United States District Court,
D. New Jersey.

BOEHRINGER INGELHEIM ANIMAL HEALTH, INC,
Plaintiff.
v.
SCHERING-PLOUGH CORPORATION and Schering Corporation,
Defendants.

No. CIV. 96-04047(HAA)

Oct. 6, 1997.

Patentee brought action for infringement of patent for method of growing and isolating swine infertility and respiratory syndrome virus. Patentee moved for preliminary injunction. The District Court, Harold A. Ackerman, J., held that: (1) patent was possibly obvious; (2) patentee did not engage in inequitable conduct in prosecution of patent; and (3) patentee failed to demonstrate irreparable harm if injunction were not granted.

Motion for preliminary injunction denied.

5,476,778. Cited.

Jonathan A. Marshall, Jennifer Gordon, Scott D. Simpson, Pennie & Edmonds, New York, N.Y., H. Curtis Meanor, William Sandelands, Podvey, Sachs, Meanor, Catenacci, Hildner & Cocoziello, Newark, New Jersey, for Plaintiff.

Sidney David, Paul H. Konchanski, Lerner, David, Littenberg, Krumholz & Mentlik, Westfield, NJ, for Defendants.

OPINION

HARLOLD A. ACKERMAN**, District Judge.**

This matter comes before the court on plaintiff's motion for a preliminary injunction in its patent infringement action. FN1 For the reasons detailed below, plaintiff's motion is **DENIED**.

FN1. This court held a hearing on this matter from June 11 until June 19, 1997. Prior to that hearing, the parties submitted briefs in support of their position (cited herein as "Plaintiff's Br."; "Defendant's Br."; "Plaintiff's Reply Br."; "Plaintiff's Supplemental Br." ; "Defendant's Supplemental Br.") On August 18, 1997, the parties submitted to the court the following post-trial papers: proposed findings of fact and conclusions of law and a critique of their adversary's submission (cited, herein, as "Plaintiff's Finding";

"Plaintiff's Conclusion"; "Plaintiff's Critique"; "Defendant's Finding"; "Defendant's Conclusion"; "Defendant's Critique.") Finally, on August 29, I asked the parties for an additional submission on the significance of whether a virus is zoonotic for purposes of the Section 103 obviousness determination. *See* Plaintiff's Zoonotic Br.; Defendant's Zoonotic Br.

I. Background

This patent litigation arises from two company's endeavors to develop a vaccine for a disease known as Porcine Reproductive Respiratory Syndrome ("PRRS")-"the most challenging infectious disease facing the [swine] industry today." Hays Declaration para. 6, Ex. 5 (copy of Schering letter to Swine Industry Professionals from Robert J. Young, Product Director, Large Animal Business Unit). This disease, PRRS, also known as Mystery Swine Disease ("MSD") and Swine Infertility and Respiratory Syndrome ("SIRS"), infects pigs and causes them to give birth to dead or sickly piglets. In addition, it causes reproductive failure, respiratory disease, and other symptoms such as anorexia, fever, dyspnea, and neurological impairment.

A. Basic Principles of Virology

Before one can begin to analyze the issues involved in this case, it is important to outline the some general principles of virology. Viruses, such as PRRS, are parasitic organisms that grow and multiply within "host cells." A virus depends on the host cell's "machinery" for survival and uses that machinery to reproduce. It will use this machinery to produce its own proteins and nucleic acids-the blueprint of all genetic information in living organisms. When a higher organism such as an animal or human is exposed to a virus and its cells become viral hosts, the animal or human develops a natural immunity. This immune response operates at two levels: first, at the initial stage of the infection before the virus has invaded the host and second, after the virus has invaded. When the virus stimulates certain specialized cells, these cells produce antibodies which prevent future infection. But this exposure still produces disease symptoms. Thus, the universal objective of virologists is to develop a vaccine which produces an immune response without the attending sickness.

There are two common types of vaccines-killed virus vaccines and modified-live virus vaccines. Both Boehringer and Schering's vaccines are derived from modified live viruses. A modified-live virus is made by obtaining a strain of the virus and putting it through the process of "attenuation." To "attenuate" a virus, like PRRS, means to repeatedly pass it through an appropriate in vitro culture system. In very crude terms, this means taking a tissue sample from a diseased animal and putting it into some kind of a vessel, like a bottle, with a host cell. When placed in a favorable medium, the tissue simple and cells interact in such a way as to facilitate the growth of the virus. That is the first passage. Then, the fluid or material containing the virus is transferred to another vessel with the host cell and passaged through a similar process. That is the second passage. Ultimately, the attenuation process alters the virus enough so that it produces the immune response and thereby protects against any subsequent infection without causing the disease. To be sufficiently attenuated, a virus may be passaged several times. The number of passages varies with each vaccine. For example, Schering has developed a PRRS vaccine which has been passaged ninety-four times.

B. Boehringer's Effort

In the early 1990's, Boehringer initiated an "extensive research program to study PRRS and develop a vaccine." Plaintiff's Br. at 4. First, Boehringer focused its energies on the task of "finding a suitable host

cell" in which to grow and replicate the causative virus. *See* Gorcyca Declaration para. 12; Plaintiff's Br. at 4. In 1990, at the Conference of Research Workers in Annual Diseases, Joseph Harris, a Boehringer research assistance met Dr. James Collins and Dr. David Benfield, two scientists from the University of Minnesota and South Dakota State University scientist, respectively. Collins and Benfield had been working together on the cause of PRRS. They had successfully collected specimens from various organs of diseased pigs, reduced the organs to a tissue homogenate from which an inoculum could be prepared, and inoculated the inoculum into gnotobiotic pigs. FN2 *See* Defendant's Br. at 5. As a result of their work, they could reproduce the symptoms of PRRS in the pigs. However, they were unable to observe CPE on cell lines. *Id.* at 6. CPE refers to "cytopathic effect" which the plaintiff has defined as a "change in the microscopic appearance of a cell after infection with a virus" or some observable effect shown on the simian cells. As the defendant has explained, this observable effect is the killing of inoculated cells. The court will elaborate on the significance of CPE below, (*see infra,* at 252), but for now, it is sufficient to know that one needs to observe CPE to be able to grow the virus on a cell line. Thus, Collins and Benfield could not grow the virus.

FN2. Gnotobiotic pigs are sterile, germ-free piglets.

At some point, Boehringer agreed to work with Collins and Benfield on PRRS. Thereafter, Harris sent Collins a number of cell lines, but Collins did not try them. Collins sent his inoculum samples to Harris at the Boehringer lab so that Harris could try the inoculum on his own cell lines. On April 25, 1991, Harris observed CPE on the partial cell line derived from a monkey kidney, MA-104.

To confirm that it has been able to recover the PRRS virus, Boehringer need to perform what is known as "Koch's Postulates." In the instant case, this entailed sending the third passage of the virus to Benfield. Dr. Benfield took the viral agent recovered by Harris and introduced it into gnotobiotic pigs who then exhibited symptoms of the disease. Benfield took tissue samples from the diseased pigs and sent them back to Dr. Collins and then to Harris. Using the same method described above, Harris inoculated and incubated the sample and observed CPE. This satisfied Koch's Postulates and confirmed that Boehringer had been successful in recovering the PRRS virus.

After it "discovered that PRRS viruses could be grown and isolated on a full or partial sheet of simian monkey cells," specifically MA-104, Boehringer filed a patent application on August 26, 1991. On December 19, 1995 the Patent Office issued as Boehringer Patent No. 5,476,778 ("the '778 Patent"). The '778 Patent made the following five claims:

1. A method of growing and isolating swine infertility and respiratory syndrome virus, ATCC-VR2332, which comprises inoculating the virus on a full or partial sheet of simian cells in the presence of serum in a suitable growth medium and incubating the inoculated cell sheet at about 34 (deg.)C. to 37 (deg.)C. until CPE is observed.

2. The method as recited in claim 1 wherein the simian cell line is MA-104.

3. A method of attenuating swine infertility and respiratory syndrome virus, ATCC-VR2332, which comprises passaging the virus through simian cell line on maintenance medium in the presence of serum at ph about 7.6 about twenty-five time at about 35 (deg.)-37 (deg.)C without carbon dioxide, and then passaging the resulting virus through a simian cell line on maintenance medium in the presence of serum at ph about 7.6 about twelve times at about 31 (deg.)>>>> C.

4. The method as recited in claim 3 wherein the simian cell line is MA-104.

5. The method as recited in claim 4 wherein the passages occur without CO_2.

In the instant action, only claims 1 and 2 are at issue. Notably, these two claims do not cover a vaccine. Rather, Boehringer believes that its patent covers a method which is instrumental in developing a vaccine for PRRS. After the patent issued, Boehringer obtained two licenses for modified-live vaccines-RespPRRS ™ and RespPRRS/Repro ™-which prevent the respiratory form of PRRS. Boehringer alleges that these vaccines were made using patented methods at issue in this litigation.

C. Schering's Alleged Infringement

Like Boehringer, the defendant in this case Schering-Plough and Schering Corp. (collectively "Schering") was interested in the PRRS disease. In October 1991, Schering isolated its own strain of the PRRS virus using porcine alveolar macrophages as a host cell. Then, Schering created its "Master Seed Virus" by putting the virus through an attenuation process comprising ninety-four passages. It then developed a vaccine production process whereby it produced more of the virus using MA-104, a simian cell line, as a host cell line. According to the plaintiff, on August 20, 1996, Schering-Plough and Schering Corp. (collectively "Schering") "commenced sales of a swine vaccine for the prevention of PRRS that is made by a method that infringes the '778 Patent." Plaintiff's Br. at 1. As a result, the plaintiff alleges that Schering has infringed upon claims 1 and 2 of its '778 Patent, both literally and under the doctrine of equivalents.

II. Motion for Preliminary Injunction

A party seeking a preliminary injunction must establish four factors:

1. a reasonable likelihood of success on the merits

2. an irreparable harm

3. the balance of hardships tipping in its favor; and

4. a tolerable effect on the public interest.

Sofamor Danek Group v. DePuy-Motech, 74 F.3d 1216, 1219 (Fed.Cir.1996).

The court "must balance these factors against one another and against the extent of the relief sought." Id. The movant bears the burden of proving entitlement to relief. *See* Id. However, irrespective of how the court resolves the third and fourth factors, the movant must demonstrate the existence of the first two before this court grants a motion for a preliminary injunction. *See* Reebok Int'l v. J. Baker, Inc., 32 F.3d 1552, 1556 (Fed.Cir.1994). The court may deny the motion based upon a plaintiff's failure to establish either of the first two factors. *See Id*. Moreover, where the plaintiff has not established either of the first two factors, the court need not articulate findings regarding the others. *Id*.

A. Reasonable Likelihood of Success

[1] [2] [3] At the preliminary injunction stage, a patentee must establish a likelihood of success on the merits with respect to the patent's validity, enforceability, and infringement. *See* Nutrition 21 v. United States, 930 F.2d 867, 869 (Fed.Cir.1991). There are two steps in a patent infringement analysis: the first being the construction of the claim and the second being the determination as to whether the accused method infringes the asserted claim as properly construed. Markman v. Westview, 52 F.3d 967 (Fed.Cir.1995) (en banc), *affirmed,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Under *Markman,* as a matter of law, the court must construe the claim.

[4] In a preliminary injunction context, a court may, in exercising its discretion, decide to interpret the claim conclusively. *See Sofamor Danek, supra,* at 1221 (Although "the trial court has no obligation to interpret [a claim] conclusively and finally during a preliminary injunction proceeding.... [It] may exercise its discretion to interpret claims at a time when the parties have presented a full picture of the claimed invention."). Since the Supreme Court decided *Markman,* many courts have held a " *Markman* hearing" before trial in order to construe the claims involved. In the instant proceeding, I conducted a *Markman* hearing in conjunction with the preliminary injunction hearing.

1. Claim Construction under Markman

a. General Principles

[5] [6] [7] [8] In interpreting an asserted claim, the court looks at "the intrinsic evidence of record, i.e. the patent itself, including the claims, the specification, if in evidence, the prosecution history ..." because it is the "most significant source of the legally operative meaning of disputed claim language. Vitronics v. Conceptronic, 90 F.3d 1576, 1582 (Fed.Cir.1996) (citing *Markman, supra*). First, the court must examine the words of the claim itself, both asserted and nonasserted, to define the scope of the patented invention. When interpreting technical terms used in a patent, the court must construe those terms as "having the meaning that it would be given by persons experienced in the field of the invention, unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning." Id. at 1582 (citing Hoechst Celanese Corp. v. BP Chemicals Ltd., 78 F.3d 1575, 1578 (Fed.Cir.), *cert. denied,* 519 U.S. 911, 117 S.Ct. 275, 136 L.Ed.2d 198 (1996)). That means that while patent terms should generally be construed to have their ordinary meaning, at the time of the patent application, a patentee is still entitled to "choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." *Id.* Under those circumstances where the patentee's meaning is clear, the court must adopt the special definition of the term.

[9] Therefore, the court's second step in construction of a claim must be to review the specification "to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." *Id.* As I have already indicated, the Federal Circuit has noted, "the specification acts as a dictionary when it expressly defines terms or when it defines terms by implication." *Id.* It is "the single best guide to the meaning of a disputed term" but it "must be clear and complete enough to enable those of ordinary skill in the art to make and use it." *Id.* Nevertheless, if the specification does not use a term in a "special" or "unique" way, "its ordinary meaning to one skilled in the art controls." Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1303 (Fed.Cir.1997).

[10] As a third step in claim construction, the court may consider the prosecution history of a patent in interpreting claims. This history may include a "complete record of all the proceeding before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of its

claims," and in some circumstances becomes critically significant. *Vitronics, supra,* at 1582.

[11] [12] Finally, although the court generally does not consider extrinsic evidence in addition to the intrinsic evidence already mentioned, it may do so in limited circumstances. While it is improper to consider extrinsic evidence where an "analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term" (*Id.* at 1583), the court may do so where necessary to resolve any persisting ambiguities. Thus, a court may not rely on any extrinsic evidence "where the public record unambiguously describes the scope to the patented invention, reliance on any extrinsic evidence is improper." *Id.* In the event that a court does look to extrinsic evidence such as expert testimony, it may do so only to the extent that such evidence does not contradict the specification and file history. *Id.*

The Federal Circuit's reticence regarding extrinsic evidence is rooted in its understanding of the purposes of the patent system. Excessive use of extrinsic evidence could undermines the public's right to rely upon the public record. *See Id.* As the Federal Circuit has noted, "competitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention and thus, design around [it]." *Id.*

[13] Notwithstanding the discussion above, there exists one small exception to the rule disfavoring extrinsic evidence: a court may consult technical treatises and dictionaries, notwithstanding the fact that they fall within the category of extrinsic evidence, in order to "better understand the underlying technology." *Id.* at 1584 n. 6. It may rely on dictionary definitions to construe claim terms "so long as [the definition] does not contradict any definition found in or ascertained by a reading of the patent documents." *Id.* at 1584 n. 6.

b. Construing the '778 Patent

The parties have three fundamental disagreements over the construction of Claim 1. They have vigorously disputed: first, the meaning and significance of the term "isolating" located in the preamble, second, the significance of the phrase "swine infertility and respiratory syndrome virus, ATCC-VR2332," and third, the meaning of "until CPE is observed."

i. Isolating

The preamble to Claim 1 describes the patent as a "method of growing and isolating ..." Neither side disputes that "growing" means "propagation or cultivation of the virus, whereby the virus increases in number," but there is fervent debate over the term "isolating." Initially, Boehringer argues the position that as a general rule, preamble language never serves as a limitation. The preamble is that portion of the claim preceding the word "comprising." *See* Judin v. United States, 27 Fed.Cl. 759, 775 (Fed.Cl.1993). While the significance of preamble language is a vexing issue for federal courts interpreting patent claims, Boehringer's position is untenable.

[14] [15] A "claim preamble has the import that the claim as a whole suggests for it" and when the drafter uses "both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects." Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620 (Fed.Cir.1995). In other words, where the preamble language is "necessary to give life, meaning and vitality to the claim" or it is deemed "essential to point out the invention defined by the claim," the Federal Circuit has found that the language effectively limits the scope of the claim. *Bell, supra,* at 620-21. Conversely, "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the

preamble is not a claim limitation." Rowe v. Dror, 112 F.3d 473, 478 (Fed.Cir.1997).

[16] In *Bell Communications,* the court clarified that the construction of preamble language does not present some "deep[ ] mystery." *See Bell Communications, supra,* at 621. *Bell Communications* dictates that the mechanics of preamble construction are the same as those for general claim construction. *See Id*. Therefore, this court must employ the interpretive principles elucidated in *Markman* and *Vitronics,* cited *supra*. First, I must look to the preamble language itself and then to the specification to further clarify the scope of the claim. *See Bell Communications, supra,* at 619-20. The court should also consider the prosecution history and when necessary, any extrinsic evidence. *See Vitronics, supra*.

[17] The entire record in this case makes clear that Boehringer was working on the problem of both "growing" and "isolating" the PRRS virus. Boehringer has argued that "isolating" does not limit the scope of the claim because the body of the claim does not contain an isolation step. To some extent, that is true. When the claim language talks about "inoculating the virus ... and incubating the inoculated cell sheet," that defines how to grow the virus and not necessarily how to isolate it. Nevertheless, to construe the claim as not involving "isolation" "would be divorced from reality." *See* Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed.Cir.1989). The specification makes clear that "isolation" is an integral part of the process which cannot be separated from the growing component. There is no question that steps involved in the body of claim 1 facilitate isolation. As will be discussed below, the specification anticipates that the claimed method will be repeated in several passages and while there are no isolation steps in the body of the claim, the elements of the claim facilitate isolation and the isolation step is necessary to be able to repeat the method. By introducing its claim as a "method of growingand isolating," Boehringer has defined the environment in which its process takes place. Once we understand that the term "isolating" impacts upon the scope of the claim, the construction of the term "isolating" becomes the more important task.

According to Schering, the clear meaning of the word "isolating" is recovering the causative (viral) agent from the tissue homogenate. Under that interpretation, the patent would cover the initial isolation of PRRS, but it would not cover "subsequent passages." In response, Boehringer argues that the term should be construed much broader. Boehringer posits that "isolation" is the "separation of the virus from its surroundings '-a construction which encompasses' the initial recovery from a tissue sample [or homogenate] or separating or harvesting the virus from a cell culture system." Plaintiff's Finding No. 117. Certainly, the latter definition comports more with the common definition of isolation meaning: "to set or place apart, detach or separate." *See* RANDOM HOUSE COLLEGE DICTIONARY (1980). Moreover, nothing in the claim, specification, or prosecution history supports Schering's interpretation.

First and most importantly, when the claim refers to isolating the virus, it does not indicate whether the source of isolation is either the tissue homogenate from the diseased pig or the virus recovered from a previous passage. Second, under the heading, "Isolation," the specification discusses "initial isolation" and "subsequent passages." In that section, which discusses the use of serum in the process, the patent states that:

The presence of serum may be helpful for the *initial isolation* of the viral agent. *Subsequent passages* of the viral agent in the MA 104 cell line will produce the CPE without the presence of serum. However, more pronounced CPE is observed with the use of serum in the growth medium for the MA-104 cell line. *See* '778 Patent, Col. 3, lines 37-42 (emphasis added).

The specification language anticipates that there will be an "initial isolation" and other isolations "in subsequent passages." Schering does not believe that this is a valuable distinction because the specification does not mention "other isolations," just "subsequent passages." If the patent covered "other isolations," Schering intimates, the specification would need to distinguish between "initial isolation" and "subsequent" isolations, not just passages. However, such a degree of precision is not necessary. The language assumes that other isolations occur and therefore, the term "isolating" should not be limited to the initial isolation from the tissue homogenate. Finally, because the prosecution history does not suggest anything to the contrary, I find that the term "isolating" references the recovery of the virus from either the tissue homogenate or a previous passage.

A question remains as to how isolation is performed. In its post-trial briefs, Boehringer has argued that isolation means to recover the virus from its surroundings. At the hearing, Boehringer argued that isolation meant to "decant fluids containing virus and separate out debris." *See* Plaintiff's Ex. 10 (copy of chart demonstrating "Passaging PRRS Virus According to claim 1"). Looking at the specification, which is the most relevant indicator-isolation is effected when, after incubation, the "[f]luid [containing the virus] is separated from the bottle, and passed into a new bottle." Although the differences between these definitions may be insignificant, the court will use the language of the specification because apart from the claim language itself, it is "the single best guide to the meaning of a disputed term." *Vitronics, supra,* at 1582

ii. Swine infertility and respiratory syndrome virus, ATCC-VR2332

The parties also dispute the significance of the term "swine infertility and respiratory syndrome virus, ATCC-VR2332" located in the preamble of claim 1. In July 1991, Boehringer made a deposit with the American Type Culture Collection in Rockville, Maryland. That deposit contained a strain of the PRRS virus. ATCC-VR2332 refers to the accession number assigned to the deposit. At the hearing, the court learned that the actual deposit was a strain of PRRS after its eighth passage. This particular isolate was the first PRRS virus to be deposited and Boehringer has described it as " 'prototype' PRRS virus." Boehringer Finding No. 61.

Initially, Boehringer argues that as a matter of law, preamble language has no limiting effect. But, for reasons which I have already stated, Boehringer is wrong. *See Bell Communications, supra*. In what has become the seminal case on the import of preamble language, *Bell Communications,* the court interpreted a claim of a patent which recited in the preamble "a method for transmitting a packet over a system comprising a plurality of networks said packet including a source address and a destination address." *Id*. at 621. The claim then recited the steps of "assigning, by said source device, one of said trees to broadcast said packet and associating with said packet an identifier indicative one of said trees." *Id*. The court found that because the two steps of the claimed method referred to "said packet" and thereby "expressly incorporate[d] by reference the preamble phrase 'said packet' including a source address and a destination address," the claim should be limited to a method for transmitting packets that have both source and destination addresses. *Id*. While use of the word "said" does not have a "talismanic effect," *Bell Communications* typifies a situation where the court found that a preamble clearly defined an element of the claim. *See* ADC Telecommunications, Inc. v. Siecor, 954 F.Supp. 820, 829 (D.Del.1997).

[18] In the instant case, the claim speaks of a "a method of growing and isolating swine infertility and respiratory syndrome virus, ATCC-VR2332, which comprises inoculating the virus...." Schering posits that the term, "the virus," refers to the "swine infertility and respiratory syndrome virus, ATCC-VR2332" because the only "antecedent" in the claim for the words "the virus" is that which is mentioned in the

preamble. According to Schering, the claim drafter used both the preamble and the body of the claim to define its subject matter and therefore, *Bell Communications* compels this court to treat the preamble as a limitation.

There is no question that the preamble language "swine infertility and respiratory syndrome virus, ATCC-VR2332" "breathes life" into the body of the claim. A contrary conclusion would be incredible because without the preamble language, the claim would refer to any virus. Claim 1 clearly denotes "swine infertility and respiratory syndrome virus, ATCC-VR2332" as the virus upon which it focuses its attention. However, a larger question remains as to whether the language limits the patent to "virulent" viruses.

Boehringer argues that this language is "understood by those skilled in the art to be a name associated with the first PRRS virus isolated in North America, and therefore, representative of all PRRS viruses." Boehringer's Finding No. 130. Schering counters with two limitations. First, it posits, the language means the "virulent, disease-causing virus and etiological (causative) agent of [PRRS]." Schering Conclusion No. 7. Second, the phrase identifies the same strain of the PRRS virus deposited as ATCC-VR2332, thereby limiting the claim to a particular strain.

To this second limitation, Boehringer has not made a significant challenge. In its Reply Brief filed before the hearing, the plaintiff explained that it had used the ATCC accession number in the preamble to merely refer to the "strain" of virus represented by the deposit. *See* Plaintiff's Reply Br. at 5. Since its Reply Brief, Boehringer has made the following argument:

-> At the time Boehringer made its deposit, the virus was the first of its kind.

-> The deposit "is merely representative of the invention and permits the public to make and use the invention without having to 're-discover' the organism."

-> Because the "inventors were the first ever to identify the viral agent associated with PRRS, it would be draconian to limit the scope of their claims to the exact form deposited at the ATCC, when that deposit was only made due to the necessity of ..." the requirements of the patent act.

See Boehringer Finding No. 61.

I disagree. Regardless of when it was deposited, the ordinary meaning of the term refers to a specific strain of PRRS. Moreover, throughout the prosecution of its patent,the strain of virus was "essential" to the claimed invention. *See* Plaintiff's Ex. 30(B).

There is a more substantial debate over whether the patent is limited to cover "virulent" forms of the virus. The patent, itself, never uses the term virulence. For purposes of this analysis, to be virulent means to cause the symptoms of disease. But, being able to define the term "virulent" does not make claim interpretation any easier because the term, itself, is inexact. Virulence is not something that is turned off like a light switch, but instead, it is diminished over a continuum, as if it were controlled by a dimmer switch. After each passage in the attenuation process, the virus becomes more avirulent. Although the first passage is more virulent than the second, the second may still cause disease symptoms. Moreover, successful vaccine production does necessitate the creation of the most avirulent form of the virus because some level of virulence is needed to trigger the immune response. That immune response might not occur if the virus is too avirulent. Thus, vaccine producers must discover a point over the continuum where the most effective

vaccine resides.

Notwithstanding that virulence operates on a continuum, Schering wants to argue that claim 1 of the '778 Patent only covers virulent forms of the virus. Boehringer argues that it covers both virulent and avirulent forms. Schering's vigorous defense of its position has less to do with sound claim interpretation, than with finding an interpretation that suits its strategy. Generally, in the game of patent construction, the patentee argues that the claim covers the world while the alleged infringer will argue that the claim extends to everything, but its continent. From Schering's virulence argument, it follows that Claim 1 would be limited to earlier passage levels that are "virulent." Because Schering's allegedly infringing vaccine production process starts at what it considers the later "avirulent" passage levels, its process would not infringe. This strategy was followed in its construction of "isolating." Under Schering's construction of isolating, claim 1 would be limited to the first passage level, thereby exempting any method used at subsequent passage levels. The "virulence" argument does not draw the line at the first level, but Schering believes that it only covers early passage levels. Metaphorically speaking, if Schering's process were California, its "isolating" argument would draw the line at New Jersey and its "virulence" argument would draw it at the Mississippi river. Both would have the same effect for Schering's purposes. Perhaps to Schering's chagrin, claim construction is not such a result oriented process.

Following *Markman,* the court should first turn to the claim language itself. That language says nothing about virulence, but merely describes a "method of growing and isolating swing infertility and respiratory syndrome virus, ATCC-VR2332...." In this analysis, it is of paramount importance to recognize something that Schering is not arguing. Interestingly, Schering does not limit the claim to a "method of growing and isolating" a virus that has characteristics identical to that which was actually deposited in Rockville. That deposit represents a Boehringer's strain of the PRRS at the eight passage. Even under Schering's construction of the claim, the patent would extend to passage levels beyond eight.

Neither party suggests that the ATCC-VR2332 should be read literally. If the language were read literally, the claim would be limited to the eighth passage. At the time Boehringer filed its application, using the accession number was the best way for the company to identify what it had found.

Both parties rely upon the fact that there is no modifying language before ATCC-VR2332. If the patent limited the claim to virulent viruses, Boehringer argues, the claim would have said as much. Conversely, Schering argues, that if the patent had not limited the claim, it would have included indicative language. Based upon the patent language itself, neither is convincing. The court must now turn to the specification.

Schering draws upon the following language from the patent specification to support its virulence argument. Under the heading "The Invention," the patent states:

A viral agent has been recovered from the tissue homogenate. The viral agent will [cause] a disease that mimics SIRS in pigletsand pregnant sows. A deposit of the viral agent has been made on Jul. 18, 1991, with the American Type Culture Collection ... under the accession number ATCC-VR2332. '778 Patent, col. 2, lines 34-40.

Under the heading, "Viral Characteristics," the patent states:

ATCC-VR2332 consistently caused clinical signs and pulmonary lesions in gnotobiotic pigs.... *Id*. at col. 4, lines 19-20.

Finally, under the section discussing "Modified Live Vaccine Preparation," the patent notes that:

The pigs vaccinated with the attenuated virus did not develop any symptoms of SIRS after challenge [injection] with ATCC VR2332 ... whereas the control pigs did develop symptoms of SIRS. *Id*. at col. 7, lines 9-12.

There is no question that the patent specification informs the reader that the virus deposited in Rockville is that which causes PRRS. If the deposit did not cause PRRS, it would have little utility. The existence of disease causing characteristics were crucial to obtaining a patent. Nevertheless, that the patent describes the deposit does little to advance Schering's argument. It would be different if Schering were claiming that the claims are limited to a virus identical to that which was deposited-the PRRS virus in the eight passage. However the defendant does not propose that argument because the specification anticipates that the method will be performed at a number of passages and does not identify a stopping point.

In the patent, there is no discussion of either "virulence" or "final" passage levels. This further advances the court's belief that Schering's line drawing contributes little to the problem of reading the patent because the term is far too nebulous. The term is useless because virulence operates on a continuum. There can be obvious stopping point. Schering's interpretation only makes the claim language more confusing and difficult to follow. Under their interpretation, a reader would never know at which passage level it would be infringing.

Finally, there is the prosecution history. Here Schering makes much of the fact that the Examiner rejected Boehringer's initial patent application because Boehringer had "provide[d] insufficient evidence that the infectious agent [or the virus] is the etiological agent of mystery swine disease." Plaintiffs Ex. 30(E)(5) at 3 (copy of Office Action dated September 8, 1994). In a subsequent interview between the Patent Office and Boehringer, Boehringer agreed that it would "provide arguments and exhibits as set forth demonstrating ATCC-VR2332 is the agent which causes Mystery Swine Disease [PRRS]." Plaintiffs Ex. 30(E)(7). Boehringer submitted two published articles to the Examiner who eventually acknowledged that "applicants have provided [him] with copies of certain articles establishing that the infectious agent is the etiological agent of mystery swine disease." Plaintiffs Ex. 30(E)(8) at 2. Shortly thereafter, the patent issued. Based upon these facts, Schering has argued that Boehringer should be estopped from extending Claim 1 to avirulent viruses.

[19] Initially, I note that Schering has misused patent law terms. While prosecution history is important to claim interpretation, the doctrine of "prosecution history estoppel" is a subsidiary of the doctrine of equivalents. Prosecution history estoppel operates within the universe of the doctrine of equivalents. It serves as a "check" on the application of the doctrine of equivalents so that patentees cannot regain, through an infringement action, subject matter which it relinquished during prosecution of the patent application in order to obtain allowance of the claims. Wang Laboratories v. Mitsubishi Electronics America, 103 F.3d 1571, 1577 (Fed.Cir.1997); *see also,* Lockwood v. American Airlines, 107 F.3d 1565, 1574 (Fed.Cir.1997). At the claim interpretation stage, there is no concern with "regaining," because nothing has been defined yet. Nevertheless, prosecution history plays an important role in claim interpretation for many of the same reasons that it does in an equivalency analysis. The court may choose to limit claim language based upon the prosecution history.

However, in the instant case, Schering's argument is unavailing. As Schering has suggested, the Examiner

found the utility of the patent to be dependent on the fact that the PRRS strain causes the disease, but there is nothing to indicate that the claims should be restricted to virulent strains. Boehringer did not surrender something to obtain the patent. Rather, it clarified that it is dealing with a strain of virus that causes PRRS. Thus the virus is a particular strain, but it is not necessarily virulent.

Thus, the preamble language, "swine infertility and respiratory syndrome virus, ATCC-VR2332" limits the claim to the PRRS strain deposited, but not to any level of virulence.

iii. Incubating "until CPE is Observed"

[20] The term "until CPE is observed" is a timing device incorporated in the claimed method. It informs the reader on how to know when the incubation period has been completed. Here, incubation occurs "until CPE is observed." CPE refers to "cytopathic effect" which the plaintiff has defined as a "change in the microscopic appearance of a cell after infection with a virus" (Plaintiff's Br. at 8) or "some observable effect shown on the simian cells." Plaintiff's Finding No.146. As the defendant has explained, this observable effect is the killing of inoculated cells. When incubation is completed, the virus may be isolated and passaged again. The longer the virus is incubated, the more CPE occurs. Essentially, the parties do not disagree over the definition of CPE, but the claim language does not indicate whether the process should be terminated at the initial observation of CPE, at some degree of CPE, or at a time period which is determined independently of any degree of CPE.

According to Boehringer, the phrase, "until CPE is observed," requires that the incubation period continue long enough for CPE to be observed, but that the process need not be stopped immediately after the first observation of CPE. *See* Boehringer Finding No.146. Additionally, Boehringer believes that while the development of CPE is a significant moment, the term, itself, is not a precise one. In contrast, Schering argues that "until CPE is observed" is capable of precision and means that the onset of CPE requires the cessation of the claimed method. *See* Defendant's Br. at 15-16.

Looking at the claim language itself, Boehringer contends that Schering is attempting to engraft the word "first" on to the claimed method before "observed." In other words, Boehringer argues that a court could only adopt Schering's reading if the patent provided that the incubation period continue "until CPE is first observed." That argument reaches too far and defies principles of claim interpretation. If CPE were a precise moment, the court could adopt Schering's interpretation even though the word "first" is absent. If a recipe instructs its reader to cook a turkey "until the skin is browned," it would be fair to assume that the recipe requires the cook to stop at that point. It would also be safe to assume that if the cook waited much longer, at some point, the turkey would no longer be browned, but rather, singed and black. Therefore, the term "until CPE is observed" may conform to Schering's interpretation, but the term may also be construed as either requiring a particular degree of CPE or an independent determination. Therefore, the court must look to the specification for further guidance.

Under the section entitled "Isolation," the specification describes CPE when it discusses the "swelling or the forming of holes in the layer of cells at the edges of the culture bottle." '778 Patent, Col. 3, lines 27-29. "Fluid was separated from the bottle, and passed into a new bottle of MA-104 cells then subsequently passed a third time. .... CPE became stronger with each passage." The specification speaks further about the "[viral] agent [being] passed eight times in the MA-104 cell line with good CPE developing in three days ... at passage five and greater." Id. at lines 46-48. The specification language confirms that the discovery of CPE is an important benchmark within the patented process and that after a period of time, good CPE may

be observed. Because this language discusses CPE becoming "stronger" and "good CPE" developing, it does not appear that the process stopped immediately after the initial observation of CPE.

The specification also precludes a construction of the claim language that would permit the process to be continued indefinitely withoutconsidering CPE. Once some significant level of CPE develops, whether "strong" or "good," the incubation period stops so that the virus may be isolated. The patent does not define "good" or "strong" CPE. In its construction of the claim language, this court contemplates that incubation will be halted after the observation of some degree of CPE and rejects any wholesale adoption of Boehringer's position. Boehringer would like to eviscerate the word "until" so that the claim would cover a process that did not depend on the observation of CPE and continued independently and indefinitely. However, the court's construction contemplates that the process focuses on CPE and that there is some stopping point. That point is not when minimal CPE is observed, but when there is a significant degree of CPE.

Ultimately, one would prefer a more precise definition, but the patent language does not lend itself to that. That does not mean that such precision is impossible. In the section entitled, "Modified Live Vaccine Preparation," the patent describes a process where the "virus [is] allowed to grow until 50% of the MA-104 cell sheet [is] destroyed by the virus." '778 Patent, Col. 5, lines 37-39. Boehringer has argued that its position is bolstered by the specification's reference to "50% CPE." This court's construction of the patent does not rely upon that reference because while Boehringer is correct that this attenuation method anticipates continuing beyond the initial observation of CPE, it describes Claims 3 through 5 and not Claim 1 of the patent. Boehringer does not allege that Schering has infringed Claims 3-5 and they are not at issue in this litigation. However, it is helpful to look at the following example.

In an illustration of this method discussed in claims 3-5, the specification provides the following example: "24 hours after fluid change, CPE should be showing and, when 50-60% holes are present in cell sheet, freeze down." Id., Col. 6., lines 28-30. When the patent specification discusses the method in claims 3-5, it instructs the reader to harvest the virus "until 50%" destruction of the cell sheet. *See* Id., Col. 5, lines 37-39. Thereafter, the sample is frozen down. *See* Id. Thus, in claims 3-5, when the patent uses the word "until," it anticipates that incubation will stop at that point, i.e. when 50% destruction is reached, the harvesting is terminated. Therefore, when the patent uses the term, "until CPE is observed," without specifying the percentage of CPE, it may be argued that the patent anticipates that the growing process focuses on CPE and terminates at a point within an inexact range of CPE. The moment contemplated by the first claim of the '778 Patent is subject to a more qualitative determination.

2. Validity and Enforceability of the Patent

[21] Before this court considers whether Schering has infringed upon the '778 Patent, either literally or under the doctrine of equivalents, it is absolutely imperative that it entertain Schering's challenges to the validity of the patent. The exclusive rights guaranteed by the patent system are only granted to that which is patentable. One cannot infringe upon a invalid patent. Even if this court were to find that Schering's vaccine production process is an exact replica of Boehringer's method, Boehringer would not be entitled to any protection if its patent was invalid. It is implicit in that reasoning that a successful infringement action is dependent upon an invention being patentable. Once a patent issues, it is entitled to a presumption of validity, but as I will explain below, in the preliminary injunction context, the plaintiff bears the burden of proving that the alleged infringer's defense lacks "substantial merit." New England Braiding Co., Inc. v. A.W. Chesterton Co., 970 F.2d 878, 882-83 (Fed.Cir.1992); *see also* M & R Marking Systems, Inc. v. Top Stamp, Inc., 926

F.Supp. 466 (D.N.J.1996). Here, Schering's most compelling challenge is that Boehringer's patented method was made obvious by prior art.

a. Obviousness

Under Section 103(a) of the patent law provides:

[A] patent may not be obtained through though the invention is not identically disclosed or described as set forth in section 102 ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. 35 U.S.C. s. 103(a).

Therefore, if Boehringer's invention was not patentable under Section 103(a), its infringement action instantly melts away like water being thrown onto the wicked witch of the west. Here, Schering appears to make two kinds of arguments for why Boehringer's method was not patentable. First, it posits that Boehringer's invention was not patentable because it merely employed general principles of virology and therefore, it was so conventional that it was obvious. Second, it points out to the court that prior to Boehringer's invention, a porcine respiratory virus, swine influenza, was isolated on simian cells, thereby making the claims of the '778 Patent obvious. For reasons upon which the court will elaborate, Schering's first argument fails, but the second succeeds. These challenges will be considered below.

[22] [23] Given the stakes involved in the determination of the prior art issue, it is crucial that the Section 103 analysis be applied with circumspection. The analysis dictates that the court look at the claimed invention as a whole and not just individual elements. *See* Gillette Co. v. S.C. Johnson & Son, Inc., 919 F.2d 720, 724 (Fed.Cir.1990). Moreover, the court must conduct its inquiry as if it were to "step backward in time and into the shoes worn by a person of ordinary skill in the art when the invention was unknown and just before it was made." In re Fine, 837 F.2d 1071, 1073 (Fed.Cir.1988).

[24] Generally, in a patent infringement action, the patentee is entitled to a presumption of validity and the defendant bears the burden of proving obviousness by clear and convincing evidence. Litton Systems v. Honeywell, 87 F.3d 1559, 1566 (Fed.Cir.1996), *judgment vacated on other grounds,* 520 U.S. 1111, 117 S.Ct. 1240, 137 L.Ed.2d 323 (1997). But, a preliminary injunction is an extraordinary form of relief and therefore, it imposes different burdens. At this stage, because the patentee bears the burden of proving likelihood of success, when the validity of the patent is challenged, the patentee must demonstrate that "in light of the presumptions and burdens that will inhere at trial on the merits, ... its infringement claim will likely withstand [the defendant's] challenge to the validity ... of the ... patent." Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1364 (Fed.Cir.1997). In other words, to succeed in its preliminary injunction motion, the patentee must demonstrate that the alleged infringer's defense lacks "substantial merit." New England Braiding Co., Inc. v. A.W. Chesterton Co., 970 F.2d 878, 882-83 (Fed.Cir.1992); *see also* M & R Marking Systems, Inc. v. Top Stamp, Inc., 926 F.Supp. 466 (D.N.J.1996). Through this lens, the court must consider Schering's challenge to the validity of the patent.

[25] Obviousness under section 103 is ultimately a question of law which involves four factual inquiries:

(1) the level of ordinary skill in the pertinent art; and

(2) the scope and content of the prior art; and

(3) the differences between the claims and the prior art; and

(4) secondary considerations, if any, of nonobviousness.

See B.F. Goodrich Company v. Aircraft Braking Systems Corp., 72 F.3d 1577, 1582 (Fed.Cir.1996).

Secondary considerations include "evidence of factors tending to show nonobviousness, such as commercial success of the invention, satisfying a long-felt need, failure of others to find a solution to the problem at hand, and copying of the invention by others." *Id*.

[26] In the instant case, Schering asserts that the '778 Patent is unenforceable because "when viewed in the context of the prior art from the perspective of an ordinarily skilled virologist ... the growing and isolating of swine infertility and respiratory syndrome virus ATCC-VR2332 on simian cell lines was nothing more than the predictable result of an application of routine prior art procedures to the prior art." Defendant's Br. at 34. Additionally, it argues that the patent was made obvious by the earlier isolation of anotherporcine respiratory virus, swine influenza, using simian cells.

i. Level of Ordinary Skill in the Pertinent Art

In the instant case, the pertinent art is veterinary virology and the level of ordinary skill is a bachelor's degree in microbiology or biology with several years experience.

ii. Scope and Content of Prior Art

For the most part, Boehringer and Schering agree as to what constitutes prior art. It is commonly known by virologists that viruses may be grown by inoculating a sample of the virus onto either a full or partial sheet of cells and then incubating the virus and looking for the presence of CPE. Virologists also know that the presence of a "suitable growth medium" and "serum" are conventionally used to facilitate the growing. Moreover, there is nothing unusual about choosing an incubation temperature of 34 to 37 degrees. Choosing a cell line is perhaps the most challenging task faced by virologists.

Success is critically dependent on choosing the right cell line, but whether a particular virus will grow on a given cell and under what conditions remains uncertain and unknown. The "usefulness of any given cell line appears to depend on luck...." Defendant's Ex. J at 415 (copy of Bernard N. Fields, VIROLOGY, at 415). The daunting aspects of this complex problem do not place the virologist in complete darkness because virologists anticipate that most cell lines will be ineffective. Moreover, they are aware that with an unknown virus, there is a need conduct several tests with many cell lines. This knowledge makes the number of potentially viable cell lines almost infinite. Success may be achieved by using either cell lines derived from a species that differs from source of the diseased homogenate or from the actual source species. Boehringer does not dispute that cell lines from different animals have been used, but it argues that it was not "routine" to use a host cell from the same species as the infected animal. e.g. using porcine alveolar macrophages as a host cell for a porcine virus. At the time that Boehringer's PRRS virus was first isolated, simian cell lines and in particular MA-104, had never been used to isolate PRRS, but this particular cell line had been commercially available for culturing other viruses since the 1970's.

For purposes of Schering's second and more specific argument, it is important to note that while the prior art is not replete with examples of simian cells being used with porcine viruses, scientists did isolate a porcine

respiratory virus, swine influenza, using a simian cell line prior to Boehringer's isolation of PRRS. *See* Schering Finding No. 68, Boehringer Critique No. 68. That particular prior art is highly relevant, but Boehringer has attempted to distinguish it on the grounds that swine influenza is a zoonotic disease-meaning that it is a virus that affects more than one species-and PRRS is non-zoonotic. Scientists characterize a virus as zoonotic when it is communicable to all species, and they characterize a virus nonzoonotic when it affects only one species. For example, I might contract swine flu, but no person I know will get PRRS. The significance of that distinction will be discussed below.

iii. The Differences Between the Claims and the Prior Art

In the instant case, the court must consider whether, in light of the prior art at the time, one could have reasonably expected that the PRRS virus could be grown and isolated on simian cells, MA-104 in this case. *See Gillette, supra,* at 724 (obviousness does not require "absolute predictability of success," but only a "reasonable expectation of success"). As I have already indicated, there are two prongs to Schering's challenge.

First, it posits that the '778 Patent claims "nothing more than the routine obvious application of conventional virus isolation methodology using the predictable result of one of a plurality of cell lines, (in this case MA-104), to demonstrate CPE." Schering Conclusion No. 49. According to Schering, one may not have known that CPE would develop using MA-104, one could have reasonably expected success. For the following reasons, the court rejects that argument.

[27] There is no question that the prior art teaches that "one could attempt to isolate viruses from a mammalian tissue homogenate by inoculating a plurality of cell lines from different species," but based upon that, alone, it was not obvious to combine the conventional methodology and to try a battery of cell lines, among which included MA-104. As Boehringer has indicated, the prior art identified by Schering may have made using MA-104 as a host cell for PRRS "obvious to try," but nothing more. When an invention is merely "obvious to try," it is not unpatentable under Section 103. *See* In re Deuel, 51 F.3d 1552, 1559 (Fed.Cir.1995).

[28] [29] Patent jurisprudence has long dismissed any attempts to equate "obvious to try" with Section 103 obviousness. *See Id*. Prior art makes an invention "obvious to try" when a "general disclosure may pique the scientist's curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain sufficient teaching ... or that the claimed result would be obtained if certain directions pursued." Gillette Co. v. S.C. Johnson & Son, 919 F.2d 720, 725 (Fed.Cir.1990). In the "obvious to try" situation, the "prior art gives either no indication of which parameters are critical or no direction as to which of many possible choices is likely to be successful." Merck & Co., Inc. v. Biocraft Laboratories, Inc., 874 F.2d 804, 807 (Fed.Cir.1989). "Teachings of references [may] be combined" to establish obviousness, but there must be some teaching, suggestion or incentive supporting the combination. In re Fine, 837 F.2d 1071, 1074 (Fed.Cir.1988); In re Geiger, 815 F.2d 686, 688 (Fed.Cir.1987). Finally, obviousness analysis of a claimed combination must include consideration of the results achieved by that combination. *Gillette, supra,* at 724.

The general principles of virology already discussed in the first part of Schering's argument only made Boehringer's invention "obvious to try." These general principles only informed us that an unknown virus should be inoculated on a plurality of cell lines. With so many available cell lines, one could not have reasonably expected success from such a random selection. At the time of the invention, MA-104 was a

known and available cell line and viruses had been isolated using cell lines from animals other than the affected species, but based upon that teaching alone, it was counterintuitive to use simian cell lines to isolate a porcine virus. *See* Boehringer Critique No. 49. When asked why he had not used simian cells, Dr. Collins, one of the scientists working on the PRRS problem, testified that "[i]t wasn't intuitive to me to use a simian cell line....what we use routinely here for isolating viruses from swine is cell cultures of swine origin because by and large most of the swine viruses grow best in cell cultures native to the species." Plaintiff's Ex. 84 at 209-210. Therefore, based upon the prior art mentioned above, one could not conclude that the 778 Patent was obvious under Section 103. It does not even suggest that MA-104 would work with PRRS.

However, the strength of Boehringer's patentability arguments are diminished by Schering's second argument. At the hearing, there was testimony indicating that prior to the isolation of PRRS by Boehringer, scientists grew the swine influenza virus on simian cell lines. *See* Boehringer Finding No. 41; Schering Critique No. 41. Like PRRS, swine influenza is a respiratory virus. Boehringer does not dispute that the isolation of swine influenza occurred and that it is part of the prior art. It does question the value of that prior art.

At the very most, Boehringer suggests, based upon the teachings of this prior art, one could reasonably expect success with zoonotic viruses such as rotaviruses FN3 and swine influenza, but not with nonzoonotic ones such as PRRS. *See* Boehringer Critique Nos. 65-68. Notably, before the court read Boehringer's post-trial submissions, the plaintiff had never apprised the court or even intimated that there was a fundamental or even, a relevant distinction between isolating zoonotic and nonzoonotic viruses. The position taken by Boehringer in its post-trial brief is slightly different than that adopted by it before. Previously, Boehringer had always argued that the prior art did not teach that simian cells could be used to grow or isolate any porcine respiratory viruses. In his report, Boehringer's expert, Dr. Edward Dubovi, stated that "culturing a porcine virus on simian cells" was nonobvious. There was no distinction made between zoonotic and non-zoonotic diseases. At the hearing, Schering introduced evidence that swine influenza, a porcine respiratory virus, had been grown on simian cells. Only at that point did Boehringer raise the zoonotic distinction.

FN3. A rotavirus is a zoonotic virus that is enteric, which means that it infects the intestinal tract.

Interestingly, though, Boehringer has not attacked the prior art directly. It structures its argument differently. Boehringer does not answer the question of whether the isolation of swine flu even makes obvious the isolation of zoonotic respiratory viruses on simian cells. It merely states that the prior art, "at the very most," leads to that result. Rather than fight Schering on this level, Boehringer makes the point that even if the isolation of swine influenza makes the isolation of porcine respiratory on simian cells obvious, the prior art only covers zoonotic diseases. Therefore, Boehringer's argument is entirely dependent upon the distinction between zoonotic and nonzoonotic viruses. Because Boehringer hangs its hat on this distinction, if it cannot demonstrate that the distinction is a meaningful one, it cannot prove that Schering's defense lacks substantial merit.

Boehringer believes that there is "absolutely no rational basis for trying to culture [a zoonotic virus] on a close relative of human cells." Plaintiff's Zoonotic Brief at 1. For that reason, it persists with the assertion that Schering has not mounted even a remotely legitimate defense. Because the record completely undermines the significance of Boehringer's zoonotic distinction, I find that Schering's defense possesses, at the very least, substantial merit. At the time of the invention, no one knew that PRRS was non-zoonotic and nothing in the record suggest that anyone suspected as much. Moreover, Boehringer has not identified any

virological principles which suggest that zoonotic and nonzoonotic viruses should be isolated differently. Certainly, Boehringer might have a point if something in the prior art indicated that the lessons learned from zoonotic diseases are inapplicable to nonzoonotic viruses, but that is not the case here. The prior art in this case does not suggest that replicating the process with non-zoonotic viruses will be unproductive. *See* In re Gurley, 27 F.3d 551, 553 (Fed.Cir.1994) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.... [A] reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant.").

Boehringer expects the court to dismiss Schering's defense just because it has identified a difference between PRRS and swine influenza-one is zoonotic, the other is not. The court is aware of the difference between the viruses. Nevertheless, Boehringer has not demonstrated why that difference impacts upon the methodology behind growing viruses. For that reason, I cannot adopt the plaintiff's position that Schering's defense lacks substantial merit.

iv. Secondary Characteristics:

Objective indicia, such as the secondary characteristics mentioned above are "invariably relevant" to a Section 103 determination. *Litton Systems, supra,* at 1569. Boehringer believes that the commercial success of its vaccine, the long felt need for it, and evidence that Schering had copied its process weighs in its favor. However, the court finds, at the most, that the commercial success factor supports its position. That is not enough to overcome Schering's obviousness defense.

-> Commercial Success

[30] To satisfy its burden here, the plaintiff must not only demonstrate that Schering's obviousness defense lacks "substantial merit," (*See* New England Braiding Co., Inc. v. A.W. Chesterton Co., 970 F.2d 878, 882-83 (Fed.Cir.1992); *see also* M & R Marking Systems, Inc. v. Top Stamp, Inc., 926 F.Supp. 466 (D.N.J.1996)), but it also bears the initial burden of establishing a prima facie case of nexus between the secondary characteristic-commercial success-and the merits of the claimed invention. In re GPAC Inc., 57 F.3d 1573, 1580 (Fed.Cir.1995). "Thus, the patentee bears the initial burden of demonstrating both that there is a commercial success and that there is a nexus between that which is patented and that which is sold." Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1392 (Fed.Cir.1988).

In the instant case, Boehringer's vaccines, RespPRRS ^{TM} and RespPRRS/Repro ^{TM} are the single largest selling veterinary vaccine in the United States. They are produced by growing the virus on a monolayer of MA-104 simian cell line at temperature of 34 to 37 degrees in suitable growth medium and in presence of Bovine calf serum until at least 10% CPE is observed. This production process is subsumed within the definition of the '778 Patent and therefore, the court finds a direct nexus. Therefore, the court acknowledges that Boehringer's commercial success weighs in favor of nonobviousness.

-> Failure of others to Solve the PRRS mystery

Additionally, Boehringer has argued that "long felt need for a PRRS vaccine" and the failure of others to solve the PRRS mystery supports a nonobvious determination. *See* Plaintiff's Br. at 14; Plaintiff's Reply Br. at 14; Boehringer Finding No. 193. I find that while a need existed, it has been embellished. In the late 1980's, PRRS became a devastating disease and as Schering noted, "demanded the attention and effort of

every segment of the swine industry." *See* Boehringer Finding No. 16, 17 (citing Plaintiff's Ex. 20 Schering's "Animal Health Forum" at 1). Because the disease confounded the scientific community and because Boehringer's did not manufacture a vaccine until 1994, Boehringer argues that a "long felt need existed." That claim is somewhat exaggerated. Boehringer's story should be contrasted with other illuminating facts. The disease first became "alarming" in 1988. Boehringer isolated the virus in 1991, three years later. The attenuation process which eventually produced the vaccine was time consuming and was completed in 1994. Thus, while there was definitely a need to isolate the virus, it should not be characterized as long felt.

-> Evidence of Copying

Evidence of copying is a relevant secondary characteristic which should be considered. Boehringer has argued that one of Schering's scientists, Dr. Richard Hesse, copied Boehringer's method of isolating PRRS on simian cell lines. *See* Boehringer Finding No. 72-80. In September 1991, Hesse attended the Minnesota Swine Conference where Drs. Collins, Benfield and Harris reported on their progress in isolating and characterizing the PRRS virus. Dr. Benfield showed slides of the PRRS virus growing, but he did not identify the cell line. Boehringer has alleged that Hesse studied the slide and eventually figured out that Boehringer was using MA-104 cell lines. Schering did not initially isolate the virus on simian cells, but it used MA-104 at later passages. Essentially, Boehringer believes that Hesse's attendance at the conference evidences copying.

That Hesse attended the conference cannot confirm Boehringer's accusation. It is one thing to be intellectually stimulated and inspired by a speech made at a conference; it is another to equate that occurrence with evidence of copying. Certainly, the speech at the conference was illuminating, but without any direct or concrete evidence whatsoever, this court cannot conclude that Hesse copied Boehringer's method.

v. Summary

Although the secondary characteristics add weight to Boehringer's claim, it does not tip the scale in the plaintiff's favor. At this preliminary stage, the court need not conclusively resolve the validity question, but rather, it must "make an assessment of the persuasiveness of the challenger's evidence recognizing that it is doing so without all evidence that may come out at trial." *New England Braiding, supra,* at 883. The court may deny a preliminary injunction because the evidence raises a substantial question even though the defense may not be "entirely fleshed out." *See Id*. Based upon the prior art discussion, one cannot ignore that Schering's defense raises substantial questions about the validity of the '778 Patent. Proof of commercial success cannot turn the tide in this case. Therefore, Boehringer has not satisfied its burden of proving likelihood of success.

b. Other Validity Arguments-Schering's Inventorship Claims

In light of my conclusion that Schering has raised a substantial defense with respect to obviousness, I need not consider other validity arguments. Nevertheless, it is worth noting that under two different yet related legal theories which I will discuss below, Schering argues that Boehringer's patent does not name all of the proper inventors and is therefore invalid and unenforceable. Specifically, the '778 Patent named Danny Chladek, David Gorcyca, Louis Harris, but not James Collins and David Benfield, even though the latter two worked with Boehringer on PRRS. Boehringer has named the two scientists as inventors on other PRRS related patent applications, but not the '778 Patent. *See* Boehringer Finding No. 68. Before getting together with Boehringer, Collins and Benfield produced a tissue homogenate from which an inoculum could be

prepared, but they had not discovered a receptive cell line to grow the virus. Collins sent his inoculum samples to Boehringer and Boehringer's scientists observed CPE on a partial cell line derived from a monkey kidney, MA-104. Subsequently, Boehringer used Collins and Benfield to perform Koch's Postulates and confirm its success. Even though my decision on this issue will not impact upon the final decision, the court finds that for reasons which will be explained below, Schering's defenses lack substantial merit and are unavailing.

i. Defendant's Checkpoint Analogy

In reliance upon the foregoing, Schering argues that Collins and Benfield were joint inventors and that Boehringer's failure to name them invalidates the patent. The law prescribes that "[w]hen an invention is made by two or more persons jointly, they shall apply for patent jointly...." 35 U.S.C. s. 116. The Federal Circuit has explained that "a joint invention is the product of collaboration of the inventive endeavors of two or more persons working toward the same end and producing an invention by their aggregate efforts." Kimberly-Clark v. Procter & Gamble, 973 F.2d 911, 916 (Fed.Cir.1992). Following *Kimberly-Clark,* the defendant asserts that "isolation," as claimed in the '778 Patent was a "collaborative effort." *See* Defendant's Br. at 26. According to Schering, had Collins and Benfield not provided the "inoculum containing 'the virus,' " Harris would never have been able to "inoculate" the virus on sheet of simian cells. *See* Id. at 27.

Schering analogizes the instant case to Checkpoint Systems, Inc. v. United States International Trade Commission, 54 F.3d 756 (Fed.Cir.1995), where the court grounded its decision to invalidate a patent on the fact that the plaintiff's patent application did not name a prior inventor. According to the court, where the patentee misdesignates the inventor with deceptive intent, the court may invalidate the patent. Id. at 763. However, a good faith error in a designation of inventorship does not render a patent invalid. *Id.*

In *Checkpoint,* the plaintiff patented a deactivatable resonant tag for use in electronic security systems by retailers to deter shoplifting. The patent named one of plaintiff's employees, Lichtblau, as the inventor. Another employee, Kaltner, had previously developed a tag which fell within the scope of the patented claims. When inquiries were made regarding whether Checkpoint intended to patent Kaltner's invention, Checkpoint responded that it would take care of the matter. In the litigation, Checkpoint claimed that it did not name Kaltner because it believed that Kaltner had abandoned his invention. Under 35 U.S.C. s. 102(g), a person cannot obtain a patent if the invention was made by another who had not abandoned it. In *Checkpoint,* the Federal Circuit disagreed with the abandonment argument and invalidated the patent because Checkpoint had not inadvertently failed to name Kaltner as the inventor. Rather, the court concluded, the employer had dodged Kaltner's inquiries and intentionally deceived the PTO. As the court explained,

Checkpoint might have responded to Kaltner's inquiries by filing a patent application on Kaltner's invention and letting the PTO resolve the questions of prior Inventorship and entitlement to a patent rather than ignoring Kaltner's Inventorship role and attempting to enforce a Lichtblau patent on an invention that Kaltner made first. *Id.* at 763.

The court suspected that Checkpoint did not name Kaltner because he would not have been obligated to assign his invention to his employer. The court assumed that Checkpoint's decision was financially motivated and offered the following dicta: a first inventor should not be "cavalierly tossed aside in favor of a second inventor from who the employer has more advantageous contract rights." *Id.*

Following *Checkpoint,* Schering argues that although this case involves joint inventorship and not prior inventorship, Boehringer could have advised the PTO of the facts and let it resolve the issue of proper Inventorship, rather than attempt to enforce a patent listing only plaintiff's employee's with whom plaintiff had "advantageous contract rights." *See* Defendant's Br. at 30. On the other hand while Boehringer does not challenge Schering's interpretation of the law, it finds somewhat dubious the suggestion that Collins and Benfield were joint inventors.

Here, the validity of the '778 Patent turns on whether Schering can prove: first, that Collins and Benfield were joint inventors and second, that Boehringer deceptively omitted them from the patent. As with the Section 103 inquiry, because the patentee is entitled to a presumption of validity, at a trial on the merits, the defendant would bear the burden of proving invalidity by clear and convincing evidence. Litton Systems v. Honeywell, 87 F.3d 1559, 1566 (Fed.Cir.1996), *judgment vacated on other grounds,* 520 U.S. 1111, 117 S.Ct. 1240, 137 L.Ed.2d 323 (1997). But, at the preliminary injunction stage, the patentee must demonstrate that "in light of the presumptions and burdens that will inhere at trial on the merits, ... its infringement claim will likely withstand [the defendant's] challenge to the validity ... of the ... patent." Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1364 (Fed.Cir.1997). In other words, to succeed in its preliminary injunction motion, the patentee must demonstrate that the alleged infringer's defense lacks "substantial merit." New England Braiding Co., Inc. v. A.W. Chesterton Co., 970 F.2d 878, 882-83 (Fed.Cir.1992); *see also* M & R Marking Systems, Inc. v. Top Stamp, Inc., 926 F.Supp. 466 (D.N.J.1996).

(a) *Checkpoint: the Joint Inventorship Prong*

[31] With respect to *Checkpoint* 's first prong, the court finds that Boehringer properly omitted Collins and Benfield. There is no question that the subject matter claimed-a method of growing and isolating the virus-was conceived solely by the named inventors. The court agrees that had Collins and Benfield not provided Harris with the inoculum containing the virus, they would not have been able to isolate the virus, but that does not mean that they should be entitled to joint inventorship rights. Harris might have obtained necessary material from Collins and Benfield, but the patent does not claim a compound. It claims a method developed exclusively by Harris. Additionally, for purposes of considering the validity of this particular patent, I do not find it significant that Collins and Benfield were the ones to do the confirmatory work. That Collins and Benfield were the ones to perform Koch's postulate and conclude that Harris had been successful does not mean that they are joint inventors. The patent claims a method and nothing else.

(b) *Checkpoint: Deceptive Intent*

[32] Even if Collins and Benfield were joint inventors, Boehringer would still meet its burden because Boehringer did not exhibit any deceptive intent in "misdesignating" the inventors of the patent. *See Checkpoint, supra,* at 763. Here, Schering relies solely on the existence of commercial incentive to exclude Collins and Benfield from the patent. Under 35 U.S.C. s. 262, in the absence of any agreement, joint inventors "may make, use, offer to sell, or sell the patented invention ... without the consent of and without accounting to the other owners." Because Collins and Benfield were not members of Boehringer's laboratory, they were not controlled by Boehringer and therefore, if named as joint inventors, would have an undivided interest in the patent. From this, Schering asks the court to infer that Boehringer excluded Collins and Benfield to maintain a financial advantage. Essentially, Schering suggests, Boehringer wanted to monopolize all potential financial benefit.

Other than the general principle that joint inventors may independently pursue opportunities to make money off their inventions, there is no evidence of deceptive intent. A defendant should not be permitted to support

its claim by invoking financial incentive motive because that motive would appear in every case. The defendant must point to something more concrete to demonstrate a substantial defense. Here, Schering's defense lacks substantial merit and the court is not inclined to accept it.

ii. Inequitable Conduct

[33] [34] In a related legal argument, Schering posits that the '778 Patent is unenforceable because it was procured through inequitable conduct. Inequitable conduct means any " 'affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive.' " Refac International, Ltd. v. Lotus Development Corp., 81 F.3d 1576, 1581 (Fed.Cir.1996) (quoting Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed.Cir.1995)). Where a court finds that a patentee engaged in inequitable conduct, it may invalidate the patent. *See* Refac International, Ltd. v. Lotus Development Corp., 81 F.3d 1576 (Fed.Cir.1996). The party alleging "inequitable conduct" must prove the "threshold elements" of materiality and intent by clear and convincing evidence. *Id.* However, in the instant preliminary injunction proceeding, the plaintiff bears the burden of demonstrating that Schering's defense lacks substantial merit.

[35] [36] [37] [38] Specifically, defendant contends that Boehringer's failure to name Collins and Benfield as joint inventors and its failure to identify Collins and Benfield's work as prior art constituted inequitable conduct. In conducting its analysis, this court must examine the totality of the circumstances and decide whether the patent applicant's conduct was so "culpable that the patent should not be enforced." *Molins, supra,* at 1178; *see also Id.* "Material" information exists when there is a "substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent. " *Refac, supra,* at 1581. "Intent" means "design, resolve, or determination with which a person acts; a state of mind in which a person seeks to accomplish a given result through a course of action." *Molins, supra,* at 1180. It "need not be proven by direct evidence" and is "most often proven by a showing of acts, the natural consequences of which are presumably intended by the actor." *Id.* Because this court's inquiry must consider materiality and intent together, "the more material the omission or misrepresentation, the less intent that must be shown to reach a conclusion of inequitable conduct." Akzo N.V. v. United States International Trade Commission, 808 F.2d 1471, 1481-82 (Fed.Cir.1986).

(a) ***Failure to Disclose Material Information***

Schering's first argument-"failure to disclose material information "-requires the same analysis as that conducted above to consider the *Checkpoint* analogy. First, because Collins and Benfield were not joint inventors, failure to disclose that information is not material. Second, for the reasons mentioned above, there is no deceptive intent. Therefore, Schering's "failure to disclose" argument fails.

(b) ***Affirmative Misrepresentation***

[39] Schering's second inequitable conduct argument-affirmative misrepresentation of a material fact-focuses on Boehringer's alleged failure to apprise the Examiner of prior art in existence at the time of its patent application. Essentially, Schering contends that patent specification refers to work performed by Collins and Benfield and disguises it as its own. If Collins and Benfield were not joint inventors, their work constitutes prior art, which, according to Schering should have been disclosed to the Examiner.

In the section entitled "Invention," the specification states that:

A tissue homogenate obtained from piglets in SIRS-infected herds consistently reproduced the respiratory and reproductive forms of SIRS when intransally inoculated in gnotobiotic piglets and pregnant sows. Gnotobiotic piglets so inoculated with either unfiltered or filtered ... inoculum became anorectic and developed microscopic lung lesions similar to lesions seen in SIRS-affected herds. The same inoculum also caused reproductive effects identical to those seen in SIRS-infected herds. A viral agent has been recovered from the tissue homogenate.... *See* '778 Patent.

All but the last sentence represents the prior work performed by Collins and Benfield. However, even if it constitutes prior art not disclosed to the examiner, it is not material to the obviousness inquiry. There is nothing in Collins and Benfield's work that would have made the '778 Patent obvious. Collins and Benfield might have discovered that PRRS was a porcine virus, but for that, in itself, did not make the invention obvious. If the '778 is unenforceable under Section 103(a), it is because swine influenza had already been isolated. Anyway, the examiners already assumed that PRRS was caused by a virus. Moreover, even if it were material, Schering cannot satisfy the intent prong.

With respect to intent, Schering has argued that intent "flows from the initial commercially motivated decision to exclude Collins and Benfield as inventors." Defendant's Br. at 33. However, that argument has been dismissed in my *Checkpoint* analysis. *See* discussion, *supra*.

iii. Summary

For the foregoing reasons, Schering's other validity and enforceability challenges fail.

3. Literal Infringement Claim and Infringement under the Doctrine of Equivalents Claim

As I have already noted, at the preliminary injunction stage, a patentee must establish a likelihood of success on the merits with respect to the patent's validity, enforceability, and infringement. *See* Nutrition 21 v. United States, 930 F.2d 867, 869 (Fed.Cir.1991). If Boehringer's had satisfied its burden with respect to validity, it would also have had to establish the likelihood of either literal infringement or infringement under the doctrine of equivalents. But in light of my findings, even if Schering's method were identical to the claims in the '778 Patent, Boehringer could not establish likelihood of success because Schering has demonstrated that substantial questions exist as to whether the patent is valid. *See* Id. Therefore, without considering the infringement issue, I find that Boehringer cannot establish likelihood of success.

4. Failure to Establish Likelihood of Success

The plaintiff is not entitled to a preliminary injunction unless it carries its burden on both the likelihood of success and the irreparable harm factor. *See Reebok, supra,* at 1556 (Fed.Cir.1994). The court must deny the preliminary injunction where the movant has failed to carry its burden on either factor. Therefore, the court need not consider any other factors if the defendant has not demonstrated likelihood of success. *See Id.; New England Braiding Co., supra,* at 883. Nevertheless, the court will make findings with respect to irreparable harm.

B. Irreparable Harm

If Boehringer had satisfied its burden of proving the likelihood of success by demonstrating both validity and infringement, it would have been entitled to a rebuttable presumption of irreparable harm. *See* Polymer Technologies, Inc. v. Bridwell, 103 F.3d 970, 973 (Fed.Cir.1996). Boehringer has failed to meet its burden

and thus, cannot avail itself of that presumption. *See* PPG Industries v. Guardian Industries Corp., 75 F.3d 1558, 1566 (Fed.Cir.1996); Circle R, Inc. v. Smithco Mfg., 919 F.Supp. 1272, 1301 (N.D.Iowa 1996).

[40] In the instant case, Boehringer alleges that if it is denied the preliminary injunction, it will be irreparably harmed for the following reasons: first, it will lose market share; second, the loss in revenue and in the size of its workforce will result in a decrease in funding for research and development; third, it will suffer damage to its goodwill; and fourth, the duration of the monopoly will be cut short.

At the moment, Schering and Boehringer are the only ones selling this kind of PRRS vaccine. There is no question that Boehringer will suffer in its market share due to Schering's sales, but Schering has indicated that it will be able to compensate any loss in revenues. The court is aware that the loss in market share is not easily recoverable. *See* Stein Industries v. Jarco Industries, 934 F.Supp. 55, 58 (E.D.N.Y.1996). As the Federal Circuit has stated, "because the principal value of a patent is its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole." Hybritech Inc. v. Abbott Laboratories, 849 F.2d 1446, 1457. Nevertheless, the "application of a concept that every patentee is always irreparably harmed by an alleged infringer's pretrial sales would ... disserve that patent system." See *Reebok, supra,* at 1558. Here, Schering is a major drug company and will be able to compensate Boehringer for any loss. To prove irreparable harm, Boehringer must provide some "reasoned analysis" for why monetary damages would be insignificant and it has not done so. *See Nutrition 21, supra,* at 871. Instead, it chooses to rely upon a presumption to which it is not entitled. Therefore, loss of market share does not weigh in Boehringer's favor. *See Id., supra,* at 871 (finding no irreparable harm because the defendant would be "answerable in damages" and the plaintiff had not provided any "reasoned analysis" for the inadequacy of money damages).

Additionally, I note that Boehringer has suggested that as a result of its loss in revenue and in the size of its workforce, there will be a decrease in funding for research and development. *See* Plaintiff's Br. at 19 (citing Genentech, Inc. v. Novo Nordisk A/S, 935 F.Supp. 260, 283 (S.D.N.Y.1996), *vacated on other grounds,* 108 F.3d 1361 (Fed.Cir.1997)). This factor weighs in Boehringer's favor.

Thirdly, Boehringer argues that it will suffer irreparable damage to its goodwill. Allegedly, this damage will be particularly severe given the remarkably different approaches taken by Schering and Boehringer in selling their product. Whereas Boehringer sells directly to veterinarians, Schering sells its product as over the counter medication. Boehringer believes that because PRRS is difficult to diagnose without the assistance of a veterinarian, it should not be sold over the counter. If a farmer uses the vaccine on a pig sick with something other than PRRS, when the pig does not get better, the farmer will blame the vaccine. During the hearing, Paul Hays testified that there are

examples of cases where people have gotten a hold of PRRS vaccines without the use of diagnostics, and because they had a coughing piglet or sick piglet, they vaccinated with PRRS and expected that to be the end all to their problems. And in fact pigs were still coughing because the PRRS vaccine didn't work, and with a continued approach of having a product on the market over the counter, this is beginning to give all PRRS vaccines a black eye. Hays Testimony, Tr. at 2.93.

Here, Boehringer warns that all PRRS vaccines will suffer and its reputation and sales will be impugned by over the counter sales. *See* Plaintiff's Br. at 21. While loss of goodwill may qualify as irreparable harm, (*see* Bio-Technology General Corp. v. Genentech, Inc., 80 F.3d 1553, 1565 (Fed.Cir.), *cert. denied,* 519 U.S. 911, 117 S.Ct. 274, 136 L.Ed.2d 197 (1996); Gateway Eastern Railway Co. v. Terminal Railroad, 35 F.3d

1134, 1140 (7th Cir.1994)), Boehringer has not offered any concrete evidence in support of its claim. There are advantages and disadvantages to both sales strategies, but both have been approved and this court will not make any judgments about them where the evidence is so lacking.

Finally, Boehringer has argued that the monopoly afforded it may be of "shortened duration" due to first, "ongoing research in the field that may make that patented invention obsolete" second, the fact that "some herds becoming naturally immune to PRRS," and third, some farmers vaccinating only sows. The Federal Circuit has recognized that in some situations, the value of the patent may be fleeting because it may be bypassed by new technology. *See Hybritech, supra,* at 1456. Boehringer has not demonstrated the existence of that factor. For one reason, only Boehringer's first argument regarding "ongoing research" relates to new technology and that argument is far too speculative. Boehringer's invention may be replaced by new technology, but it has not provided anything more specific. Moreover, even if Boehringer could satisfy this factor, it might make the case closer, but it would not overcome its other problems with respect to its market share and goodwill arguments. *See* Hewlett-Packard Company v. Genrad, Inc., 882 F.Supp. 1141, 1153 (D.Mass.1995).

For the foregoing reasons, Boehringer has not satisfied the "irreparable harm" factor. Even if it had satisfied this factor, the court could not grant its motion because it has not demonstrated likelihood of success. *See Reebok, supra*.

C. Other Factors

Because Boehringer has failed to satisfy the first two preliminary injunction findings, the court need not make findings on the final two-the balancing of interests and the public interest. *See Id*. at 1556. Even if those factors weighed in favor of Boehringer, the plaintiff could not avail itself of the extraordinary injunctive relief it requests.

III. Conclusion

For the reasons detailed in this opinion, plaintiff's motion for a preliminary injunction is **DENIED**.