IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF WISCONSIN

THIRD WAVE TECHNOLOGIES, INC.,

OPINION AND ORDER

Plaintiff,

04-C-0680-C

v.

STRATAGENE CORPORATION,

Defendant.

This is a patent infringement case involving two patents owned by plaintiff Third Wave Technologies, Inc. that disclose a means for cleaving nucleic acids in a manner that results in the release of distinctive, detectable non-target cleavage products from which scientists can identify genetic information useful for research and for medical diagnostics. In September, a jury found that defendant Stratagene had willfully infringed the patents in issue directly, by inducement and contributorily and that plaintiff was entitled to an award of damages of \$5,290,000 plus royalties. The jury found also that defendant had failed to prove its claims that the patents at issue were invalid for lack of an adequate written description, for lack of enablement or as anticipated by prior art. A permanent injunction was entered on September 27, 2005. Pending resolution of defendant's appeal, I stayed one

provision of that order requiring defendant to destroy its existing inventory of accused products.

The case is before the court on post-trial motions. Defendant is seeking judgment as a matter of law, or, in the alternative, a new trial on both liability and damages or a remittitur. Plaintiff is seeking enhanced damages and attorney fees. I conclude that the court's alleged errors do not require a new trial, that defendant has failed to show that the jury erred in its determination of liability and damages or that it lacked sufficient evidence to support its verdict. I conclude also that plaintiff is entitled to trebled damages because of defendant's willful and knowing infringement and to attorney fees because of defendant's conduct in this litigation.

I. THE PATENTS AT ISSUE

Plaintiff's U.S. Patent No. 6,090,543, "Cleavage of Nucleic Acids," issued on July 18, 2000. Plaintiff's U.S. Patent No. 6,348,314, "Invasive Cleavage of Nucleic Acid," issued on February 19, 2002. The '543 patent issued from an application filed as a third continuation-in-part in a chain of applications and continuations-in-part that began with an application filed on January 24, 1996 and was a division of an application filed on December 2, 1996. The '314 patent issued from a division of an application filed on November 29, 1996 that was also a third continuation-in-part in a chain of applications, the earliest of

which was the same application filed on January 24, 1996 that led to the issuance of the '543 patent and which issued in December 1998 as U.S. Patent No. 5,486,717.

Both the '543 and the '314 patents are directed to the detection and characterization of nucleic acid sequences in DNA and variations in those sequences. Both relate to methods for cleaving a nucleic acid cleavage structure formed on a target sequence of DNA, causing the release of distinct, detectable non-target cleavage products that signify the existence of the particular base sequence in the target strand. Both patents disclose a method in which the structure-specific nuclease activity of an enzyme is used to cleave a target-dependent cleavage structure. The inventive disclosure is the recognition that when scientists mix a source of target nucleic acid with a cleavage means and two oligonucleotides, the oligonucleotides will anneal to the target nucleic acid and form a cleavage structure, in response to which the cleavage means will cleave a nucleic acid molecule. '543 pat., col. 6, ln. 65-col. 7, ln. 19; '314 pat., col. 6, ln. 66-col. 7, ln. 20. (The difference between the '543 and the '314 patents is in the nature of the cleavage structure: the '543 patent claims a three region structure; the '314 patent claims a two region structure.)

The cleavage means is a "structure-specific nuclease." As the inventors explain in the specifications, the means may be one of a number of enzymes that have cutting or nuclease ability, including but not limited to "native DNAPs having 5' nuclease activity (e.g., *Taq*DNA polymerase, *E.coli* DNA polymerase I) and, more specifically, modified DNAPs

having 5' nuclease but lacking synthetic activity." '543 pat., col. 20, lns. 58-61; '314 pat., col. 18. lns. 9-12. "The ability of 5' nucleases to cleave naturally occurring structures in nucleic acid templates (structure-specific cleavage) is useful to detect internal sequence differences in nucleic acids without prior knowlege of the specific sequence of the nucleic acid." '543 pat., col. 20, lns. 61-65; '314 pat., col. 18, lns. 12-16.

Plaintiff contends that defendant has infringed the claims of its '543 and '314 patents by making and selling two FullVelocityTM products: the QPCR Master Mix and the QRT-PCR Master Mix, both of which are designed and used for the probe-based detection of target nucleic acid molecules. Both products contain reagents used for polymerase chain reaction amplification and probe-based detection of a target nucleic acid. Both include a buffer, a reference dye and an enzyme formulation comprising two enzymes: a DNA polymerase and a flap endonuclease. This enzyme formulation possesses cleavage activity and can cleave a probe. Defendant's products use the V93R Pfu Exo-DNA as a polymerase to extend oligonucleotides. The Pfu polymerase extends a primer along a target strand by adding bases complementary to the target to the 3' end of the primer. (Each strand of DNA has two ends: a 5' end and a 3' end; the 3' end of one nucleotide connects to the 5' end of the adjoining nucleotide.) While the Pfu polymerase is extending the primer, it is bound to both the target nucleic acid and to the 3' end of the primer. The front end of the Pfu polymerase arrives at a nucleotide on the complementary strand before the portion of the

polymerase that adds nucleotides. When it encounters a downstream hybridized oligonucleotide, it will extend the primer so that the 3' end of the extended primer displaces the downstream oligonucleotide, creating an overlap structure.

The FullVelocity^m products contain the endonuclease Pfu FEN-1, which is a thermostable and structure-specific nuclease having 5' nuclease activity (meaning that it cuts primers at their 5' ends) and which is capable of cleaving the cleavage structures created by the Pfu polymerase that are claimed in claim 16 of the '543 patent and in claim 1 of the '314 patent.

II. DEFENDANT'S MOTIONS FOR NEW TRIAL OR JUDGMENT AS A MATTER OF LAW

As the losing party, defendant Stratagene is entitled to judgment as a matter of law only if it can show that no legally sufficient evidentiary basis supports the verdict, Fed. R. Civ. P. 50(a), or, stated another way, if no reasonable jury could have found in favor of plaintiff, taking into consideration all of the record evidence and drawing all reasonable inferences in plaintiff's favor. Applebaum v. Milwaukee Metropolitan Sewerage District, 340 F.3d 573, 578-79 (7th Cir. 2003). Defendant is entitled to a new trial under Fed. R. Civ. P. 59(a) only if it can establish that the "'verdict is against the weight of evidence, the damages are excessive, or if for other reasons, the trial was not fair to the moving party."

Westchester Fire Ins. Co. v. General Star Indemnity Co., 183 F.3d 578, 582 (7th Cir. 1999) (quoting Winger v. Winger, 82 F.3d 140, 143 (7th Cir. 1996)). See also Mentor H/S, Inc. v. Medical Device Alliance, Inc., 244 F.3d 1365, 1374 (Fed. Cir. 2001).

Although it should go without saying, I will add that a party cannot obtain judgment as a matter of law or the grant of a new trial in reliance on evidence that was never admitted at trial, on the repudiation of positions it adopted before and during trial, on the mischaracterization of trial testimony and events occurring during trial, on issues never raised until the filing of the post-trial motions or on arguments forfeited before or during trial.

A. Motion for New Trial on Evidentiary Grounds

1. Disallowance of defendant's request to challenge plaintiff's expert under Daubert

Defendant begins by asserting that a new trial should be ordered because the court "failed to act as a gatekeeper of the key expert witness of plaintiff." Def.'s Mem., dkt. #173, at 1. Defendant contends that it was denied the opportunity to test the qualifications of plaintiff's expert witness, John Tainer, before he testified, even though its "counsel inquired as to the Court's preference for conducting a voir dire examination of Tainer's expert qualifications" immediately before Tainer's direct testimony. <u>Id.</u> In making this assertion, defendant omits the critical fact that it had ample opportunity before trial to bring a

challenge to Tainer's qualifications under <u>Daubert v. Merrell Dow Pharmaceuticals, Inc.</u>, 509 U.S. 579, 589 (1993), but never took advantage of that opportunity.

Defendant argues that it was never told in so many words that any <u>Daubert</u> challenge would have to be made before trial was underway. This argument is disingenuous at best. As counsel is well aware, the court made extensive efforts to streamline the trial for the jury by addressing all of the areas of controversy in advance of trial. Defendant cannot say it did not know of the deadline for filing motions in limine or that the purpose of such motions was to determine what evidence would be allowed at trial; its counsel filed three such motions directed to the preclusion of evidence other than Tainer's testimony and it opposed plaintiff's motion to disqualify defendant's expert.

Having failed to raise a <u>Daubert</u> challenge to Tainer's testimony at the proper time, defendant forfeited its right to try to show that Tainer was not qualified to testify at all or on specific topics, but it was not without recourse. It had the opportunity to cross-examine Tainer about his credentials and his knowledge of the science underlying the patents in issue, which it did at length. (Defendant's cross and re-cross of Tainer take up 220 pages of transcript.)

Defendant objects not only to the ruling that any <u>Daubert</u> challenge had been forfeited but to the ruling I made that the jury would determine whether Tainer was an expert witness rather than the court's deciding the point. It is not the court's role to

"anoint" a witness as an expert; it is the jury's job to decide whether any proposed witness has the expert qualifications that will assist it in reaching its verdict. Although defendant argues that it was plaintiff's responsibility to "prequalify" Tainer, once defendant forfeited its right to show that his testimony was of a sort that the jury should not hear, Tainer was prequalified by default.

In any event, any challenge to Tainer's credentials would have been an exercise in futility. Tainer is an expert in nucleic acid enzymes and the behavior of polymerases. Not only does he serve as full professor at Scripps Research Institute's Department of Molecular Biology, he has served as the head of the National Science Foundation's Center for Computation and Macromolecular Structure. He built Lawrence Berkeley National Laboratory's facility for Structurally Integrated Biology for Life Sciences, which he designed to study molecules that recognize and interact with DNA such as polymerases and FEN-1 enzymes; he has grants from the National Institute of Health and the National Cancer Institute to research the FEN-1 enzyme as well as enzymes that interact with nucleic acids, AP endonucleases (enzymes that repair damaged DNA) and an enzyme that cuts DNA as part of a repair process. He headed one of the first laboratories to make and express three of the archeal FEN-1 enzymes, one of which is *Pfu*, an enzyme on which he has published papers and which is of particular significance to the issues in this case.

In a footnote, defendant seems to be trying to re-argue that the court erred in

disallowing some of the testimony of defendant's expert, Joseph Falkinham. In its reply brief, defendant denies that it had this intent, saying that it merely wanted to show the court that allowing Tainer to testify after restricting Falkinham's testimony compounded the initial error of disallowing defendant's challenge to Tainer. Whether it was error to allow Tainer to testify is one question; whether it was error to restrict Falkinham's testimony is a separate and independent one. If defendant is trying to re-argue Falkinham's credentials, it is wasting its time; nothing that Falkinham said during trial convinced me that it was error to restrict him from testifying about the FEN-1 nuclease.

2. Use of summary judgment opinion at trial

Defendant makes a peculiar argument about the use of the court's summary judgment opinion at trial. Without acknowledging that its counsel made the suggestion that the lawyers put certain facts from the court's opinion into the notebooks given to the jurors at the start of trial, it asserts that the court committed clear error by allowing plaintiff to provide the opinion and order to the jury. A person unfamiliar with the trial who read defendant's briefs on this point might think that the entire summary judgment opinion was given to the jury to read, which is not the case. The jury saw only the portions of the prior opinion and order that were the subject of agreement between the parties or were facts that defendant had not put into dispute during briefing on the summary judgment motion.

Defendant argues that the order was unfairly prejudicial because it contained the court's characterizations of defendant's arguments such as "defendant relies on carefully crafted conjecture," or defendant's "evidence is insufficient to support such an argument." Defendant might have a valid argument if the record supported its assertion that the jury had seen those characterizations, but it cites no instance in which the jury heard or saw the portions of the summary judgment order to which it objects.

Defendant asserts that plaintiff's counsel went beyond the court's order in his closing argument. Trial transcript (hereafter Tr.), dkt. #185, at 1473, lns. 21-24. A review of that portion of the transcript shows both that counsel made no objection to counsel's argument at the time *and* that counsel's references were to facts found by the court to be undisputed in the summary judgment order and thus well within the court's trial directive. Defendant cites two other instances of allegedly improper use at Tr., dkt. #180, at 353, ln. 9, and 354, ln. 20. In each instance, a review of the cited pages shows that plaintiff's counsel referred only to facts in the opinion that defendant had not put into dispute.

3. Precluding testimony by defendant's general counsel

At trial, defendant was barred from adducing evidence from its general counsel, Ronni Sherman, about her lack of knowledge regarding the patents-in-suit on the ground that defendant's witnesses had claimed attorney-client or work product privilege when asked

about their discussions with Sherman. Defendant contends that this ruling was erroneous. It does not deny that its chief executive officer, Joe Sorge, refused to answer questions about his conversations with Sherman concerning plaintiff's patents, on the ground that such conversations were privileged, Sorge Dep., dkt. #71, at 101, lns. 5-24-109, ln. 2 (objections to questions about discussions with Sherman), but makes the wholly unpersuasive argument that because Sorge testified at his deposition that the *first* time he discussed plaintiff's '543 patent with anyone was on the day plaintiff sued defendant, <u>id.</u> at 108, plaintiff knew all it needed to know about Sherman's actual knowledge of the patents-in-suit. If defendant's position were correct and a party were required to accept a deposition statement as true without having the opportunity to probe the answer, there would be little point in taking a deposition.

Defendant disagrees with plaintiff that plaintiff did not have a sufficient opportunity to question Nicolas Roelofs, a former employee of defendant, about his conversations with general counsel Sherman. A review of the transcript of the deposition supports plaintiff. Roelofs testified that he knew the general subject matter of plaintiff's '543 patent before December 21, 2001 and that he had had conversations with Sherman about "potential IP issues related to *Pfu* FEN." Roelofs Dep., dkt. #97, at 92, ln. 18-94, ln. 12. Defendant's counsel refused to allow Roelofs to testify at any more length about the conversations, so it was not possible for plaintiff to determine what patents Roelofs had discussed with Sherman.

If there was additional discovery that filled the void that defendant's counsel's objections created, defendant did not inform the court at the time the issue arose. It is not my practice to let a party introduce evidence at trial on a relevant topic that it has prevented its adversary from exploring during discovery. Defendant chose to stonewall plaintiff on the topic of Sherman's knowledge of plaintiff's patents. It has to live with the consequences.

4. Barring defendant from introducing evidence of the existence of its own patents

Defendant agreed during the damages phase of trial that it would not discuss its own patents if plaintiff would not pursue its contention that defendant's outside counsel knew about the patents in suit. Tr., dkt. #186, at 1711, ln. 16-1722, ln. 2. The parties proceeded on that understanding. Now defendant wants to repudiate its agreement, arguing that it should have been allowed to pursue the subject. It offers no reason for relieving it of the consequences of its own agreement and I can think of none.

B. Defendant's Motion for Judgment as a Matter of Law or New Trial - Liability

In support of its motion for judgment as a matter of law or a new trial on its liability for infringement, defendant begins with its defenses of invalidity under 35 U.S.C. § 112 for lack of a written description and enablement and under 35 U.S.C. § 102 for anticipation.

1. Invalidity of claims for lack of written description and enablement

35 U.S.C. § 112, ¶ 1, requires that the specification of every patent contain a written description of the invention "and of the manner and process of making and using it . . . as to enable any person skilled in the art" to make and use the same. This language has been interpreted to include two requirements: a written description and "enablement." The requirement of a written description is independent of the enablement requirement. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991) ("The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed.") See also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 736 (2002) ("What is claimed by the patent application must be the same as what is disclosed in the specification; otherwise the patent should not issue."). The enablement requirement is more straightforward. As the statute says, the specification of the patent must enable a person skilled in the art to make and use and claimed invention. <u>In re Wands</u>, 858 F.2d 731, 735 (Fed. Cir. 1988).

Defendant contends that because plaintiff claimed January 24, 1996, as the date of filing of the parent application (and an earlier date of conception of December 26, 1995),

the sufficiency of the disclosures of the patents must be judged solely on the basis of the disclosures in the January 1996 application, which, in defendant's opinion, do not meet the requirements of § 112, ¶ 1. Plaintiff takes issue with defendant's attempt to limit plaintiffs defense of the adequacy of its claims to what it included in its initial application. Citing Reiffin v. Microsoft Corp., 214 F.3d 1342, 1346 (Fed. Cir. 2000), plaintiff argues that the only effect of a successful attack upon the primacy of the 1996 application would be to deprive plaintiff of the advantages of the earlier filing date. Reiffin holds that "[C]laims to subject matter in a later-filed application not supported by an ancestor application in terms of § 112 ¶ 1 are not invalidated; they simply do not receive the benefit of the earlier application's filing date." Id. (citing Hyatt v. Boone, 146 F.3d 1348, 1352 (Fed. Cir. 1998)).

Defendant argues that the holding in <u>Reiffin</u> is unavailable to plaintiff because of the "binding" answers it gave to contention interrogatories defendant served on plaintiff during discovery. Although the interrogatory answers are not part of the court's record, it appears that, in response to an interrogatory asking about the date of conception for the inventions in the '543 and '314 patents, plaintiff stated that it was claiming December 26, 1995 as the date of conception and January 24, 1996 as the date of priority. Plaintiff's 30(b)(6) witness repeated this position during his deposition.

Defendant maintains that these representations blindsided it, leading it to believe that

application, but it is hard to understand how it can make this argument with a straight face. A party who brings a lawsuit for specific performance of a business contract might answer contention interrogatories to the effect that it has a signed contract with the defendant for widgets for \$.07 each. One would not expect the party propounding the interrogatories to treat such an answer as binding in the sense that it would not try to develop information to prove the contention wrong. Rather, one would expect the propounder of the interrogatories to make an effort to prove, for example, that the contract was amended by subsequent agreement of the parties or that the plaintiff is wrong about the price to which it agreed. Yet defendant is contending that once plaintiff claimed a conception and priority date determined by the January 1996 filing of its patent application, it had to prove that its application satisfied the statutory requirements of enablement and adequate written description and could not rely on its later-issued patents if the application was deficient in any respect.

If it is hard to understand defendant's "blindsiding" argument, it is even harder to understand why it wastes time raising such a weak argument. The logical conclusion to be drawn from its doing so is that it cannot counter plaintiff's assertion that establishing deficiencies in a plaintiff's original application does not invalidate the derivative patents, but means only that the plaintiff loses the advantages of the earlier filing date, Reiffin, 214 F.3d

at 1346. Therefore, it is forced to argue that the validity of the patents in issue rises or falls on the original application.

Defendant has a two-pronged argument about the adequacy of the written description. First, it argues that plaintiff has never described an invention either in the '543 or '314 patent or in the parent application "that included the use of a polymerase having polymerization function for the purpose of creating the oligonucleotides necessary for the invasive cleavage structure." Dft.'s Br., dkt. #168, at 11. This argument is not affected by the date of conception. If defendant is correct, it does not matter which date of conception plaintiff uses; its inventions fail the § 112, ¶ 1 requirements. Defendant's second argument is that plaintiff did not disclose in the January 24, 1996 application the two region embodiment claimed in the '314 patent. Defendant argues, without any reference to its argument that plaintiff can rely only on its original application for adequacy of description, that plaintiff must rely on the application filed on July 9, 1999 for the invention claiming the two region embodiment, which would make the '314 patent invalid as anticipated or obvious by prior art. However, the only prior art that defendant cites is the following: (1) Murante et al., "Calf 5' to 3' Exo/Endonuclease Must Slide from a 5' End of the Substrate to Perform Structure-specific Cleavage," J. Biol. Chem. 270:30377-83 (Dec. 22, 1995) and (2) Harrington et al., "DNA Structural Elements Required for FEN-1 Binding," J. Biol. Chem. 270:4503-08 (Mar. 3, 1995). Dft.'s Br., dkt. #168, at 17. Obviously, if the 1995

disclosures anticipated the claims in the '314 patent, they would have anticipated the application filed on January 24, 1996. (It is impossible to know whether the 1995 publications were anticipatory in fact because defendant never introduced either one into evidence or elicited evidence about them that would establish that they disclosed each and every element of the claims of the patent.)

In its reply brief, defendant asserts that plaintiff's unfair trial tactics (leading defendant to believe that it could rely on the conception date sworn to in the interrogatory answers) caused it to refrain from presenting prior art references that it would have introduced at trial or even investigating the possibility of prior art references post-dating January 24, 1996. It notes that a "cursory review" turned up two such references, apparently after the trial was over. Dft.'s Br., dkt. #198, at 9. Even if plaintiff's position on the date of conception was unfair and misleading, as defendant contends, defendant waived its opportunity to show that the patents at issue were anticipated or made obvious when it did not raise the argument in its opening brief. A party cannot bring up new matters in a reply brief to which its opponent has no opportunity to respond.

2. Merits of challenge to adequacy of written description and enablement

In concentrating its efforts on the adequacy of plaintiff's January 24, 1996 patent application, defendant failed to adduce any evidence at trial to show that the patents *as*

issued were deficient in their written description or enablement. On that basis alone, defendant's challenge can be denied. However, even if plaintiff is "bound" to the disclosures in its January 24, 1996 patent application, defendant presented no evidence at trial to show that the application does not meet the statutory requirements of enablement and written description.

The claims at issue require the practice of three steps: (1) providing the claimed reagents; (2) mixing the reagents to form the claimed cleavage structure and (3) detecting the cleavage of that cleavage structure. '543 pat., claim 1; '314 pat., claim 16. The January 1996 application describes ways of making oligonucleotides and forming the claimed cleavage structure: "The oligonucleotide may be generated in any manner, including chemical synthesis, DNA replication, reverse transcriptase, or a combination thereof." Dft.'s Trial Exh. #85, Tab 4 at 52. At trial, witnesses testified that polymerase chain reactions (PCR) were well known and commonly used in 1996. <u>E.g.</u>, Hall, Tr., dkt. #182, at 904, ln. 21-905, ln.10; Brow, Tr., dkt. #184, at 1235, ln. 15-1236, ln. 7. Defendant adduced no evidence to the contrary.

Defendant tried its best to confuse the jury by failing to differentiate between cleavage structures and cleavage means in its questioning. It added to the confusion by cross-examining witnesses in a way that suggested that the inventors had described polymerases with reduced synthetic activity but had failed to explain in their application

how the use of such polymerases could produce the cleavage structure described in the patents. As the inventors testified, however, the January 24, 1996 patent application discussed the use of polymerases with reduced synthetic activity in connection with the cleavage means; it did not discuss their use with the cleavage structure because the cleavage structure can be formed only by polymerases that have synthetic activity. It was not necessary to spell out in the patent application the specifics of DNA synthetic activity when it was well known in the field at the time. <u>In re Wands</u>, 858 at 735 ("A patent need not disclose what is well known in the art.") (citing Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1463 (1984)). It is telling that defendant cites Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361 (Fed. Cir. 1997), to support its position that the specification must enable the use and practice of the claimed invention. In fact, the case supports plaintiff's assertion that its obligation was only to disclose those aspects of its invention that persons skilled in the art would not have known. "It is the specification, not the knowledge of one skilled in the art, that must supply the *novel* aspects of an invention in order to constitute adequate enablement." Id. at 1366 (emphasis added).

Curiously enough, defendant never called any witness to testify that a person of ordinary skill in the art would be unable to understand the invention or to practice it. Without that evidence, the jury had no basis on which to find that the patents were invalid for lack of a written description of basic polymerase chain reaction. Apparently, defendant

wanted the jury to take it on faith that the description was incomplete. Faith does not meet the standard applicable to invalidity defenses, which require clear and convincing evidence.

As to the alleged failure to describe the two region cleavage structure of the '314 patent in the January 1996 application, inventor Brow's testimony and the language of the application refute defendant's contention. Brow described the two region structure shown in Fig. 29 of the application, Plt.'s Trial Exh. #85, Tab 4, at 29, as showing the two region overlapping cleavage structure claimed in the '314 patent. Tr., dkt. #184, at 1230, ln. 15-1232, ln. 21. As Brow explained, unlike the three region structure, the two region structure does not require complete complementarity of the 3' portion of the invader with the target. ("Invader" refers to the cleavage means: the structure-specific nuclease.) <u>Id.</u> at 1234, lns. 5-10. In the January 1996 application, the inventors say that the term "invader oligonucleotide" refers "to an oligonucleotide which contains sequences at its 3' end which are substantially the same as sequences located at the 5' end of a probe oligonucleotide; these regions will compete for hybridization to the same segment along a complementary target nucleic acid." Plt.'s Trial Exh. #85, Tab 4 at 29. The reference to *substantially the same* shows that this structure need not have complete complementarity.

Defendant presented no credible evidence that the patent application did not disclose the two region structure. The only "evidence" it cites are purported admissions to that effect by Brow and another named inventor, Lyamichev, during cross-examination. A review of

the complete testimony of both inventors shows no admission by either that the January 1996 application does not disclose the two region structure. Brow testimony, Tr., dkt. #179, at 173-226; Tr., dkt. #184, at 1222-88; Lyamichev testimony, Tr., dkt. # 182, at 887-909, 911-78.

Defendant raises one more argument, contending that the inventors did not enable the claims for the full scope of the patent because they did not explain how to cleave a nucleic acid cleavage structure in a site-specific manner. Although this argument does not advance defendant's cause because defendant never adduced any evidence that a person of ordinary skill in the art would have to engage in any experimentation, let alone *undue* experimentation in order to do site-specific cleavage using the inventions of the patents, it does identify an issue that has me perplexed.

In both of the patents at issue, the abstracts and the description of the invention section of the specifications, '543 patent, col. 25, lns. 66-67; '343 patent, col. 22, lns. 61-62, say that the invention relates to methods for "forming a nucleic acid cleavage structure on a target sequence and cleaving the nucleic acid cleavage structure *in a site-specific manner.*" (Emphasis added.) Plaintiff described the inventions this way in its summary judgment briefing and I incorporated the description in the order on summary judgment. Aug. 4, 2005 Op. & Order, dkt. #98, at 8 ("Both [the '543 and the '314 patents] claim methods for detecting the presence of a target nucleic acid molecule by forming nucleic acid cleavage

structures and cleaving them in a site-specific manner"). At trial, however, plaintiff denied that it was asserting any claim covering site-specific cleavage. Plaintiff's witnesses Jeff Hall and Mary Ann Brow, two of the named inventors on the '543 patent, disavowed any intention to claim cleavage in a site-specific manner. Hall testimony, Tr., dkt. #181, at 830; Brow testimony, Tr., dkt. #184, at 1224 ("[site-specific cleavage] is not a requirement for the overlap invention").

When there is a discrepancy between what is said in the abstract and the description of the invention and what is claimed, the language of the claims governs. The claims at issue do *not* disclose a method for cleaving the nucleic acid cleavage structure in a site-specific manner, despite the language in the abstract and in the description of the invention. The inventors make this clear in the '543 patent at col. 21, lns. 2-7 and in the '314 patent at col. 18, lns. 20-25 ("it is not necessary that the cleavage means cleave the cleavage structure at any particular location within the cleavage structure"). It is hornbook law that "[c]laims are not correctly construed to cover what was expressly disclaimed." Cultor Corp. v. A.E. Staley Mfg. Co., 224 F.3d 1328, 1331 (Fed. Cir. 2000). Therefore, I conclude that the '543 and '314 patents should not be read as claiming site-specific cleavage.

Defendant argues that the January 1996 application talked about cleaving a nucleic acid cleavage structure in a site-specific manner to generate single, discrete cleavage products of uniform size, yet neither Lyamichev nor Brow was able to explain how this could be done.

What defendant fails to acknowledge is that both Hall and Brow testified that it was not their intention as inventors to include cleavage in a site-specific manner in the two patents in issue. It is irrelevant what the January 1996 application said about site-specific cleavage; that technique is not at issue in this law suit because it is not part of the claims in the two patents in suit. To claim a priority date of an earlier-filed application, a patentee must show that each of the claims asserted in its issued patent can be found in the predecessor application; it does not have to show that the issued patent contains all of the claims in the application.

3. Anticipation

A patented invention must be novel. 35 U.S.C. § 102. It is not novel if a prior art "reference . . . discloses *every limitation* of the claimed invention either explicitly or inherently." Eli Lilly & Co. v. Barr Laboratories, Inc., 251 F.3d 955, 970 (Fed. Cir. 2001). "A reference includes an inherent characteristic if that characteristic is the 'natural result' flowing from the reference's explicitly explicated limitations." Id. (citing Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1269 (Fed. Cir. 1991)). Defendant's anticipation argument rests on a group of references that relate to the *Taq* polymerase and an article by Lyamichev, Brow and Dahlbert, three of the named inventors of the patents in issue, published in 1993 in Science.

a. TaqMan references

The TaqMan references include, among others, U.S. Patent No. 5,210,015 and U.S. Patent No. 5,487,972 (both issued to Gelfand et al.); U.S. Patent No. 5,792,614 issued on August 11, 1998 and assigned to Dade Behring; an article by Holland, et al., "Detection of specific polymerase chain reaction product by utilizing the 5'-3' exonuclease activity of *Thermus aquaticus* DNA polymerase," 88 Proc. Natl. Acad. Sci. 7276-80 (Aug. 1991); an article by Lee et al., "Allelic discrimination by nick-translation PCR with fluorogenic probes," 21 Nucleic Acids Research 3761-66 (1993); an article by Urs, et al., "Structure of Taq DNA polymerase shows a new orientation for the structure-specific nuclease domain," Acta Crysta. (1999); and an article by Lundquist and Olivera, "Transient Generation of Displaced Single-Stranded DNA during Nick Translation," 31 Cell 53 (1982).

It is undisputed that the TaqMan assay was well known in the art before January 24, 1996; therefore, if the *Taq* polymerase were capable of cleaving in the manner disclosed in the patents in issue, it would anticipate those patents. However, plaintiff introduced ample evidence from which a reasonable jury could find that the patents and other TaqMan references cited by defendant do not anticipate the required overlap between the 3' portion of the second oligonucleotide and a portion of the first oligonucleotide that is completely complementary to the target nucleic acid. For example, the inventors of the Dade Behring patent describe a method for detecting the presence of a particular nucleic acid sequence by

means of detection of the cleavage of an oligonucleotide by the 5' nuclease activity of an enzyme. They employ a target nucleic acid, two oligonucleotides, *Taq* polymerase and dNTP, but they do not disclose the required overlap of the '314 patent. By its nature, the *Taq* polymerase cannot form an overlap because its dual activity (polymerizing and cleaving) prevents it from adding a nucleotide at the point of overlap. Instead, it would either cut the downstream probe upon contact or displace the probe. (Even defendant's own expert, Dr. Falkinham, testified that the *Taq* polymerase stretches out in front of the 3' end of the growing primer, chugging along like a locomotive engine, adding cars behind the engine in the form of bases as it moves forward and pushing bases out of the way in front of it. Tr., dkt. #183, at 1206-09.)

The Dade Behring patent fails to disclose a second requirement of claim 1 of the '314 patent: a portion of the first oligonucleotide must be completely complementary and annealed to the first region of the target. Again, the presence of the *Taq* polymerase would prevent this from occurring. The other references all disclose the use of *Taq* polymerase and do not discuss the use of a separate nuclease. For that reason, they fail to anticipate every limitation of the patents in issue.

Defendant spends considerable time on the Lundquist article, Dft.'s Trial Exh. #451, contending that Lundquist showed that *E. coli* DNA Polymerase I would inherently create the claimed cleavage structure. Defendant says that Lundquist demonstrated that the

natural result flowing from the extension of an upstream primer in nick substrate is the generation of such a structure and it cites Figure 5 in the article as exemplifying its point that *E. coli* DNA polymerase I will inherently form and cleave the claimed overlapping cleavage structure. Plaintiff's expert, Dr. Tainer, repudiated this point and said it was "without basis." Dft.'s Br., dkt. #168, at 37-38. Moreover, defendant's own expert, Dr. Falkinham, testified that the structures shown in Figure 5 were created by incubating a nicked DNA circle with a fragment of *E. coli* DNA polymerase I that lacked 5' to 3' exonuclease activity. He noted that the authors of the article were not carrying out the functions simultaneously, "so the polymerase wasn't working while the 5' nuclease activity [sic]." Tr., dkt. #183, at 1096, lns. 22-23. Another difference exists that prevents the structures shown in Figure 5 from anticipating the structures claimed in the patents at issue: they do not comprise a target nucleic acid and two oligonucleotides. Dft.'s Trial Exh. #451, Fig. 5.

In its reply brief, defendant asserts that "the vast amount of admissions from [plaintiff's expert] Tainer himself during the trial and the overwhelming evidence presented by" defendant would have required the jury to find that the TaqMan references disclose the required overlap of the asserted claims. Dft.'s Reply Br., dkt. #198, at 23. According to defendant, Tainer agreed that "when a polymerase extends an upstream primer beyond a junction where a downstream probe has annealed[,] the polymerase will displace portions of the annealed probe and extend the primer [to] create a flap," id., and this amounts to an

admission that the "method disclosed by the TaqMan patents would create a complementary overlap between the extended primer and the displaced probe before the probe was cut." Id. (citing Tr., dkt. #181, at 601, lns. 1-13 (cross-examination of Tainer on teachings of defendant's exhibit #642, Xu Y et al., "Coordination between the Polymerase and 5' Nuclease Components of DNA Polymerase 1 of *Escherichia coli*," J. Biol. Chem., 275:20949-55 (2000)). A review of the record shows that this is an inaccurate characterization of Tainer's testimony. In fact, Tainer denied vehemently that the Xu Y reference showed the creation of an overlap structure as opposed to flaps, which Tainer said were not equivalent to the overlap structure claimed in the patents. Id. at 599, ln. 13-600, ln. 3; 604, ln. 2-606, ln. 17.

The TaqMan references could not have anticipated the patent claims by inherency unless they necessarily and inevitably generated the required overlap. With ample evidence before it to support the conclusion that Taq polymerase is incapable of forming the requisite overlap, the jury did not err in finding that the references did not anticipate inherently.

b. 1993 article by Lyamichev et al.

Although defendant's anticipation argument relied in part on an article by Lyamichev, Brow and Dahlberg, "Cleavage-Specific Endonucleolytic Cleavage of Nucleic Acids by Eubacterial DNA Polymerases," published in <u>Science</u> in 1993, defendant never called a

witness at trial to testify about the article's contents, leaving the jury without any way of evaluating the article's relevance to the '314 patent. Defendant argues in its brief that plaintiff's expert Tainer testified that the structure set forth in the article met each and every limitation of the '314 patent claims. However, the transcript excerpts that it cites, Tr., dkt. #180, at 440, ln. 9-449, ln. 6, do not support its characterization of the testimony. At the cited pages defendant's counsel is cross-examining Tainer about the claims of the '314 patent; neither he nor Tainer makes any reference to the Lyamichev article (which defendant introduced into evidence twice, once as exhibit 452 and once as exhibit 454). At another place in the proceedings, Tr., dkt. #180, at 530-534, defendant's counsel cross-examined Tainer about the publication, using a schematic that counsel had annotated, but was unable to obtain an admission from Tainer that the figure in the Lyamichev publication was the same as that disclosed in the '314 patent.

To the extent that defendant asserts that the inventors of the '314 patent characterized the structure shown in Figure 1 of the <u>Science</u> publication as having a 5' arm that is completely complementary and annealed to the first region of the target nucleic acid, it has failed to support its assertion. The cited portions of the file history, Plt.'s Trial Exh. #85, Tab 25, at 14, contain nothing to this effect. Therefore, defendant's arguments about the binding effect of this supposed concession can be ignored.

The Lyamichev article related to the *Taq* polymerase and analogized the cleavage

method discussed in the article to that of Holland. As explained above, the jury had ample evidence from which to conclude that a method using *Taq* polymerase could not create the requisite cleavage structure. The *Taq* polymerase would be removing bases from in front of it while polymerizing behind or simultaneously displacing and cleaving a downstream probe.

4. Infringement

a. Claim construction

Defendant's only defense against a finding of infringement is its assertion that the jury could not have found infringement had the court construed the claims correctly. Defendant contends that it is entitled to judgment as a matter of law or at least a new trial on the issue of infringement because the court's claim construction was wrong and because defendant made it clear throughout the case that it thought the claim construction erroneous and proceeded under the disputed construction "while reserving its right to appeal the erroneous construction of the claims." Dft.'s Br., dkt. #168, at 50.

The sheer effrontery of this assertion is breathtaking. Defendant does not cite any instance during this litigation in which it made it known to the court that it was reserving "its right to appeal" the court's claim construction. The citations it gives are to a statement to that effect it made in an answer to an interrogatory that was never filed with the court; the position it took during summary judgment that its products do not infringe because they

do not practice the method claimed by the patents under the court's claim construction, Dft.'s Opp. Br. on Summ. J., dkt. #48, at 37-39; its in limine motion to restrict plaintiff to the same claim construction that it had argued during summary judgment, Dft.'s Mot. in limine, dkt. #91, at 2; Final PTC Order, dkt. #119, at 3-4; plaintiff's response to that motion in limine, saying that the issue was moot in view of the court's claim construction in the summary judgment order, Plt.'s Response, dkt. #102, at 6; and the court's order on summary judgment. These citations to irrelevant matters do not enhance defendant's counsel's credibility.

Of course, for a party to say that it is reserving its right to appeal would not give it the right to appeal if it gave up any such right by passing up the opportunities it was given to contest the claim construction adopted by the court. During briefing on summary judgment, defendant did not challenge the construction of the terms of the '543 and '314 patents on which the court had relied in Third Wave Technologies, Inc. v. EraGen Biosciences, Inc., 02-C-0507-C, 2003 WL 23100277, at *10 (W.D. Wis. Mar. 18, 2003). It says now that it chose this course because the court had only recently construed the same claims and it had "no reasonable expectation that this Court would alter its prior claim construction." Dft.'s Br., dkt. #168, at 50. Defendant never raised any challenge to the construction during trial or adduced any evidence that would have supported a change in the construction. Whatever reason it had for staying on the sidelines on this issue, it is stuck

with its decision. Abbott Laboratories v. Syntron Bioresearch, Inc., 334 F.3d 1343, 1352 (Fed. Cir. 2003) ("Abbott cannot wait until after the jury returns a verdict against it and then on JMOL request a different construction by attempting to have the district court delete a portion of the construction that Abbott itself agreed to.") (citing Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1345-46 (Fed. Cir. 2001)); Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1314 (Fed. Cir. 2003) ("The doctrine of waiver as applied to claim construction prevents a party from offering a new claim construction on appeal."). Trial has been held, the jury has reached its verdict, the world has moved on. It is far too late to ask for a re-do, even if defendant had persuaded me that the original construction was erroneous. It has not.

Alternatively, defendant asserts that if the claim construction is correct, the claims are invalid because they necessarily encompass prior art and are neither supported by the written description nor enabled. I understand from these assertions that defendant cannot deny direct infringement under the claims as I have construed them.

Although defendant does not challenge the jury's finding of direct infringement, it asserts that no rational jury could have found it liable for indirect infringement. In doing so, however, it relies on an inaccurate representation of the law. Citing Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990), defendant states accurately that proof of inducement to infringe requires a showing that defendant had actual intent to

cause the acts that constitute the infringement, Dft.'s Br., dkt. #168, at 57, but goes on to say that "[k]nowledge of the patent in question is another condition precedent to finding inducement." Id. For this proposition, it cites three cases, none of which holds that knowledge of a patent is a requirement for a finding of inducement of infringement. See MercExchange, LLC v. eBay, Inc., 401 F.3d 1323, 1332 (Fed. Cir. 2005) (noting that infringement requires proof of intent but that it is not always clear whether the required intent is merely to induce the specific acts of infringement or to cause an infringement; "a patentee must be able to demonstrate at least that the alleged inducer had knowledge of the infringing acts in order to demonstrate either level of intent"); Moba, B.V., 325 F.3d at 1318 (knowledge requirement met with "'proof of actual intent to cause the acts which constitute the infringement'") (quoting Hewlett-Packard, 919 F.2d at 1469); C.R. Bard, Inc. v. Advanced Cardiovascular Systems, 911 F.2d 670, 675 (Fed. Cir. 1990) ("person induces infringement under § 271 (b) by actively and knowingly aiding and abetting another's direct infringement"); Water Technologies Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988) (noting that person may infringe by actively and knowingly aiding and abetting another's direct infringement).

Defendant seems to forget that at trial its counsel agreed explicitly that knowledge of the patent is not an element of inducement of infringement. Tr., dkt. #184, at 1354, lns. 6-23 (Plaintiff's counsel: "There's no knowledge of the patent by [defendant] required [for

inducement of infringement]." Defendant's counsel: "I would agree.")

Although defendant asserts that knowledge of the patents is a prerequisite to liability, it does not cite any evidence that it did not know of plaintiff's patents. Instead, it focuses on its contention that it did not intend that its customers would use the accused FullVelocity[™] products in an infringing manner but rather made clear to its customers that they could use the products with all existing probe systems. Unfortunately for defendant, the contention has no support in the record. Defendant stipulated that it intended its customers to use the accused products in accordance with the instructions in the product manuals. The examples in the instruction manuals for the accused Full Velocity[™] products show only probes that can be cut; they do not show any examples of probes that are not cut. In addition, the manuals tell the kit users that "[t]he hydrolysis probe fluoresces when FullVelocity enzyme formulation cleaves the fluorophore from the quencher." To a person skilled in the art this statement indicates that the product is intended to work with a probe that can be cut and that the signal comes from cutting. Moreover, one of the basic components of the accused products is a Pfu FEN-1 enzyme, which has no function in the products other than cleavage of DNA, as defendant's chief executive officer testified at trial. Tr., dkt. #181, at 738, lns. 22-24; 747, lns. 5-9. See also Tainer testimony, Tr., dkt. #180, at 329, ln. 19-330, ln. 7 ("In my opinion, there's no useful reason to add FEN-1 enzyme [to the FullVelocity[™] kit] which is an enzyme that specifically cuts DNA other than to have it cut the probe to release a signal.").

Although defendant argues that the FullVelocity™ products have non-infringing uses, the uses its manuals encouraged are infringing ones. The mere possibility that the kits could be used for non-infringing uses does not relieve defendant of liability for inducement of infringement, particularly when it has not made any showing that any non-infringing uses would be viable ones.

C. Motion for Judgment as a Matter of Law, New Trial or Remittur as to Damages

In the damages phase of trial, plaintiff sought damages in the form of a reasonable royalty for the period from April 2004 to September 2, 2005. In its closing argument, plaintiff asked for \$12,000,000 plus a running royalty of 4% of sales in the research market and 15% of sales in the molecular diagnostics field. The jury awarded plaintiff \$5,290,000 plus a running royalty of 4% for sales in the research field and 14% for sales in the molecular diagnostics field. Defendant contends that the amount of the award was not supported by the credible evidence and was based on plaintiff's counsel's improper remarks during his closing argument, inviting the jury to "send a message" to defendant to punish it for its infringement. Not surprisingly, plaintiff believes that the verdict is reasonable and supported by the testimony of its damages expert. Also, it takes the position that defendant is not entitled to judgment as a matter of law because it did not preserve its right to ask for

one by making such a motion either at the end of plaintiff's damages case or at the end of the entire damages case before the case went to the jury.

The procedural issue is a good starting point. Plaintiff is correct that defendant did not move for judgment as a matter of law as to damages either at the end of plaintiff's case or at the end of the entire case before it went to the jury. (The motions it made at the end of plaintiff's liability case and at the end of the entire liability case or after the jury had returned its damages verdict do not count. Fed. R. Civ. P. 50(b) ("Motions for judgment as a matter of law may be made at any time before submission of the case to the jury."); see also Mid-America Tablewares, Inc. v. Mogi Trading Co., Ltd., 100 F.3d 1353, 1364 (7th Cir. 1996) (declining to entertain motion for judgment as matter of law because moving party had not renewed motion at close of all evidence).) Technically, defendant is barred from obtaining such a judgment. As a practical matter, however, the lapse is of little consequence. It is a rare event for a judge to enter a judgment on damages as a matter of law after a jury has reached its own determination. It is far more likely that a judge will react to a showing of an erroneous damages verdict by either setting the matter for a new trial on her own motion or offering the winning party the choice between a remittitur and a new trial. McKinnon v. City of Berwyn, 750 F.2d 1383, 1392 (7th Cir. 1984) ("A federal judge can set aside a jury verdict as excessive, but he can fix the proper level of damages only if the plaintiff is entitled to a particular amount of damages as a matter of law").

Plaintiff raises another matter, which requires little discussion. It contends that defendant's attack on the testimony of plaintiff's damages expert, Brian Napper, is improper and can be disregarded by the court because the challenge goes to Napper's method of analysis. In plaintiff's opinion, defendant should have raised this challenge at or before trial, either by motion in limine or after the expert had testified. Plaintiff is cutting matters too fine. Defendant is not challenging the method of analysis, but the results of the analysis. Therefore, it is entitled to argue that Napper's expert testimony was insufficient to support the damages verdict without having to move before or at trial to strike the witness as unqualified to render an opinion.

On the other hand, it is a little silly for defendant to challenge Napper's testimony as improper just because Napper did not go separately through each one of the interminable Georgia-Pacific factors. Anyone who has sat through a factor-by-factor review once can only applaud Napper's decision to group the overlapping factors and avoid the tedium that results from parsing them one by one. Defendant knew from reading Napper's report exactly what his views were on each one of the 15 factors; it was not prejudiced by his approach.

As to the allegedly improper remarks of counsel, I am not persuaded that it was improper for plaintiff's counsel to say at the end of his closing argument:

Mr. Napper's proposed reasonable royalty is too low in this case. The evidence here shows the value of this technology. It shows the value of other technologies and, I believe, warrants damages of \$12 million as an upfront payment,

4 percent of a running royalty for research sales, and 15 percent in the molecular diagnostic market.

We trust your judgment on these important issues both willfulness and damages. We ask you to send a strong message to Stratagene and to the other Stratagene's [sic] out there who would choose to willfully infringe Third Wave's hard-earned patents. If you knowingly take other people's properties and you use them as your own, there is a consequence.

Defendant calls these statements prejudicial but it did not object to them at trial when the court could have issued a curative instruction if it agreed with defendant. Having failed to seek a cure at the time, it is in a poor position to object to an allegedly improper remark in its post-trial briefs.

The remarks may have bordered on the prejudicial. It is improper to ask a jury to "send a message" to other potential tortfeasors when asking for compensatory damages. Like any other defendant, a tortfeasor is entitled to be judged solely on its own wrongdoing and not used as an example to others. In my view, however, plaintiff avoided crossing the line by limiting the "message" to teaching defendant and others that there is a consequence to willful infringement. Plaintiff did not suggest in so many words that the jury increase its damage award in order to punish defendant but encouraged the jury simply to show defendant and others that they would suffer consequences if they engaged in willful infringement.

The test for assessing the effect of improper remarks by counsel is whether "there is

a reasonable probability that the verdict of a jury has been influenced." <u>DeRance, Inc. v. Painewebber Inc.</u>, 872 F.2d 1312, 1327 (7th Cir. 1989) (quoting <u>City of Cleveland v. Peter Kiewit Sons' Co.</u>, 624 F.2d 749, 756 (6th Cir. 1980)). Even if I found that plaintiff's counsel's remarks crossed the line, which I do not, they were of minimal import in the context of the closing argument and the ten days of trial. The jury was instructed that arguments of counsel are not evidence. Moreover, the jury's verdict indicates that the remarks did have any improper influence on it. It did not give plaintiff the \$12,000,000 its counsel asked for in closing or even the \$6,000,000 that Napper had suggested would constitute reasonable royalty damages.

I turn next to the more substantive question whether plaintiff presented sufficient evidence through Napper and others to support the jury's decision to award the damages it did. Defendant characterizes Napper's testimony as "speculative and vague" and of no value because Napper rested his entire analysis on what he considered to be the parties' information, strategies and understanding of the market as of the time the infringement began and did not take into account any subsequent events. Had he considered these actual events, defendant argues, he would have realized that an upfront award of \$6,000,000 was wholly unjustified in view of defendant's actual earnings of only about \$236,000 from its FlowVelocity™ products as of April 2005.

Defendant's argument has two flaws. First, in undertaking a reasonable royalty

analysis, it was not improper for Napper to look solely at the situation as it would have appeared to two companies attempting to enter into a licensing agreement as on April 2004, the date the infringement began. (Whether he reached the right result is a separate question.) 35 U.S.C. § 284 authorizes the court to award a prevailing patentee in a patent case "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer." To do this, courts engage in a fiction: they imagine a negotiation between the patentee and infringer taking place at the moment the infringement began. This is an approach that experts have employed for decades in patent cases. See, e.g., Faulkner v. Gibbs, 199 F.2d 635, 639 (9th Cir. 1952); Horvath v. McCord Radiator & Mfg. Co., 100 F.2d 326, 335 (6th Cir. 1938) ("In fixing damages on a royalty basis against an infringer, the sum allowed should be reasonable and that which would be accepted by a prudent licensee who wished to obtain a license but was not so compelled and a prudent patentee, who wished to grant a license but was not so compelled. In other words, the sum allowed should be that amount which a person desiring to use a patented machine and sell its product at a reasonable profit would be willing to pay.").

Since 1970, courts have come to rely upon the factors enumerated in <u>Georgia-Pacific</u> <u>Corp. v. U.S. Plywood Corp.</u>, 318 F. Supp. 1116 (S.D.N.Y. 1970), a case in which the district judge pulled into one opinion a comprehensive list of evidentiary facts that can bear

upon the determination of a reasonable royalty, that is, the amount that willing seller and willing buyer would have agreed upon, id. at 1122, taking into consideration some or all of a number of factors. These include the royalties received by the patentee for the licensing of the patent in suit; the rates paid by the licensee for the use of other comparable patents; the nature and scope of the license; the licensor's established policy and marketing program to preserve its patent monopoly by not licensing others; whether the parties are competitors in the same territory in the same line of business or inventor and promoter; the effect of selling the patented specialty in promoting sales of other products of the licensee and the existing value of the invention to the licensor as a generator of sales of non-patented items and the extent of such derivative or convoyed sales; the duration of the patent and the term of the license; the established profitability of the product made under the patent; the utility and advantages of the patented property over other devices; the nature of the patented invention and the benefits to those that have used it; the extent to which the infringer has made use of the invention and any probative evidence of the value of the use; the portion of the profit or selling price that may be customary in the particular business to allow for the use of the invention; the portion of the realizable profit that should be credited to the invention as distinguished from other factors contributing to its commercial success, the opinions of qualified experts; and the amount that the parties would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been

acceptable to a prudent patentee willing to grant a license. Id. at 1121.

None of the Georgia-Pacific factors relate to events taking place after the hypothetical negotiations—for good reason. The point of the analysis is its focus on the information the negotiators would have had at the time of their negotiations. "[The approach contemplates] a marshaling of all of the pertinent facts which, like cards dealt face up, are for all to see." Georgia-Pacific, 318 F. Supp. at 1122. It does not rest on subsequent events beyond the hypothetical negotiators' ability to foresee. Interactive Pictures Corp. v. Infinite Pictures, Inc., 274 F.3d 1371, 1384 (Fed. Cir. 2001) (infringer's failure to meet projections irrelevant to its state of mind at time of hypothetical negotiation and does not necessarily imply that projections were grossly excessive or based only on speculation and guesswork).

The second flaw in defendant's attack on Napper's approach is that although Napper had no obligation to take into consideration defendant's subsequent sales when developing his hypothetical negotiation analysis, he did do so. As he explained, he took the subsequent sales into account but gave them less weight than the information that the parties would have had before them at the time of the negotiation.

I turn then to defendant's attack on the substance of Napper's analysis. Defendant begins by challenging the award of an upfront fee in addition to a running royalty. Such a fee is proper when the evidence shows that it is commonly utilized in the industry. <u>See, e.g.</u>, <u>Interactive Pictures</u>, 274 F.3d at 1384 ("We have previously upheld awards of damages

premised on a lump sum royalty payment based on an infringer's expected sales. E.g., Snellman v. Ricoh Co., 872 F.2d 283, 289 (Fed. Cir. 1988).") Napper testified that such fees are "fairly common" because companies in the biosciences and life sciences are willing to pay upfront royalties for access to the kinds of technology that will enable them to achieve early entry into markets. Although defendant contests this proposition, its own expert, Stephen Jizmagian, acknowledged the use of such royalties in the biotech industry. As the evidence showed, both parties have entered into arrangements with upfront royalty fees and other biotech companies have entered into multi-million dollar lump sum licenses. For example, one industry company paid more than \$10,000,000 in a lump sum to Applied Biosystems for TaqMan technology; another paid \$32,000,000 to the company that licenses the TagMan technology. Plaintiff's agreement with a company known as Aclara involved an upfront payment plus running royalties approaching ten percent. Although defendant disputes the actual amount of the upfront payment plaintiff received from Aclara, it concedes that the payment was at least \$1.5 million. Moreover, the license that plaintiff gave Aclara was more limited than the hypothetical license for which defendant would have bargained.

As of April 2004, defendant was projecting sales for its FullVelocity[™] products of \$2 million in 2005 and \$12 million in 2006. It was anticipating an 85% gross margin on sales of FullVelocity[™] products after the expiration of Roche's PCR patents freed defendant from

its license payments. It hoped to price FullVelocity[™] about 15-20% higher than its other QPCR product, Brilliant.

For its part, plaintiff anticipated sales in the neighborhood of nearly \$750 million for its Invader technology for the years 2005-09. In a hypothetical negotiation, it would have been extremely reluctant to give defendant a license to its key technology. Plaintiff considered defendant a competitor to whom it be giving away key technology related to its core product. Indeed, it had no real reason to negotiate with defendant.

Defendant asks how anyone could reasonably find it would have been willing to pay \$5,290,000 to plaintiff for a license that would allow it to enter the molecular diagnostics market for only five months. (It arrives at the five-month term by figuring the time between the entry of the injunction in this case and when Roche's patent would have run out on its PCR technology in March or April 2005, leaving defendant free to use its PCR technology in the molecular diagnostics market as well in the research market to which it was limited by the terms of its license with Roche.) Napper answered this question by explaining the financial and strategic advantages of having access to the marketplace and being an early entry in the lucrative market that molecular diagnostics represented. He testified that the documents from defendant that he had reviewed showed a consistent indication of its strong desire and intent to enter the molecular diagnostics market as soon as possible. The evidence showed that defendant reiterated this intent in calls to shareholders and at public

forums, emphasizing its belief that FullVelocity™ (the infringing kits) represented "one of our most important opportunities for long-term growth" and that the product was its lead tool on the reagent side in the company's effort to move to 20% market share. Defendant called Full Velocity™ critical to its molecular diagnostic initiatives. It told investors that the early feedback it had received on the competitive performance of the FullVelocity™ QPCR kits led it to believe that it was well positioned to succeed on its molecular diagnostic initiatives, that the company had expanded discussions with several laboratories and *in vitro* diagnostic companies that had the potential to become partners with defendant in future molecular diagnostic development opportunities and that it had had talks with potential partners about helping with the commercialization of Full Velocity™-based products for the diagnostic market. Defendant saw the value of the molecular diagnostics market as reaching \$1.2 billion in 2004, \$1.5 billion in 2005 and \$3.7 billion by 2010 in the United States alone. Both parties saw the commercial value of the diagnostics market as far exceeding the research market.

Defendant argues that Napper never considered the length of time that defendant would have to wait for FDA approval before it could enter the molecular diagnostics market with its FullVelocity™ products, making it impossible for defendant to enter the market before September 2005. Defendant never adduced any evidence at trial that FDA approval would be necessary but it argues that it was up to plaintiff to prove that FDA approval was

not a consideration. The argument is a non-issue. As Napper explained, it was clear from defendant's press releases and discussions with investment analysts that defendant did not believe that the need for FDA approval would keep it out of the diagnostic market for two to three years or longer; defendant was projecting market penetration much sooner than that. Napper was entitled to rely on what defendant believed about its ability to enter the market because this was the kind of information defendant would have been relying upon in the hypothetical negotiation.

Defendant's expert, Stephen Jizmagian, admitted he had not studied defendant's projections and did not understand the advantages of the Invader technology. He believed that defendant would not have paid plaintiff a large upfront royalty for two patents that defendant could not have exploited for more than five months; the effort the company would have had to put into marketing the technology would not have been worthwhile for such a short term license. Jizmagian was of the opinion that plaintiff had no established royalty rate but he had not studied defendant's licensing agreements and was unable to say much about them. He believed that plaintiff would have benefited from licensing the patented inventions, both from defendant's marketing efforts and from the ability to be able to say that defendant was using the same technology. Further, he did not think defendant would have wanted to pay much for a non-exclusive license from plaintiff.

The jury was justified in finding Napper's testimony more credible than Jizmagian's.

The jury's decision did not result in a damages award that was "grossly excessive and wholly unreasonable," as defendant characterizes it, Dft.'s Reply Br., dkt. #196, at 1, or one that was based on "speculation." Id. Instead, it was based upon defendant's own internal documents and projections it made to others, along with testimony from Joe Sorge (defendant's chief executive officer) that he had seen the potential to launch diagnostic products using the accused technology before defendant even launched its accused products into the research market. The jury could have taken into consideration testimony from defendant's employee, Mary Jo Deal, describing a series of steps defendant had taken to get its FullVelocity™ products into the diagnostics market: meeting with a series of clinical laboratories and companies to solicit their interest in developing a FullVelocity™-based diagnostic product, entering into an agreement with the Sidney Kimmel Cancer Center to license a set of proprietary cancer markers that would be used to develop a diagnostic product and merging with Hycor, which defendant saw as its conduit into the clinical diagnostic market.

Defendant asserts that Napper's opinion was based upon "misleading market projections that do not even remotely approximate reality," <u>id.</u>, but the reality is that the market projections were defendant's own. Defendant asserts also that plaintiff did not introduce any evidence to prove that the projections Napper relied upon were prepared before or at the time of the hypothetical negotiation, <u>id.</u>, yet in its opening brief it criticized

Napper's opinion as "based largely upon [defendant's] internal projections, made *prior to* the April date of the hypothetical negotiation." Dft.'s Br., dkt. #170, at 3, 4 (emphasis added).

The jury had ample credible evidence from which to reach its decision on damages.

Defendant's motion for judgment as a matter of law, a new trial or remittitur will be denied.

III. MOTION FOR ENHANCED DAMAGES AND ATTORNEY FEES

A. Standards for Award of Enhanced Damages and Attorney Fees

35 U.S.C. § 284 allows a court to increase the amount of the damages payable by an infringer up to three times the damage award. Although the statute does not specify the circumstances in which an increase is proper, courts have developed the basic principle that any increase should be tied to the infringer's misconduct. E.g., Johns Hopkins University v. CellPro, Inc., 152 F.3d 1342, 1365 (Fed. Cir. 1996) ("in exercising this discretion [to increase the damage award], the trial court considers the weight of the evidence of the infringer's culpability"). See also Read v. Portec, Inc., 970 F.2d 816, 826 (Fed. Cir. 1992) (holding increased damages to be appropriate where "the infringer acted in wanton disregard of the patentee's patent rights, that is, where the infringement is willful.") Guiding the exercise of the court's discretion is the list of factors set out in Read: (1) deliberate copying by the infringer; (2) whether the infringer investigated the scope of patent and formed a good faith belief that it was invalid or not infringed once he learned of its existence; (3) the

infringer's behavior in litigation; (4) the infringer's size and financial condition; (5) the closeness of the case; (6) the duration of the infringer's misconduct; (7) any remedial action by the infringer; (8) the infringer's motivation for harm; and (9) whether the infringer tried to conceal its misconduct. Id. at 827.

35 U.S.C. § 285 authorizes an award of reasonable attorney fees to the prevailing party "in exceptional cases." What is an exceptional case is another discretionary determination. "Cases awarding attorney fees to prevailing patentees have typically found 'exceptional' circumstances in willful and deliberate infringement by an infringer, or in the prolongation of litigation in bad faith." Rohm & Haas Co. v. Crystal Chemical Co., 736 F.2d 688, 691 (Fed. Cir. 1984). Other factors include (1) the degree of culpability of the infringer; (2) the closeness of the question; (3) litigation behavior; and (4) "any other factors whereby fee shifting may serve as an instrument of justice." National Presto Industries, Inc. v. West Bend Co., 76 F.3d 1185, 1197 (Fed. Cir. 1996).

______If there is a more suitable candidate for enhanced damages and attorney fees than this case, it is hard to imagine what it might be. This case is notable for the burdens that defendant's lack of candor and willingness to argue unsupportable positions placed on the court and opposing counsel. Defendant's briefs on just its own post-trial motions ran 217 pages, after a trial that lasted two weeks, yet almost none of defendant's arguments have any legal merit or factual support.

B. Enhanced Damages

1. Deliberate copying

The evidence of copying is tantalizing, particularly in light of defendant's belated productions of documents sought by plaintiff since the beginning of the case, but I am not persuaded that the evidence is sufficient to support a finding that copying occurred. Therefore, I give no weight to this factor.

2. Defendant's investigation of scope of patent

Nicolas Roelofs, defendant's chief executive officer, knew about plaintiff's '543 patent when he started working for defendant and knew about plaintiff's '314 patent at the time it issued (while he was serving as chief executive officer) and discussed the patents with defendant's in-house counsel. Defendant identified plaintiff's '543 patent as prior art when it filed two of its own patent applications, U.S. Pats. Nos. 6,350,580 and 6,589,743. Gothami Padmabandu, one of defendant's scientists, learned of plaintiff's patents in the course of research in nucleic acid amplification and detection before the summer of 2004. She testified that at one meeting, she heard one of defendant's employees raise the question of the need to undertake an immediate investigation of potential intellectual property issues with *Pfu* FEN. Padmabandu Dep., dkt. #89, at 38. Despite this knowledge, defendant took no steps to investigate the scope of the patents or the possibility that the patents might be

infringed by the products defendant was developing. It was not until plaintiff served defendant with its summons and complaint in this case that defendant consulted its outside patent counsel, who produced an opinion addressing invalidity issues only. She did not undertake an infringement analysis, saying that she would not have done so because this court's previous construction of the claims of the two patents at issue in <u>Third Wave Technologies v. EraGen Biosciences</u>, 02-C-0507-C, was "not a legally permissible claim construction." Tr., dkt. #187, at 1993, lns. 15-22. (If she believed that it was impermissible because it would have encompassed prior art, it makes defendant's decision not to contest the claim construction even more unfathomable. Courts can be persuaded to change their rulings when they are shown the error of a previous ruling, particularly when the previous ruling was made in another case to which the challenger was not a party.)

It is worth noting that when outside counsel wrote her opinion, she believed that the FullVelocity[™] products contained Taq polymerase. Id. at 2000, ln. 24-2001, ln. 9. Defendant produced no evidence that anyone at the company set her straight about her misunderstanding. In fact, it is undisputed that the products contain the DNA polymerase, V93R Pfu Exo-DNA, which does not exhibit nuclease (cleaving) activity, and the flap endonuclease Pfu FEN-1.

Defendant maintains that it relied on "the detailed advice of an extremely competent outside patent counsel who opined that the patents, as construed by the Court, were invalid

as a matter of law." Dft.'s Resp. Br., dkt. #189, at 1. The credibility of this contention is belied by the record.

Defendant's belated effort to obtain an opinion letter is no more helpful to its attempt to fend off an award of enhanced damages than that of the infringer in <u>SRI</u> International, Inc. v. Advanced Technology Laboratories, 127 F.3d 1462 (Fed. Cir. 1997). In <u>SRI</u>, the infringer had not shown that it had sound reason to believe it had the right to act in the manner that was found to be infringing. The court of appeals noted that

To serve as exculpatory legal advice the opinion of counsel is viewed objectively, to determine whether it was obtained in a timely manner, whether counsel analyzed the relevant facts and explained the conclusions in light of the applicable law, and whether the opinion warranted a reasonable degree of certainty that the infringer had the legal right to conduct the infringing activity. See Westvaco Corp. v. International Paper Co., 991 F.2d 735, 745 (Fed. Cir.1993).

<u>Id.</u> at 1467. Defendant's effort flunks the <u>SRI International</u> test. The opinion it obtained was not timely; it did not rest on an accurate analysis of the relevant facts; and it included no opinion on infringement but rested entirely on counsel's opinion that the patents were invalid as construed by the court.

One last point on this factor. Defendant quotes <u>Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.</u>, 383 F.3d 1337, 1345 (Fed. Cir. 2004), for the proposition that "it is inappropriate to draw an adverse inference from the failure to consult counsel." Relying on this statement, it argues that even if it had been aware of plaintiff's

patents before plaintiff filed suit, the jury could draw no adverse inference from that knowledge. Dft.'s Resp. Br., dkt. #189, at 6. The quotation is truncated; when read in full and in context, it does not support defendant's argument. In Knorr-Bremse, the court of appeals held that "no adverse inference that an opinion of counsel was or would have been unfavorable flows from an alleged infringer's failure to obtain or produce an exculpatory opinion of counsel." Id. (Emphasis added.) The court did not say that it was improper for a jury to infer from an infringer's failure to consult counsel that the infringer had no prior knowledge of its opponent's patents or that it had not acted properly in other respects. The court's ruling was limited to its concern for protecting the attorney-client privilege. For that reason, it prohibited factfinders from drawing any inferences about what the opinion might have said had it been issued; it went no farther than that.

3. <u>Litigation behavior</u>

Defendant's litigation behavior includes untruthful answers to interrogatories, evasive answers to requests for admission (such as saying that it lacked sufficient information to respond to a request concerning its and its attorneys' awareness of the patents in suit without adding that it had made reasonable inquiry, as required by Fed. R. Civ. P. 36), disobedience of a court order to produce *all* documents relating to the research and development of the FullVelocity™ products, cancelling depositions unilaterally, its CEO's

egregious behavior during his depositions, giving frivolous responses to plaintiff's proposed findings of fact in support of its motion for summary judgment, violating the protective order by allowing its expert access to at least one deposition transcript marked "highly confidential" when the parties had not agreed that the expert could view the transcript, raising a meritless challenge to plaintiff's ownership of the patents in issue, raising a wholly unsupported experimental use argument and submitting an exhibit list that evinced defendant's counsel's disregard for professionalism, civility and simple courtesy.

Defendant denies plaintiff's characterization of its actions but does not do so persuasively. For example, it denies that it was a violation of the protective order to allow its expert access to highly confidential information, saying now that the expert had signed the confidentiality undertaking required by the protective order long before the July 2005 deposition at which the subject came up. At the deposition, defendant's counsel did not tell plaintiff's counsel that the expert had signed the confidentiality undertaking but said instead that the copy the expert had reviewed "was not a complete copy of the transcript." Falkinham Dep., dkt. #85, at 39, lns. 10-14. More to the point, defendant did not say then and does not say now that it complied with the additional provision in the protective order that neither party was to make any disclosure to an expert unless the party had actually served the other party a notice identifying the expert and attaching a copy of the signed undertaking.

4. <u>Infringer's size and financial condition</u>

Defendant employs 467 full-time employees and has a market capitalization of approximately \$200 million. In fiscal year 2004, its gross income was more than \$84 million and its net income was more than \$7 million, twice its net income in the previous year. Neither defendant's size nor its financial condition militates against an award of enhanced damages.

5. Closeness of case

After summary judgment, only one issue was left for trial on plaintiff's infringement claim. Defendant gave this issue little attention; it all but conceded infringement and concentrated on invalidity. It would have been well advised to have conceded invalidity as well. Instead it tried to mislead the jury into believing that the patents were invalid for lack of an adequate written explanation and for lack of enablement because persons of ordinary skill in the art would not have known how to make oligonucleotides in 1996. Defendant's anticipation case was undermined by its wholesale reliance on prior art that involved the use of *TaqMan* probes that did not and could not form the claimed overlapping structure. The jury was not confused by the lack of enablement and written description arguments or by defendant's reliance on the non-anticipatory *TaqMan* reactions.

In opposing the motion for enhanced damages, defendant argues that the case was

much closer than plaintiff characterizes it. It asserts that "the USPTO itself determined that [defendant's] patented products were free and clear of the patents-in-suit." Dft.'s Resp. Br., dkt. #189, at 1. This is a preposterous assertion. The patent office has no idea of the makeup of defendant's products, how they are designed to be used or whether they use any patented methods. It would never make a determination of the kind defendant attributes to it. The patent office issued patents to defendant; in doing so, it made no determination whether the issued patents would be "free and clear of the patents-in-suit." That is not its job. Finally, as defendant's counsel well knows, the record is devoid of any evidence about defendant's patents because counsel agreed not to discuss them at trial. In making this argument and the assertion on which it rests, defendant merely underscores the frivolity of its infringement defense.

As it did at trial, defendant contends that its products were capable of substantial non-infringing uses. The jury was not persuaded of the truth of that contention and had no reason to be. Defendant was unable to show that the products would have been useful to any user had they not performed the infringing method, that the company made any real effort to promote the non-infringing uses to users or that it even instructed users how to use the product in a non-infringing manner.

Defendant adds the argument that defendant's patented products operated in a way that the patents in suit taught away from, but this is another argument that the jury rejected.

Defendant presented no persuasive evidence on the point.

6. Remedial action by defendant

The record contains no evidence that defendant made any effort to remedy its infringement, even after the jury had found that defendant did infringe and did so willfully. This factor provides no support for defendant's opposition to an award of enhanced damages.

7. Defendant's attempts to conceal its misconduct

Defendant's failure to comply with all aspects of this court's orders on discovery suggests that it tried to conceal its misconduct, as do its efforts to prevent plaintiff's counsel from questioning defendant's employees about their conversations with defendant's general counsel. These conversations might have shed light on defendant's knowledge of plaintiff's patents but defendant did not allow plaintiff to obtain discovery of them.

C. Attorney Fee Award

Plaintiff's motion for an award of attorney fees will be granted. For all the reasons catalogued above, this is an exceptional case for which an award of attorney fees is well justified. Plaintiff has not said what fees and costs it incurred; it will have an opportunity

to file and serve an itemized statement.

ORDER

IT IS ORDERED that defendant Stratagene Corporation's motions for judgment as

a matter of law, new trial or remittur as to liability and damages are DENIED; plaintiff Third

Wave Technologies, Inc.'s motion for an award of enhanced damages and attorney fees is

GRANTED; plaintiff is entitled to enhanced damages in an amount equal to three times the

jury's determination of its reasonable royalty (\$15,870,000) and to attorney fees in an

amount to be determined. Plaintiff may have until January 6, 2006 in which to file and

serve its itemized fee request. Defendant may have until January 20, 2006 in which to file

and serve its objections to the fee request (but not to the decision to award fees); plaintiff

may have until January 27, 2006 in which to reply to defendant's objections.

Entered this 16th day of December, 2005.

BY THE COURT:

/s/

BARBARA B. CRABB

District Judge

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