indus. Ltd.*, Case No. 1:13-cv-00138-GMS (D. Del. Jan. 24, 2013).
- *AbbVie Inc. et al. v. Dr. Reddy’s Labs. Ltd. et al.*, Case No. 1:13-cv-01012-GMS (D. Del. June 5, 2013).
- *AbbVie Inc. et al. v. Hikma Pharma Co., Ltd. et al*., Case No. 1:13-cv-01557-GMS (D. Del. Sept. 13, 2013).
- *AbbVie et al. v. Aurobindo Pharma Ltd.*, Case No. 1:14-cv-00215-GMS (D. Del. Feb. 19, 2014).

(Tr. at 532:8–13, 547:16–548:6, 607:22–608:1 (Mr. Thomas); JX-058; JX-059; JX-060; JX-063; JX-064; JX-065; JX-066; JX-416.)

419. In three of those cases—the *Banner*, *Sun*, and *Hikma* cases—the ’815 patent was the only patent asserted and thus the only means for WARF and Abbott to maintain Zemplar’s market exclusivity. (Tr. at 294:2–5 (Dr. Cleare); Tr. at 532:8–13,

547:16–548:6 (Mr. Thomas); Tr. at 852:14–17, 854:1–6 (Mr. Lentz); JX-059–60; JX-066.)

2. WARF Continues to Pay WashU

420. Meanwhile, WARF continued to pay WashU as if the ’815 patent were worth no more than the dozens of other Ancillary Patents in the 1998 Abbott License—even though those patents have *never* been asserted to protect Zemplar, the sole revenue generator under that license. (Tr. at 1032:12–22 (Dr. Severson); Tr. at 231:10–239:2 (Dr. Cleare); Tr. at 548:7–550:7, 555:6–556:5; 586:22–587:1, 590:15–591:5, 591:10–24, 592:16–593:1 (Mr. Thomas).)

3. WARF Kept WashU in the Dark About the Assertion of the ’815 Patent in the Generic Litigation

421. WARF did not discuss its decision to file those actions with WashU or otherwise inform WashU before it filed those actions. (Tr. at 220:13–222:15 (Dr. Cleare); Tr. at 400:8–11, 418:9–22, 433:9–15, 437:14–21 (Mr. Surber).)

422. The defective assignment of the ’815 patent, *see infra* ¶¶ 427–436; (*see also* JX-056 at 2), served to keep WashU in the dark about WARF and Abbott’s assertion of the ’815 patent in ANDA litigation against generics, because WashU never received any Paragraph IV certifications or any other notice relating to those actions.[93] (Tr. at 220:13–222:15 (Dr. Cleare); Tr. at 420:1–19 (Mr. Surber).) This was exacerbated by the fact that WARF incorrectly asserted, in the aforementioned complaints filed against generic manufacturers in this Court, that WARF was the sole owner of the ’815 patent in complaints filed in this Court against generic

[93] Would-be generic manufacturers must notify the owners of patents listed in the Orange Book of the manufacturers’ intent to seek FDA approval for a generic form of the corresponding drug. The patent owners may then file suit. (Tr. at 838:19–839:4 (Mr. Lentz).)

manufacturers.[94] (JX-063 at ¶ 8; *see also* JX-058 at ¶ 11; JX-059 at ¶ 9; JX-064 at ¶ 16.) As a result, WashU did not learn about Abbott's listing of the '815 patent in the Orange Book and WARF and Abbott's assertion of the '815 patent in litigation until September 27, 2012, when Hospira served a third-party subpoena on WashU.[95] (JX-363; JX-174; Tr. at 220:13–222:15 (Dr. Cleare); Tr. at 400:8–11, 418:9–22, 433:9–15, 437:14–21 (Mr. Surber).)

423. As a matter of fact, during the Hospira litigation WARF's counsel contacted Dr. Slatopolsky directly without notifying WashU's counsel. WashU's in-house IP counsel, Mr. Surber, testified that when Hospira served WashU with a subpoena in the *Hospira* litigation in September 2012, he began investigating the IIA and the '815 patent. According to Mr. Surber, he talked to Dr. Slatopolsky and learned that Dr. Slatopolsky had already been served with a document subpoena in the *Hospira* litigation, that WARF's counsel in that litigation had contacted Dr. Slatopolsky directly, and that WARF's counsel had responded to the subpoena on Dr. Slatopolsky's behalf—without contacting counsel for his employer, Washington University. (Tr. at 410:7–23; *see also* JX-359 (emphasis added) ("[P]lease find attached the subpoena served on Dr. Slatopolsky, *the response we served on his behalf*, and *a copy of the protocol that Dr. Slatopolsky sent us*.").)

424. Thus, the Court concludes that, in 2012, not only did WARF fail to inform WashU about its assertion of the '815 patent in the generic litigation, but WARF took affirmative action to keep WashU from learning these facts. All these events underscore the lengths to which WARF went to keep WashU in the dark as to the '815 patent's true relative value.

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[94] [redacted]

Y. Other Findings of Fact

1. WARF's Performance on the IIA

425. It is undisputed that WARF communicated with WashU about the '815 patent and its license on numerous occasions, *e.g. supra* ¶ 218; provided WashU with a copy of the '815 patent (albeit nine months after it issued), *supra* ¶ 238; answered WashU's questions, *e.g.*, *supra* ¶¶ 252–255; paid patent maintenance fees, *e.g.*, *supra* ¶ 232; made the annual calculation under the IIA, and paid WashU license revenues on an annual basis for the life of the '815 patent, *e.g.*, *supra* ¶ 350.

2. WashU's Performance on the IIA

426. It is undisputed that WashU performed all its obligations under the IIA. (Tr. at 1003:21–24 (Dr. Severson); JX-448 at 8.)

3. WARF's Assignment of the '815 Patent Was Defective

427. Consistent with WARF's obligations as the senior party to the IIA, WARF recorded the assignment of the '288 patent application with the USPTO. (JX-001, § 2.A.(i), (iii).)

428. On October 30, 1995, Dr. Eduardo Slatopolsky assigned his interest in the '288 patent application to WashU. (JX-193; *see also* JX-088 (sending the assignment to WARF on November 7, 1995).)

429. On November 20, 1995, WARF submitted Dr. Slatopolsky's assignment agreement to the USPTO for recordation under a cover sheet that indicated WARF was the sole assignee. (JX-056 at JX056.002.)

430. On March 31, 1996, the USPTO sent WARF a Notice of Recordation of Assignment Document. In what appears to have been an administrative error by the USPTO, the Notice of Recordation indicated that WARF—not WashU—was the sole assignee of Dr. Slatopolsky's interest in the '815 patent. The notice stated in all caps

that WARF should "review all information contained on this notice" and contact the USPTO "if you should find any errors." (JX-055 at JX055.011.)

431. WARF did not submit any correction in response to the Notice. (JX-055 at JX055.011.)

432. The '815 patent issued on January 28, 1997. *See supra* ¶ 22.

433. Six months later, on September 19, 1997, WARF sent WashU a copy of the issued patent. (JX-044.) There is no evidence in the record that WashU noticed the defective assignment or sought to correct it at the time.[96] (Tr. at 962:18–22 (Dr. Severson).)

434. WashU appears to have first discovered the defective assignment of the '815 patent in February 2010. (JX-181 at 1 (seeking an "[a]nswer as to why W[ash]U is not assignee on patent.").)

435. WashU appears to have asked WARF to correct the assignment at some point in 2012. (JX-194 at JX194.001; *see also* Tr. at 963:3–10 (Dr. Severson testifying that WARF took "prompt steps to correct the error once it became aware of it[.]").)

436. WARF's attorneys filed papers with the USPTO in November 2012 to record the assignment to WashU, (JX-194 at JX194.002), and in January 2013 requesting a Certificate of Correction to the patent, (JX-055).

4. Patent Valuation Practice in Technology Transfer

437. The factors commonly used in the tech transfer industry to measure a patent's relative value as compared to other patents include (1) whether the patent covers the drug or an approved indication of the drug, (2) whether the patent is valid and would be infringed by the licensed product in the absence of a license, (3) the

[96] Breach of the IIA based upon the defective assignment is not at issue in the case at bar.

duration of the remaining patent term at the time of licensing, (4) whether the patent confers exclusivity over the licensed product, and (5) whether the patent has been exclusively or nonexclusively licensed. (Tr. at 183:8–184:21, 204:14–205:17 (Dr. Cleare); Tr. at 887:20–888:1, 890:3–891:19, 895:13–17 (Mr. Lentz); Tr. at 990:16–20, 997:5–9 (Dr. Severson); D.I. 163-9, ex. I at 79:17–21 (Mr. Stoveken); Tr. at 353:23–355:7, 363:1–364:13 (Dr. Brandt); JX-010 at 3; JX-015 at 2.)

5. WARF's Written Valuation Policy

438. WARF maintains a written policy for valuing patents. The record includes a March 2011 internal policy document entitled "Allocation of Licensing Income to Inventors" (the "Valuation Policy"). (JX-010.)

439. WARF's Valuation Policy discusses various default policy provisions and exceptions to those defaults. (*E.g.*, JX-010 at 2 of 4 ("By default, the individual cases within the family will be assigned an equal portion of the Patent Family's share, although the Licensing Manager has the discretion to modify this weighting.").)

440. Of note, WARF's Valuation Policy discusses "weighting each licensed patent or patent family" and states that "[t]he Licensing Manager may assign a percentage to each Licensed Patent to reflect the disproportionate value of the Patent Families in the development and commercialization of product(s) under the agreement." (JX-010 at 3 of 4.)

441. WARF's Valuation Policy does not rely on the same patent groupings found in the 1993 License, namely the "Licensed Patents" and "Ancillary Patents" categories. For example, the Valuation Policy discusses "Licensed Patents" and defines them as all "patents and patent applications included in the license in countries in the Licensed Territory." (JX-010 at 2 of 4.) The 1993 and 1998 Licenses define

"Licensed Patents" as those identified in Appendix B and "Ancillary Patents" as those identified in Appendix C. (*E.g.*, JX-005, appx. A at 12 of 26.)

442. Aside from default allocations between patents within the same family, WARF's Valuation Policy does not identify any required allocations between patents. (JX-010 at 2 of 4.)

443. And aside from a default equal weighting of patents within the same family, WARF's Valuation Policy does not require an equal weighting between any patents within the same family or any other grouping. (JX-010 at 3 of 4.) The only limitation that the Valuation Policy places on the Licensing Manager's discretion is that "[t]he aggregate percentage assigned to the patent groups of an agreement must equal 100%." (*Id.*)

444. There is no evidence that, prior to the litigation at bar, WARF shared its Valuation Policy with WashU. (Tr. at 998:14–17 (Dr. Severson).)

(a) Extrinsic evidence

445. WARF's written valuation policy reflects the kind of patent-specific valuation approach that the university tech transfer industry employs. (*See* JX-010 at 3.) WARF's policy vests its Licensing Managers with discretion to assign unequal value percentages to patents in a licensed portfolio "to reflect the disproportionate value of the Patent Families in the development and commercialization of product(s) under the agreement." (JX-010 at 4; Tr. at 998:4–13 (Dr. Severson).)

446. Mark Stoveken, a WARF Licensing Manager, confirmed that when he analyzes patent claims from a business-licensing perspective, he looks to see whether the patent is "something that a licensee would be interested in taking a license to for enablement of product development and commercialization." (D.I. 163-9, ex. I at 79:17–21 (Mr. Stoveken).) Mr. Stoveken also testified that if WARF were to exercise its

discretion under WARF's written policy to assign unequal percentages to some patents over others in a licensed portfolio, WARF would "do what's best for all parties involved." (D.I. 163-9, ex. I at 87:7–15 (Mr. Stoveken).)

447. Some of WARF's historical valuation practices embody a patent-specific valuation approach—at least when it favored WARF's interests to perform that kind of analysis. (*See* JX-015 at 2, 14–15.) *See supra* ¶ 234.

448. As WARF's tech transfer expert acknowledged, it would have been highly unusual in the university tech transfer industry for a senior party with responsibility for assigning relative values to a portfolio of patents to ignore patent-specific valuation information relevant to those patents. (Tr. at 983:7–14 (Dr. Severson); *see also* Tr. at 184:11–21 (Dr. Cleare).) Specifically, Dr. Severson admitted that "if one party had information about the value of a [patent], that there would be a reasonable expectation that that party would use that information when valuing that patent." (Tr. at 983:7–14 (Dr. Severson).)

449. Dr. Brandt testified that "usually valuation of patents is done in a fair and equitable way relative to the strength of support a given patent is providing to the commercialization of the product," and that she understood WARF would exercise its "authority" to assign relative values within a licensed portfolio consistently with this common practice. (Tr. at 356:15–19 (Dr. Brandt); *see also id.* 352:15–357:10, 363:1–364:18 (Dr. Brandt).)

450. The common industry practice is for the senior party to apply fair and reasonable patent-specific valuation criteria when assigning relative values, and for the senior party to discuss its valuation process honestly and accurately with the junior party. (Tr. at 990:16–20 (Dr. Severson); Tr. at 184:11–21, 204:14–205:17 (Dr. Cleare); Tr. at 887:20–888:1, 891:1–14 (Mr. Lentz).)

451. Dr. Severson admitted that WashU had a reasonable expectation that WARF would use all known information regarding the value of the parties' co-owned '815 patent when exercising its "authority" to assign relative values under the IIA. (Tr. at 184:11–21 (Dr. Cleare); Tr. at 983:7–14, 1000:21–1001:18, 1009:2–4 (Dr. Severson).)

452. Dr. Severson admitted that WARF had a "professional obligation to treat [WashU] fairly," and that this obligation extended to "not adopting a more favorable standard when it serve[d] [WARF's] interests and a less favorable standard when it [could] be used adverse to [WashU's] interests." (Tr. at 1000:21–1001:18, 1009:2–4 (Dr. Severson).)

6. WARF's 1998 Valuation of the '815 Patent Lacked Economic Justification

453. As explained in detail below, there was no economic justification for WARF to have assigned such a low relative value to the '815 patent in October 1998, when WARF first assigned a 0.968% relative value to the parties' '815 patent. (*See generally* Tr. at 527:22–546:15 (Mr. Thomas); JX-012 at 15–16.) Nor was there any economic justification for WARF to have assigned the exact same relative value to each of the other so-called "Ancillary Patents," the vast majority of which did not read on Zemplar or the approved use of Zemplar, as it did for the '815 patent. (*See generally* Tr. at 231:10–239:2 (Dr. Cleare); Tr. at 548:7–550:7 (Mr. Thomas).)

454. WARF knew at the time it performed its relative valuation that the '815 patent was one of the most important patents in the Abbott portfolio, as demonstrated by its repeated statements to Abbott in 1996 and 1998 that the '815 patent provided "additional protection" for and "directly support[ed]" Zemplar. (JX-042 at 1; JX-047 at 2; Tr. at 189:7–21, 198:12–199:1, 215:18–216:18 (Dr. Cleare); Tr. at 528:18- 529:6 (Mr. Thomas).) WARF ignored these conclusions when it categorized the '815 patent as "ancillary," and assigned it less than 1% relative value.

455. WARF also knew at that time that the ’815 patent represented a significant contribution to the development and commercialization of Zemplar. For example, WARF knew that physicians would have had significant concerns about administering a Vitamin D analog to patients having renal osteodystrophy, and particularly to certain patients, based on fears of causing or exacerbating hyperphosphatemia (elevated levels of serum phosphorous levels). (JX-085 at ¶ 47; Tr. at 157:8–158:4 (Dr. DeLuca).) Dr. Slatopolsky’s study that led to the ’815 patent demonstrated for the first time that paricalcitol could suppress PTH (which is elevated in patients with chronic kidney disease) without leading to a dangerous increase in serum phosphorous levels and thus causing or exacerbating hyperphosphatemia. (Tr. at 128:1–15, 137:2–12, 138:7–17 (Dr. Slatopolsky); Tr. at 197:2–10, 227:16–228:21 (Dr. Cleare); JX-188 at 1.)

456. WARF also knew at the time of its initial valuation that Dr. Slatopolsky’s study that led to the ’815 patent was a gating item to the development of Zemplar. (JX-005 at 26.) In 1993, WARF and Abbott entered into the 1993 Abbott License. (*Id*. at 1.) Appendix F to that license specifically referred to research to be performed by Dr. Slatopolsky as the first “Action” item for Abbott to complete under its “Development Plan” for paricalcitol. (*Id*. at 26; Tr. at 186:14–189:1 (Dr. Cleare).) In 1994, WARF received a copy of Abbott’s 1993 Development Plan, in which Abbott referred to Dr. Slatopolsky’s research as demonstrating that paricalcitol was the better candidate for developing into a drug because it both suppressed PTH and did not induce hypercalcemia. (JX-086 at 4.) Dr. Slatopolsky’s studies were again discussed in a March 1998 NDA Medical Review for Zemplar, copies of which were produced from WARF’s files in this litigation, as demonstrating the advantages of paricalcitol over Calcijex. (JX-052 at 6–7; Tr. at 191:3–193:6 (Dr. Cleare).)

457. WARF also knew at the time of its initial valuation that the ’815 patent was exclusively licensed to Abbott under the terms of the 1998 Abbott License, that it

covered Zemplar's approved indication, and thus generated 7% "earned royalties" on Zemplar's sales. (JX-426 at 105:7–17, 106:9–107:4, 109:6–14, 113:23–114:3 (Mr. Stoveken Rule 30(b)(6) testimony); JX-047 at 1; Tr. at 1012:6–1015:17 (Dr. Severson); Tr. at 329:8–330:1, 334:19–335:4 (Dr. Cleare); Tr. at 542:15–544:19 (Mr. Thomas).)

458. The only other patents in the Abbott portfolio licensed under the 1998 Abbott License that shared similar value characteristics to the '815 patent, to which WARF assigned 0.968% value, were WARF's '497 and '925 patents, to which WARF allocated 70% of the value of the portfolio. (Tr. at 1030:8–1033:8 (Dr. Severson); Tr. at 906:17–908:18 (Dr. Lentz); Tr. at 231:10–239:2 (Dr. Cleare); Tr. at 527:22–548:6 (Mr. Thomas); JX-008; JX-002-JX-004, JX-209-JX-256.) WARF knew at the time of its initial valuation that the '815 patent was equally as valuable, if not more valuable, than the '497 and '925 patents. The '497 and '925 patents describe "many" different 19-nor Vitamin D compounds, including paricalcitol, without disclosing any bio data relating to paricalcitol or any other Vitamin D_2 compounds. (Tr. at 150:19–23, 153:8–18 (Dr. DeLuca); Tr. at 879:2–14 (Mr. Lentz).) Nor do the '497 and '925 patents contain any teachings about which of the "many" disclosed and claimed compounds could treat chronic kidney disease patients without causing dangerous increases in serum phosphorous. (Tr. at 163:9–24 (Dr. DeLuca); Tr. at 880:10–19 (Mr. Lentz); Tr. at 227:16–228:21 (Dr. Cleare); JX-085 at ¶¶ 238–246; JX-083 at ¶ 100; JX-002-JX-004.)

459. For example, neither the '497 or '925 patents tested PTH levels and therefore did not directly establish whether any of the claimed compounds actually suppressed parathyroid hormone. (Tr. at 163:9–19 (Dr. DeLuca).) In addition, neither patent tested the effect of any of the claimed compounds on serum phosphorous levels, which was important to establishing whether the claimed compounds could be used to treat secondary hyperparathyroidism without inducing the dangerous side effects of

hyperphosphatemia. (Tr. at 163:20–24 (Dr. DeLuca); Tr. at 227:16–228:21 (Dr. Cleare); Tr. at 880:10–19 (Mr. Lentz); JX-085 at ¶¶ 238–240; JX-083 at ¶ 100; JX-002-JX-004.)

460. By contrast, the ’815 patent disclosed a study in uremic rats showing that paricalcitol suppressed PTH levels while causing only minimal increases in serum phosphorous levels across a wider therapeutic window, which helped show that Zemplar was safe and effective for use in patients with chronic kidney disease. (Tr. at 156:8–158:4 (Dr. DeLuca); Tr. at 197:2–198:11 (Dr. Cleare); JX-085 at ¶ 334; JX-052; JX-082 at ¶¶ 15, 24–27; JX-188.)

461. WARF also knew at the time of its initial valuation that the ’815 patent had a longer patent life than the ’497 and ’925 patents, providing an additional 1.55 years of patent protection over the ’497 patent and an additional 3.24 years of patent protection over the ’925 patent. (D.I. 154-1, ex. 1, Uncontested Fact Nos. 20–21, 25; Tr. at 545:9–15 (Mr. Thomas).)

462. Other than the ’497, ’925, and ’815 patents, the other 29 patents in the 1998 Abbott License, which were solely owned by WARF, had little to no relationship to Zemplar but served only to benefit WARF by over allocating value to WARF’s irrelevant and valueless patents at the expense of the parties’ co-owned ’815 patent. Washington University’s tech transfer expert, Dr. Cleare, reviewed all the Ancillary Patents in the 1998 Abbott License. Bringing to bear his education, training, and experience as a technology transfer expert, a Ph.D. in chemistry, and a named inventor on 10 pharmaceutical compound patents, Dr. Cleare analyzed what value, if any, WARF’s solely-owned Ancillary Patents contributed to the manufacture, use, or sale of Zemplar. (Tr. at 230:24–239:2 (Dr. Cleare).) Dr. Cleare concluded that 18 Ancillary Patents disclosed methods of manufacturing Vitamin D compounds other than the class of 19-nor Vitamin D compounds to which paricalcitol belongs. (Tr. at 232:24–235:12 (Dr. Cleare); JX-209, JX-210, JX-211, JX-212, JX-213, JX-214, JX-215, JX-216, JX-217, JX-

219, JX-220, JX-221, JX-222, JX-223, JX-224, JX-226, JX-227, JX-249.) Because paricalcitol is a 19-nor Vitamin D compound, the methods disclosed in those 18 Ancillary Patents do not disclose processes for manufacturing paricalcitol. (*E.g.*, Tr. at 233:17–234:10 (Dr. Cleare).) Those patents have no relation to Zemplar, provided no support to Zemplar in the marketplace, and generated no earned royalties to WARF. (Tr. at 233:17–234:10 (Dr. Cleare); Tr. at 555:6–556:5 (Mr. Thomas); Tr. at 505:3–20 (Mr. Stoveken); Tr. at 907:17–908:1 (Mr. Lentz); Tr. at 1030:17–24 (Dr. Severson); Tr. at 1108:21–1109:4 (Ms. Mulhern).) In addition, many of those patents had been filed in the 1980s—nearly a decade before Dr. DeLuca synthesized the class of 19-nor Vitamin D analogs claimed in the ’497 and ’925 patents—and therefore expired within 1–3 years of the execution of the 1998 Abbott License. (JX-008 at 14–26 (showing expiration dates of all Ancillary Patents in the 1998 Abbott License); Tr. at 233:14–235:1 (Dr. Cleare); Tr. at 548:24–549:16 (Mr. Thomas).)

463. No WARF witness disputed Dr. Cleare’s analysis that these 18 Ancillary Patents do not relate to making 19-nor Vitamin D compounds like paricalcitol. (Tr. at 907:17–908:1 (Mr. Lentz); Tr. at 1030:17–24 (Dr. Severson); Tr. at 1108:21–1109:4 (Ms. Mulhern).) Yet WARF’s arbitrary and self-dealing relative value assignment allocated 18 times the value to this irrelevant group of WARF-owned patents as to the parties’ co-owned ’815 patent, which directly supported the development and commercialization of Zemplar. (JX-012 at 11.)

464. Dr. Cleare also concluded that 6 Ancillary Patents disclosed methods of using paricalcitol for treating illnesses that had no relationship to Zemplar’s approved use, including: (1) a patent for preventing transplant rejection, (2) a patent for treating symptoms of multiple sclerosis, (3) a patent for treating arthritic disease, (4) a patent for treating psoriasis, (5) a patent application relating to the prevention of transplant rejections, and (6) a patent for the treatment of immune deficiency. (Tr. at 235:13–

237:13 (Dr. Cleare); JX-238; JX-248; JX-253; JX-254; JX-246; JX-251.) Unlike the '815 patent, which WARF knew "directly support[ed]" Zemplar and generated 7% earned royalties for WARF, this group of 6 Ancillary Patents did not cover any approved use of Zemplar, provided no support to its development and commercialization, and generated no earned royalties to WARF. (Tr. at 235:13–236:2 (Dr. Cleare); Tr. at 1108:21–1109:4 (Ms. Mulhern).) One of the "patents" in this group was actually a patent application relating to preventing transplant rejections that WARF had abandoned in January 1999. (Tr. at 480:13–481:10 (Mr. Surber); Tr. at 1002:17–1003:16 (Dr. Severson); JX-246.)

465. No WARF witness disputed Dr. Cleare's analysis that these 6 Ancillary Patents had no relationship to Zemplar. (Tr. at 908:2–18 (Mr. Lentz); Tr. at 1031:1–12 (Dr. Severson); Tr. at 1108:21–1109:4 (Ms. Mulhern); Tr. at 162:11–163:6 (Dr. DeLuca).) Mr. Stoveken, who analyzed each patent in the Abbott portfolio in 2007 and 2008 with an eye to determining which ones supported Zemplar, admitted that the 6 Ancillary Patents in this group did relate to Zemplar. (D.I. 163–9, ex. I at 51:22–66:19 (Mr. Stoveken).) Although WARF's technical expert, Mr. Lentz, testified that he believed assigning zero value to these patents would be "a bit harsh" because Abbott might have wanted to use them at some unspecified point in the future, Mr. Lentz admitted that Abbott never received FDA-approval for the indications recited in these 6 Ancillary Patents. (Tr. at 908:15–18 (Mr. Lentz).) Further, as the evidence at trial showed, WARF created *separate* relative value allocations to apply to anticipated new indications, such as when WARF assigned 29% relative value to its multiple sclerosis treatment patent to be used "exclusively for royalty payments deriving from the multiple sclerosis field." (Tr. at 994:23–996:16 (Dr. Severson); JX-015 at 2, 14–15.) By contrast, as applied to Zemplar royalties, WARF allocated 6 times the relative value to these WARF-owned treatment method patents that did not relate to Zemplar as it did to the co-owned '815 patent.

466. Dr. Cleare also concluded that one of the WARF-owned Ancillary Patents was entirely duplicative of the ’497 patent and served no purpose other than to further inflate the value WARF allocated to its own patents at the expense of the parties’ co-owned ’815 patent. (Tr. at 237:14–238:7 (Dr. Cleare); JX-252; JX-377.) No WARF witness disputed Dr. Cleare’s analysis on this point either. (Tr. at 1033:5–8 (Dr. Severson).)

467. Dr. Cleare also concluded that only 4 Ancillary Patents *potentially* related to processes and/or intermediates for the manufacture of 19-nor Vitamin D compounds like paricalcitol. (Tr. at 238:8–239:2 (Dr. Cleare); JX-225; JX-232; JX-229; JX-230.) But, as Dr. DeLuca explained, none of those 4 Ancillary Patents would have been able to block generic competition for Zemplar because of the possibility that a competitor could design around those patents by taking advantage of multiple different chemical pathways to synthesize Zemplar. (D.I. 163–2, ex. B at 117:12–22 (Dr. DeLuca).) WARF offered no evidence at trial to show that Abbott (or anyone else) manufactured Zemplar using any methods disclosed or claimed in these 4 Ancillary Patents. (Tr. at 829:18–830:4 (Mr. Lentz); Tr. at 1033:5–8 (Dr. Severson); Tr. at 1108:21–1109:4 (Ms. Mulhern).) Abbott paid no “earned royalties” on these patents. (Tr. at 505:3–20 (Mr. Stoveken); Tr. at 1108:21–1109:4 (Ms. Mulhern).) Further, these 4 Ancillary Patents could not have been listed in the Orange Book, which does not permit listing of process, manufacturing, and intermediate patents. (Tr. at 290:8–20 (Dr. Cleare).) As a result, there is no evidence that these 4 Ancillary Patents supported the development or commercialization of Zemplar, generated earned royalties, or provided exclusivity over Zemplar. Yet WARF’s arbitrary and self-dealing relative value assignment allocated 4 times the value to this group of WARF-owned patents as to the parties’ co-owned ’815 patent.

468. Dr. Cleare's analysis that 29 Ancillary Patents had no substantial value with respect to the manufacture, use, or sale of Zemplar stands unrebutted. WARF's licensing manager, Mr. Stoveken, testified that he reviewed each Ancillary Patent in 2008 to determine whether any patents that had a longer patent term that the '497 patent would be infringed by Zemplar but for a license and therefore would generate earned royalties for WARF. (Tr. at 505:3–20 (Mr. Stoveken).) Mr. Stoveken concluded that only the '815 patent met those criteria. (Tr. at 505:3–20 (Mr. Stoveken).) Dr. Severson admitted that no Ancillary Patent, other than the '815 patent, blocked generic competition for Zemplar, was listed in the Orange Book, was asserted in litigation, generated earned royalties, was licensed exclusively to Abbott, or added any substantial value to Zemplar at all. (Tr. at 1032:6–1033:8 (Dr. Severson).)

469. As a result of WARF's assignment of an equal value to all ancillary patents, WARF improperly favored its own affiliated university and its own inventors at the expense of Washington University and Dr. Slatopolsky. Not surprisingly, WARF believed that its relative valuation approach and its refusal to "rebalance" its allocations "worked beautifully" for WARF. (Tr. at 711:9–16 (Mr. Gulbrandsen).) WARF appropriated *$426.5 million* in earned royalties from Abbott for itself, while remitting *a little over $1 million* to Washington University. (JX-476A at 1.)[97]

III. CONCLUSIONS OF LAW

A. Undisputed Conclusions of Law

The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(1). (D.I. 178 at ¶ 1 at 48.)

[97] Specifically, WARF received $427.6 million in "earned royalties" from Abbott based solely on the '497, '925, and '815 patents. (JX-476A at 1.) WARF allocated 0.968%—or only $4.1 million—to the '815 patent. (*Id*.) WARF then paid itself nearly $620,000 in administration fees in "consideration for securing and administering" the 1998 Abbott License on Washington University's behalf. WARF took $2.3 million as WARF's two-thirds share in recognition of Dr. DeLuca's contributions as the compound owner, deducted over $117,000 in patent expenses, and remitted only $1,053,426 to Washington University. (*See* JX476A at 1–2.)

The Court has personal jurisdiction over the parties for the purpose of adjudicating the present dispute, and venue is proper for this action under 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b). (*Id.* at ¶ 2 at 48.)

B. Construction of Relevant Terms

At summary judgment, WashU moved for, *inter alia*, "partial summary judgment on threshold questions of law concerning the interpretation of" the IIA. (D.I. 99 at 1.) Specifically, WashU sought an Order that "the Relative Value Clause of the parties' 1995 Inter-Institutional Agreement requires WARF to assign a fair value to the '815 Patent in light of all relevant circumstances, to do so relative to the value of the other patents licensed with it, and to do so fairly[.]" (*Id.* at 2 (emphasis omitted).) Although the subject was fully briefed, (D.I. 100 at 6–16; D.I. 113 at 6–14; D.I. 120 at 1–5), and this Court granted-in-part WashU's motion on other grounds,[98] it did not interpret the "Relative Value Clause" of the IIA, (D.I. 130).

In their post-trial briefing related to terms in the Relative Value Clause, the parties have taken positions similar to those they argued previously. For instance, at summary judgment, WashU argued that "value" should mean "a fair value in light of all relevant circumstances." (D.I. 100 at 7 (emphasis omitted).) And in its Proposed Findings of Fact and Conclusions of Law, WashU contends that "the Relative Value Clause of the IIA required WARF to assign a fair value to the '815 patent in light of all the circumstances." (D.I. 175 at ¶ 205 at 94 (citing JX-001, § 3.A.(iii), D.I. 175 at ¶ 44 at 21 n.4).) Similarly, at summary judgment, WARF had argued that "'authority to assign relative values' should be construed as 'the power to determine and assign a nonarbitrary value to the '815 patent relative to the other licensed patents in accordance with WARF's policies.'" (D.I. 113 at 8 (emphasis omitted).) Although WARF had made

[98] Specifically, this Court granted-in-part WashU's motion that "the implied covenant of good faith and fair dealing applies to the parties' 1995 Inter-Institutional Agreement[.]" (D.I. 99-1 at 2 (proposed Order); *see also* D.I. 130 at 21; D.I. 131.)

abundantly clear at the time that it had accepted WashU's dictionary definitions as plain meaning solely for the purposes of summary judgment, (*id.*), this same construction is, nonetheless, reflected in WARF's argument on breach of contract. For example, WARF avers that it did not breach the IIA, because "WashU granted WARF the authority to set the relative value, and WARF did so based on long-standing practices—which by definition are not arbitrary[.]" (D.I. 178 at ¶ 63 at 68.)

Thus, tasked with determining whether WARF breached the express and/or implied terms of the IIA, the Court concludes that there remain terms in the Relative Value Clause and elsewhere in the IIA that require construction. The Court discusses these terms below. Wisconsin law applies to the construction of these terms as well as the claims and defenses at bar. (JX-001, § 12 ("This Agreement shall be governed by and interpreted—and its performance enforced—in accordance with Wisconsin law[.]").)

1. Legal Standard

"When interpreting an agreement, the court's objective is to ascertain the true intentions of the parties as expressed by the contractual language." *First Bank & Trust v. Firstar Info. Servs. Corp.*, 276 F.3d 317, 322 (7th Cir. 2001) (applying Wisconsin law) (quotations and citations omitted). "If the contract is unambiguous, [the court's] attempt to determine the parties' intent ends with the four corners of the contract, without consideration of extrinsic evidence." *Town Bank v. City Real Estate Dev., LLC*, 793 N.W.2d 476, 484 (Wis. 2010) (citation omitted). The court construes the contract language according to its plain or ordinary meaning. *Id.* In addition, the Court "must reject a construction that renders an unfair or unreasonable result" and "should adopt a construction that will render the contract a rational business instrument so far as reasonably practicable." *Gottsacker v. Monnier*, 697 N.W.2d 436, 442 (Wis. 2005) (citation omitted).

"[W]hen a contract is ambiguous and consequently is properly construed by use of extrinsic evidence, the contract's interpretation presents a question of fact for the [trier of fact]." *Town Bank*, 793 N.W.2d at 484 (citation omitted). Under Wisconsin law, extrinsic evidence of "custom and usage is permissible 'to define what is ambiguous or is left undetermined in a contract, where both parties have knowledge of the custom or are so situated that such knowledge may be presumed.'" *Dieck v. Oconto Co.*, 180 N.W. 932, 935 (Wis. 1921) (citation omitted); *Fid. Nat'l Title Ins. Co. v. Intercounty Nat'l Title Ins. Co.*, No. 00 C 5658, 2001 U.S. Dist. LEXIS 9626, at *8 (N.D. Ill. July 9, 2001) ("[E]xperts are allowed to testify about the customs and standards of an industry when that testimony is used to explain the terms of ambiguous contracts or to supplement the terms of a contract.").

2. Ambiguous Terms

Before the Court construes terms in the IIA, the Court notes that there is some confusion about the parties' positions on whether or not specific terms of the IIA are ambiguous. At summary judgment, when it sought construction of specific terms of the Relative Value Clause, WashU asserted that those terms are not ambiguous. (D.I. 100 at 8 n.3 ("Here, the IIA is not ambiguous for the reasons stated below.").) WashU's constructions at the time relied largely on the intrinsic evidence and remained within the four corners of the IIA. (*Id.* at 8–13.) Meanwhile, WashU argued in the alternative that "[a]lthough unnecessary to construe the Relative Value Clause, if the Court were to look beyond the four corners of the IIA and the doctrine of *contra proferentem* to interpret the Relative Value Clause," the "undisputed extrinsic evidence" also supports WashU's construction. (D.I. 100 at 14–15.)

WARF presently overstates WashU's summary judgment position on the Relative Value Clause as applying to the entire IIA. (D.I. 178 at ¶ 48 at 64 n.18 (citing D.I. 105 at

12 n.3)[99] ("WashU has previously argued . . . that the terms of the 1995 IIA are unambiguous.").) Meanwhile, WARF's position on ambiguity is, itself, ambiguous. For example, WARF appears to agree with WashU but has left it for the Court to infer. (*See* D.I. 178 at ¶ 3 at 1 ("The parties agree that the terms of the IIA are clear and unambiguous."); *id.* at ¶ 48 at 64 (citation and internal quotation marks omitted) ("[T]he interpretation of an unambiguous contract presents a question of law.").) Nonetheless, beyond the summary judgment arguments on specific terms of the Relative Value Clause, there is no evidence in the record that either party has taken the position that the entire IIA is unambiguous.[100] Therefore, unless the parties highlight specific ambiguities in terms of the IIA, the Court will approach terms of the IIA as if those terms are unambiguous. In cases where the Court determines that terms are ambiguous, the Court will identify those terms along with any extrinsic evidence it has considered in construing those terms.

3. "Patent Rights," "Property Rights," and "The '815 Patent"

The IIA defines two terms related to the property rights at the core of the dispute between the parties. "Patent Rights" is a defined term that means "all United States and foreign patent applications and patents issued therefrom that both: (i) claim the Invention or any part thereof; and (ii) name as inventors at least one WARF Inventor and at least one [WashU] Inventor." (JX-001, § 1.B.) And "'Property Rights' means all WARF's and [WashU's] proprietary rights in biological or other materials useful in the practice of the inventions of Patent Rights. In no case, however, will Property Rights include Patent Rights." (*Id.* at § 1.C.)

[99] D.I. 105 is WashU's redacted opening brief on WashU's motion for partial summary judgment. (D.I. 99.) The citation is unclear—footnote 3 appears on page 8 of the brief, which is CM/ECF page 12 of 25 in the document.

[100] In their respective Proposed Findings of Fact, each party has relied heavily on extrinsic evidence to interpret terms of the IIA. (*E.g.*, D.I. 175 at ¶ 27 at 15–¶ 50 at 24–25 (interspersing extrinsic evidence with the plain language of the IIA in describing terms of the contract); D.I. 178 at ¶ 21 at 8–¶ 30 at 11–12 (using extrinsic evidence to explain various IIA terms).)

The parties agree that the "Patent Rights" are associated with the '815 patent. (D.I. 154-1, ex. 1 at ¶¶ 22–27.) And the invention that led to the "Patent Rights" and "Property Rights" is "WARF Case No. P95011[.]" (JX-001, § 1.A.) WARF, in its own materials and in its communications with licensees, employs Case No. P95011 to encompass a group of rights that includes the '815 patent, various foreign patents, and other related proprietary rights. (JX-047, Appx. A at JX047.003; JX-049; JX-205 at JX205.002.) In essence, WARF uses "P95011" to refer to the "Patent Rights" and/or "Property Rights" described in the IIA.

Meanwhile, in the briefing, the parties use the term "the '815 patent"[101] interchangeably to refer to: (1) U.S. Patent No. 5,597,815, and (2) the "Patent Rights" and/or "Property Rights" as defined in the IIA and associated with WARF Case No. P95011. (*Compare* D.I. 175 at ¶ 6 at 8 (identifying U.S. Patent No. 5,597,815 as "the '815 patent"), *with id.* at ¶ 44 at 21 n.4 (summarizing the Relative Value Clause and replacing "Patent Rights and/or Property Rights" with "[the '815 patent]" in a quotation).) In the case at bar, the Court refers to both the individual patent and the bundle of rights under the IIA as "the '815 patent."

4. "Sharing Income" Recital

The preamble to the 1995 Inter-Institutional Agreement for Prevention of Hyperphosphatemia in Kidney Disorder Patients recites the following:

> This Inter-Institutional Agreement ("Agreement"), is effective as of the first day of November, 1995, between the Wisconsin Alumni Research Foundation (hereinafter "WARF"), . . . and Washington University (hereinafter "INSTITUTION"), ...
>
> Whereas, the Invention (defined below) was made by Professor Hector F. DeLuca of the University of Wisconsin-Madison ("UW"), and Dr. Eduardo Slatopolsky of

[101] Similarly, the parties discuss "the '497 patent" and "the '925 patent" in reference to the group of domestic and foreign patent (and other) rights associated with those specific U.S. patents.

> INSTITUTION (collectively referred to as "Inventors"), is claimed in and;
>
> Whereas, the Patent Rights and/or Property Rights will be owned jointly by WARF and INSTITUTION;
>
> Whereas, WARF and INSTITUTION wish to enter into this Agreement to establish a means for filing and prosecuting the Patent Rights, for administering and licensing the Patent Rights and/or Property Rights, and *for sharing income* derived from licensing of the Patent and/or Property Rights;

(JX-001 JX001.001 (emphasis added).) This portion of the IIA plainly states, as a background to the agreement, that the objective for the contract is to secure what was to become the '815 patent (and related foreign patent rights), to license the '815 patent, to administer that license, and to "shar[e] income" between the parties from the license. (*Id*.)

5. Cooperation Clause

Section 2.A. of the IIA, which describes "patent prosecution and protection[,]" includes the Cooperation Clause. (JX-001, § 2.A.) To this end, the IIA states:

> (i) [WashU] grants to WARF the exclusive right to prepare, file, prosecute, and maintain Patent Rights and related Property Rights, and WARF shall have sole discretion to make decisions with respect thereto.
>
> (ii) During the term of this Agreement, neither party will assign its undivided interest in the Patent Rights or Property Rights without the consent of the other party.
>
> (iii) WARF and [WashU] will use all reasonable efforts to *cooperate with each other* with respect to patent application preparation, filing, prosecution, maintenance, licensing, and execution of assignments of Patent Rights contemplated under this Agreement.

(Id., § 2.A. (emphasis added)) Section 2.A.(iii), the "Cooperation Clause," is a bit of a hybrid, because it includes reference to both: (a) "Patent Prosecution and Protection" in the form of "patent application preparation, filing, prosecution, [and] maintenance[,]"

which are discussed in Section 2.A., and (b) "Licensing[,]" which is identified in Section 2.B., as "licensing, and execution of assignments of Patent Rights[.]" The Cooperation Clause bridges these two sections and requires the parties to "use all reasonable efforts to cooperate with each other" in both of these activities. (*Id.* at § 2.A.(iii).) Although the Cooperation Clause is found in the "Patent Prosecution and Protection" section, the inclusion of language related to "licensing" leaves little doubt that the parties expected the Cooperation Clause to apply to licensing activities as well.

The licensing activities are in question in the case at bar. (*Id*.) In addition, it is foreseeable that WashU may need to make Dr. Slatopolsky available to support WARF's licensing activities, were his participation necessary.[102] (*Id.*)

As to WARF's duties to cooperate with respect to licensing under the Cooperation Clause, clearly the parties intended for WARF to have *some kind* of duty, but the IIA is ambiguous about what those duties to "cooperate with" WashU specifically are. (*Id.*) For example, WashU granted to WARF "the sole discretion to make decisions with respect" to filing, prosecuting, and maintaining the '815 patent, (JX-001, § 2.A.(i)), the latter of which includes decisions to: (a) pay an issue fee, 35 U.S.C. § 41(a)(4)(A), and (b) pay ongoing maintenance fees at 3.5, 7.5, and 11.5 years, *id.*(b)(1)(A)–(C);[103] s*ee supra* ¶ 232. At the same time, the IIA gives WashU the ability to opt-into foreign patent prosecution and to, therefore, participate in foreign license revenues. (JX-001, § 3.B.(ii) ("Foreign Rights").) Clearly the parties could not have intended, as WARF vigorously contends,[104] that WashU should make those decisions in the blind, absent

[102] *E.g.*, *supra* ¶ 243.

[103] As a patent gets older, the maintenance fees become more expensive. For example, the current U.S. fees are $1,600 at 3.5 years, $3,600 at 7.5 years, and $7,400 at 11.5 years. 37 C.F.R. §§ 1.20(e)–(g).

[104] The Court rejects WARF's contention that there is *no duty* for the senior party to communicate any information about licensing, because the only express provision in the IIA is that "WARF agrees that it will supply to [WashU] a copy of all issued patents within the scope of this Agreement naming Dr. Eduardo Slatopolsky as co-inventor." (JX-001 § 2.A.(v) (*cited by WARF alongside extrinsic evidence in* D.I. 178 at ¶ 22 at 9).) As a matter of contract interpretation, WARF essentially argues that the Cooperation Clause (§ 2.A.(iii)), which is a term WARF drafted, is ambiguous. (D.I. 178 at ¶ 22 at 9.)

any information about the ’815 patent, its value, the potential for future licenses, or the nature of any existing licenses.

Turning to extrinsic evidence, the Court finds that the Cooperation Clause imposes on WARF, as the senior party, a duty to communicate, in a timely manner, all material information concerning the “Patent Rights” and/or “Property Rights” that is available to WARF and that is relevant to the licensing thereof. *See supra* at ¶¶ 189–193. This duty is consistent with the senior party–junior party relationship between the parties, whereby WARF received the majority of the “Net Revenues,” and collected a 15% Administration Fee on “Income” (gross license revenues). *See supra* at ¶ 175; (JX-001, §§ 1.G., 1.H., 2.B.(iv).)

6. Mutual Benefit Clause

The IIA contains the requirement that “WARF will seek a Licensee(s) for the commercial development of Patent Rights and/or Property Rights and will administer all License Agreement(s) *for the mutual benefit* of the parties of this Agreement.” (JX-001, § 2.B.(ii) (emphasis added).) This language requires that WARF’s administration of license agreements be of mutual benefit to both WARF and WashU. However, on its face, this term does not require the amount of benefit to be equal between the parties (e.g., that any decision that WARF makes benefits WARF 50% and WashU 50%). Moreover, the Mutual Benefit Clause does not appear to prohibit grossly inequal benefit

Therefore, WARF contends that the Court should interpret this clause “(iii)” according to extrinsic evidence related to a different and wholly unambiguous clause (clause “(v)”). (*Id*.) In so doing, WARF asks the Court to draw the inference that, because the extrinsic evidence shows that WashU’s Dr. Brandt did not negotiate for any other specific information disclosures by WARF, the IIA, therefore, requires no other disclosures of any kind. (*Id*.) In essence, WARF asks the Court to construe the IIA—a contract drafted by WARF—to give WARF free rein to keep WashU in the dark about just about every aspect of the ’815 patent and its licensing. This is a construction that the tenets of contract interpretation, including the doctrine of *contra proferentem*, cannot support. As is discussed herein, in addition to disclosures inherent to the reporting requirements of Section 5 of the IIA, (JX-001 § 5.A.–B.), extrinsic evidence shows that the Cooperation Clause requires WARF to share numerous types of information with WashU that are not specifically identified in the IIA.

(e.g. that WARF benefits 90% and WashU benefits 10% from a given decision by WARF).

WashU argues that the Mutual Benefit Clause "expressly prohibit[s] WARF from engaging in self-dealing by administering any licensing agreements in a manner that enriche[s] WARF at the expense of [WashU.]" (D.I. 175 at ¶ 44 at 21 n.4.) Specifically, WashU contends that it would not be to the parties mutual benefit if WARF assigned *more* than a "fair value to WARF's wholly-owned patents at the expense of the . . . '815 patent." (*Id.*) According to WashU, there is a point where an unreasonable valuation to a WARF patent would benefit WARF at WashU's expense.

WARF's only argument about the Mutual Benefit Clause is that "what matters here is that WashU granted WARF the authority to set the relative value, and WARF did so based on long-standing practices—which by definition are not arbitrary—and, moreover, WARF views these standard practices as fair." (D.I. 178 at ¶ 63 at 68 (citing *id.* at ¶ 70 at 70–¶ 79 at 73).) In effect, WARF avers that the Mutual Benefit Clause does not place *any additional* obligations on WARF under the IIA. (*Id.*)

Based upon the plain language of the Mutual Benefit Clause, the Court agrees with WashU that a portion[105] of the Mutual Benefit Clause may be described as negative limitation on WARF's behavior under the IIA—namely that WARF cannot administer a license agreement in a way that unreasonably benefits one party but not the other.

7. Relative Value Clause

As presented, above, the Relative Value Clause states as follows:

> (iii) In licensing Patent Rights and/or Property Rights, WARF may include rights under other patents and/or other proprietary rights to which WARF owns a part of or all right title and interest, or include in other licenses certain Patent Rights or Property Rights, which licenses may be directed

[105] Neither party discussed an obvious inclusion to the Mutual Benefit Clause, a scenario in which WARF administers a patent license in a way that does not benefit either party—a situation that would violate the Mutual Benefit Clause. (JX-001, § 2.B.(ii).)

> primarily to other invention subject matter or technology than that contemplated in this Agreement. *In such event WARF shall have the authority to assign relative values to Patent Rights and/or Property Rights*, and other patent and/or other proprietary rights as are included in any such license and the portion of the gross receipts from royalties and other fees received by WARF under any such license, which shall be Income hereunder to be divided with [WashU] as provided in Section 3A(i), shall be determined in accordance with such relative values assigned to Patent Rights and/or Property Rights *in proportion to the total value represented by all patent rights* and/or proprietary rights which are included within such license.

(JX-001, § 3.A. (emphasis added).) WashU moved for partial summary judgment as to the construction of the Relative Value Clause, (D.I. 99), and argued for the constructions discussed herein, (*compare* D.I. 100 at 6–16, *with* D.I. 175 at ¶ 44 at 21 n.4.). WARF opposed the motion. (D.I. 113.) This Court issued a Memorandum Opinion on summary judgment and found WashU's claims to be time barred—as such, this Court did not resolve WashU's motion. (D.I. 130; D.I. 131.)

(a) "Authority"

The Relative Value Clause identifies two situations where WARF may include other patent rights in a license that includes the '815 patent. These are: (1) when licensing the '815 patent, "WARF may include rights under other patents and/or other proprietary rights to which WARF owns a part of or all right title and interest," or (2) when the '815 patent is "include[d] in other licenses . . . , which licenses may be directed to other invention subject matter or technology than that contemplated in this Agreement." (JX-001, § 3.A.(iii).) "In such event WARF shall have *the authority* to assign relative values to [the '815 patent] . . . and other patent and/or other proprietary rights as are included in any such license[.]" (*Id*. (emphasis added).) Moreover, the division, between WARF and WashU, of WARF's gross receipts under such a license "shall be determined in accordance with such relative values . . . in proportion to the

total value represented by all patent rights and/or proprietary rights which are included within such license." (*Id*.)

The parties have disputed the scope of the "authority" granted in the Relative Value Clause of the IIA. At summary judgment, WashU argued that "the IIA did not grant WARF unbridled discretion, but rather required WARF to assign the '815 patent a relative value fairly." (D.I. 100 at 7 (emphasis omitted).) Presently, WashU argues that "the term 'authority' expressly grants narrower rights that the term 'sole discretion,' which the parties used to refer to WARF's decision-making rights under the [IIA] with respect to [] patent prosecution and licensing activities." (D.I. 175 at ¶ 44 at 21 n.4.) WARF does not discuss its position on the scope of its "authority" under the Relative Value Clause in its post-trial briefing, but at summary judgment, it averred[106] that "authority to assign relative values" should be given its plain an ordinary meaning and "should be construed as 'the power to determine and assign a nonarbitrary value to the '815 patent relative to the other licensed patents in accordance with WARF's policies.'" (D.I. 113 at 8 (emphasis omitted).) In so doing, WARF combined two terms ("authority" and "relative values") into a single definition that WashU, and the Court, discuss separately.

(i) A Narrowed Scope of "Authority"

The parties have included a dictionary definition for "authority" in the record:

> 1. The power to determine, adjudicate, or otherwise settle issues or disputes; jurisdiction; the right to control, command, or determine.

[106] Technically, at summary judgment, WARF relied on WashU's dictionary definition and stated that it "does not take issue with WashU's interpretation on its face, and does not dispute that the 1995 Agreement gives WARF 'the power to determine' and assign a relative value to the '815 patent as part of a licensed portfolio." (D.I. 113 at 7.) In what appears to have been an attempt to "hide" the proverbial "ball," WARF essentially disagreed with WashU's position (which was to narrow the dictionary definition in light of the other terms of the contract) under the guise of what it contended was full agreement between the parties. (*Compare* D.I. 100 at 8–12, *with* D.I. 113 at 6–8.)

> 2. A power or right delegated or given; authorization: *Who has the authority to grant permission?*

(JX-362 at JX362.003 (emphasis in original).) At summary judgment, WashU presented both of these definitions and argued that the second was appropriate. (D.I. 100 at 9 (emphasis omitted) ("In the context of the Relative Value Clause, the term 'authority' refers to a delegated power that [WashU] entrusted to WARF to assign relative values to the '815 patent . . . , and to do so fairly.").) Meanwhile, WARF selected the first definition, and modified it to so that "authority" meant "the power to determine and assign[.]" (D.I. 113 at 7–8.)

In the context of the IIA, and from within the four corners of that document, the Court agrees with WashU that the second definition of "authority" is most appropriate. This is in large part because the first dictionary definition articulates a scope of "authority" that is broader than that contemplated by the IIA.

First, the Cooperation Clause requires the parties to "use all reasonable efforts to cooperate with each other with respect to" patenting activities, licensing, and so forth. (JX-001, § 2.A.(iii).) To read "authority" as "the power to determine, adjudicate or settle issues or disputes" between WARF and WashU would give WARF the ability to overrule WashU without reaching some form of consensus, which would defeat the purpose of the Cooperation Clause. Similarly, an "authority" defined as "jurisdiction" or "the right to control, command, or determine" would also be at cross purposes with the Cooperation Clause. Had the parties intended for WARF to have such a strong and controlling role, they would have defined that role clearly, especially in "adjudicating" disputes.[107]

[107] Given the dearth of argument from WARF in its proposed Findings of Fact and Conclusions of Law, (D.I. 178), about the interpretation of the terms of the IIA, the Court relies on WARF's arguments elsewhere. Of course, at trial, WARF's attorneys stepped back from this, harsh interpretation and argued that the relative value term was much more cooperative. For example, Mr. Shaffer, counsel for WARF, argued in its opening statement and explained that "at the bottom of the letter, as WARF always did, for every letter that you'll see in evidence, that comes into evidence, they always said *if you have any questions or concerns, please contact us.* And as the evidence will show in this case, every time they got a question or concern from WashU, they answered it." (Tr. 93:15–22 (emphasis added); *see also* D.I. 162, ex. A at DDX-22 (citing JX-021).) Mr. Shaffer has asked the Court to draw the inference that WARF answered questions and communicated with WashU openly, presumably under the guise that

Moreover, were the Court to read the Cooperation Clause as creating an obligation to cooperate with respect to WashU but not WARF, that would require bending the meaning of "cooperate" beyond the plain meaning and in a fashion clearly not intended within the IIA. (JX-001, § 2.A.(iii).) Thus, the scope of the "authority" in the Relative Value Clause cannot be as broad as the first dictionary definition.

Second, when WARF drafted the IIA, it employed other language where stronger rights are necessary in the IIA. For example, where the interests of WashU and WARF are aligned[108] as against others, the IIA grants WARF the "exclusive right" to: (1) "prepare, file, and maintain Patent Rights and related Property Rights," (JX-001, § 2.A.(i)), and (2) "negotiate, execute, administer, and enforce License Agreement(s)," (*Id.* at § 2.B.(i)). Within those grants of an "exclusive right," where WashU and others[109]

WARF would listen to WashU's concerns and would adjust its actions accordingly. Absent such an inference, WARF's arguments would be hollow and disingenuous, if not outright misleading—if WARF had the broad authority of the first definition, then WARF would not have to listen to WashU's "questions or concerns."

Although the Court does not resort to extrinsic evidence to construe the "authority" term in the Relative Value Clause, the experts largely agreed that WARF would have a duty to revalue if its original valuation of a patent (*i.e.,* the '815 patent) were challenged by the junior party. *See supra* ¶¶ 196–202. Thus, the extrinsic evidence also supports the conclusion that the "authority" in the Relative Value Clause is not as absolute as that suggested by the first dictionary definition.

[108] (*See* D.I. 175 at ¶ 44 at 21 n.4 (citations omitted) ("In situations where WARF's and [WashU's] interests were aligned, such as when filing for patent rights, securing licenses, or enforcing patent rights, the parties agreed that WARF would have greater latitude ('sole discretion' or 'sole and exclusive right') when making decisions. However, in the royalty apportionment context, when WARF's assignment of relative values might come at [WashU's] expense, the parties[] agreed that WARF would have narrower rights ('authority')").) WARF's response is conclusory—it argues that "what matters here is that WashU granted WARF the authority to set the relative value, and WARF did so based on long-standing practices[.]" (D.I. 178 at ¶ 63 at 68.) Nothing in the express language of the IIA discusses WARF "policies" or "long-standing practices[,]" and given that the parties agree that the terms of the IIA are "clear and unambiguous[,]" (D.I. 178 at ¶ 3 at 1), there is no reason for the Court to look to extrinsic evidence (such as WARF's policies or long-standing practices) to construe this term of the IIA.

[109] Within the context of the activities contemplated by the IIA, it is conceivable that a third party licensee may (in addition to WashU, which is named in the IIA) also be involved in patent prosecution and licensing. As against WashU, WARF has the "exclusive right" and "sole discretion" in patent prosecution and administering license agreements. (JX-001 §§ 2.A.(i), 2.B.(i).)

may potentially be involved in, or cooperating with,[110] patent prosecution and licensing, as against WashU, the IIA also gives WARF the "sole discretion" to "make decisions with respect thereto[.]" (JX-001, §§ 2.A.(i), 2.B.(i).) Additionally, in the licensing context, another activity in which WashU may cooperate with WARF,[111] as against WashU, "WARF will have the final authority to enter into negotiations and execute License Agreement(s)." (*Id.* at § 2.B.(ii).)

In light of the "exclusive right," "sole discretion," and "final authority" terms used elsewhere within the IIA, the Court concludes that the "authority to assign relative values" to the '815 patent is a narrow right that is neither "exclusive" nor is it in WARF's "sole discretion." WARF drafted this agreement. WARF had the ability to use any of these specific words. WARF chose to have WashU grant it the "authority to assign relative values" as opposed to the "exclusive right to assign relative values" or the "sole discretion to assign relative values."

Third, in addition to these other rights granted to WARF, within the four corners of the IIA, WARF's "authority" in the Relative Value Clause is also constrained by other provisions of the contract that include the Sharing Income Recital,[112] the Cooperation Clause, and the Mutual Benefit Clause.[113] Therefore, the Court concludes that the second dictionary definition of "authority" best describes the right that WashU grants to WARF in the Relative Value Clause. Reading this second definition in the context of the IIA, the Relative Value Clause is clear that if the '815 patent is licensed as part of a

[110] (*E.g.*, JX-001 § 2.A.(iii) ("WARF and [WashU] will use all reasonable efforts to cooperate with each other with respect to patent application preparation, filing, prosecution, maintenance, licensing, and execution of assignments of Patent Rights contemplated under this Agreement.").)

[111] *See supra* note 110.

[112] Although this is a recital and not a term of the IIA, the Sharing Income Recital helps to contextualize the Relative Value Clause.

[113] For example, WashU has argued that the Cooperation Clause and Mutual Benefit Clause limit the scope of WARF's "authority" in the Relative Value Clause. (D.I. 175 at ¶ 44 at 21 n.4.)

patent portfolio,[114] WashU delegates to WARF the power to assign a "relative value" to the '815 patent so that the parties may "shar[e] income"[115] from the patent license "for the mutual benefit of the parties"[116] "in proportion to the total value"[117] of the rights included in the license.[118] For these reasons, the Court construes "authority" in the Relative Value Clause according to the plain meaning, which is "a power or right delegated or given: authorization[.]" (JX-362 at JX362.003.)

(b) "Value" and "Relative Value"

The Relative Value Clause grants WARF "the authority to assign relative values" to the '815 patent "and other patent and/or proprietary rights as are included in any such license[.]" (JX-001, § 3.A.(iii).) However, the IIA does not define "relative value." (*See* JX-001, § 1 (outlining "Definitions").) During summary judgment and in post-trial briefing, the parties have discussed possible definitions of this term. For example, WashU has proposed that the plain meaning of "value" is "relative worth, merit, or importance[;]" "monetary or material worth, as in commerce or trade[;]" or "estimated or assigned worth; valuation[.]" (D.I. 175 at ¶ 44 at 21 n.4 (citing JX-362); D.I. 100 at 10–11 (citations and internal quotation marks omitted).)[119] And WashU contends that the

[114] (JX-001 § 3.A.(iii).)

[115] (*Id.* at 1 of 8.)

[116] (*Id.* at § 2.B.(ii).)

[117] (*Id*. at § 3.A.(iii).)

[118] WashU further argues that WARF's authority under the IIA is to assign value to the '815 patent fairly. (D.I. 175 at ¶ 44 at 21 n.4; *see also* D.I. 100 at 7.) To read "fair" into "authority" overstates that which is already implied under Wisconsin law. *Wis. Nat. Gas Co. v. Gabe's Const. Co.*, 582 N.W.2d 118, 121 (Wis. Ct. App. 1998) (citations omitted) ("Although the covenant of good faith and fair dealing that is implied in all contracts 'cannot override' a contract's 'express' terms, obligations under those terms must be performed subject to that implied covenant, and 'a party may be liable for breach of the implied contractual covenant of good faith even though all the terms of the written agreement may have been fulfilled[.]'").

[119] Although WARF accepted WashU's dictionary definitions for the purposes of summary judgment, (D.I. 113 at 8), WARF did not discuss the meaning of "value" in its post-trial briefing, (D.I. 178).

plain meaning of "relative" is "considered in relation to something else; comparative."[120] (D.I. 175 at ¶ 44 at 21 n.4 (citing JX-362).) Putting these two together, WashU avers that "[o]ne cannot assign 'value' to one patent 'relative' to other patents unless one applies the same fair and objective valuation standard to all patents in the portfolio."[121] (D.I. 175 at ¶ 44 at 21 n.4.)

By contrast, WARF does not propose any definitions of "value" or "relative values." (D.I. 178.) At summary judgment, WARF argued that "relative value" should be "a nonarbitrary value to the '815 patent relative to the other licensed patents [assigned] in accordance with WARF's policies[.]"[122] (D.I. 113 at ¶ 7 at 4 (emphasis omitted).) And a similar "not arbitrary" construction appears, nonetheless, in WARF's post-trial brief where it argues that it did not expressly breach the Relative Value Clause, because it set the relative value of the '815 patent "based on [its] long-standing practices—which by definition are not arbitrary[.]" (D.I. 178 at ¶ 63 at 68.)

At the same time, WARF also argues that parol evidence, (*e.g.*, JX-039), indicates that the parties intended to apply WARF's Blended Approach to the Relative Value Clause, (D.I. 178 at ¶ 24 at 10–¶ 26 at 11; ¶¶ 81–82 at 26; ¶ 137 at 41), and did not intend to revalue the '815 patent at any point in time, (*id.* at ¶ 11 at 50). WARF has not argued that the IIA is not integrated, nor has WARF argued fraud, duress or

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[120] At summary judgment, WashU had proposed that "'value' means a fair value in light of all relevant circumstances. . . . [and] 'relative' means relative to the value of the other patents licensed in the portfolio." (D.I. 100 at 7 (emphasis and footnote omitted).)

[121] As discussed above, the use of "fair" in this definition is redundant with the implied terms present in the IIA and asserted by WashU. *See supra* note 118.

[122] The definition proposed by WARF at summary judgment does not comport with the intrinsic evidence or the record. For instance, the Relative Value Clause does not employ the terms "arbitrary" or "nonarbitrary" with respect to "relative values"—these terms are not found elsewhere in the IIA or in the dictionary definitions. Moreover, the only mention of internal policies is found in Section 3.A.(ii), which immediately precedes the Relative Value Clause and states that "[d]uring the term of this Agreement, each party will be solely responsible for calculating and distributing its share of Net Revenues to its respective Inventors in accordance with its own policy." (JX-001 § 3.A.(ii).) This mention of policy is with regard to internal policies at WARF and WashU does not address the relationships and obligations between the parties.

mistake; therefore, the Court declines to rely upon this parol evidence to interpret the Relative Value Clause. *See supra* ¶ 203 (discussing the IIA's integration clause); *Town Bank*, 793 N.W.2d at 485 (footnote omitted) ("If the contract is integrated, absent the existence of fraud, duress, or mutual mistake, the court construing the contract may not consider evidence of any prior or contemporaneous oral or written agreement between the parties.").

In the Relative Value Clause, WashU authorizes WARF to "assign relative values" in order to share income between the parties when WARF licenses the '815 patent as part of a portfolio of patents. (JX-001, § 3.A.(iii).) Therefore, of the plain meanings discussed above, the "value" in question is a "monetary or material worth." (JX-362 at JX362.005.) Combining the dictionary definitions of "relative" and "value," a "relative value" is defined as "monetary or material worth considered in relation to something else."[123] The Court next considers whether additional constraints are necessary to define "relative value" within the IIA.

(i) Additional Constraints

Beyond the plain meaning, WARF has, at times, proposed that the relative value be "nonarbitrary," (D.I. 113 at 4), but within the four corners of the IIA, which does not define the term "arbitrary" or use it in any way, it is unclear what a "nonarbitrary" value is, (JX-001). The Court notes that there are many potential values that may not be arbitrary but that may also not reflect the monetary or material worth of a licensed patent in relation to the licensed application and the other licensed patents in the

[123] The IIA is plain that in licensing the '815 patent, "WARF may include rights under other patents . . . to which WARF owns a part or all right title and interest" or that WARF may include the '815 patent "in other licenses . . . which [] may be directed [] to other invention subject matter or technology than that contemplated in this Agreement." (JX-001, § 3.A.(iii).) This suggests two scenarios: (a) that the license to the '815 patent may include other patents that may not have very much to do with the subject of the IIA (and the '815 patent has a higher value in relation to some or all of these other patents), or that (b) the '815 patent may be included in other licenses that have little to do with the subject of the IIA (and the '815 patent may have little to no value in relation to the other patents).

portfolio. Thus, WARF proposes language that would broaden the scope of the "relative values" term well beyond that contemplated in the Relative Value Clause.[124]

Meanwhile, WashU seeks to narrow the scope of the "relative values" term, arguing that the Relative Value Clause places limits on what the relative value is—specifically the value must have an objectively reasonable basis. (D.I. 175 at ¶ 44 at 21 n.4.) At summary judgment, WashU had proposed that "'value' means a fair value in light of all relevant circumstances[,]" and "'relative' means relative to the value of the other patents licensed in the portfolio." (D.I. 100 at 7 (emphasis omitted).)

Under the Relative Value Clause, WARF cannot assign a random value to the '815 patent. Instead, the value must represent the "monetary or material worth" of the '815 patent in relation to the other patents licensed in the portfolio. (JX-001, § 3.A.(iii).) This "relative value" is not an absolute determination of the '815 patent's total worth for all potential licenses in the entire marketplace, rather, it is an assessment of the '815 patent's monetary or material worth for the specific licensed application in comparison to the other patents in the licensed portfolio. And while it is easy to infer that the parties intended that the relative values be objectively reasonable and fair, the Relative Value Clause does not specify a method for determining relative values,[125] nor does the Relative Value Clause place any specific limitations on the relative values themselves. (JX-001, § 3.A.(iii).) Given the operation of the IIA, the fairness and objective reasonableness discussed in relation to the Relative Value Clause would most likely fall

[124] In what appears to be a nominal concession, WARF has proposed a narrowing of this broader scope, which is that the relative value be determined "in accordance with WARF's policies." (D.I. 113 at 8 (emphasis and internal quotation marks omitted).) Seemingly, such a narrowing could bring the range of possible values closer to the intent of the parties. But within the four corners of the IIA, there is no support, (JX-001), for WARF's assertion that the parties intended for "relative values" to be determined in accordance with WARF's "policies," "long-standing practices," traditions, or otherwise, (D.I. 113 at 4; *cf.* D.I. 178 at ¶ 63 at 68). Moreover, the imposition of the "WARF policies" requirement could lend support to an explanation why a "relative value" is "nonarbitrary," even if the value does not reflect the monetary or material worth of the '815 patent in a specific licensing situation. WARF's proposed definition is at such cross purposes with the IIA that the Court has no other option than to reject it.

[125] Here, the Court concludes that the parties have left this choice to WARF as part of "the authority to assign relative values[.]" (JX-001 § 3.A.(iii).)

under the other provisions discussed above, including the Cooperation Clause and the Mutual Benefit Clause.[126] Reading fairness or objective reasonableness into the "relative values" term could potentially read out these other provisions. *See, e.g.*, *Kasten v. Doral Dental USA, LLC*, 733 N.W.2d 300, 315 (Wis. 2007) (alteration and citation omitted) ("When construing the language of a contract, we give meaning to every word, avoiding constructions 'which render portions of a contract meaningless, inexplicable or mere surplusage.'").

Although the Court declines to read fairness into the "relative values" term, the plain meaning discussed above does not capture the additional constraints imposed by the Relative Value Clause. Specifically, the Relative Value Clause requires that: (1) the relative value relates to "such license[,]" which is a specific license; (2) the relative value is determined in comparison to the other patents licensed in the portfolio, and (3) these relative values are combined into a "total value represented by all patent rights and/or proprietary rights which are included within such license." (JX-001, § 3.A.(iii).) This first requirement is a valuation of the patent with respect to the specific license. The second two require that WARF determine a "total value" of all the patent rights and compare the patent in question to the other patents—it goes without saying that patents in the portfolio with *no value to the license* should be identified and assigned a low (or zero) "relative value" accordingly.[127] WashU's proposal from summary judgment reasonably captures these constraints. (D.I. 100 at 7 (emphasis and footnote omitted) (proposing "'value' means a [] value in light of all relevant circumstances" and "'relative' means

[126] In its post-trial brief, WARF argues that "there is no provision in the IIA that requires WARF to seek input from WashU when determining relative value, to work with WashU to set the relative value for the '815 patent, or to even inform WashU of the reasoning behind the relative value that it was authorized to set." (D.I. 178 at ¶ 62 at 68.) The Court does not treat this as a proposed construction but, rather, as an argument against express breach.

[127] The Court recognizes that patent owners group patents into "portfolios" and license different aspects of those portfolios to one or more licensees in various geographies to make, sell, and use different products in various fields of use. Presumably, some patents within a portfolio may have no relative value to one license and yet may be a critical aspect to another license and may have a high relative value in that license.

relative to the value of the other patents license in the portfolio.").) Combining this language with the plain meaning discussed above, the Court concludes that in the Relative Value Clause, "relative value" is defined as "the monetary or material worth, in light of all circumstances relevant to such license, considered in relation to the value of the other patents licensed in the portfolio." This is a *patent-specific* relative value.

(c) Duty to Revalue

When the Third Circuit reversed this Court's grant of summary judgment, it presented the Court with specific findings of fact related to the duty to revalue, stating:

> On this record, we believe there is a genuine issue of material fact as to whether WARF and [Washington] University intended that the '815 Patent would be revalued if it became clear that the value originally assigned to the '815 Patent was insufficient to fairly compensate the University under the 1998 Agreement.

Washington Univ., 703 F. App'x at 109. WashU argues that there is a duty to revalue the '815 patent under Wisconsin's periodic payment doctrine and the IIA itself. (D.I. 175 at ¶ 56 at 27.) In its proposed Conclusions of Law, WARF contends that "[a]s the Third Circuit previously found, *there is no express provision* in the 1995 IIA that requires WARF to revisit its assignment of relative value to the '815 patent." (D.I. 178 at ¶ 10 at 50 (emphasis added).) In light of the Third Circuit's holding and clearly-stated findings of fact for the Court, WARF's claim of a "no express provision" finding is puzzling to say the least. The Court is responsible for construing the IIA, and the Third Circuit's statements in this regard are relevant.[128]

[128] For example, if the Third Circuit specifically found that "there is no express provision" in the IIA that requires WARF to revalue the '815 patent, then the duty to revalue would be an implied duty. But if the Third Circuit found, for example, that the IIA is silent or ambiguous about a duty to revalue, then the Court could make factual findings and rely upon extrinsic evidence, to determine whether a duty to revalue is an express term of the contract. A third option is that the Court's construction herein of the Relative Value Clause could address the question of a duty to revalue without necessitating the findings of fact identified by the Third Circuit.

(i) WARF's Representations

WARF moved for summary judgment that WashU's claims are time barred. (D.I. 96; D.I. 97 at 11–14.) At the time, WARF argued, *inter alia*, that "[t]he 1995 Agreement does not include *any* requirement, express or otherwise, that WARF revisit the valuation [of the '815 patent]." (D.I. 97 at 16 (emphasis in original); *see also* D.I. 122 at 2; D.I. 113 at 15.) This Court granted summary judgment, finding there to be no genuine issue of material fact as to whether WashU's claims under the annual payment exception to Wisconsin's statute of limitations were time-barred. (D.I. 130 at 14.)

On appeal, WARF again argued that "the express terms of the 1995 Agreement do not require WARF to revisit, reevaluate, or modify the relative value." Br. of Def.-Appellee at 41, *Washington Univ.*, 703 F. App'x at 106 (No. 16–1419). When the Third Circuit reversed this Court's grant of summary judgment, it noted (without citation) that "*[d]espite WARF's arguments to the contrary*, the express terms of the contract do not answer [the] question" of "whether WARF and [WashU] intended that the '815 Patent would be revalued if it became clear that the value originally assigned to . . . [it] was insufficient to fairly compensate [WashU] under the . . . [IIA]." *Id.* at 109 (emphasis added). At the time, this Court had not construed the Relative Value Clause and had not resolved WashU's motion for partial summary judgment in which WashU sought to construe the Relative Value Clause. (D.I. 130.)

Presently, WARF represents that the Third Circuit specifically found that "there is no express provision" of the IIA that imposes a duty to revalue.[129] (D.I. 178 at ¶ 10 at 50.) The Third Circuit specifically disagreed with WARF and made a point of voicing this disagreement; therefore, it is plain that WARF misstates the Third Circuit's holding. *Washington Univ.*, 703 F. App'x at 109.

[129] As is discussed below, this is essentially an argument about construction of the Relative Value Clause, which was the term WashU sought to construe at summary judgment.

The Court interprets the Third Circuit's statements to mean that, within the four corners of the contract, *absent a construction of the Relative Value Clause by this Court*, the IIA is ambiguous about a duty to revalue; therefore, extrinsic evidence is necessary to determine whether the parties intended a duty to revalue.[130] *See, e.g.*, *Dieck*, 180 N.W. at 935 (citation and internal quotation marks omitted) ("[P]roof of custom and usage is permissible to define what is ambiguous or is left undetermined in a contract, where both parties have knowledge of the custom or are so situated that such knowledge may be presumed.").

(ii) Discussion

The Relative Value Clause does not specify when WARF is to assign a relative value to the '815 patent. (JX-001, § 3.A.(iii).) Presumably, and this does not appear to be in dispute, there is an initial duty to assign a relative value at some point when there are licensing revenues to apportion under the IIA. (*Id*.) As chronicled above, WARF argues that under the Relative Value Clause, once it assigns an initial relative value to the '815 patent under a specific license, the Relative Value Clause does not require it to revalue the '815 patent again. (D.I. 178 at ¶ 14 at 51 ("WARF had no obligation to revalue the '815 patent at any point after its initial valuation of that patent and the other patents in the Abbott portfolio in 1998.").)[131] In addition, WARF has argued extensively that the text of the IIA, as well as the parol evidence of communications between Dr. Brandt and Mr. Bremer, do not discuss a duty to revalue. (D.I. 178 at ¶ 31 at 12, ¶ 11 at

[130] Put another way, if the Court were to accept WARF's statement that "there is no express provision" of the IIA that imposes a duty to revalue, any reading of the Relative Value Clause would also lead the Court to conclude the converse, that there is also "no express provision" that *does not* impose a duty to revalue. But imputing these characteristics to "express provisions" is misleading, because it puts the cart before the horse and suggests that a court has construed the contract terms in the first place, *which had not happened when the Third Circuit last spoke on this subject*.

[131] That WARF actually *did revisit the valuation of the '815 patent* two months after its original valuation, *see supra* ¶¶ 344–347, suggests that even WARF thought otherwise about its duty to revalue. Oddly, after revaluing the '815 patent, WARF did not bother to adjust the calculation in its accounting system and proceeded to pay royalties according to a lower percentage for the next sixteen years. *See supra* ¶ 348.

50.) WashU responds that there is a duty to revalue, and under the doctrine of *contra proferentem*, the Court is to construe this term against the drafter, which is in this case, WARF. (D.I. 100 at 13–14.)

Before the Court turns to the extrinsic evidence identified by the Third Circuit, which it would do if the Relative Value Clause were ambiguous about WARF's duty to revisit the "relative value," the Court first addresses the question of whether, within the four corners of the document, the IIA is clear about whether and under what circumstances the parties intended for WARF to revisit the relative value assigned under Section 3.A.(iii). *See Washington Univ.*, 703 F. App'x at 110 & n.22 (reversing this Court's grant of summary judgment and identifying a non-exhaustive list of issues of material fact that the Third Circuit concluded meant that WARF was not entitled to judgment as a matter of law).

(iii) Four Corners of the IIA[132]

The Court concludes that the four corners of the IIA support the determination that the parties intended an annual re-evaluation of the "relative value" of the '815 patent. There are several reasons for this, including the context for the Relative Value Clause, the annual calculation required by the IIA, the lack of specific relative value proportions, the inherently evolving nature of a patent portfolio, and the doctrine of *contra proferentem*.

First, the Relative Value Clause exists to perform an annual calculation of WashU's share of Net Revenues. Section 3 of the IIA is entitled "Consideration" and discusses primary sources of revenue and expenses—revenues take the form of net revenues from licensing fees, and expenses relate to patent filing, prosecution and

[132] WARF's entire argument against the duty to revalue being an express term of the IIA is based upon (1) its misrepresentation of the Third Circuit's holding, and (2) parol evidence. (D.I. 178 at ¶ 10 at 50–¶ 14 at 51–52.) These materials do not assist the Court in determining what the parties intended in the IIA, and the Court, therefore, declines to consider them.

maintenance fees. (JX-001, § 3.) The Relative Value Clause is in Section 3.A., which focuses on the calculation of Net Revenues and WashU's share of Income. (*Id.*, § 3.A.)

The IIA defines "Net Revenues" as "Income less the [15%] Administration Fee."[133] (*Id.*, § 1.H.) Moreover, the IIA specifies that "WARF will pay to [WashU] its share of Net Revenue due under this Agreement every 12 months by August 31 for the preceding 12-month period beginning July 1 and ending June 30." (JX–001, § 5.B.)

Based upon the plain language of the IIA, the parties expected that, for every 12 months during the life of the agreement, WARF would make a series of calculations to determine WashU's share of Net Revenues. (*Id.*, § 5.) The IIA specifies that WARF is to identify the amount of Income associated with the '815 patent, (*id.*, § 3.A.(iii)), to subtract a 15% Administration Fee, (*id.*, § 1.G.–H.; § 2.B.(iv)), to allocate 33 1/3% of Net Revenues for relevant geographies to WashU, (*id.*, § 3.A.(i)), and to subtract various patent fees, (*id.*, § 3B). This calculation was complex enough that the parties gave WARF two months to perform it and to then send payment to WashU. Based upon this language, it is apparent that many of the amounts would change from year to year and that the parties expected WARF to make a *new calculation* of WashU's share of Net Revenues every year.

Second, within this annual calculation of WashU's share of Net Revenues, when the parties sought to include specific percentage allocations, they did so clearly. For example, the IIA identifies: the 15% Administration Fee, (JX-001, § 1.G), the 33 1/3% allocation of Net Revenue to WashU, (*id.*, § 3.A.(i)), the 33 1/3% allocation of Foreign Patent Cost Estimate to WashU, (*id.*, § 3.B.(ii)), and the limitation of patent fees subtracted from any given payment to WashU to "one-half of the share of Net Revenue due [WashU,]" (*id.*, § 3.B.(i)). However, there is no evidence that, at any point in time,

[133] "'Income' means any monetary payments or other forms of compensation received by WARF[.]" (JX-001, § 1.F.)

the parties intended to assign such a specific and unvarying percentage of Income to any patent addressed by the Relative Value Clause, including the '815 patent.

Third, as discussed above, in the IIA, WashU granted WARF the "authority to assign relative values to Patent Rights[]" for the purpose of dividing the "Income" to be used in the above calculation "in proportion to the total value represented by all patent rights . . . which are included within [a given] license." (*Id.*, § 3.A.(iii)); *see supra* Section III.B.7(a)–(b). This is relatively broad and open language granting a wide range of latitude to WARF in terms of how it assigned the relative value. Reflecting such an openness, the Court construed "relative value" to mean "the monetary or material worth, in light of all circumstances relevant to such license, considered in relation to the value of the other patents licensed in the portfolio." *See supra* Section III.B.7(b).

The IIA employs this "relative value" term to give WARF the authority to assign income to the '815 patent according to this relative value as part of an annual calculation of Net Revenues due to WashU. At the same time, it is clear from this definition that the parties wanted to give WARF some amount of flexibility to specifically reflect the value of the '815 patent in the portfolio over time. Had the parties intended differently, they could have defined a process or a formula for assigning relative value, and they could have limited the number of times that the relative value was assigned. Absent such limiting language, the primary boundary of the Relative Value Clause is the annual calculation of WashU's share of Net Revenues.

Fourth, the Court notes that, by their very nature, patent portfolios are constantly changing. For example, in the context of a license to a portfolio of patents, every year some patents will expire, some applications will be abandoned, and new patents will issue. And for a variety of reasons, licensees may begin (or cease) making, using, or selling products that drive license revenues. Over time, as these variables naturally change, the relative values of patents within a portfolio will also change.

Fifth, WARF drafted the IIA and now argues that the IIA cannot be read to include a duty to revalue *under any circumstance*. (D.I. 178 at ¶ 32 at 12–¶ 34 at 13.) WashU avers that the IIA includes a duty to revalue. (D.I. 175 at ¶ 304 at 140–¶ 308 at 142.) Under the doctrine of *contra proferentem*, this disputed language is construed against WARF.[134] *E.g.*, *Md. Arms Ltd. P'ship v. Connell*, 786 N.W.2d 15, 25 (Wis. 2010) (citation omitted) ("The principle that ambiguities are construed against the drafter is a 'deeply rooted doctrine' of contract interpretation.").

Therefore, given that the assignment of "relative values" in the Relative Value Clause exists to facilitate WARF's annual calculation of WashU's share of Net Revenues under the IIA, the Court concludes that the parties expected that WARF would revisit the "relative value" of the '815 patent each year when it made the calculation.[135]

(iv) Extrinsic Evidence

Although the Court is able to resolve the question of whether the parties intended to revisit the "relative value" within the four corners of the IIA, for the sake of completeness, the Court addresses the question posed by the Third Circuit. *See supra* Section III.B.7(c) at 151. At trial, WARF's Dr. Gulbrandsen testified that "WARF's 'standard practice'[136] going back at least 20 years was not to re-evaluate the relative value of any one patent within a larger Vitamin D portfolio." (D.I. 178 at ¶ 32 at 12

[134] For the reasons above, the duty to revalue is not ambiguous within the four corners of the IIA. Thus, the doctrine of *contra proferentem* only serves to reinforce that which the Court has already determined through the intrinsic record.

[135] The Court recognizes that there may be circumstances where patent licenses include expired patents and distribute revenues amongst inventors according to a license long after some of the patents have expired. Although there may be extrinsic evidence of such practices in other license relationships between parties other than those in the case at bar, the four corners of the IIA provide ample support for the interpretation that the parties intended for WARF to periodically revisit the relative value of the '815 patent for purposes of making the annual calculation of WashU's share of Net Revenues.

[136] WARF does not identify anything within the four corners of the IIA that suggests that the parties intended for WARF's "standard practice" to govern any aspect of the operation of the agreement.

(citing Tr. at 693:1–13).) The extrinsic evidence supports a similar conclusion—in technology transfer environments (where other types of licenses may prevail), it is not common for a senior party to revalue a patent in a licensed portfolio.[137] Nonetheless, there are numerous factual scenarios that could give rise to a duty to revalue. These fact patterns appear to revolve around the senior party's actual knowledge of facts that could call into question the prior valuation of a patent. *See supra* ¶¶ 196–201.

Therefore, the Court concludes that, according to the extrinsic evidence, an inter-institutional agreement includes a duty for the senior party to revalue the patents that are the subject of the agreement: (1) when patents in the portfolio expire, (2) when total license revenues range above $10 million or more, (3) when the junior party challenges the senior party's valuation of a patent, (4) when an inventor challenges the valuation of a patent, (5) when the senior party discovers that the valuation of a patent is based upon a mistaken assumption, such as whether a patent reads on an FDA-approved indication for a patented compound, or (6) to avoid injustice. *See supra* ¶ 202.

(d) WARF Had A Duty Under the Relative Value Clause to Be Fair

In addition to the aforementioned express terms and extrinsic evidence, under the implied covenant of good faith and fair dealing, WARF had a duty to be fair in the manner in which it assigned relative values to patents under the Relative Value Clause. (Tr. at 982:4–7 (Dr. Severson).) This Court previously determined on summary judgment that the duty of good faith and fair dealing required WARF "to exercise its authority to assign relative values fairly and in good faith" under the IIA. (D.I. 130 at 21.) WARF did not appeal this Court's summary judgment ruling, which now stands as the

[137] Of course, at the same time, it does not appear to be standard industry practice for senior parties to assign value to large numbers of patents that have no relevance to the licensed application. Thus, in light of the facts of the instant litigation, it appears that WARF's practices may be exceptional.

law of the case. *See Chlystek v. Kane*, 540 F.2d 171, 173 (3d Cir. 1976) ("[W]e are bound by the determination of the district court, which has not been appealed.").

C. Express Breach of Contract

WashU alleges that WARF breached the IIA when it assigned a relative value of less than 1% to the '815 patent in 1998. (D.I. 1 at ¶ 53 at 14.) The Court defines "relative value" as "the monetary or material worth, in light of all circumstances relevant to such license, considered in relation to the value of the other patents licensed in the portfolio." *See supra* Section III.B.7(b). WARF admits that it did not assign a patent-specific value to the '815 patent and instead argues that it assigned a value consistent with its practices and policies. *See supra* ¶ 324; (D.I. 178 at ¶ 76 at 24 ("WARF's allocation of relative value to the patents in the 1998 WARF-Abbott License portfolio was consistent with WARF's practices and policies for Dr. DeLuca's Vitamin D portfolios[.]"); *id.* at ¶ 63 at 68 ("[W]hat matters here is that WashU granted WARF the authority to set the relative value, and WARF did so based on long-standing practices[.]"); *see also* D.I. 122 at 8 ("It is undisputed that WARF assigned a relative value in accordance with its standard practice."); D.I. 97 at 15 ("WARF abided by its customary practice and procedure[.]").)

1. Legal Standard

The elements of breach of contract in Wisconsin are "a contract (duty), a breach of that contract and damages flowing reasonably from that breach." *Nw. Motor Car, Inc. v. Pope*, 187 N.W.2d 200, 202 (Wis. 1971).[138]

[138] WashU's contract claims arise under state law. *Volt Info. Scis., Inc. v. Bd. of Trs. of Leland Stanford Junior Univ.*, 489 U.S. 468, 474 (1989). Specifically, Wisconsin law applies to the parties' IIA pursuant to a Wisconsin choice-of-law provision. (JX-001 § 12.)

2. Discussion

(a) The IIA is Valid and Enforceable

The parties agree that the IIA is valid and enforceable as between the parties. *See supra* ¶ 27. Therefore, the first factor is not in dispute.

(b) WARF Breached the IIA When It Used the Blended Approach to Assign an Equal Value, Instead of a Patent-Specific Relative Value, to the '815 Patent in 1998

As to the second factor breach of contract, within the four corners of the IIA, it is clear that the parties did not refer to WARF's "standard practices" and did not intend to apply these unstated and identified policies to the assignment of relative value. Therefore, WARF's extensive arguments in this regard are irrelevant to WashU's allegations of breach.[139]

The Court next turns to the material aspects of breach of the Relative Value Clause of the IIA. Section 3.A.(iii) of the IIA states that in situations where WARF includes other patents in a license including the '815 patent, for the purposes of an annual calculation of Net Revenues due to WashU, "WARF shall have the authority to assign [a] relative value[] to" the '815 patent so that WARF may divide Income "in proportion to the total value represented by all patent rights" in the license. (JX-001, § 3.A.(iii).) This not an obligation, but a "power or right delegated or given: authorization." *See supra* Section III.B.7(a). When WARF chooses to apply this authorization to assign a relative value, that "relative value" is defined as "the monetary

[139] WARF has argued extensively that it did not breach the IIA, because it simply followed its own practices in the form of the Blended Approach. This is an untenable position based upon the facts and the law. First, as a factual matter, the evidence in the record is that the Blended Approach, specifically the assignment of equal value to patents in a given group, directly contradicts WARF's *written policies* on patent valuation for dividing income in licenses. *See supra* ¶¶ 328, 369–374, 438–452. Second, as a legal matter, the Blended Approach directly contradicts the requirements of the Relative Value Clause as construed by the Court—within the four corners of the IIA, there is no evidence that WashU gave WARF the authority to apply the Blended Approach when it assigned a relative value to the '815 patent. By asserting the Blended Approach as a defense, WARF is effectively admitting that it breached the Relative Value Clause.

or material worth, in light of all circumstances relevant to such license, considered in relation to the value of the other patents licensed in the portfolio." *See supra* Section III.B.7(b).

The facts in the record show that WARF licensed the '815 patent exclusively to Abbott in the 1998 License. *See supra* ¶¶ 293–309. At the time, WARF and Abbott knew that the '815 patent read on the FDA-approved indication of paricalcitol/Zemplar. *See supra* ¶¶ 260–262. Included in the 1998 License were a number of other patents. *See supra* ¶¶ 263–280. Some of these patents were licensed exclusively, and others were subject to nonexclusive licenses. *See supra* ¶¶ 281–289. WARF admits that it did not perform a patent-specific valuation of the '815 patent. *See supra* ¶ 324. Instead, WARF relied on an unwritten policy called the "Blended Approach," which assigned equal value to all patents in the ancillary group, regardless of the actual relative value of those patents. *See supra* ¶¶ 325–329.

Specifically, based upon the unrebutted expert testimony in the record, when WARF assigned a 0.968% relative value to the '815 patent, *supra* ¶¶ 310–311, 314–320, it assigned: (1) an equal value to a patent duplicative of the '497 patent (which was already licensed exclusively and assigned 35% of incoming revenues), *supra* ¶¶ 276, 364–366; (2) equal values to six method of use patents for non-approved medical uses of paricalcitol, two of which were patent applications that were abandoned and combined into a single patent, amounting to five method of use patents, not six, *supra* ¶ 278; (3) equal values to another eighteen patents that *had absolutely nothing to do with paricalcitol/Zemplar* or any of the 19-Nor Vitamin D compounds licensed to Abbott, *supra* ¶ 279; and (4) equal values to four "low value" patents that Dr. Cleare determined *may relate* to the manufacture of paricalcitol/Zemplar, *supra* ¶ 277.

Had WARF assigned the '815 patent a relative value as it was authorized under the IIA, it would have determined some measure of "the monetary or material worth, in light of all circumstances relevant to [the 1998 L]icense, [of the '815 patent] considered

in relation to the value of the other patents licensed in the portfolio[,]" and *at a minimum*, WARF would have assigned zero value to the eighteen patents that had nothing to do with the license. The Court appreciates that there is nothing in the IIA that prevents WARF from licensing no-value or low-value patents alongside the '815 patent—as a matter of fact, this is precisely what Section 3.A.(iii) anticipates. To this end, the IIA includes a remedy for bundling these low- or no-value patents in the license, which is to assign a relative value so that the division of revenues under the license is proportional to the value of the patent *to that license*. (JX-001, § 3.A.(iii).)[140]

That is not what happened in the case at bar. WARF did not perform a patent-specific valuation of the '815 patent. Instead, WARF licensed the '815 patent alongside a number of other patents, many of which had low-value or no-value to the licensed application. Next, WARF assigned an equal value to all of the patents in the ancillary group of the 1998 License, regardless of their value to the license, and regardless of whether those patents were licensed exclusively or nonexclusively.

Based upon these facts, WARF did not assign a patent-specific "relative value" as WashU authorized it to do in Section 3.A.(iii) of the IIA. Therefore, the Court concludes that WARF breached the IIA for at least the above reasons.

(c) Other Breaches

The Court recognizes that WARF has also breached other provisions of the IIA.[141] First, WARF's assignment of equal value to all the patents in the ancillary group is a clear breach of the Mutual Benefit Clause, because by assigning equal value to WARF-owned patents wholly unrelated to the license, WARF gained a benefit at the

[140] Of course, the IIA also anticipates that the '815 patent could, at times, be the low value patent in the license. (JX-001, § 3.A.(iii).)

[141] Given that damages reasonably flow from the breach of the Relative Value Clause, the Court limits its discussion here of the other breaches of the IIA.

expense of WashU and, hence, was not administering the license to the "mutual benefit" of the parties. *See supra* Section III.B.6; (JX-001, § 2.B.(ii).)

Second, the Court has construed the Cooperation Clause to "impose[] on WARF, as the senior party, a duty to communicate, in a timely manner, all material information concerning the ['815 patent] . . . that is available to WARF and that is relevant to the licensing thereof." *See supra* Section III.B.5; (*see also* JX-001, § 2.A.(iii).) The record is replete with numerous situations where WARF did not communicate material information related to licensing of the '815 patent with WashU. For example, WARF refused to share the 1993 License and 1998 License with WashU, citing non-existent "confidentiality provisions" in those contracts. During prosecution of the '815 patent, WARF ignored Dr. Slatopolsky's researchers and not only did not credit any of them with inventorship but also did not discuss the decision with WashU. When the '815 patent issued, WARF waited nine months before sending a copy to WashU. When WashU asked for information about the valuation of the '815 patent, WARF responded with a legalistic letter (the 2001 Valuation Letter) that shared very little information about the other patents included in the 1998 License. And when the time came to litigate over the '815 patent, WARF took every step possible to avoid informing WashU of the litigation, even misrepresenting in documents in this Court that it was the sole assignee of the '815 patent. Moreover, WARF's litigation counsel saw fit to contact Dr. Slatopolsky directly and without informing WashU, Dr. Slatopolsky's employer, when responding to subpoenas in the *Hospira* litigation. Taken together, these facts, and the many others discussed herein demonstrate a clear breach of the Cooperation Clause.

3. Conclusion–Express Breach of Contract

The Court concludes that WARF breached the IIA when it failed to assign a relative value to the '815 patent as specified in the Relative Value Clause. (JX-001,

§ 3.A.(iii).) WARF also breached the Mutual Benefit Clause and the Cooperation Clause.[142] The Court will address damages in Section III.G below.

D. Statute of Limitations

WARF argues that WashU's claims are time barred by Wisconsin's six-year statute of limitations. (D.I. 178 at ¶ 117 at 36–¶ 120 at 37.) WARF claims the alleged breach arising from the assignment of relative value occurred on November 10, 1998, (*id.* at ¶ 118 at 36), and that WashU's filing of the Complaint in the case at bar on December 26, 2013 was not within the statute of limitations, (JX-337). WashU contends that WARF cannot assert a statute of limitations defense under equitable estoppel and Wisconsin's continuing payment exception. (D.I. 175 at ¶ 263 at 119.)

1. Legal Standard

Wisconsin law provides a six-year statute of limitations for "[a]n action upon any contract, obligation or liability, *express or implied*." Wis. Stat. § 893.43 (2016). "[I]n an action for breach of contract, the cause of action accrues and the statute of limitations begins to run from the moment the breach occurs. This is true whether or not the facts of the breach are known by the party having the right to the action." *CLL Assocs. Ltd. P'ship v. Arrowhead Pac. Corp.*, 497 N.W.2d 115, 117 (Wis. 1993) (citations omitted). The "discovery rule" does not apply to breach-of-contract claims under Wisconsin law. *Id.*

2. Equitable Estoppel

"The doctrine of equitable estoppel applies where there is: '(1) action or non-action; (2) on the part of one against whom estoppel is asserted; (3) which induces reasonable reliance thereon by the other, either in action or non-action; (4) which is to

[142] Although the parties have argued extensively that there is a breach of the covenant of good faith and fair dealing, the Court has found that WARF has breached at least three express clauses of the IIA. Therefore, the Court declines to consider breach under the covenant.

the relying party's detriment.'" *Washington Univ.*, 703 F. App'x at 109 (citing *Affordable Erecting, Inc. v. Neosho Trompler, Inc.*, 715 N.W.2d 620, 628 (Wis. 2006)).

"This 'action or non-action' includes concealing evidence needed by the relying party to file a claim." *Washington Univ.*, 703 F. App'x at 109 (citing *Barry Aviation, Inc. v. Land O'Lakes Mun. Airport Comm'n*, 377 F.3d 682, 689 (7th Cir. 2004)). "The conduct or representations of the party asserting the statute of limitations must be 'so unfair and misleading as to outbalance the public's interest in setting a limitation on bringing actions.'" *Id*. (quoting *State ex rel. Susedick v. Knutson*, 191 N.W.2d 23, 26 (Wis. 1971)). Equitable estoppel requires proof by clear and convincing evidence. *Gonzalez v. Teskey*, 465 N.W.2d 525, 530 (Wis. Ct. App. 1990).

Actual fraud is not required to invoke equitable estoppel. Estoppel requires only a showing of fraudulent or inequitable conduct that induced reasonable reliance; it does not require a showing of actual fraudulent intent. *Susedik*, 191 N.W.2d at 26 ("Actual fraud, in a technical sense, is not required to find estoppel *in pais*."); *see also Pick Foundry, Inc. v. Gen. Door Mfg. Co*., 55 N.W.2d 407, 411 (Wis. 1952) ("[A]ctual fraudulent intent is not a necessary incident to the application of the principle of estoppel[.]").

(a) Discussion

The parties disputed the question of equitable estoppel and argued it before the Third Circuit. In its opinion, the Third Circuit specified the following questions of material fact for the Court to resolve:

> (1) whether WARF concealed information Washington University needed to determine if it had a valid claim; (2) whether that information was necessary to pursue the claim; (3) whether Washington University reasonably relied on WARF's statements and conduct; and (4) whether Washington University had the ability to obtain that information, notwithstanding WARF's alleged concealment.

Washington Univ., 703 F. App'x at 110.

In its Findings of Fact, the Court has answered the above questions based upon the record before it. As such the Court has found clear and convincing evidence of each of the relevant factors. First, WARF concealed the information WashU needed to determine that it had a valid claim. *See supra* ¶¶ 380, 385–392. Second, the information that WARF concealed was necessary to pursue the claim. *See supra* ¶¶ 381, 392. Third, WashU reasonably relied on WARF's statements and conduct. *See supra* ¶ 383. Fourth, WashU did not have the ability to obtain that information, notwithstanding WARF's alleged concealment. *See supra* ¶¶ 384, 393. Therefore, the Court concludes that, based upon its actions, WARF is estopped from asserting its statute of limitations defense. *Washington Univ.*, 703 F. App'x at 109.

3. Periodic Payment Exception

At summary judgment, this Court held that Wisconsin's periodic payment exception does not apply to the case at bar. (D.I. 130 at 14.) When the Third Circuit reversed the grant of summary judgment, it spoke as to the periodic payment exception, but only in terms of findings of fact with respect to a duty to revalue. *Washington Univ.*, 703 F. App'x at 109.

At present, WashU argues that it may recover damages dating to July 1, 2006 based upon well settled Wisconsin law that each annual payment gives rise to a new duty that is breached by an improper valuation of the '815 patent. (D.I. 175 at ¶ 291 at 133–134.) WashU argues in the alternative that the Third Circuit's direction for findings of fact related to a duty to revalue as a "prerequisite for applying Wisconsin's periodic payment doctrine[,]" misreads Wisconsin law but that, nonetheless, WashU has shown that WARF has a duty to revalue. (*Id.*) WARF contends that the periodic payment exception does not apply, because there is no duty to revalue in the IIA, and under

Wisconsin law, it would require a duty to revalue, because there was only one alleged breach of the IIA in 1998. (D.I. 178 at ¶ 9 at 49–¶ 27 at 56.)

(a) Legal Standard

Contract claims are ordinarily subject to a six-year statute of limitations period in Wisconsin. Wis. Stat. § 893.43 (2016). Under Wisconsin law, however, where a party has an obligation to make "periodic payments" under a contract, a new claim for breach of contract arises upon each improper periodic payment, triggering a new six-year limitations period from the date of each periodic payment. *See Washington Univ.*, 703 F. App'x at 108 ("[G]enerally a new claim accrues for each separate breach . . . [, and] the injured party may assert a claim for damages from the date of the first breach within the period of limitation.") (quoting *Noonan v. Nw. Mut. Life Ins. Co.*, 687 N.W.2d 254, 262 (Wis. Ct. App. 2004)).

(b) Discussion

The gravamen of the dispute between the parties is over the nature of Wisconsin law. WARF contends that "[f]or WashU to succeed on a 'periodic payment' excuse, it would have to show that WARF was required by the 1995 IIA to *recalculate* the relative value of the '815 patent every year in order for there to be an alleged underpayment." (D.I. 178 at ¶ 18 at 54 (emphasis in original).) Essentially, WARF argues that there was a single total breach in 1998 stemming "from a purportedly erroneous calculation[,]" but that is not subject to the rule. (*Id.* at ¶ 16 at 52 (citing *Messner Manor Assocs. v. Wisconsin Hous. & Econ. Dev. Auth.*, 555 N.W.2d 156, 159–60 (Wis. Ct. App. 1996)).) The Court concludes that the periodic payment exception applies here, and WashU may recover damages beginning July 1, 2006.

(i) The Payment Exception Applies Regardless of a Duty to Revalue

WARF's argument is based upon a single case in which the parties agreed to an interest rate in a mortgage contract, and plaintiff discovered some twelve years later that it was paying a higher interest rate than it expected but not higher than that in the mortgage. *Messner Manor*, 555 N.W.2d at 159-60. In *Messner Manor* the Wisconsin Court of Appeals concluded that there was no breach of the contract in the first place and held the claim to be time-barred. *Id.* at 160 ("We conclude that the parties agreed to the 6.75% figure, whether or not it was calculated correctly, and that payments of the note at that rate did not constitute breaches of the agreement.").

Messner Manor is inapposite—the parties did not agree to a relative value of the '815 patent in 1995, nor did they agree in 1998. Rather, the only agreement is that WashU granted WARF the authority to assign a relative value to the '815 patent. (JX-001, § 3.A.(iii).) Meanwhile, WashU contends that the breach arose from a failure to properly assign a relative value to the '815 patent in 1998. (D.I. 175 at ¶ 291 at 133–134.) And the "relative value" is only one component of a much larger annual calculation that the IIA requires WARF to perform. *See supra* Section III.B.7(c). For example, as WARF's damages expert acknowledged, the IIA required WARF to calculate the amounts to remit to WashU by taking "the top line revenue from Abbott," "look[ing] at what relative value it has allocated to Washington University," and "us[ing] that as one of the inputs to the calculation." (Tr. at 1105:3–23 (Ms. Mulhern).)

As multiple decisions from Wisconsin courts dating back over 136 years make clear, the periodic payment exception applies when an improper periodic (e.g., annual) payment traces back to a single event outside the limitations period. For example, in *Butler v. Kirby*, 10 N.W. 373, 374–75 (Wis. 1881), an employee's claims for underpayments within six years before filing suit were timely even though each underpayment traced back to an earlier dispute over whether the monthly salary was

$40 or $48. In *Jensen v. Janesville Sand & Gravel Co.*, 415 N.W.2d 559, 562 (Wis. Ct. App. 1987), claims beginning six years before suit were timely even though the breaches were based on the company's earlier decision to repudiate the contract. According to the Wisconsin Court of Appeals, the same was true in *Noonan*, 687 N.W.2d at 262, even though all underpayments traced back to the defendant's decision to change the way it calculated annuity payments, which occurred before the six-year limitations period. And in *Policemen's Annuity & Ben. Fund, City of Milwaukee v. City of Milwaukee*, 630 N.W.2d 236, 242 (Wis. Ct. App. 2001) the same result obtained even though all payments were calculated based on the same formula beginning thirty years before suit was filed.[143] Based upon this case law, the Court concludes that the periodic payment exception applies to the case at bar.

(ii) The IIA Required WARF to Revalue the '815 Patent Annually

In addition to the reasons discussed above, the Relative Value Clause of the IIA required WARF to revalue the '815 patent on an annual basis, *at a minimum*, to account for changes to the patent portfolio over the course of the year as well as in response to specific requests and to avoid injustice. *See supra* Section III.B.7(c). WARF conceded that the annual payment exception applies if there is a duty to revalue in the IIA. (*Cf.* D.I. 178 at ¶ 18 at 54 (arguing that "[f]or WashU to succeed on a 'periodic payment' excuse, it would have to show that WARF was required by the [] IIA to recalculate the

[143] *See Jahn Transfer, Inc. v. Horizon (H&S) Freightways, Inc.*, No. 2011AP1560, 2012 WL 2135503, at *4–*7 (Wis. Ct. App. Jun. 14, 2012) ("*Messner Manor* contains no meaningful discussion of the application of the contract statute of limitations to an arguably ongoing series of individual breaches relating to the same agreement."); *see also Md. Staffing Servs., Inc. v. Manpower, Inc.*, 936 F. Supp. 1494, 1508 (E.D. Wis. 1996) ("[B]ecause the complaint alleges a series of breaches of the contract, the plaintiffs may assert a claim for damages from the date of the first breach within the period of limitation[.]"); Restatement (Second) of Contracts § 243 cmt. c (1981) ("It is well established that if those duties of the party in breach at the time of the breach are simply to pay money in installments, not related to one another in some way, . . . then a breach as to any number less than the whole of such installments gives rise to a claim merely for damages for partial breach.").

relative value of the '815 patent[.]").) Therefore, as an alternate ground, the periodic payment exception also applies for this reason.

(iii) Conclusion—Periodic Payment Exception

WARF breached the IIA each year it made annual royalty payments less than what was "due under this Agreement" to WashU. Under Wisconsin's periodic payment rule, each annual underpayment gave rise to a new claim for breach of contract, triggering a new six-year statute of limitations period on each claim. WashU may thus pursue any breach of contract claims based on any improper annual underpayments that WARF made on or after April 9, 2007, the date six years prior to the Standstill Agreement. (D.I. 175 at ¶ 173 at 79.) WARF's first annual underpayment after that date occurred on August 21, 2007, covering the royalty period from July 1, 2006 to June 30, 2007. (JX-030.) Therefore, under Wisconsin's periodic payment rule, WashU may assert breach of contract claims based on WARF's underpayments on and after April 9, 2007, which cover underpaid royalties dating back to July 1, 2006.

E. WARF's Defenses

1. Laches

WARF argues that WashU's claims are barred by laches, because it alleges that WashU knew in 2001 about the relative valuation of the '815 patent, but "WashU did not object or otherwise contest WARF's valuation until 2012[,]" thereby prejudicing WARF. (D.I. 178 at ¶ 86 at 75–¶ 88 at 76.) WashU disputes these claims and avers that WARF has failed to satisfy any of the elements of laches. (D.I. 175 at ¶ 316 at 145–¶ 321 at 148.)

(a) Legal Standard

"Laches is an equitable doctrine whereby a party that delays making a claim may lose its right to assert that claim. Laches is distinct from a statute of limitations and may

be found where the statute of limitations has not yet run." *Zizzo v. Lakeside Steel & Mfg. Co.*, 752 N.W.2d 889, 892 (Wis. Ct. App. 2008).

"The three elements of laches . . . are (1) unreasonable delay by the party seeking relief, (2) lack of knowledge or acquiescence by the party asserting laches that a claim for relief was forthcoming, and (3) prejudice to the party asserting laches caused by the delay." *Id.* at 893 (citation omitted); *see also Schneider Fuel & Supply Co. v. W. Allis State Bank*, 236 N.W.2d 266, 272 (Wis. 1975).

(b) Discussion

WARF's entire laches defense comes down to a single assertion. WARF alleges that "WashU admits that it received no more information from WARF prior to filing this suit in 2013 than it received in 2001." (D.I. 178 at ¶ 86 at 75–76 (citing *id.* at ¶ 116 at 36).) In essence, WARF implies that, based on the fact that WashU did not receive any more "information from WARF" between 2001 and 2013, that WashU must have had all the information they needed to file suit in 2001, and, therefore, the delay in filing suit was unreasonable. (*Id.*) This statement implies that the sole source of information was WARF.

Paragraph 116 of WARF's proposed Findings of Fact states things a little differently, proposing that the Court find that "WashU admitted that it filed suit in 2013 based on the same information about WARF's valuation of the '815 patent that it had in 2001." (*Id.* at ¶ 116 at 36 (citing Tr. at 433:9-15 (Mr. Surber); JX-337 at 12-13).) In this statement WARF does not identify the source of the information. Moreover, WARF proposed that "[t]he only change in circumstance was Abbott's late listing of the '815 patent in the Orange Book and that patent's assertion in litigation, which was unforeseeable and not within WARF's control." (*Id.* (citing Tr. at 433:9-15 (Mr. Surber).) In fact, Mr. Surber did not testify about whether the listing of the '815 patent in the

Orange Book was "unforeseeable" and "not within WARF's control." Rather, the exchange was as follows:

> Question. What did you learn in 2012 that Washington University didn't know in 2001?
>
> Answer. We by then knew that the '815 patent had been added to the Orange Book. We, by that time knew that this patent was being asserted in paragraph four of the litigation against these drug companies.

(Tr. at 433:9–15.)

As discussed above, the listing of the '815 patent, which WARF knew about and agreed to, meant that Abbott represented to the FDA that the '815 patent covered paricalcitol/Zemplar's approved use. *See supra* ¶¶ 405–412. Also, WARF and Abbott (together) filed a number of lawsuits in this court, based upon the aforementioned Paragraph IV certifications, in which WARF and Abbott represented that Abbott was the exclusive licensee to the '815 patent. *See supra* ¶¶ 413–415; (*see, e.g.*, JX-058 at ¶¶ 1, 11 ("Abbott is the exclusive licensee of the '815 patent.").) Moreover, WARF knew in 1998 that the '815 patent would expire more than a year after the '497 patent and could confer additional, exclusive protection to paricalcitol/Zemplar at that time. *See supra* ¶¶ 338–342.

However, there is no evidence in the record that WARF shared this information with WashU until the instant litigation. All the evidence shows that WashU first learned that WARF and Abbott had asserted the '815 patent in litigation in September 2012, when it was subpoenaed in the *Hospira* litigation. (JX-363; JX-174); *see supra* ¶ 422. From this subpoena, WashU then learned of Abbott's exclusive license to the '815 patent, the listing of the '815 patent in the Orange Book, and the fact that WARF and Abbott believed that the '815 patent read on paricalcitol/Zemplar's approved use. None of this information was available to WashU prior to this point in time. *E.g.*, *supra* ¶¶ 378–394.

As a factual matter, for the reasons discussed herein and in its Findings of Fact above, the Court has already concluded that WashU did not have the information it needed to pursue its claim in 2001. *See supra* ¶¶ 378–394. As such, the Court is unconvinced that WARF's contrary factual assertions have merit. WARF has failed to satisfy the first laches factor, unreasonable delay. Therefore, WARF has not met its burden to establish a laches defense.

2. Accord and Satisfaction

As discussed above, in its Answer, WARF asserts an accord and satisfaction defense. *See supra* Section I.A. WARF contends that "[it] enclosed a memo with each check, signifying that the check represented a *payment in full* for the annual shared royalties under the 1998 assigned relative value." (D.I. 178 at ¶ 103 at 80 (citing *id.* at ¶ 100 at 30–¶ 102 at 31, ¶ 104 at 31).) WashU contends that WARF waived this defense, because it failed to disclose it in an "on point" contention interrogatory during discovery. *Supra* Section I.A.

(a) Legal Standard

(i) Interrogatories

Pursuant to the Federal Rules of Civil Procedure, "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case[.]" Fed. R. Civ. P. 26(b)(1). To that end, a party may serve interrogatories on another party, and "[a]n interrogatory may relate to any matter that may be inquired into under Rule 26(b)." Fed. R. Civ. P. 33(a)(2). Parties must either object to an interrogatory or answer it "separately and fully in writing under oath." Fed. R. Civ. P. 33(b)(3).

(ii) Accord and Satisfaction

"An 'accord and satisfaction' is an agreement to discharge an existing disputed claim . . . [and] constitutes a defense to an action to enforce the claim." *Hoffman v. Ralston Purina Co.*, 273 N.W.2d 214, 217 (Wis. 1979) (citation omitted). "There must be expressions sufficient to make the creditor understand or to make it unreasonable for him not to understand that the performance is offered in full satisfaction of the claim." *Id.*

The standard situation is when "a debtor offers a check to its creditor as full payment for a claim, and the creditor cashes that check," in which event the law "treat[s] the creditor as having accepted the debtor's offer to settle the debt for the amount of the check." *Schuetta v. Aurora Nat'l Life Assurance Co.*, 27 F. Supp. 3d 949, 955 (E.D. Wis. 2014) (citation omitted) (applying Wisconsin law). "This is, essentially, a contract: for there to be a valid accord and satisfaction, there must be an offer, acceptance, and consideration." *Id.*

(b) Discussion

WashU alleges that it:

> served [WARF with] a contention interrogatory on February 6, 2015, asking WARF to "[d]escribe in detail all facts and circumstances surrounding the bases for . . . each affirmative defense that WARF has asserted or will assert in its pleadings . . . ." WARF responded on March 12, 2015, subject to various objections, that "Defendant directs Plaintiff to its Motion to Dismiss and reply brief in support thereof." WARF's Motion to Dismiss and reply brief disclosed only a statute of limitations defense. It did not disclose an accord and satisfaction defense. (*See* D.I. 14 at 9-12, 14; D.I. 19 at 3-6, 8.)

(D.I. 154 at 10.) WARF responds that it filed its Answer according to this Court's scheduling order, (D.I. 144), and that the accord and satisfaction defense did not need to be disclosed until the Answer, (D.I. 178 at ¶ 106 at 81.)

On the record before the Court, WARF did not disclose its accord and satisfaction defense in response to WashU's interrogatory. Thus, it is apparent that WARF waived its accord and satisfaction defense when it failed to timely disclose it during discovery.[144] Fed. R. Civ. P. 37.

Alternatively, the defense fails on the merits. The evidence identified by WARF lacks all the hallmarks of an accord and satisfaction. The letters do not use the language "payment in full" or reflect that the individual payment had been part of a counteroffer to resolve a disputed contract. (*E.g.*, JX-022.) None of the letters discuss the "assigned relative value," that such a value had been assigned in 1998, or that the assigned relative value was 0.968%. (*E.g.*, JX-036.) And even after WashU filed the instant lawsuit, the language of the letters did not change, nor did these letters include any of the elements recommended by Wisconsin case law. (JX-037 (Sept. 2014); JX-038 (Aug. 2015); JX-485 (Aug. 2016); JX-486 (Aug. 2017).) Although the Court has concluded that WARF waived its accord and satisfaction defense, for the sake of completeness, the Court also concludes that WARF has failed to adequately raise or prove such a defense.

F. Motion to Strike

Mr. Thomas testified without objection at trial about the methodology and source materials he used to calculate WashU's damages. (Tr. at 564:19-571:1, 616:21-617:24 (Mr. Thomas); JX476A at 4-20.) WARF not only did not dispute Mr. Thomas's methodology or arithmetic at trial, but WARF's damages expert, Ms. Mulhern, relied on his methodology and source materials to present her own alternative damages calculations. (Tr. 1099:16-1102:9 (Ms. Mulhern).) During closing argument, the Court

[144] Because WARF filed a motion to dismiss in early 2014, (D.I. 12), which the Court took under submission and disposed of as moot at the summary judgment stage, (D.I. 130), WARF did not file an Answer identifying its affirmative defenses until more than two years after March 16, 2015, which was the close of fact discovery. (D.I. 145.)

asked WashU about an alternative calculation commencing on the date of Mr. Stoveken's October 14, 2008 email. (Tr. at 1149:19-21.) WashU stated that it would provide the alternative calculation during post-trial briefing using Mr. Thomas's "backup spreadsheet." (*Id.* at 1150:14-18.) WARF did not object to that exchange. (*Id*.) As promised, WashU submitted materials describing the arithmetic needed to calculate those damages using Mr. Thomas's methodology and source materials. (D.I. 166.) Mr. Thomas's declaration also contains relevant prejudgment interest calculations, (*id*. at ex. B), that WARF does not challenge or otherwise seek to strike in its motion.

Predictably, WARF moved to strike, (D.I. 168), this declaration, (D.I. 166), as an untimely expert report as well as paragraph 315 of WashU's proposed Findings of Fact and Conclusions of Law, (D.I. 175 at ¶ 315 at 145). WashU opposes the motion. (D.I. 179.) The motion was fully briefed on May 14, 2018. (D.I. 180.)

The motion is denied. The Court cannot discern any prejudice, surprise, or bad faith in the Thomas Declaration. The Court requested damages calculations from the dates discussed at trial so that the Court could work from one document, or set of documents, as opposed to calculating damages itself. There is no evidence in the record that, aside from the relevant dates of the calculated damages, these calculations differed fundamentally from those presented and discussed at trial. (*Compare* D.I. 166, ex. A, Schedule 11 at 1 of 2 (1/3 damages), *with* JX-476A, Schedule 4 at 1 of 2 (1/3 damages).)

G. Damages

With liability and the defenses resolved, the Court turns to damages.

1. WARF Owes WashU Damages

(a) Legal Standard

"The fundamental idea in allowing damages for breach of contract is to put the plaintiff in as good a position financially as he would have been in but for the breach.

Damages are the compensation which the law will award for an injury done." *Schubert v. Midwest Broad. Co.*, 85 N.W.2d 449, 452 (Wis. 1957). The measure of damages for a breach of contract is therefore the amount that will compensate the party for the loss suffered because of the breach. *Thorp Sales Corp. v. Gyuro Grading Co.*, 331 N.W.2d 342, 346 (Wis. 1983). The injured party is entitled to the benefit of his agreement, which is the net gain he or she would have realized from the contract but-for the failure of the other party to perform. *Id.*

(b) Discussion

WashU seeks damages from WARF based on the amounts WARF should have paid to WashU under a patent-specific relative value of the '815 patent. As discussed below, based upon the testimony of WashU's damages expert, Mr. Thomas, the Court concludes that there is sufficient evidence in the record to support a patent-specific relative value of the '815 patent of 27.1% of the portfolio in the 1998 Abbott License.

The record shows that WARF grossly undervalued the '815 patent when it assigned it less than a 1% relative value and paid millions and millions of dollars in royalties to dozens of inventors at the University of Madison-Wisconsin who made absolutely no contribution whatsoever to Zemplar, while Dr. Slatopolsky—whose seminal study led directly to the issuance of one of the most important patents licensed to Abbott—received only a fraction of the royalties as those other inventors. *See supra* ¶¶ 453–469.

WashU suffered damages as a result of WARF's misconduct and underpayment of royalties in breach of the IIA because the '815 patent was one of the most important patents in the 1998 Abbott License, and worth far more than the negligible 0.968% value that WARF allocated to it. (Tr. at 527:22–548:6 (Mr. Thomas); *supra* ¶¶ 453–469.) The '815 patent covered Zemplar's approved indication. (Tr. at 528:8–529:6 (Mr. Thomas); JX-042 at 1; JX-047 at 1; JX-050 at 1; JX-085 at ¶ 71.) Generic forms of

Zemplar infringed the ’815 patent. (Tr. at 528:8–529:6 (Mr. Thomas); JX-085 at ¶¶ 189–236.) Abbott and WARF asserted the ’815 patent in litigation to protect Zemplar’s exclusivity. (Tr. at 531:9–532:13 (Mr. Thomas); JX-058; JX-059; JX-060; JX-063; JX-064; JX-065; JX-066; JX-416.) The ’815 patent’s listing in the Orange Book gave rise to automatic 30-month stays in ANDA litigations involving the ’815 patent. (Tr. at 903:19–904:1 (Mr. Lentz); Tr. at 531:24–532:13 (Mr. Thomas); JX-415.) [redacted] And the ’815 patent is the longest-lived patent in the 1998 Abbott License to confer exclusivity over Zemplar. (Tr. at 545:9–546:15 (Mr. Thomas).)

WARF’s argument at trial that the ’815 patent did not confer “actual” exclusivity over Zemplar because WARF and Abbott entered into settlement agreements before any “actual” exclusivity took effect ignores that WARF and Abbott’s Hatch-Waxman litigations generated exclusivity in the form of an automatic 30-month stay, which WARF and Abbott traded for favorable terms in their settlement agreements with generics. (Tr. at 904:12–16 (Mr. Lentz).) As WARF’s pharmaceutical licensing expert acknowledged, the Hatch-Waxman scheme allows for “late listing” of patents. *See supra* ¶¶ 405–413; (Tr. at 906:10–16, 915:4–10 (Mr. Lentz).) WARF and Abbott’s “late listing” of the ’815 patent in the Orange Book allowed them to take advantage of an automatic 30-month stay against generic companies that filed Zemplar ANDAs after the date of listing. (Tr. at 902:5–16, 903:19–904:1, 906:10–16 (Mr. Lentz).) In the absence of a settlement agreement, the automatic 30-month stay would have continued in effect until either the stay expired or the patent expired. (Tr. at 902:17–903:13 (Mr. Lentz).)

The ’815 patent’s relative value goes beyond its exclusionary power. As an exclusively-licensed patent under the 1998 Abbott License that would have been infringed by Zemplar but for the 1998 Abbott License, the ’815 patent generated 7%

earned royalties on Abbott's sales of Zemplar under the "earned royalty" provision of the 1998 Abbott License. *See supra* ¶¶ 288–289; (JX-008 at 3; *see also* Tr. at 529:7–531:8, 541:23–545:8 (Mr. Thomas); JX-426 at 100:5–7, 105:7–17, 109:6–14 (Mr. Stoveken's Rule 30(b)(6) testimony); JX-085 at ¶ 1.) The FDA recognized the importance of Dr. Slatopolsky's '815 patent study during its medical review of Zemplar. (JX-052 at 6–7.) The '815 patent study also helped demonstrate Zemplar's superiority over Calcijex in treating patients with chronic kidney disease because the '815 patent taught how to administer Zemplar to treat chronic kidney disease while avoiding hyperphosphatemia. (JX-081 at ¶ 36; JX-082 at ¶¶ 15, 56–57; JX-083 at ¶¶ 63–64, 121; JX-085 at ¶¶ 254, 328–34; JX-087 at 1.) As WARF and Abbott's expert in the *Hospira* litigation, Dr. Vigil, recognized, the benefits and advantages associated with the '815 patented treatment method substantially contributed to Zemplar's commercial success and 30% price premium over Calcijex, precisely because of the '815 patent's disclosure (and claims) of a method of using paricalcitol while avoiding hyperphosphatemia. (Tr. at 532:14–541:17 (Mr. Thomas); JX-084 at ¶¶ 22, 28, 31–36, 40, 50; JX-087 at 1; JX-085 at ¶¶ 329–334.)

(c) Mr. Thomas's Economic Damages Models

Below, the Court evaluates Mr. Thomas's damages models, which offer relative values for the '815 patent in the 27-33% range.[145] All the damages models proposed by Mr. Thomas are net of the 15% administrative fee and WARF's two thirds share of the '815 patent as provided in the IIA.

[145] Mr. Thomas also discussed a relative valuation approach of assigning 29% relative value to the 29 Ancillary Patents, with 42% relative value allocated to the '497 patent and 29% relative value split equally between the '925 (14.5%) and '815 (14.5%) patents. This model has no factual support in the record; therefore, the Court declines to consider it.

(i) 33% Relative Valuation

As shown above, WARF breached the IIA by failing to assign a patent-specific relative value to the ’815 patent. If WARF had assigned such a relative value to the ’815 patent, it could have assigned it at least equal value to the ’497 and ’925 patents because the ’815 patent had certain attributes that made it as valuable, if not more valuable, as the ’497 and ’925 patents. (Tr. at 558:4–20 (Mr. Thomas).)

Significantly, only three patents in the Abbott portfolio—the ’497, ’925, and ’815 patents—generated “earned royalties” for WARF. *See supra* ¶¶ 288–289. WARF licensed all three on exclusive terms to Abbott in the 1998 License, (Tr. at 513:16–515:9 (Mr. Stoveken Rule 30(b)(6) testimony)); *see supra* ¶¶ 293–309. That means that all three patents equally supported Abbott’s obligation to pay “earned royalties” up to the full 7% royalty cap in the 1998 Abbott License, with the ’815 patent generating those royalties over a longer duration than either the ’497 and ’925 patents. *Supra* ¶¶ 288–289.

In addition, of all the patents in the portfolio, only the ’497 and ’925 patents shared similar value characteristics as the ’815 patent. *See supra* ¶¶ 453–469; (Tr. at 558:4–20 (Mr. Thomas).) Specifically, the ’815 patent:

- Contributed to FDA approval of Zemplar. *See supra* ¶ 337.
- Covered the only FDA approved indication of Zemplar. *See supra* ¶ 337.
- Was exclusively licensed to Abbott. *See supra* ¶¶ 293–309.
- Generated 7% earned royalties under the 1998 Abbott License. *See supra* ¶ 374.
- Was infringed by generic forms of Zemplar. (Tr. at 528:8–529:6 (Mr. Thomas); JX-085 at ¶¶ 189–236.)
- Was listable in the Orange Book for Zemplar. *See supra* ¶ 341 n.79.

- Was assertable in litigation to block generic competition. (*Id.*)
- [redacted]

Moreover, in comparison to the ’497 and ’925 patents, the ’815 patent expired about 1.55 years after the ’497 patent and about 3.24 years after the ’925 patent. *See supra* ¶¶ 20–21, 25.

Because the ’815, ’497, and ’925 patents were the only patents that directly read on the Zemplar compound or the approved use of Zemplar, generated 7% “earned royalties” under the 1998 Abbott License, were listed in the Orange Book, and were asserted in litigation as blocking patents against generic Zemplar—Mr. Thomas testified that, under one possible valuation, these three patents could receive an equal allocation of 33.3%. (Tr. at 558:4–20 (Mr. Thomas).)

(ii) 30% Relative Valuation

Mr. Thomas provided a calculation in which he assigned a 30% relative valuation to the ’815 patent and no value to the four ancillary patents discussed above. (Tr. at 563:17–564:6; *see also* JX-476A, Schedule 6.) The rationale for this valuation is that, other than the ’815, ’497, and ’925 patents, none of the other patents in the Abbott portfolio contributed substantial value to Zemplar. *See supra* ¶¶ 272–280. Six patents disclosed methods of using paricalcitol for which Zemplar had never been approved. *Id.* Eighteen Ancillary Patents had nothing to do with making 19-nor Vitamin D_2 compounds like Zemplar. *Id.* Another Ancillary Patent was entirely duplicative of the ’497 patent and served no purpose other than to dilute the ’815 patent’s royalty share. *Id.* Only four Ancillary Patents *potentially* related to methods of making Zemplar, but no evidence suggests that Abbott’s authorized manufacturing process relied on any of those

methods to make Zemplar. *Id.* None of WARF's fact or expert witnesses disputed WashU's showing that no Ancillary Patent, other than the '815 patent, contributed substantial value to Zemplar. *Id.* WARF's tech transfer expert, Dr. Severson, for example, admitted that he couldn't "identify any Ancillary Patents at all in the 1998 Abbott License that added substantial value to Zemplar." (Tr. at 1033:5–8 (Dr. Severson).)

Mr. Lentz's testimony that assigning no value to the Ancillary Patents would be "a bit harsh" because Abbott "may be using them, may not be" (Tr. at 827:4–18 (Mr. Lentz) ignores Dr. Cleare's unrebutted testimony that 25 Ancillary Patents had *no* potential to contribute to Zemplar. *See supra* ¶¶ 272–280. Only 4 Ancillary Patents *potentially* related to methods of making paricalcitol, but those patents would have been easy to design around, as Dr. DeLuca acknowledged. *Id.* WARF offered no evidence that those 4 Ancillary Patents contributed in any way to Zemplar or generated "earned royalties" under the 1998 Abbott License. *Id.* To the extent Mr. Lentz was suggesting that Abbott might one day obtain a new FDA-approved indication for Zemplar, WARF had a policy and practice of reallocating substantial value to ancillary treatment patents shown to cover a newly anticipated FDA-approved indication, as it did when it assigned 29% relative value to its multiple sclerosis ancillary patent in anticipation of multiple sclerosis revenue. (JX-010 at 3; JX-015 at 2, 15.)

(iii) 29% Relative Valuation

Mr. Thomas also testified that, based upon the Multiple Sclerosis IDM, WARF could have made an allocation of at least 29% value to the '815 patent. (Tr. at 556:6–558:3 (Mr. Thomas)); *see supra* ¶¶ 235–237. In the Multiple Sclerosis IDM, WARF allocated 42% relative value to the '497 compound patent, singled out the multiple sclerosis treatment patent from all the other Ancillary Patents to receive 29% of any royalties deriving from the multiple sclerosis field, and assigned the remaining 29%

to all other Ancillary Patents. (JX-015 at 2, 14–15.) In other words, WARF did not allocate equal value to all ancillary patents regardless of whether those patents were being used, but assigned substantial value to one ancillary patent that covered an anticipated new indication.

Because none of the other patents in the ancillary group generated substantial value for Zemplar, a patent-specific relative value allocation under the standards that WARF applied to its own ancillary patents would be a 42% relative value allocation to the ’497 patent, with an equal share of the remaining 58% to the two other Orange Book listed patents—the ’815 and ’925 patents—resulting in a 29% relative value allocation to the ’815 patent. (Tr. at 556:6–558:3 (Mr. Thomas).)

(iv) 27.1% Relative Valuation

Mr. Thomas discussed a relative valuation approach of assigning 4% relative value to the 4 Ancillary Patents relating to manufacturing processes that *potentially* related to Zemplar, but where no evidence suggested that Abbott used them or that they generated “earned royalties” under the 1998 Abbott License. (Tr. at 559:3–560:7 (Mr. Thomas).) No WARF witness explained why these 4 Ancillary Patents should receive any relative valuation allocation at all. Without any evidence showing that these 4 Ancillary Patents have value, allocating them any relative value would be unsupported and/or against the great weight of the evidence. In addition, assigning each of these 4 Ancillary Patents a 0.968% relative value likely overstates the value of those patents. These patents cover processes, syntheses, and intermediates, which are not eligible to be listed in the Orange Book. *See supra* ¶ 278.

Assuming 3.9% relative value were allocated to these patents, Mr. Thomas determined that the ’497 patent would receive 42% value and the remaining 54.1% value would be split equally between the ’925 patent (27.1%) and the ’815 patent (27.1%). (Tr. at 559:3–560:7 (Mr. Thomas).)

(v) A Proper Relative Valuation Is Between 29% and 33%

According to Mr. Thomas, the patent-specific relative value of the ’815 patent is, therefore, between 29% and 33% of the value of the Abbott portfolio, instead of the 0.968% value WARF assigned. A relative value allocation to the ’815 patent of between 29% and 33% translates to an effective royalty rate of between about 2.03% to 2.33% as a percentage of Zemplar’s sales. (Tr. at 1120:12–23 (Ms. Mulhern).) These rates are well supported in light of evidence of the bargained-for rate that Abbott paid for an exclusive license to the ’815 patent, which equaled either: (1) 7%, assuming the truth of WARF’s Rule 30(b)(6) deposition that WARF licensed the ’815 patent exclusively to Abbott under the terms of the 1998 Abbott License (Tr. at 489:4–9, 514:12–18 (Mr. Stoveken)); or (2) 5.6%, applying WARF’s damages expert’s calculation of the bargained-for rate on a blended basis, assuming that WARF’s license to the ’815 patent became exclusive for the first time in 2012. (Tr. at 1124:5–10 (Ms. Mulhern).)

(d) Ms. Mulhern’s Economic Damages Model

WARF’s economic damages expert, Ms. Mulhern, presented a model based in retrospect. Ms. Mulhern’s analysis showed that the ’815 patent contributed $4.1 million in additional royalties at the end of the life of the portfolio. According to Ms. Mulhern, before March 2015, the ’815 patent generated nothing in additional royalties because of the seven percent cap on Abbott’s royalty payments and the dominance of the ’497 compound patent. (Tr.at 1076:14–1077:6 (Ms. Mulhern).) Ms. Mulhern testified that, after March 2015, Abbott paid a 7% royalty on the ’815 patent in the United States and Spain and 5% in other countries, (Tr.at 1077:16–1084:18 (Ms. Mulhern); JX-163; JX-165; JX-168; JX-490), but by then, Zemplar sales had diminished because of generic competition.

For this reason, Ms. Mulhern expressed the opinion that the amount of royalties WashU had received over a period of 18 years was about the same as its share of

incremental income from the ’815 patent. (Tr.at 1097:5–16 (Ms. Mulhern).) Based upon this royalty income, Ms. Mulhern testified that the present value of actual payments to WashU was about $1.5 million. (Tr.at 1095:8–1096:13 (Ms. Mulhern); JX-511A; JX-512A.) According to Ms. Mulhern, WashU’s share of incremental income was $1.2 million, or slightly less than what WashU had actually received. (Tr.at 1088:3–1092:16 (Ms. Mulhern); JX-509A; JX-510A.)

(e) Conclusion

After arguing extensively that WashU was engaging in hindsight, WARF presented a retrospective damages analysis that provided little helpful insight to the Court. Ms. Mulhern explained that her incremental value model validates WARF’s Blended Approach, (Tr.at 1096:14–1097:16), but the Court construes the IIA to require a *patent-specific* relative value, *see supra* Section III.B.7(b), not one that simply applies equal value to all patents obtained by the researchers in Dr. DeLuca’s laboratory. Therefore, it is unreasonable to apply a damages model that applies the Blended Approach to damages.

In light of Ms. Mulhern’s opinions, the Court finds Mr. Thomas to provide far better insight into the type of patent-specific relative valuation that WARF could have applied in 1998, based upon what was known to it at the time.

Given the roughly equal values of the ’925 and ’815 patents as method of use patents, the Court is comfortable with a valuation that assigns these patents equal relative value. As virtually every expert testified, the ’497 compound patent should receive more than the method of treatment patents. To this end, 42% is greater than the ’497 patent received under the 35% valuation WARF gave it in 1998.

Of the ancillary group in the 1998 License, Dr. Cleare identified four patents that *may* have some relation to the manufacture of paricalcitol. Dr. Cleare’s testimony about the ancillary group was unrebutted by any of WARF’s experts; therefore, the Court had

no testimony supporting anything other than a low value for these four patents in the ancillary group. Applying the 0.968% valuation to each of these four patents, which is the same value these patents received from WARF in 1998, equals 3.872% relative valuation. Applying an equal value to the remaining '815 and '925 method of treatment patents yields 27.1% to each of those patents. Thus, the Court finds Mr. Thomas's 27.1% relative valuation for the '815 patent to most closely match the patent-specific relative value that WARF could have applied in 1998,[146] based upon what was known to WARF at the time. *See supra* ¶¶ 335–343.

For the above reasons, following Mr. Thomas's calculations for a 27.1% relative valuation of the '815 patent beginning in 1998, the Court awards damages to Washington University in the amount of $31,617,498.[147][148] (JX-476A, Schedule 9 at 1 of 2.)

2. WashU Also Seeks Prejudgment Interest

WashU also seeks any further and additional relief as this Court may deem just and proper, including prejudgment and postjudgment interest.

(a) Legal Standard

Wisconsin law recognizes the availability of prejudgment interest in breach of contract cases to fully compensate the injured party.[149] "The general rule is that

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[146] WARF argued that "WashU's damages are based on hindsight and assume that WARF would have known in 1998 about certain facts and circumstances of the '815 patent that didn't happen until 2011 and 2012." (D.I. 178 at ¶ 146 at 43.) Given the specific findings of fact that the Court has made, it disagrees with this contention. *See supra* ¶¶ 335–343.

[147] Under the periodic payment exception, damages at the 27.1% relative valuation would be $21,125,575. (D.I. 175 at ¶ 302 at 138.) However, the court finds that damages accrue from 1998.

[148] The damages award of $31,617,498 to WashU is based on "Income" attributable to the '815 patent in the amount of $115,735,126, from which the 15% administrative fee of $17,360,269 to WARF has been subtracted. (JX-476A at Page 1 of 2.) From this amount, WARF receives two thirds, or $65,586,518. (*Id.*) Thus, after expenses, WARF's share of income plus the administrative fee is $82,766,369. (*Id.* at Page 2 of 2.)

[149] In Wisconsin, prejudgment interest accrues at a rate of five percent. Wis. Stat. § 138.04 (2017).

prejudgment interest may be recovered only when damages are either liquidated or liquidable, that is, there is a reasonably certain standard of measurement by the correct application of which one can ascertain the amount he or she owes." *Teff v. Unity Health Plans Ins. Corp.*, 666 N.W.2d 38, 53 (Wis. Ct. App. 2003). The rationale for this rule is that "if the amount of damages is either liquidated or determinable by reference to some objective standard, the defendant can avoid the accrual of interest by simply tendering to the plaintiff a sum equal to the amount of damages." *Id.*

(b) Discussion

WARF has argued that prejudgment interest cannot be ascertained with reasonable certainty where a contract is ambiguous and genuine disputes exist over how to interpret a contractual provision relating to the determination of damages. (D.I. 178 at ¶ 94 at 78–¶ 99 at 79.) To be sure, WARF has argued elsewhere that the contract is *not* ambiguous, *supra* Section III.B.2, and there is no identified provision within the IIA discussing damages, so there is no dispute over such a provision. Moreover, WARF's conclusory argument does not identify a single factual issue that would prevent the Court from determining damages with reasonable certainty. (D.I. 178 at ¶ 94 at 78–¶ 99 at 79.) As such, the "dispute over the proper method under the contract for determining the amount of reconciliation payments [does] not require the resolution of factual issues." *Teff*, 666 N.W.2d at 53–54; *see also Giffen v. Tigerton Lumber Co.*, 132 N.W.2d 572, 575 (Wis. 1965) ("Mere difference of opinion as to amount [owed] is, however, no more a reason to excuse him from interest than [a] difference of opinion whether he legally ought to pay at all, which has never been held an excuse.").[150]

[150] WARF's cited cases are inapposite. In *Loehrke*, unlike this case, there was a "real dispute as to which of the extra charges were necessary and properly authorized." *Loehrke v. Wanta Builders, Inc.*, 445 N.W.2d 717, 722 (Wis. Ct. App. 1989). Here, WARF does not generally dispute WashU's method of calculating damages, and WARF's repudiation of its prior admissions about the '815 patent's value do not give rise to a genuine dispute over some measure of damages. Similarly, in *Jones v. Jenkins*, 277 N.W.2d 815, 820 (Wis. 1979), the court denied prejudgment interest because damages under the

In the instant case, WashU's damages are determinable by "reference to some objective standard"—namely, WARF's relative valuation methods as applied to patents similarly situated to the '815 patent. Had WARF applied its own written policy when assigning value to the '815 patent in 1998, it would have taken into consideration the objective value attributes of the '815 patent, comparing them to the same objective attributes of the other patents in the Abbott portfolio. Such an analysis should have yielded a reasonable range of patent-specific relative values between 27.1% and 33%. Notwithstanding such a rational result, it cannot be said that this reasonable standard of measurement or the correct application of which one was sufficiently certain to ascertain the amount owed before this lengthy opinion.

(c) Conclusion

Prejudgment interest is not appropriate.

IV. CONCLUSION

For the foregoing reasons, the Court has construed the relevant contract terms and concludes that, based upon WARF's own admissions, WARF breached the 1995 Inter-Institutional Agreement in 1998 when it: (1) used the so-called "Blended Approach" to assign equal values to the '815 patent and the other patents in the "Ancillary Patents" group of the 1998 WARF-Abbott License, and (2) did not assign a patent-specific relative value to the '815 patent. Based upon the information known to WARF in 1998 when it breached the IIA, the Court awards Washington University damages of $31,617,498.

WARF's statute of limitations defense does not apply, because WARF is equitably estopped from asserting it. Alternatively, Wisconsin's periodic payment

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contract "did not have to be paid until the assets had been distributed, an event which had not occurred as of the time of trial" in that case. By contrast, in the case at bar, WARF breached the IIA each year it underpaid WashU royalties due under a patent-specific relative valuation of the '815 patent, which are events that occurred in the past, although the amount of underpayment was unresolved until this order.

exception applies. WARF's laches defense does not apply. And WARF waived its accord and satisfaction defense by failing to respond to WashU's contention interrogatory on the subject. WARF's motion to strike is also denied.

Because this Opinion may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Opinion. Any such redacted version shall be submitted no later than December 10, 2018 for review by the Court, along with a motion for redaction that includes a clear, factually-detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Opinion.

An appropriate order shall issue.

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