IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF WISCONSIN

INNOGENETICS, N.V.,

Plaintiff,

OPINION AND ORDER

05-C-0575-C

v.

ABBOTT LABORATORIES,

Defendant.

This civil suit for patent infringement is before the court on a variety of motions filed by the parties following the entry of judgment on the jury's verdict in favor of plaintiff Innogenetics, N.V on its claims of literal and willful infringement. Defendant Abbott Laboratories has moved for (1) a new trial on plaintiff's claim of infringement and its own affirmative defense of invalidity; (2) judgment as a matter of law or a new trial on the issues of damages and willful infringement; (3) and a new trial on damages, pursuant to Fed. R. Civ. P. 60(b)(2) and (3). Plaintiff has moved for a permanent injunction, an accounting and prejudgment interest and enhanced damages and attorney fees.

I conclude that defendant has not shown that it is entitled to a new trial on the issues of infringement or invalidity or to judgment as a matter of law on the issue of damages but that it is entitled to judgment as a matter of law on the issue of willful infringement. Defendant conceded at the start of trial that it had no evidence to defeat plaintiff's claim of infringement other than what was before the court on defendant's motion for summary judgment, which I found insufficient to defeat the claim. Defendant conceded that it would be unable to prove obviousness to the jury in light of the court's rulings and it failed to adduce sufficient evidence to persuade the jury that plaintiff's '704 patent was invalid because it had been anticipated by the prior art. As to damages, plaintiff adduced sufficient evidence to support the jury's award of \$7,000,000 in damages. On the issue of willful infringement, however, plaintiff's evidence was not sufficient to allow a reasonable jury to find that defendant acted willfully when it developed and sold its infringing products.

Defendant is not entitled to a new trial on damages pursuant to Rule 60(b)(2) or (3) because it has not shown that plaintiff obtained its jury verdict through fraud or that newly discovered evidence would affect the outcome of the trial. Plaintiff is entitled to an accounting and to prejudgment interest; it is not entitled to enhanced damages or attorney fees because defendant's infringement was not willful and nothing about its litigation conduct makes this an exceptional case so as to warrant an award of attorney fees to plaintiff.

I will reserve a decision on plaintiff's motion for a permanent injunction and on the scope of that injunction until I have held an evidentiary hearing on the matter to determine

whether barring defendant from selling its infringing assays will or will not harm the public's interest in having access to adequate HCV testing technology.

I. BACKGROUND

The patent at issue is U.S. Patent No. 5,846,704, which issued in December 1998 on an application filed in July 1994. It is owned by plaintiff Innogenetics, N.V. Entitled "Process for Typing of HCV Isolates," it claims a method of genotyping the hepatitis C virus (HCV) by specifically hybridizing probes to a particular region of the HCV genome known as the 5 prime untranslated region (5' UTR). The speed and relative inexpensiveness of the method disclosed in the patent make it possible for clinicians to learn quickly what particular genotype of HCV virus has infected their patient and thus, what antiviral medications will be most effective.

Claim 1 of the patent is the only independent claim. It reads as follows:

A method of genotyping HCV present in a biological sample comprising hybridizing nucleic acids in a biological sample with at least one probe and detecting a complex as formed with said probe and said nucleic acids of HCV, using a probe that specifically hybridizes to the domain extending from the nucleotides at positions -291 to -66 of the 5' untranslated region of HCV.

The asserted novelty of the '704 patent is its disclosure of a method of gentotyping the HCV present in a particular biological sample. Although other researchers had developed methods of *detecting* HCV in the 5' UTR, plaintiff contends, and the jury found, that the inventors of the '704 patent made the important and unanticipated discovery that they could *distinguish* among different types and subtypes of HCV in a sample, using probes that hybridize specifically to the 5' UTR of the HCV genome. This is a region of the HCV nucleic acid that other scientists knew could be used to detect the presence of HCV but had not realized could be used to determine and classify different HCV genotypes.

Defendant sells HCV genotyping assays that practice the method claimed in the '704 patent but do so using Realtime polymerase chain reaction (PCR), a technology that defendant asserted was not covered by the '704 patent. Plaintiff disagreed with this assertion and filed suit against defendant, alleging that defendant's products infringed the '704 patent and that the infringement was willful. Defendant responded by raising affirmative defenses of invalidity (anticipation and obviousness), plaintiff's failure to comply with the provisions of 35 U.S.C. §§ 102, 103 and 112 and inequitable conduct before the United States Patent and Trademark Office.

Prior to trial, the parties filed cross motions for partial summary judgment on defendant's claim of inequitable conduct. Defendant's motion was denied; plaintiff's was granted. Op. & Order, dkt. #131. Defendant filed a second motion for summary judgment on the issues of infringement and invalidity. This motion was denied in an order entered on August 11, 2006, on the ground that defendant had not shown as a matter of law that no reasonable jury could find in plaintiff's favor on these issues. Op. & Order, dkt. #218.

At the final pretrial conference, I determined that defendant had no evidence to support a claim of obviousness but that it could argue anticipation on the basis of a patent application filed by Dr. Cha and others that is prior art to the '704 patent.

The case went to trial on August 28, 2006. At the outset, I granted plaintiff's motion for judgment as a matter of law on the issue of infringement after defendant conceded that it had no evidence to support its defense to plaintiff's claim of infringement beyond what it had adduced in support of its motion for summary judgment. That evidence was limited to a showing that defendant used Realtime PCR to perform the genotyping process in the '704 patent. As explained in the August 11, 2006 order, I do not agree with defendant's contention that its products did not infringe because they employed Realtime technology. This ruling left only the affirmative defense of anticipation to be tried during the liability phase. On this defense, the jury returned a verdict in favor of plaintiff.

In a second phase of the trial, the jury found that if the plaintiff and defendant had engaged in negotiations for a license at the time that defendant put its infringing products on the market, defendant would have paid \$7,000,000 for the license, \$5,000,000 of which represented the jury's determination of the lump sum payment owed to plaintiff and \$2,000,000 represented the running royalty due from defendant. The jury found that defendant had infringed plaintiff's patent willfully.

II. DEFENDANT'S MOTION FOR NEW TRIAL ON LIABILITY ISSUES

A. Infringement

Defendant bases its motion for a new trial on infringement on its contention that the court's construction of the term "detecting a complex as formed" was erroneous. Prior to trial, when I construed the disputed terms of the patent, I held that "detecting a complex as formed" meant "detecting a complex that is or has been formed." Op. & Order, dkt. #218, at 18, 31. Under this construction, the patent claim extends to Realtime PCR technology, which employs the Taq polymerase to destroy a complex that has been formed between the probe and the nucleic acids of HCV, thereby liberating the "reporter" end of a probe and causing it to glow. Although the complex is destroyed, the probe will not emit light unless the Taq polymerase has found the specific complex to which it is directed. Realtime is as reliable a means of detecting a formed complex as the older methods in which the reporter signaled the formation of the complex while still attached to the hybridization complex. Nothing in defendant's arguments persuades me that it was error to construe the claim as I did or to find as a matter of law that defendant's use of Realtime PCR in its assays to not make the products noninfringing.

Defendant raises a new argument in its post-trial brief to the effect that the court's construction of "detecting a complex as formed" reads out of existence crucial limitations of claim 1. Apparently, defendant believes that it was error not to consider or construe the

phrase "with said probe and said nucleic acids of HCV," which modifies "formed." I do not agree that failing to consider the phase "read [it] out of existence," as defendant contends. There was no need to consider the phrase because neither party contested its meaning or denied that it described the formed complex. Even now, defendant does not contend that the complex identified by the Realtime PCR technology was not formed "with said probe and said nucleic acids of HCV."

Defendant has another variant of its attack on the court's claims construction. It contends that it was error to construe the meaning of a claim term without limiting the construction to what would have been known by a person of ordinary skill at the time the patent application was filed. In other words, if Realtime PCR was not in routine use at that time, it was error to construe the patent to include it as part of the patented method.

Defendant did not raise this issue before trial when it could have been given thorough consideration. Instead, it raised the issue for the first time at 9:30 p.m. on the night before the start of trial and did so simply by submitting a proposed jury instruction, rather than by bringing the matter directly to the attention of the court and opposing counsel. According to the new proposal, the jury would be instructed that it could find that defendant's products did not infringe if it found that the products used new technology that had not been available at the time the patent application was filed. Oddly enough, defendant did not raise this new theory of non-infringement when plaintiff moved at the outset of trial for judgment

as a matter of law on infringement. This would have been the time to bring it up, if defendant believed that the court had erred in deciding the motion for summary judgment by not acknowledging that the claims of a patent were limited to technology known in the art at the time of the patent application. Rather than doing so, however, defendant's counsel told the court that defendant had no evidence of non-infringement beyond what it had submitted in support of its motion for summary judgment on the issue of infringement. Trial Transcript, dkt. #310, at 73-74.

Defendant argues incorrectly that it had no obligation to move for reconsideration of the court's claim construction or come forward with an offer of proof to support new arguments it did not raise during the briefing on claim construction. In support of this position, it cites <u>Wilson v. Williams</u>, 182 F.3d 562, 567 (7th Cir. 1999), in which the court held that

once the ruling is definitive, the function of the objection requirement has been served, and both parties are entitled to formulate trial strategies that make the best use of the evidence that the judge has decided to admit or exclude. We overrule [United States v.] York, [933 F.2d 1343, 1360 (7th Cir. 1991)] to the extent it holds that an objection at trial is invariably required to preserve for appeal arguments that were fully presented to the district court before trial.

In citing <u>Wilson</u>, defendant seems to overlook the significant difference between it and this case. As the quotation makes clear, the objecting party in <u>Wilson</u> had fully presented its arguments before the court issued its "definitive" ruling. By contrast, in this case, defendant kept the court in the dark about many of its arguments. That kind of conduct constitutes forfeiture. <u>E.g.</u>, <u>Backwater</u>, <u>Inc. v. Penn-American Insurance Co.</u>, 448 F.3d 962, 965 (7th Cir. 2006) (parties' argument is "not a bad argument, but unfortunately for the [plaintiffs] it's also not an argument they made during the trial; instead of responding to [defendant's] objection with an offer of proof or by asking that the testimony be admitted subject to a limiting instruction, they simply moved on, forfeiting any charge of error."). I conclude that defendant forfeited its argument that the court's claim construction was flawed because that construction did not limit the reach of the claim to technology known at the time of the invention.

This ruling has no effect of the outcome of the case. Even if defendant had not forfeited its challenge, its argument would fail on its merits. First, it is likely that plaintiff could have shown that Realtime PCR was known to persons of ordinary skill in the art in 1992, when the inventors applied for their European patent, or in 1994, when they applied for the '704 patent. In the proposed findings of fact, submitted in support of its motion for summary judgment on infringement, defendant proposed the fact that "Realtime PCR was developed in the early 90's," Dft.'s PFOF, dkt. #52, at No. 28, and its expert stated in his report that "Realtime PCR using 5' to 3' exonuclease activity was pioneered around 1991," Patterson Non-infringement Opin., dkt. # 39, at 6. In addition, the Resnik '708 patent that defendant asserted as prior art to the '704 patent disclosed Realtime PCR as "another

suitable assay system" for "detecting hybrids formed" between probes and target nucleic acids. Resnick '718 pat. at col. 18, lns. 47-57, Exh. 5 to Anstaett Decl. dkt. #390.

Second, it is immaterial whether defendant had evidence that persons of ordinary skill would not have known about Realtime PCR before the application for the '704 patent was filed. Plaintiff made it plain in the '704 specifications that the detection of hybrids formed between the specific target region and the probes was not confined to any one method. Rather, it said, the detection depends on the nature of the reporter molecule used "and may be determined by means of colorimetric, fluorescent, radiometric detection *or any other method comprised in the state of the art.*" '704 pat., col. 6, lns. 36-42. Defendant never identified or produced any evidence to suggest that the language in claim 1 would not include Realtime PCR. Moreover, it has never produced any evidence that when researchers use defendant's products, hybrids do not form between the specific target regions and the probes.

Defendant cites a numbers of cases for the proposition that the literal scope of a claim term is limited to what it was understood to mean at the time of filing. That proposition is unremarkable. It is also inapplicable. Although a court must consider what was known to one of ordinary skill in the art at the time of filing, <u>Bayer AG v. Biovail Corp.</u>, 279 F.3d 1340, 1348 (Fed. Cir. 2002), the claims of the patent are not necessarily limited to technologies known at the time of filing. <u>SuperGuide Corp. v. DirecTV Enterprise, Inc.</u>, 358

F.3d 807, 879 (Fed. Cir. 2004) ("The law 'does not require that an applicant describe in his specification every conceivable and possible future embodiment of his invention.'") (quoting <u>SRI International v. Matsushita Electric Corp. of America</u>, 775 F.2d 1107, 1121 (Fed. Cir. 1985)). "[I]t is not necessary to embrace in the claims or describe in the specifications all possible forms in which the claimed principle may be reduced to practice." <u>See also CCS Fitness, Inc. v. Brunswick Corp.</u>, 288 F.3d 1359, 1366 (Fed. Cir. 2002) (no requirement that patentee describe in patent every possible future embodiment of his invention).

Finally, defendant devotes considerable space in its post-trial briefs to arguing that the doctrine of equivalents would not apply to support a finding of infringement. It is not necessary to address these arguments in light of my conclusion that defendant's products infringe the patent claims literally.

I conclude that defendant has not shown that it was error to grant judgment as a matter of law on plaintiff's claim of literal infringement.

B. Obviousness

Although defendant failed to show at the time why it would be error to deny it the right to put in evidence of obviousness at trial, it contends now that the court's decision was unsupportable. It argues that its expert witness, Bruce Patterson, and other witnesses would

have shown the jury why the '704 patent was obvious in light of the prior art.

Some additional background is necessary to provide context for the various rulings to which defendant takes exception. At the final pretrial conference, I ruled that defendant's expert, Bruce Patterson, would not be allowed to testify on obviousness. In an earlier order, I had granted plaintiff's motion to strike Patterson's supplemental expert report because it violated the court's order on the filing of such supplemental reports. Op. & Order, dkt. #158. This left only the question whether Patterson's original report was sufficient to support a jury finding of obviousness. Defendant was unable to show that it was.

Patterson never explained in his report why someone reading the prior art references he listed would have had any motivation to combine those particular references in order to practice the method that the '704 patent claims. In addition, he did not explain how or why the prior art could be combined to reproduce the patented invention with a reasonable expectation of success, how the nature of the problem would have suggested to those of ordinary skill in the art how to combine the prior art references to arrive at the patented method or what effect secondary indications of non-obviousness would have on his opinion. Instead, he simply said that persons skilled in the art would have found it obvious from previous methods of genotyping using the 5' UTR and "the motivation provided by Kanai, the 1992 Cha article, and the Okamoto reference," Patterson Invalidity Opin., dkt. #33 at 24, to perform the genotyping method claimed by the '704 patent. The motivation to which he referred was the motivation "to detect and classify HCV genotypes to appropriately manage patients." Id. at 22.

Patterson's report did not supply the kind of evidence that a reasonable jury would need in order to make the determination that the '704 patent claims would be obvious to those of ordinary skill in the art. A generalized motivation to develop a method is not the kind of motivation required by the patent laws. Otherwise, simply identifying a need would allow one to claim an invention. The jury had to know why researchers looking at the Cha application together with the other prior art references would have known to combine some or all of those references in order to genotype the HCV virus, that is, to distinguish among types and subtypes of the hepatitis C virus and classify the HCV into a genotype or subtype.

Defendant is correct when it argues that motivation need not be suggested in any particular piece of prior art but can be found in a number of sources, including common knowledge, the prior art as a whole or the nature of the problem itself. <u>Dystar Textilfarben</u> <u>GmbH & Co. Deutschland KG v. C.H. Patrick Co.</u>, 464 F.3d 1356, 1365-66 (Fed Cir. 2006). Nevertheless, some kind of motivation must be shown from some source, so that the jury can understand why a person of ordinary skill would have thought of either combining two or more references or modifying one to achieve the patented method. It is all too easy for a jury looking at a patented method to conclude in hindsight that the invention was obvious. The motivation requirement implements the Supreme Court's recognition of the

"importance of guarding against hindsight, as is evident in its discussion of the role of secondary considerations as 'serv[ing] to guard against slipping into use of hindsight and to resist the temptation to read into the prior art the teachings of the invention in issue." <u>Alza Corp. v. Mylan Laboratories, Inc.</u>, 464 F.3d 1286, 1290 (Fed. Cir. 2006) (quoting <u>Graham</u> v. John Deere Co., 383 U.S. 1, 36 (1966)).

It is true, as defendant asserts, that one prior art reference may be sufficient to show the obviousness of the invention. This does not mean, however, that it is not necessary to show *why* the single reference makes an invention obvious. Patterson did not do this with the Cha application. Defendant argues that it was not necessary for him to do so because any differences between Cha and the patented invention are minimal and may not even exist. Defendant does not identify what those differences might be or even describe the supposed similarities. It is not credible to think that a lay jury could examine the Cha application, the Resnick '718 patent that defendant cited as prior art or any of the other references and determine on its own whether there were differences among them and the '704 patent.

Defendant says only that because all of the prior art references discussed by Patterson describe "*probe-based hybridization methods of genotyping HCV using the 5' UTR*, there remained little if anything to say about any alleged 'differences' between the references and the prior art." Dft.'s Br., dkt. #364, at 2. (I assume that defendant meant to say "between the

references and the '704 patent claims."). In fact, most of the prior art references do not describe *genotyping* HCV but rather methods of *detecting* HCV. Detecting HCV is not the same as distinguishing isolates and classifying them into genotypes, which is what is taught in the '704 patent. As for the Cha application, Patterson did not explain how a person of ordinary skill would understand from reading that reference how to specifically hybridize a probe to target nucleic acids in the 5' UTR, detect hybridization and then identify the genotype of the virus in the biological sample.

When I held at the final pretrial conference that Patterson's testimony on obviousness would not be allowed at trial, I withheld ruling on testimony from other witnesses on the same subject. In the written order commemorating the conference rulings, I said inaccurately that I had ruled that defendant could put in no evidence of obviousness. Defendant never moved for correction or reconsideration of the written order. Instead, it advised plaintiff's counsel in writing that it would not be contesting the written ruling and would put in no evidence of obviousness. It confirmed this decision on the first day of trial, noting that it wished to preserve an objection on the issue, which it did.

In the post-trial briefing, defendant contends that it would have been able to support its claim of obviousness had it been allowed to call witnesses on the issue other than Patterson, such as fact witnesses Dr. Cha, Dr. Leckie or Dr. White, or if it had been allowed to conduct a thorough cross-examination of plaintiff's witnesses, Drs. Worman and Maertens. Defendant never asked for the opportunity to do this. Moreover, defendant says nothing about what these witnesses would have had to say about obviousness. Without such information, I cannot determine whether defendant was prejudiced by not being permitted to adduce evidence on obviousness.

Again, defendant seems to be arguing that once the court denied it the opportunity to try to prove obviousness at trial, it had no obligation to make an offer of proof or to reargue the matter to the court in order to preserve the issue for appeal. A party *always* has an obligation to alert the court to the full nature of its objection and to bring judicial errors to the court's attention. No defendant that fails to advise the court of the evidence it intends to present and explain how it would do so can argue later that it was prejudiced by being denied the opportunity to put in the evidence. If defendant thought that the court had made an error in the final pretrial conference ruling, it should have said so at a time when it could have been corrected.

One of the obstacles defendant faced when it stated that it would be calling certain "fact" witnesses to testify on the issue of obviousness is that it had never identified them as persons it would be calling for that purpose. Another obstacle was the unlikelihood that Drs. Cha, Leckie and White could show that they are persons of ordinary skill in the art. According to defendant's expert, Dr. Patterson, such a person would "be capable of performing molecular biology and virology techniques at the research technician (B.S. level) or graduate student level." Patterson Invalidity Opin., dkt. #33, at 2. Drs. Cha, Leckie and White have qualifications that far exceed those of the person described by Dr. Patterson. Dft.'s Reply Br., dkt. #399, at 22-23 (describing qualifications of witnesses). Thus, their own observations about the Cha application would not be relevant to what a person of ordinary skill would have observed. Had they been named as experts and complied with Fed. R. Civ. P. 26(a)'s requirements for experts, they would have been allowed to testify to what persons of ordinary skill in the art would have known about the Cha application and its obviousness to those persons (provided, of course, that they showed they had the requisite knowledge to do so). If there are other matters about which the three witnesses might have testified, defendant has not identified any that would have been both factual and relevant to the issue of obviousness.

Defendant argues that it was improper to deny it the opportunity to cross examine plaintiff's witnesses on the subject of obviousness. It is difficult to see the point of this argument. Had plaintiff moved for judgment as a matter of law at the end of defendant's case in chief, and defendant had put in no evidence to support its invalidity claim, the motion would have been granted. Under such circumstances, defendant would not have had the opportunity to cross examine plaintiff's witnesses because they would never have been called to testify. (Defendant does not assert that it would have called them adversely in its own case.) In summary, I conclude that defendant has failed to show that it was error to deny it the right to pursue its defense of obviousness at trial.

C. Anticipation

On the issue of anticipation, defendant focuses its objections on the court's refusal to allow Dr. Cha to testify beyond the actual words and content of the Cha application. Defendant objected to the restrictions at trial and in its post-trial briefing, but it has failed to show that the restriction was improper under the circumstances.

For reasons of its own, defendant chose to treat Dr. Cha as person not retained or specially employed to provide expert testimony, apparently with the idea that so long as it did not pay Cha for his testimony, it did not have to provide plaintiff with an expert report from Cha. In arguing that this treatment was correct, defendant compared Cha to a physician who would be allowed to testify about the treatment he gave the plaintiff in a personal injury action. The comparison was not an apt one. As defendant's pretrial disclosures indicated, defendant viewed Cha's testimony as extending far beyond that of a treating physician. Defendant notified plaintiff that it expected that Cha would be testifying about his scientific work, his publications and patent applications in the field of HCV genotyping and his opinions about that work based on his scientific, technical or other specialized knowledge. Although defendant offered to limit the proposed testimony after plaintiff objected to it, it advised plaintiff that it would still ask Cha to testify to his personal and technical knowledge about his application and two relatively contemporaneous articles written in 1991 and 1992. Plaintiff maintained its objections and moved in limine for an order prohibiting Cha from testifying.

At the final pretrial conference, I ruled that Dr. Cha could not offer any expert opinions at trial because defendant had not tendered him as an expert and complied with the requirements of Fed. R. Civ. P. 26(a)(2)(B). In the pretrial order, I specified that Cha's testimony would be restricted to descriptions of the work he had done and his observations and that he could not elaborate on his observations, explain anomalous results or testify as an expert. Defendant contends that this ruling was erroneous and prejudicial.

Although the Court of Appeals for the Seventh Circuit has not ruled explicitly on the question whether a witness called to give opinion testimony is excused from providing an expert report if the witness is not retain or employed, it suggested in dicta in <u>Musser v.</u> <u>Gentiva Health Services</u>, 356 F.3d 751, 757 (7th Cir. 2004), that it would not view treating physicians as exempt from the requirements of Fed. R. Evid. 702 and 703 if they were testifying to opinions based on scientific, technical or other specialized knowledge. In <u>Day v. Consolidated Rail Corp.</u>, 1996 WL 257654 (S.D.N.Y. May 15, 1996), a federal district court held that Rule 26(a)(2)(B) does not exempt from its report requirement non-retained

experts who are to give expert testimony about scientific or technical matters. In <u>Day</u>, the defendant railroad had named two expert witnesses, including an employee of the railroad, but had not furnished expert reports for the plaintiff. After reviewing the language of the relevant Advisory Committee notes for Rule 26(a)(2)(B) and its predecessor versions, the court found no reason to construe the rules to exempt experts from complying with the report requirement and "no disclosure exemption for experts who are not monetarily compensated." <u>Id.</u> at *3.

I am persuaded by the reasoning in <u>Day</u> that it would thwart the rule's purposes to allow exemptions from the report requirement for witnesses who will be giving scientific testimony, simply because they are not compensated for their work. The purpose of Rule 26 is to make discovery easier, faster and more efficient, as well as to avoid surprises at trial. It does not advance this purpose to withhold the kind of report that opposing counsel needs in order to conduct an informed deposition or cross examination of a witness, even if the witness is willing to testify without charge for reasons of his own. (In this case, of course, Dr. Cha is not entirely disinterested. He may have many reasons to want to prove that he was the true inventor of the method claimed in the '704 patent.).

Defendant made the risky choice to characterize Dr. Cha as a non-retained expert and paid the price for that choice when I concluded that the mere fact of non-payment did not relieve him of the necessity of submitting a report well in advance of trial. For this noncompliance, Cha was not allowed to give any expert opinions at trial.

Plaintiff had a second ground for barring Dr. Cha's testimony in addition to defendant's failure to disclose him properly as an expert and provide a report. If Cha testified about the preparation of the probes or the temperatures and other conditions he used for his experiments or explained why the apparently anomalous results would not have taught away from using the 5' UTR for genotyping HCV, he would be adding information about the Cha application that a person of ordinary skill in the art might not have understood in reading the application. Such testimony would have been irrelevant to the issue before the jury, which was whether the Cha application was sufficient in itself to have informed a person of ordinary skill in the art in 1992 how to distinguish among HCV genotypes by using probes in the 5' UTR.

Defendant asserts that what plaintiff feared was not Dr. Cha's opinion testimony but testimony about his work, which was "indisputably fact testimony." Dft.'s Reply Br., dkt. #399, at 26. It adds that Cha's testimony about his own work, the anomalies he witnessed and his understanding about the work he did "is the essence of fact testimony." Id. at 27. In making this assertion, defendant fails to appreciate the point that classification of Cha's testimony as opinion testimony was only one ground for excluding it. A second reason for its exclusion was its irrelevance to the issue before the jury.

Defendant adds another argument that is almost too insubstantial to address. It says

that plaintiff's counsel conceded at trial that Cha's testimony "was very, very relevant to whether the Cha PCT is indeed enabled," that "'he would march through all of his knowledge and experience in front of the jury which goes to the heart of enablement . . . what one of ordinary skill in the art would understand" and that his testimony would "'give the impression that one of ordinary skill in the art would assume that example two of the Cha PCT is enabled simply because of the knowledge that was available to one of ordinary skill in the art." Dft.'s Reply Br., dkt. #399, at 25 (quoting Trial Tr., dkt. #311, at 62, 66, and 72). Reading the quoted testimony in its entirety and in context makes it clear that plaintiff's counsel was making the point I adopted at the time, which is that the Cha testimony would make it extremely difficult for the jury to separate what the Cha application made available to persons of ordinary skill in the art from the information that Cha divulged in his testimony and also, that much of Cha's anticipated testimony would be in the nature of expert testimony for which he had not provided a report in advance of trial. Defendant's counsel was not conceding the relevance of the testimony to the issue the jury had to resolve.

2. Inherency

Defendant argues that it was error for the court to excise an instruction on anticipation by inherency from the jury instructions defendant had proposed. Conspicuously absent from its argument is any explanation of the evidence in the record that would have supported the giving of such an instruction. Defendant identified none at the time of the instruction conference when the decision was made not to give the inherency instruction. Trial Tr., dkt. #335, at 37-38. Now it says only that

The Cha PCT Application included, for example, mention of certain well known techniques and reference works that had to be explained to the jury so they would have the information necessary to understand how the application would be read by a person of ordinary skill in the art at the relevant time. But even without such mention, there is information inherent in every reference that needs to be understood by the jury to fully understand the reference, because patent applicants do "not need to include in the specification that which is already known to and available to one of ordinary skill in the art." Koito Mfg. Co. v. Turn-Key-Tech, LLC, 381 F.3d 1142, 1156 (Fed. Cir. 2004) (citing Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys., 804 F.2d 659, 664 (Fed. Cir. 1986)).

Dft.'s Br. in Supp. of M., dkt. #364, at 35-36. It is unlikely that defendant means in this paragraph to be advancing the proposition that the jury could have found inherency simply by looking at the Cha application. Clearly, it would be impossible for a lay jury to look only at the Cha application and make such a determination. If it is advancing another proposition, I cannot tell what it is.

3. Cha '693 patent

On the last day of discovery, after the parties had taken all of their depositions, defendant gave notice to plaintiff pursuant to 35 U.S.C. § 282 that it was identifying U.S.

Patent No. 6,071,693 (Cha et al.) as an anticipating piece of prior art. This was the first time that defendant ever identified the '693 patent as a prior art reference that it would be relying upon to support its anticipation defense. It did not mention the patent at the final pretrial conference or make any other reference to it until the night before trial began, when it submitted revised proposed jury instructions and special verdict forms to include the alleged prior art patent.

Although defendant was technically in compliance with the requirements of § 282, its late disclosure after the time for depositions had passed would have meant that plaintiff would be subject to unfair prejudice if defendant had been permitted to introduce evidence of the '693 patent. Defendant's expert never mentioned the patent in his expert report or in his deposition and defendant had made no reference to it at any time in response to contention interrogatories. Without any indication that defendant would be relying on the '693 patent, plaintiff had no reason to question any of defendant's witnesses about it.

Defendant argues that plaintiff knew of the patent because its own expert, Dr. Sofocleous, had discussed it in his expert report in support of plaintiff's motion for summary judgment of no inequitable conduct. Knowing of the patent in this context does not mean that plaintiff understood that defendant would assert it as a piece of anticipatory prior art. Defendant does not say why it did not advise plaintiff earlier of the possibility that the patent might be relied upon for anticipation. At trial, defendant's counsel said that its failure to say anything about the '693 patent at the final pretrial conference was inadvertent. Trial Tr., dkt. #310, at 77-84. In barring defendant from referring to the patent during trial, I agreed with plaintiff that if the failure to disclose was inadvertent and plaintiff would be prejudiced by the late disclosure, the price for the inadvertence should be borne by defendant. Defendant has shown no reason why that decision was wrong.

In any event, defendant has failed to show why barring it from introducing the '693 would have affected the outcome of the trial. It has not cited any evidence it could have submitted to support its assertion that the patent was anticipating. Although defendant says now that none was necessary because the '693 patent disclosed the same information as the Cha application, it needs evidence, and not just its own assertion, to explain why a jury could have found the two pieces of prior art the same and if so, why this would have changed the outcome of the trial. Nothing in the record suggests that defendant ever asked its own expert to explain how the '693 patent might have anticipated plaintiff's patent.

4. Dr. Patterson's testimony

In the preliminary pretrial conference order in this case, the magistrate judge warned counsel that there was to be no third round of report writing in the form of rebuttal expert reports. Supplementation *was* allowed but limited to matters set forth in the expert's first report. PPTC Order, dkt. #12, at 2. Defendant's expert, Dr. Bruce Patterson, filed two

expert reports and a supplemental expert report. The first report, dkt. #33, was filed on April 10, 2006, and addressed the alleged invalidity of the '704 patent. The second, dkt. #39, was filed on May 2, 2006. It addressed non-infringement and responded to the expert reports filed by plaintiff's experts, William A. Reznikoff and Howard J. Worman. The supplemental report, dkt. #59, was filed on May 19, 2006. Not surprisingly, the filing of the supplemental report elicited a motion to strike from plaintiff, which was granted with one exception, on the ground that the supplemental report contained new matter and thus violated the terms of the preliminary pretrial conference order. (The one exception was a correction to the citation of a reference on which Patterson had relied in his first report.). At trial, Dr. Patterson was allowed to testify about anticipating prior art that he had discussed in his expert report but was not allowed to express opinions about anticipation that he had not disclosed in his report, such as why Cha obtained the results he described or what parameters he used for the experiments. Defendant contends that this limitation on his testimony was unfounded and prejudicial.

Defendant maintained that the Cha application taught persons of ordinary skill in the art how to detect various genotypes of HCV and to distinguish among them and that it disclosed a method for carrying out a genotyping analysis that can be performed on various regions of the hepatitis C virus, including the 5' untranslated region. Plaintiff argued that the application was limited to detecting HCV and not genotyping it (distinguishing among the various types and subtypes of the virus). In support of this argument, plaintiff pointed to apparent anomalies in the application.

The Cha PCT application describes two nucleic acid hybridization experiments. In the first, the core or envelope regions of the 5' UTR of the HCV genome were said to be amplified by PCR. However, the experiment detected only genotypes I and II using the core and envelope regions for detection and not the 5' UTR. In the application's second experiment, the researchers used probes designed to the 5' UTR to detect genotypes III and IV, but used other probes designed to the envelope region to detect genotypes I and II. It is questionable whether such detection would occur unless the latter probes were capable of hybridizing to non-target sequences or if the PCR amplification were not specific to the specified region, or both. The data do not explain what may have led to the results claimed and they do not indicate the lack of cross-reactivity against other genotypes. Probes designed to the envelope region should not be capable of hybridizing specifically to the 5' UTR.

Despite Patterson's failure to discuss these omissions and apparent anomalies in his expert report, defendant wanted to ask him at trial about these matters and others that he had not disclosed. Plaintiff objected to such questioning and the objection was sustained. Allowing Patterson to testify about new opinions he had reached but had never disclosed to plaintiff would reward defendant for its failure to comply with its discovery obligations. Defendant cries foul, pointing out that Patterson reserved the right to supplement his expert report after the court had construed the disputed terms in the patent. This is a red herring: Patterson never attempted to supplement his report after the claims construction opinion issued. His earlier "supplemental expert report" was filed almost three months before the claims had been construed and made no mention of the omissions and anomalies in Cha's work despite the fact that both of plaintiff's experts had pointed out those anomalies of the Cha application in their own reports.

Defendant contends also that it was unfair to limit Patterson even on rebuttal to the opinions disclosed in his two timely reports. It would have been more unfair and inappropriate for Patterson to testify to new opinions during what was supposed to be mere rebuttal to the testimony of plaintiff's expert witnesses.

Pursuing a tit-for-tat argument, defendant takes umbrage with the court's allowance of extensive testimony from plaintiff's experts, Drs. Worman and Reznikoff, and from the inventor, Dr. Maertens, when it restricted the testimony of defendant's experts. One big difference between Drs. Worman and Reznikoff and Dr. Cha is that the former two witnesses were disclosed as experts and provided expert reports, whereas Dr. Cha did not. Like Dr. Patterson, Worman and Reznikoff were limited to testifying about matters they had discussed in their expert reports. Since they had discussed the lack of enablement in the Cha application, they were free to testify about it at trial. Maertens testified only about the development of the invention claimed in the '704 patent and did not discuss the Cha application. I conclude that defendant's objections to letting Maertens, Worman and Reznikoff testify are not well founded.

5. <u>Resnick '718 patent</u>

The Resnick '718 patent was one of the pieces of prior art that allegedly anticipated plaintiff's '704 patent. Before trial began, I advised the parties that it appeared unlikely that the Resnick patent could be found to anticipate because it was limited to detecting Hepatitis C and did not disclose a method of distinguishing among types and subtypes of HCV. Op. & Order, dkt. #218, at 28. Defendant was unable to show at trial that the Resnick patent was anticipatory because its evidence was limited to the testimony of Dr. Patterson, whose opinions rested on an inaccurate understanding of the construction of the term "genotyping." Defendant has failed to show why it was error to grant plaintiff's motion for judgment as a matter of law on this piece of prior art.

In summary, I conclude that there is no merit to defendant's motion for a new trial on defendant's defense of anticipation.

III. MOTION FOR JUDGMENT AS A MATTER OF LAW OR FOR A NEW TRIAL ON THE ISSUES OF DAMAGES AND WILLFUL INFRINGEMENT

At trial, the jury awarded plaintiff \$7,000,000 in damages, \$5,00000 of which was in a lump sum, representing the amount of a reasonable royalty to which the parties would have agreed had they negotiated for a license of plaintiff's technology in 2003. In addition, the jury found that defendant had infringed the '704 patent willfully.

A. Damages

In calculating the amount of a reasonable royalty, the jury has to pretend that the parties sat down and negotiated a reasonable royalty before the day that defendant began its infringement of the plaintiff's patent. <u>Integra Lifesciences I, Ltd. v. Merck KGaA</u> 331 F.3d 860, 870 (Fed. Cir. 1993) ("A reasonable royalty calculation envisions and ascertains the results of a hypothetical negotiation between the patentee and the infringer at a time before the infringing activity began.") (citing <u>Riles v. Shell Exploration & Production Co.</u>, 298 F.3d 1302, 1311 (Fed. Cir. 2002)). Unlike a real negotiation, this hypothetical negotiation assumes that the infringer must agree to some amount of royalty payment; it does not have the option of walking away from the table. The jury must put itself in the shoes of the parties and look at the relevant circumstances as they were at the time the negotiations would have taken place. "[T]he reasonable royalty calculus assesses the relevant

market as it would have developed before and absent the infringing activity." Id.

Dfendant attacks the \$7,000,000 damage award on four grounds: (1) it flunks the reality test because the amount the jury awarded would have left defendant without any profit, given its fixed costs; (2) plaintiff's expert relied on inadmissible sales and profit projections prepared in 2004, a year after the hypothetical license would have been negotiated; (3) plaintiff's expert relied on a single license agreement that plaintiff had negotiated with Roche Pharmaceuticals; and (4) the court erred in precluding defendant's president from testifying on a number of relevant topics.

1. Reality test

Despite defendant's view of the jury's verdict, the evidence was adequate to allow the jury to find that \$7,000,000 constituted a royalty that was fair and reasonable and not unrealistic. Defendant places great weight on its assertion that it would never have agreed to a license fee that left it with no profit. Contrary to its assertion, the effect on defendant's profit margin is not determinative of reasonableness, although it is certainly probative. "There is no rule that a royalty be no higher than the infringer's net profit margin." <u>Golight, Inc. v. Wal-Mart Stores, Inc.</u>, 355 F.3d 1327, 1338 (Fed. Cir. 2004) (quoting <u>State Industries, Inc. v. Mor-Flo Industries, Inc.</u>, 883 F.2d 1573, 1580 (Fed. Cir. 1989)). In any event, there was adequate evidence from which the jury could find that defendant would

have been able to earn a profit even after paying the license fee assessed by the jury.

The jury had evidence before it that technology companies often lose money on new products for the first few years of production, expecting to make up for the losses in future years as the market for the new technology grows. It knew that plaintiff had an ongoing license agreement with Bayer that required Bayer to pay plaintiff 15 euros for each test, making it unlikely that plaintiff would agree to a license agreement that would enable defendant to gain a competitive advantage over Bayer by being able to sell its own kits at a lower price than Bayer. It had evidence it could consider that defendant would have gained additional profits on "convoyed" sales (sales that open the door to sales of similar or associated products). Plaintiff's trial exhibit 103 showed that defendant considered its gentotyping assays to be a market share driver for other assays. The jury could have found also that defendant would have assessed the hypothetical license price in light of its anticipated profits in the future and in light of its opportunity to win a share of the market before Roche began manufacturing and selling competing products.

That defendant would have preferred to pay a lower amount is not the test for damages. <u>Golight, Inc.</u>, 355 F.3d at 1338 (citing <u>Rite-Hite Corp. v. Kelley Co.</u>, 56 F.3d 1538, 1555 (Fed. Cir. 1995)). Rather, the test is what amount defendant would have agreed to pay, knowing that plaintiff's patent was valid, knowing that it could not walk away from the negotiations without an agreement and knowing how much the HCV genotyping test

would add to its ability to sell related products and platforms. I am not persuaded that the jury's determination flunked the reality test.

2. 2004 projection

In reaching its damages decision, the jury could have relied reasonably on the 2004 projection that indicated that defendant was expecting to make much higher profits on its HCV assays in the future. Defendant raises an indefensible objection to the jury's reliance on the 2004 projection, saying that the jury could not have relied reasonably on this projection because it was created after the time the hypothetical negotiation would have taken place. Defendant must be forgetting that its own expert relied on the same projection, which defendant had marked as an exhibit. Defendant's expert testified that he and plaintiff's expert were "using the August, 2004 projections, which are actually for a different product. But we're using that as a proxy of what may have been expectations at that time, and based upon setting that royalty rate, you're going to apply that simply to past infringement damages or past sales." Trial Tr., dkt. #355, at 53. Given its own expert's description of the projection, it is difficult for defendant to argue successfully that plaintiff misled the jury by suggesting that the 2004 projections were evidence of defendant's state of mind in 2003, particularly when defendant had ample opportunity to examine and cross examine its own and plaintiff's witnesses on the projections. Defendant's counsel questioned

the witnesses comprehensively on such matters as when the projections were made, whether defendant relied on them and whether the exhibit containing the projections was a draft or a final version. It is sophistry for defendant to assert now that the jury was led to believe that the projections were in existence before the date of the hypothetical negotiations.

In any event, the time for objecting to the use of the 2004 projections was at trial, when a ruling could have been made on the admissibility of the exhibit before the jury saw it. Defendant forfeited the right to object to the use of the 2004 projection by never raising a contemporaneous objection to its introduction into evidence.

3. Reliance on Roche license

The record belies defendant's assertion that plaintiff's expert relied exclusively on the Roche license that plaintiff negotiated for the HCV assays when he determined the hypothetical negotiation price. Plaintiff's expert testified that he looked closely at the Roche license because of the similarities between it and the negotiation at issue, but that he did not limit himself to that license. He considered the Bayer royalty because he knew defendant would be competing directly with Bayer; defendant had an incentive to keep selling its assays because Roche was not yet in the market and defendant could gain market share while Roche was developing a competing product; defendant understood the importance of having an HCV genotyping product in its product offerings as well as the consumer interest in having an array of assays to run on instrument platforms; defendant recognized that the ability to offer a genotyping test would help it sell additional diagnostic assays; defendant had no real alternative to obtaining a license from plaintiff if it wanted to continue to sell an HCV genotyping test; and the HCV genotyping market was growing quickly.

Defendant introduced evidence that the Roche license involved 104 patents and patent applications and argued to the jury that the number of patents and applications was the reason Roche was willing to pay as much as it did for the license. However, its own damages expert conceded that none of those 104 patents could be used for anything but an HCV genotyping test. Plaintiff's evidence showed that the '704 patent was the critical patent of the group for anyone wanting to run genotyping assays.

4. Michael testimony

Ed Michael is president of Abbott Molecular, distributor of the accused products. He was called by defendant at trial to testify on a number of subjects relating to the value of the royalty defendant would have agreed to pay, despite the fact that at no time before trial did defendant ever name him as a person "having discoverable information that may be used by [defendant] to support its claims or defenses" relating to damages under Fed. R. Civ. P. 26(a)(1) or as a corporate representative under Fed. R. Civ. P. 20(b)(6).

Michael's testimony at trial was restricted. First, he was not allowed to testify about

a supposed error in the 2004 projections because doing so would have meant introducing a new issue that defendant had never disclosed to plaintiff or to its own damages expert. Defendant's expert's report was based upon the same projections that plaintiff had relied upon and it made no reference to the alleged error about which defendant's counsel wanted to question Michael. (Whether there was any substance to the issue is unknown because defendant never made an offer of proof.). Michael was not permitted to testify on this new issue or about any matters that bore on defendant's expert's report but had not been disclosed in the report.

Second, Michael was not allowed to testify about matters that were based on hearsay. For example, he was not allowed to testify about the markets to which Bayer and Chiron could gain access by virtue of a license with Gen-Probe, Trial Tr., dkt. #350, at 66-71, or about the size of the HCV nucleic acid testing market in 2003, <u>id.</u> at 72. Despite these rulings, Michael gave extensive testimony for most of a full day of trial. I am not persuaded that the rulings restricting his testimony were in error or that they deprived defendant of a fair trial.

B. Willfulness

1. Trial evidence

The evidence adduced on the issue of willfulness came primarily from four witnesses,

David Schodin, Norval Galloway, Thomas White and Ed Michael.

a. David Schodin

David Schodin is a patent lawyer employed by defendant. He has a Ph.D. in biochemistry and is familiar with probe hybridization assays from working with them in 1992. He worked at the Leydig, Voit & Mayer law firm from 1996-2001, not as a lawyer but as a person doing patent preparation and prosecution. In 2001, he received his law degree and went to work as a patent lawyer for defendant's parent company with responsibility for its molecular products. For a short period, from May 2004 until January 2005, he left defendant to work for his old law firm.

Schodin first became aware of questions about defendant's products in late 2003. He reviewed the '704 patent and thought defendant's products might infringe the patent's claims. He consulted with Celera, the company that manufactures the genotyping assays and with which defendant has a strategic alliance. Celera advised Schodin that it would be retaining the Dorsey & Whitney law firm as outside counsel to draft an opinion about the validity of the '704 patent. The firm provided Schodin a draft opinion on validity in the spring of 2004, concluding that the '704 patent was invalid because it was anticipated by the Cha PCT application. The authors of the opinion did not discuss infringement, the legal standard for anticipation or the enablement of the Cha PCT application. The opinion

Schodin received was clearly marked "DRAFT," although another copy sent to Victor Lee of Celera did not contain such markings.

Schodin believed that the '704 patent was anticipated in light of the Cha PCT application. His belief was confirmed by the Dorsey & Whitney opinion. He does not remember whether the opinion noted that the Cha application had been disclosed to the Patent & Trademark Office or whether Dorsey & Whitney had had a copy of the '704 file history when its lawyers were preparing their opinion.

b. Norval Galloway

Norval Galloway is another patent lawyer employed by defendant from January 2001 until February 2003 and from September 2004 to the present. He has a Ph.D. in physical chemistry as well as a law degree and previous experience as patent counsel to an oil company and the company's molecular venture. He first became aware of questions about the '704 patent in December 2004, when Gene Cartwright, General Manager of Abbott Molecular, told him that plaintiff had identified some patents to defendant and asked whether defendant would be interested in licensing opportunities. Cartwright asked Galloway whether defendant would need to consider licensing. Galloway reviewed the patent and the draft opinion in January 2005 and agreed with Dorsey & Whitney that it was anticipated by prior art. Galloway tested the Dorsey & Whitney opinion independently to determine whether it stood up to scrutiny and was satisfied that it did. He told Cartwright that defendant did not need to take a license. Later, he told defendant's president, Ed Michael, the same thing.

Galloway talked to Victor Lee at Celera about defendant's interest in obtaining a final version of the 2004 opinion from Dorsey & Whitney. Lee agreed that it would be wise to do so. Galloway chose to go back to Dorsey & Whitney for the formal opinion despite the fact that the lead lawyer was no longer with the firm because another lawyer who had worked on the opinion was still at the firm and familiar with the patent and the science and would not require additional time to master these matters. Defendant hired the firm in April 2005 to prepare a formal opinion, which was delivered to defendant in October 2005, shortly after this suit was filed. The formal opinion contained the same conclusions as the draft version, but added discussions of the relevant law. It did not include any discussion of infringement, but focused exclusively on invalidity. It did not contain a construction of the term "method of genotyping."

c. Thomas White

Thomas White is the Chief Scientific Officer and Senior Vice President for Celera. He participated in the creation of the alliance between Celera and defendant in June or July of 2002 and he proposed a project to develop ASR reagents to identify and type HCV genotypes to the alliance's joint review board in June 2002.

White read the '704 patent when it issued in 1998 but testified that he did not rely on it when his scientists began work on HCV genotyping in 2001. He did know that Bayer sold HCV genotyping products developed by plaintiff.

d. Ed Michael

Ed Michael is President of Abbott Molecular. When the company began selling its HCV genotyping product in 2003, he was not aware of the '704 patent. He learned about it for the first time in late 2003 when he was told that plaintiff had inquired whether defendant would like to take a license under the patent. His response was to talk with various people in his organization and with the president of Celera Diagnostics, Kathy Ordonez. He and Ordonez agreed that Celera would take the lead in obtaining a legal opinion about the need for a license. He assigned Schodin the responsibility of working with Celera on the patent issue. He believed Schodin to be a highly qualified patent lawyer with a scientific background that would assist him in understanding the patent.

In late 2003 or early 2004, Michael learned from Schodin that Celera was consulting an outside law firm. Later, he spoke at more length with Schodin about Schodin's conclusions and about the draft opinion received from the law firm, which confirmed Schodin's own conclusions that the patent was invalid in light of work done by scientists from Chiron.

Michael relied on Schodin's opinions. Although Michael is a lawyer, he is not a patent lawyer or a scientist with any particular skill in the area of the '704 patent. On the basis of what he learned from Schodin, he decided it was not necessary to take a license from plaintiff.

It is Michael's practice to undertake a "freedom to operate" analysis for every project the company undertakes. This involves an assessment of the relevant intellectual property.

Later in 2004, when Michael became aware of another inquiry from plaintiff, he asked Galloway to look into the patents and determine whether there was a need to take a license and also to determine whether any additional work was necessary to follow up on the inquiry done earlier in the year. At a later time, Michael met with plaintiff's president and told him that defendant did not think it needed a license from plaintiff. The reaction from plaintiff's president caused Michael to go back to his employees and ask for yet another review of the need for a patent. Michael assigned Galloway the task of following up on the patent and making sure that the initial opinion was put into final form. In light of the opinions he had received from Schodin and Galloway, Michael did not think it was necessary to stop selling the allegedly infringing products.

2. Reasonableness of jury's determination of willfulness

A jury's verdict is entitled to deference. To overturn it, a party must show that no reasonable jury could have reached the conclusion it did, taking into consideration all of the record evidence and drawing all reasonable inferences in plaintiff's favor. The court may not make credibility determinations or weigh the evidence; such functions are exclusively reserved to the jury. <u>Reeves v. Sanderson Plumbing Products, Inc.</u>, 530 U.S. 133, 150 (2002).

Willfulness requires a showing of more than mere negligence on the part of an infringing party. <u>Knorr-Bremse Systeme Fuer Nutzfahrzeuge GMBH v. Dana Corp.</u>, 383 F.3d 1337, 1342 (Fed. Cir. 2004). "Fundamental to determination of willful infringement is the duty to act in accordance with law" and to "respect valid patent rights." <u>Id.</u> at 1343.

In considering whether an infringer has acted willfully, that is, in bad faith or egregiously, courts can take into consideration such matters as (1) whether the infringer deliberately copied the ideas or design of another; (2) whether the infringer investigated the scope of the patent and formed a good faith belief that it was invalid or not infringed; (3) whether the infringer engaged in tactics designed to extend the litigation or run up costs to the patent holder; (4) the infringer's size and financial condition; (5) the closeness of the case; (6) how long defendant's misconduct continued; (7) whether defendant took any remedial action; (8) whether defendant had a motivation for harm; and (9) whether defendant made attempts to conceal its misconduct. Liquid Dynamics Corp. v. Vaughan

<u>Co., Inc.</u> 449 F.3d 1209, 1225 (Fed. Cir. 2006) (citing <u>Read Corp. v. Portec. Inc.</u>, 970 F.2d 816, 826-27 (Fed. Cir. 1992), <u>superseded on other grounds</u> as recognized in <u>Hoechst</u> <u>Celanese Corp. v. BP Chemicals. Ltd.</u>, 78 F.3d 1575, 1578 (Fed. Cir. 1996)).

The burden of proving bad faith or willfulness falls on the patent holder, who must prove it by clear and convincing evidence. In moving for a new trial or judgment as a matter of law, however, defendant has the burden of showing that no reasonable jury could have reached the conclusion that this one did, bearing in mind that the "drawing of inferences, particularly in respect of an intent-implicating questions such as willfulness, is peculiarly within the province of the fact finder that observed the witnesses." <u>Rolls-Royce, Ltd. v. GTE Valeron Corp.</u>, 800 F.2d 1101, 1110 (Fed. Cir. 1986).

Despite the deference owed to the fact finder, I am convinced that the evidence does not support its finding of willfulness on the part of defendant. Plaintiff failed to show that defendant copied plaintiff's patented method. It established only that Dr. White had read the patent when it issued in 1998, that he directed the effort at Celera to develop an HCV genotyping assay and that the scientists at Celera started with the 5' untranslated region, just as plaintiff's patent teaches. However, White testified that he chose the 5' UTR sequence by comparing it to others available either in scientific literature or in publicly available databases, Trial Tr., dkt. #345, at 61, 65, rather than by reference to the '704 patent. It is *possible* that the Celera scientists copied the '704 patent, but the evidence of copying is not sufficient to allow a jury to find it by clear and convincing evidence. Plaintiff seemed to concede this point when its counsel never mentioned copying in his first closing argument, raising it for the first time in this rebuttal argument and then devoting only nine sentences to it. Trial Tr., dkt. #358, at 62.

Plaintiff had no evidence that defendant acted improperly in the course of this litigation. The case was hard fought, as would be expected, but neither side engaged in any egregious litigation conduct that might warrant sanctions. (The only exception is defendant's motion for a finding of invalidity of the '704 patent on the ground of inequitable conduct, for which defendant has already been sanctioned.). Plaintiff suggests in its brief in opposition to defendant's motion for post-trial relief that defendant had reason to want to harm plaintiff for competitive reasons but there is no evidence to support this suggestion. Plaintiff adduced no evidence that defendant's sales of its own assays and of defendant's decision not to pursue a license with plaintiff. The size and financial conditions of the parties are subsidiary issues in a finding of willfulness; by themselves, they do not support such a finding. In any event, plaintiff presented no evidence of these for comparison purposes.

This leaves for the jury's consideration on willfulness only the actions defendant took when plaintiff asked it about a license under the '704 patent. The evidence showed that defendant's management went immediately to defendant's own experienced patent counsel. Defendant did not stop there; it asked its counsel to consult with Celera about obtaining an opinion from outside counsel on the need for a license. Despite these steps, plaintiff paints defendant's actions as insufficient, suggesting that the opinions defendant obtained were so inadequate as to demonstrate defendant's bad faith. With due respect to the jury's evaluation, I cannot agree that the opinions of either in-house or outside counsel were inadequate and certainly not so inadequate as to make it objectively unreasonable for defendant to rely on them.

"Good faith may normally be shown by obtaining the advice of legal counsel as to infringement or patent validity." <u>Liquid Dynamics</u>, 443 F.3d at 1225 (citing <u>Read Corp.</u>, 970 F.2d at 828). "Only if counsel's opinion is found to be incompetent or issued without full knowledge of the facts may a jury discount it in determining a party's good faith." <u>Id.</u>; <u>see also Goodwall Construction Co. v. Beers Construction Co.</u>, 991 F.2d 751, 758 (Fed. Cir. 1993) (holding that jury could have concluded that infringing party concealed incriminating evidence from its opinion counsel).

It is not enough that an opinion be shown to be wrong. A person can be wrong and still be acting in good faith. Rather, the opinion needs to be so obviously wrong or incomplete that a reasonable person would have been alerted to its inadequacy. <u>Read Corp.</u>, 970 F.2d at 829 (party that relied on an opinion that was incompetent would not be acting

in good faith if incompetence can be shown by objective evidence). The law does not require that "a client must itself be able to evaluate the legal competence of its attorney's advice to avoid a finding of willfulness." <u>Id.</u> Incompetence may be shown if the lawyer failed to look into the necessary facts or if the opinion contained only conclusory statements or presented a superficial or off-the-cuff analysis. <u>Id.</u> The opinions that defendant obtained do not suffer from any of these deficiencies. They are thorough, extensive and carefully considered. It is true that they did not address infringement but that omission is a red herring, since one cannot infringe an invalid patent. It was not bad faith for defendant to seek an opinion limited to validity if it believed that the '704 patent was invalid in fact.

Plaintiff makes much of outside counsel's failure to discuss enablement of the Cha PCT application. In hindsight, one can see that the lack of any discussion of enablement was a weakness in the opinion but that weakness is not so obvious (if it was obvious at all) as to make the opinion objectively incompetent. As for the fact that the Cha PCT application was before the examiner when the '704 patent application was granted, it is not unusual for others to disagree with the opinion of an examiner conducting an ex parte review of an application. Finally, the aspersions plaintiff casts on defendant for selecting the same firm to do a formal opinion are creative but unfounded. Good faith requires an accused infringer "to seek and obtain competent legal advice from counsel," <u>Underwater Devices, Inc.</u> <u>v. Morrison-Knudsen Co.</u>, 717 F.2d 1380 (Fed. Cir. 1983); it does not require a company

to bankrupt itself in the process by seeking competent legal advice from more than one qualified law firm.

As was the case in <u>Read</u>, 970 F.2d at 829, the defenses put forward by defendant in this case tracked the defenses set forth in the opinion and required a full trial. In itself, this is evidence that the opinion writers did their job.

This is not a case in which defendant withheld important information from outside counsel when it sought an opinion. <u>Cf. Golden Blount, Inc. v. Robert H. Peterson Co.</u>, 438 F.3d 1354, 1369-70 (Fed. Cir. 2006) (opinion written by person who did not have possession of accused device or prosecution history before rendering opinion); <u>nCube Corp.</u> <u>v. Seachange Int'l, Inc.</u>, 436 F.3d 1317, 1323 (Fed. Cir. 2006) (at least one important technical document not supplied to opinion counsel); <u>Goodwall Construction</u>, 991 F.2d at 758 (infringing party concealed incriminating evidence from opinion counsel). Rather, it is a case in which defendant acted in good faith by seeking the advice of its own qualified patent counsel and from outside counsel about the validity of plaintiff's '704 patent.

Plaintiff's counsel were highly effective in painting defendant's conduct as insufficient to demonstrate good faith. When that picture is examined more critically, however, it is evident that plaintiff touched up the painting more than the facts and law would allow. The standard to which the jury's verdict would hold an infringer is higher than the law demands and unsupportable in that respect. Counsel is not required to be correct or to identify every possible argument; counsel's client is not held to know more than its counsel or even enough to undertake a critical examination of the opinions it receives. <u>Union Carbide Chemicals &</u> <u>Plastics v. Shell Oil Corp.</u>, 425 F.3d 1366, 1381 (Fed. Cir. 2005) (upholding district court's finding of no willfulness in case in which defendant's in-house patent counsel interpreted claim incorrectly because counsel's "analysis was not entirely implausible").

I conclude that defendant's motion for judgment as a matter of law must be granted on this issue.

IV. DEFENDANT'S MOTION FOR NEW TRIAL PURSUANT TO RULES 60(b)(3) AND 60(b)(2)

After briefing was complete on defendant's motion for judgment as a matter of law or for a new trial on the issues of damages and willful infringement, defendant filed a new motion for a new trial on the ground of allegedly newly discovered evidence. Defendant alleges that although plaintiff maintained at trial and in its post-trial briefing that the parties were in direct competition in the analyte specific reagent market and had been since 2001, new information discloses that plaintiff's Versant HCV products were not commercially available until July 31, 2006 and not offered as research use only kits until February 1, 2006.

Fed. R. Civ. P. 60(b)(2) and (3) authorize a court to relieve a party from a final judgment "on the basis of newly discovered evidence which by due diligence could not have

been discovered in time to move for a new trial under Rule 59(b)" (subsection (b)(2)) or "fraud, whether heretofore denominated intrinsic or extrinsic" (subsection (b)(3)). Defendant characterizes the October 17, 2006 declaration of Frank M. LaDuca, Senior Director of Global Regulatory Affairs at Bayer HealthCare, LLC, Diagnostics Division, as both newly discovered evidence and evidence of fraud. In the declaration, LaDuca avers that since 2001, Bayer has been the exclusive distributor of plaintiff's LiPA HCV genotyping products, which Bayer markets under the trade name "Versant"; Bayer has provided the Versant HCV genotyping products either as RUO (research use only) kits from February 1, 2006 or as separate components available as ASRs (analyte specific Reagent, Analytical and performance characteristics are not established." Defendant reads this declaration as an admission that plaintiff was not competing in the ASR market before July 31, 2006, and relies upon it as a ground for a motion for a new trial under Rule 60.

At trial, defendant devoted considerable time to suggesting that plaintiff had no basis on which to claim that it competed with defendant in the ASR market. In its post-trial brief in opposition to plaintiff's motion for a permanent injunction, it contends that plaintiff would be unable to supply the market with ASRs if defendant were enjoined from selling its products. Despite its efforts, defendant has not shown that plaintiff did not begin selling ASRs until sometime after the date of the hypothetical negotiation. Moreover, it has failed to show that plaintiff engaged in any improper withholding of evidence on this question during discovery.

Plaintiff has submitted a second declaration by LaDuca, explaining that his October 17 declaration referred only to the labeling for the current version (Version 2.0) of the Versant HCV genotyping products sold as ASRs and was directed to the injunction plaintiff was seeking and the availability of product to supply to the marketplace. In his second declaration, LaDuca avers that Version 1.0 ASRs were available for sale prior to June 2003 and were sold continuously through the launch of the Version 2.0 ASRs. LaDuca attached labeling used on the Version 1.0 ASRs manufactured in August 20, 2002, which states "Analyte Specific Reagent. Analytical and performance characteristics are not established." (Defendant has tried to make much of the necessity of such a label for sales that are in compliance with Federal Food and Drug Agency requirements.)

Defendant attacks LaDuca's second declaration as ineffective in light of the first declaration in which he said flatly that plaintiff's HCV genotyping components were not commercially available as ASRs at any time before July 31, 2006. Defendant is grasping at straws. LaDuca's first declaration was not artfully drafted. However, the second one makes it plain that it was not intended to be a concession that plaintiff had not sold any ASRs commercially before July 31, 2006.

Defendant does not acknowledge that it knew (or should have known) before trial

began that Bayer was selling ASRs commercially and had been doing so from at least the time of the hypothetical negotiation. <u>See</u> Decl. of Shannon Bloodworth, dkt. #415, at Exhs. 1-2 (copies of third party subpoena served on Bayer by defendant and Versant 5' UTR ASR probe strip labeling produced to defendant); Exhs. 4, 5, 7 and 8 (meeting minutes and document showing HCV genotyping sales by Bayer of ASRs). At trial, John Lawson, plaintiff's international market development manager, testified that plaintiff sold its product as both an RUO and ASR test to Quest Diagnostics, veterans medical centers and pharmaceutical companies and would have been doing so in 2003. Trial Tr., dkt. #339, at 77-78.

Defendant maintains that LaDuca's declaration is "newly discovered evidence." Not only is defendant wrong in its characterization of the declaration but it has fallen far short of showing that it was diligent in pursuing discovery into plaintiff's sales of its products as ASRs. It never attempted to depose any employee of Bayer who would have first hand knowledge of the sales of the products. It has not shown that it ever made discovery requests of plaintiff about FDA compliance or percentages of sales that were ASR as opposed to RUO. Although defendant alleges now that it was critical for plaintiff to show that plaintiff's products did not have FDA approval, it did not file a motion in limine on this issue. It is far too late for defendant to assert that it should have a remedy for an error it could have prevented by acting earlier, if indeed, an error occurred at all.

IV. PLAINTIFF'S MOTION FOR PERMANENT INJUNCTION

A. Plaintiff's Entitlement to a Permanent Injunction

A successful plaintiff in a patent suit seeking a permanent injunction must satisfy the traditional four-factor test by showing that (1) it has suffered an irreparable injury; (2) the remedies available at law are inadequate to compensate for that injury; (3) considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) the public interest would not be disserved by a permanent injunction. <u>eBay Inc. v.</u> <u>MercExchange, L.L.C.</u>, 126 S. Ct. 1837, 1839 (2006). To the extent that courts once believed that injunctions followed ineluctably from a finding of infringement, <u>eBay</u> made it clear that they do not. Rather, requests for injunctions are to be granted only if they met the same four-factor test applicable to any other kind of injunction.

Defendant opposes both the grant of a permanent injunction and the scope of the one sought by plaintiff. It argues that plaintiff cannot satisfy the four-factor test for obtaining an injunction. First, plaintiff cannot claim to have suffered an irreparable injury or second, show that its injury is one that cannot be remedied by monetary damages now that the jury has awarded it \$5,000,000 for "market entry damages" and another \$2,000,000 for a running royalty. Third, plaintiff cannot show that the harm it will suffer if not granted an injunction will outweigh the harm to defendant and fourth, the public interest will be affected adversely if an injunction is issued and clinical laboratories are deprived of the only

products legally marketed for diagnostic use.

A threshold issue must be addressed before turning to the merits. Defendant filed a motion to strike the evidence submitted with plaintiff's reply brief in support of its motion for a permanent injunction or in the alternative to file a sur-reply brief. Defendant contends that it is improper for plaintiff to submit new evidence and raise new issues as it did in its reply brief.

When it filed its reply brief, plaintiff submitted an amended declaration of Anne van Den Abeele in support of plaintiff's motion for a permanent injunction, dkt. #407, the declaration of Shannon Bloodworth with attached exhibits, dkt. #404, a declaration of Frank LaDuca, dkt. #405 and a declaration of Geert Callaerts, dkt. #406. The amended van Den Abeele declaration was filed simply to show that the declarant had complied with the requirement that the declaration was filed under the "penalty of perjury *under the laws of the United States of America*," because van Den Abeele had omitted the italicized phrase from her first declaration. The remaining documents merely supplement the showing that plaintiff made in its opening brief to the effect that it has been competing with defendant in selling HCV genotyping ASRs and would be prepared to continue to sell them if defendant is enjoined from selling its competing product. The allegedly "new" evidence is not necessary because the original van den Abeele declaration and John Lawson's trial testimony establish that plaintiff has been selling competing ASRs and is prepared to continue to do so. Although I need not reach the point, I note that Bloodworth's omission of a statement that her declaration is filed under penalty of perjury is not an issue. As an officer of the court, Bloodworth files all documents subject to the provisions of Fed. R. Civ. P. 11. Moreover, the materials she submitted under her declaration were merely copies of matters already in defendant's possession, either because they are copies of defendant's own discovery requests or materials provided to defendant by plaintiff in response to discovery requests.

Defendant asserts that the LaDuca declaration shows that plaintiff has been proceeding in this litigation on false pretenses because LaDuca declares that the Versant ASRs were first sold commercially in July 2006. This issue was resolved in § IV, *supra*, at 49-51, and need not be addressed again. I conclude that neither defendant's motion to strike nor its alternative motion for leave to file a sur-reply brief should be granted. I return to plaintiff's entitlement to a permanent injunction.

1. Irreparable harm

Plaintiff contends that defendant's infringing sales of its competing HCV genotyping product have caused plaintiff irreparable harm to its reputation as a leader in the field of HCV diagnostics and to its ability to generate future business and maintain its market share. Defendant tries to counter these contentions by arguing that it does not compete directly with plaintiff because plaintiff does not sell ASRs that are FDA-compliant and can serve the diagnostic market. I will ignore this argument because it has no foundation. I have found that plaintiff does sell ASRs and that they bear labels that comply with FDA requirements.

Defendant argues that it is actually Bayer that is in competition with defendant and harm to Bayer has no effect on plaintiff. In fact, plaintiff *is* harmed when defendant sells directly competing products. As the manufacturer of the products that Bayer sells, its reputation and market share are at stake. Its consumer base sees the products as plaintiff's. Its reputation for innovation and being a market leader are affected when defendant cuts into its market share. Moreover, plaintiff has a statutory right to exclude others from practicing its invention.

Finally, defendant asserts that plaintiff has repeatedly exhibited a willingness to accept money as compensation by offering to license its products to defendant and others. Whether money is adequate compensation for the harms that plaintiff has suffered is the next inquiry.

2. Inadequate remedy in law

This element of the test for an injunction overlaps the element of irreparable harm. Defendant contends that plaintiff has no chance of showing the inadequacy of its legal remedies both because the jury awarded it compensation equal to what defendant would have paid plaintiff in a hypothetical negotiation for a license and because plaintiff had shown its willingness to enter into a licensing agreement with defendant on several occasions. Defendant's argument has some surface plausibility but not enough to carry the day. In its decision in <u>eBay</u>, the Supreme Court noted that it was improper for a court to consider a plaintiff's willingness to license its patents as sufficient to establish that the patent holder would not suffer irreparable harm if an injunction did not issue. <u>Id.</u> at 1840.

After a long, expensive and arduous trial, plaintiff has now won an award equal to what defendant would have paid had it agreed with plaintiff to take a license to the invention claimed by the '704 patent. It would denigrate the value of plaintiff's patent rights to allow defendant to continue to sell plaintiff's invention as its own in exchange for the same fee it would have paid without a lawsuit. Plaintiff has shown that money damages alone would not remedy its injury.

3. Balance of harms

Defendant contends that it would suffer if enjoined from selling the HCV genotyping product, because it would face "the prospect that its entire investment in HCV genotyping will be forfeited, even in those aspects completely unrelated to the merits of the '704 patent and its customer laboratories will suffer repercussions that will affect [its] reputation and good will." Dft.'s Br., dkt. #383, at 19. Defendant does not identify these harms with any specificity or show how they amount to anything more than the harms infringers generally suffer when subjected to an injunction against the sale of their infringing products. They do not outweigh the harm to plaintiff if it is not able to enjoy the rewards of its inventive process. Plaintiff spent significant money and time discovering and developing the method of genotyping disclosed in the '704 patent, in marketing it and in obtaining a United States patent to protect its interests. It is entitled to enforce the rights it worked to obtain.

4. The public interest

Much of defendant's opposition to plaintiff's motion for a permanent injunction hinges on its belief that plaintiff would be unable to fill the market need for ASR kits for diagnostic purposes, thus leaving a vast unserved need for diagnostic services to persons who have contracted Hepatitis C. First, defendant renews its assertion that plaintiff does not have any ASR products that are FDA-compliant. Second, it argues that even if plaintiff has such products, enjoining defendant from selling its products would disrupt the diagnostic services for persons with Hepatitis C, since it takes 1-3 months to validate a new ASR.

In response, plaintiff asserts that it does have ASRs that are FDA-compliant, that defendant's products amount to only 20% of the market and that 90% of defendant's sales are to one large laboratory. As to disruption, plaintiff asserts that this laboratory could validate a new ASR in much less than the average time needed for that process.

I agree with defendant that enjoining it from selling its product could pose a serious risk to the public health if plaintiff cannot fill the diagnostic market need. On the other hand, plaintiff has shown its entitlement to a permanent injunction in all respects other than this one of the public interest. Rather than decide this important issue on a paper record, I will schedule an evidentiary hearing to be held on January 10, 2007 at 10:00 a.m., at which plaintiff will bear the burden of proving by the preponderance of the evidence that the needs of the Hepatitis C diagnostic market could continue to be met if an injunction issued against defendant. Plaintiff should be prepared to prove that its products comply with FDA requirements for labeling and Good Manufacturing Practices and that it has the capacity to serve the market if defendant is enjoined from doing so. Until the conclusion of the hearing, I will reserve a ruling on plaintiff's motion for a permanent injunction and the scope of the injunction.

VI. PLAINTIFF'S MOTION FOR ACCOUNTING AND PREJUDGMENT INTEREST

Defendant raises only two objections to plaintiff's motion for an accounting and prejudgment interest. It objects to adding a royalty based on actual sales to the verdict reached by the jury and it opposes any award of prejudgment interest because, it alleges, plaintiff delayed unduly in bringing suit. The first objection is moot because plaintiff is not asking for double royalties. It acknowledges that both its damages expert and defendant's used estimates for some portion of their damages analyses and that an accounting will be necessary to determine the actual sales, as opposed to estimated sales. Once that determination has been made, the damages award can be adjusted to cover only the actual sales.

As for the second objection, the record does not support a finding of undue delay. Instead, it shows that plaintiff explored means of resolving the dispute through licensing, beginning in late September 2003, when it wrote to Gene Cartwright, General Manager of Abbott Molecular, informing him of the '704 patent. About this time, defendant's in-house counsel, Dr. Schodin, began investigating the alleged infringement. In December 2004, plaintiff wrote again to defendant, saying that it was prepared to discuss licensing of the '704 patent and others relating to HCV. In March 2005, plaintiff's president met with the president of Abbott Molecular, Ed Michael, and recommended again that defendant consider taking a license to the '704 patent. When the parties failed to agree on a license, plaintiff began preparation for this suit.

Given the presumption for an award of prejudgment interest in patent cases, <u>General</u> <u>Motors Corp. v. Devex Corp.</u>, 461 U.S. 648, 655 (1983) (award necessary to insure that patent holder is placed in as good a position as it would have been in had infringer entered into reasonable royalty agreement), and the relatively short time (five months) between the failure of the royalty negotiations and the filing of this suit, I conclude that an award of prejudgment interest to plaintiff is appropriate.

Plaintiff proposed the interest rate suggested by its expert at trial, which was a riskfree rate on short-term U.S. government securities (the 3 month T-Bill) after tax. Defendant has raised no objection to the rate, so I will apply it to the actual damages once they have been determined.

VII. PLAINTIFF'S MOTION FOR ENHANCED DAMAGES AND ATTORNEY FEES

Plaintiff's request for enhanced damages and attorney fees rests on its contention that defendant's infringement was willful. I have rejected that contention for reasons explained at length in § IV, *supra*. Also, for reasons explained above, I do not find anything in defendant's conduct of the litigation that warrants the sanction of an award of attorney fees, other than its motion to invalidate the patent on the ground of plaintiff's alleged inequitable conduct for which I awarded plaintiff the attorney fees it expended. I admit, however, that I am perplexed at defendant's professed inability to understand that when I denied its motion for summary judgment on infringement but failed to grant summary judgment on that issue in plaintiff's favor, I had ruled conclusively that defendant's defense to infringement was meritless to the extent it relied on the proposition that defendant could avoid infringing the '704 patent by using Realtime PCR. That aside, however, I consider defendant's defense of the case vigorous, tenacious and not improper. Defendant may have

made mistakes, but I have yet to see a mistake-free trial.

Defendant's continuing assertion of an infringement defense was questionable at best, but not so improper as to warrant a sanction. Although plaintiff was forced to devote resources to preparing for its case on infringement, I am not persuaded that it was prejudiced unduly by defendant's delay in recognizing that it had no defense to present that I had not ruled on already. It is not unusual for counsel to prepare to defend or prosecute issues that are not tried for one reason or another.

Plaintiff's motion for motion for enhanced damages and attorney fees will be denied.

ORDER

IT IS ORDERED that

1. Defendant Abbott Laboratories' motion for judgment for a new trial on the issues of infringement and invalidity is DENIED;

2. Defendant's motion for judgment as a matter of law or for a new trial on damages is DENIED;

3. Defendant's motion for judgment as a matter of law on willfulness is GRANTED; the judgment entered on September 12, 2006, is VACATED in this respect and the clerk of court is directed to enter an amended judgment finding no willful infringement by defendant; 4. Defendant's motion for a new trial on the issue of willfulness is DENIED as moot;5. Defendant's motion for a new trial on damages, based on fraud or newly discovered evidence is DENIED;

6. Defendant's motion to strike or in the alternative for leave to file a sur-reply in opposition to plaintiff Innogenetics' motion for a permanent injunction is DENIED;7. Defendant's motion to strike the affidavit of Anne van Den Abeele and exhibits A and B attached to the affidavit of Lissa R. Koop is DENIED as moot;

8. Plaintiff's motion for a permanent injunction is set for an evidentiary hearing at 9:00 a.m. on Thursday, January 11, 2007; a ruling on the motion is reserved until after the hearing has been held;

9. Plaintiff's motion for an accounting and prejudgment interest is GRANTED; plaintiff will be awarded prejudgment interest at the rate applicable to short-term U.S. government securities (the 3 month T-Bill) after tax; the parties are directed to begin the process of the accounting immediately;

10. Plaintiff's motion for enhanced damages and attorney fees is DENIED.Entered this 3d day of January, 2007.

BY THE COURT: /s/ BARBARA B. CRABB District Judge