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Analysis
As of: Oct 06, 2014

**INTEGRA LIFESCIENCES I, LTD., a Delaware corporation, and THE BURNHAM INSTITUTE, a California nonprofit corporation, Plaintiff, v. MERCK KGaA, a German corporation, Defendants.**

**Civil No: 96CV1307-B(AJB)**

**UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF CALIFORNIA**

***2004 U.S. Dist. LEXIS 20725***

**September 7, 2004, Decided**

**PRIOR HISTORY:** *Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 2003 U.S. App. LEXIS 11335 (Fed. Cir., 2003)*

**DISPOSITION:** Court issued Order re: Calculation of Reasonable Royalty.

**CASE SUMMARY:**

**PROCEDURAL POSTURE:** Plaintiff pharmaceutical company sued defendant pharmaceutical company for patent infringement. A jury found defendant guilty of willful infringement and awarded $ 15 million damages. Defendant's motion for judgment as a matter of law (JMOL) was denied. On appeal, the United States Court of Appeals for the Federal Circuit reversed the denial of defendant's JMOL motion and remanded the case for factual development and calculation of damages.

**OVERVIEW:** The patents related to a certain amino acid sequence for pharmaceutical products. The parties had negotiated for a licensing agreement prior to commencement of the lawsuit. The Federal Circuit found that the damage award was not supported by substantial evidence. On remand, the court found that August 1994 was the proper timing for a hypothetical negotiation date for a license for the disputed patents. The court declined to adopt the testimony of either party's expert witness, finding that they lacked factual and economic basis. Plaintiff's other license agreements were not useful because they were not negotiated during August 1994. The court relied on the parties' actual license negotiations as the best evidence to determine a reasonable royalty for the appropriate period. The court found that plaintiff would be entitled to $ 1.5 million per year for development funding, resulting in a reasonable royalty of $ 6.375 million. There was no basis to award any milestone payments. This determination was also supported by the price plaintiff paid to acquire the company that developed the patents. The court did not give plaintiff the option of a new trial, but reduced the jury's verdict.

**OUTCOME:** The court awarded plaintiff $ 6.375 million

damages for the patent infringement.

**LexisNexis(R) Headnotes**

***Patent Law > Remedies > Collateral Assessments > Increased Damages***
***Patent Law > Remedies > Damages > Patentholder Losses***
***Patent Law > Remedies > Damages > Reasonable Royalties***
[HN1] After finding patent infringement, a jury may award the patentee damages adequate to compensate for the infringement, but in no event less that a reasonable royalty for the use made of the invention by the infringer. *35 U.S.C.S. § 284*. A court may increase the damages up to three times the amount found or accessed. This permits an injured patentee to enjoy at least a reasonable royalty even when he is unable to show lost profits or to establish a royalty rate.

***Patent Law > Remedies > Damages > Measures***
***Patent Law > Remedies > Damages > Patentholder Losses***
***Patent Law > Remedies > Damages > Reasonable Royalties***
[HN2] A reasonable royalty calculation envisions and ascertains the results of a hypothetical negotiation between the patentee and the infringer at a time before the infringing activity began. Thus, a reasonable royalty calculus assesses the relevant market as it would have developed before and absent the infringing activity. Although an exercise in approximation, this analysis must be based on "sound economic and factual predicates." Royalties, like lost profits, are compensatory damages, not punitive. See Riles.

***Patent Law > Infringement Actions > Burdens of Proof***
***Patent Law > Infringement Actions > Infringing Acts > Contributory, Indirect & Induced Infringement***
[HN3] To be liable for inducing infringement under *35 U.S.C.S. § 271(b)*, a patentee must show that the party alleged of inducing infringement took actions to induce direct infringement, and that the party alleged of inducing infringement knew or should have known that such actions would induce direct infringement. Actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding inducement.

***Patent Law > Remedies > Damages > Reasonable Royalties***
***Patent Law > Remedies > Damages > Time Limitations***
[HN4] Royalties are compensatory damages and are designed to make the patentee whole as opposed to punishing the infringer. A reasonable royalty determination for purposes of making a damages evaluation must relate to the time infringement occurred, and not be an after-the-fact assessment. Of fundamental importance to the damages determination is that it be based on "sound economic and factual predicates." The United States Court of Appeals for the Federal Circuit has stated that although the damages calculation after a finding of infringement involves "an element of approximation and uncertainty," a "reasonable royalty" will be held valid as long as the award is supported by substantial evidence, is not grossly excessive, and is not based "only on speculation and guesswork." In determining a reasonable royalty, a court must determine the maximum royalty that a reasonable jury would find is supported by the evidence in the record.

***Patent Law > Infringement Actions > Exclusive Rights > General Overview***
***Patent Law > Ownership > General Overview***
***Patent Law > Remedies > Damages > General Overview***
[HN5] The following factors may aid in the calculation of a reasonable royalty: 1. The royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty. 2. The rates paid by the licensee for the use of other patents comparable to the patent in suit. 3. The nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold. 4. The licensor's established policy and marketing program to maintain his patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly. 5. The commercial relationship between the licensor and licensee, such as, whether they are competitors in the same territory in the same line of business; or whether they are inventor and promoter. 6. The effect of selling the patented specialty in promoting sales of other products of the licensee; that existing value of the invention to the licensor as a generator of sales of his non-patented items; and the extent of such derivative or

convoyed sales.

***Copyright Law > Civil Infringement Actions > Remedies > Damages > Infringer Profits***
***Patent Law > Infringement Actions > Infringing Acts > General Overview***
***Patent Law > Remedies > Damages > Reasonable Royalties***
[HN6] The following factors may aid in the calculation of a reasonable royalty: 7. The duration of the patent and the term of the license. 8. The established profitability of the product made under the patent; its commercial success; and its current popularity. 9. The utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results.10. The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention. 11. The extent to which the infringer has made use of the invention; and any evidence probative of the value of that use. 12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions. 13. The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.

***Patent Law > Infringement Actions > Infringing Acts > General Overview***
***Patent Law > Ownership > Conveyances > Licenses***
***Patent Law > Remedies > Damages > Reasonable Royalties***
[HN7] The following factors may aid in the calculation of a reasonable royalty: 14. The opinion testimony of qualified experts. 15. The amount that a licensor, such as a patentee, and a licensee, such as an infringer, would have agreed upon, at the time the infringement began, if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee -- who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention -- would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.

***Patent Law > Remedies > Damages > General Overview***
[HN8] The United States Court of Appeals for the Federal Circuit has held that in determining a reasonable royalty, a court may base such calculation on an established royalty, if there is one, or if not upon a hypothetical royalty resulting from arm's length negotiations between a willing licensor and a willing licensee. The Federal Circuit has further stated that when a reasonable royalty is the measure, the amount may again be considered a factual inference from the evidence, yet there is room for exercise of a common sense estimation of what the evidence shows would be a reasonable' award.

***Civil Procedure > Trials > Judgment as Matter of Law > General Overview***
***Civil Procedure > Judgments > Relief From Judgment > Additurs & Remittiturs > Remittiturs***
[HN9] When a court grants a remittitur, it must make the remittitur conditional on the prevailing party's acceptance of the remittitur with the option of a new trial. However, the United States Court of Appeals for the Federal Circuit appears to have carved out an exception to the requirement of offering the option for a new trial when damages are reduced pursuant to a motion for judgment as a matter of law. Where as a matter of law, damages are not supported by the substantial evidence in the record, trial courts do not commit legal error by not giving the party adversely affected by the reduction in damages the option for a new trial. The United States Court of Appeals for the Ninth Circuit has tacitly expressed a similar view regarding reduction of damages as a matter of law.

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**JUDGES:** HON. RUDI M. BREWSTER, United States District Judge.

**OPINION BY:** HON. RUDI M. BREWSTER

**OPINION**

**ORDER RE: CALCULATION OF REASONABLE ROYALTY ON REMAND**

**I. INTRODUCTION**

Before the Court is a Remand from the United States Court of Appeals for the Federal Circuit regarding Defendant Merck, KGaA's ("Merck") Motion for Judgment as a Matter of Law ("JMOL") filed in the above-titled case. Merck appealed the district court's denial of its Motion for JMOL regarding the damage award of $ 15 million returned by the jury at trial. The Federal Circuit held that there was not "substantial evidence" in the record to support [*4] the award of $ 15 million, reversed the district court's denial of Merck's Motion for JMOL and remanded the case to this Court for "further factual development and the calculation of damages." [1]

1 Fitzgerald, J., was a visiting judge to the United States District Court for the Southern

District of California when he presided over the trial in the above-titled action. Accordingly, Fitzgerald, J., was not available to conduct the remand proceedings after appeal from the Federal Circuit. Upon remand, this case was re-assigned to this Court for further determination.

In its remand brief, Merck alleges that the evidence in the record supports an award for a reasonable royalty of approximately $ 40,000. Plaintiff Integra Life Sciences, Ltd. ("Integra") argues that the evidence in the record overwhelmingly supports a damage award of $ 15 million and urges this Court to affirm the jury's award.

Based on the evidence in the record, and in conformity with the opinion of the United States Court of Appeals for the Federal [*5] Circuit in this case, the Court **HEREBY AWARDS** Integra $ 6.375 million in damages for the infringement regarding the patents in suit.

## II. BACKGROUND

### A. Relevant Background

Before addressing the factual background which gave rise to the instant case, it is necessary to discuss the technology involved. Integra is the owner of *United States Patent Nos. 4,988,621* ("the *'621 Patent*"), *4,792,525* ("the *'525 Patent*"), *5,965,997* ("the *'997 Patent*"), *4,879,237* ("the *'237 Patent*"), and *4,789,734* ("the *'734 Patent*") (collectively "the RGD Patents"). These RGD Patents all relate to a short tri-peptide segment of fibronectin which contains the amino acid sequence Arg-Gly-Asp ("the RGD Peptide"). In the mid 1980's scientists discovered that the RGD Peptides were important in the process of cell adhesion, and to the mechanism by which cells attach and detach from proteins in the extracellular matrix. Specifically, RGD Peptides promote cell adhesion by interacting with [alpha] [v] [beta] [3] receptors on the surface of cells. These RGD Peptides have been the subject of extensive laboratory study in the hopes that they may lead to pharmaceutical products capable of aiding [*6] to prevent angiogenesis -- the production of new blood vessels -- in patients suffering from tumors, diabetic retinopathy, rheumatoid arthritis, psoriasis, and inflammatory bowel disease.

### B. Factual Background

#### 1. Telios' Activities

In the mid 1980's, Drs. Erkki Ruoslahti and Michael Pierschbacher discovered that peptides which contain the RGD amino acid sequence play a significant role in cell adhesion. Drs. Ruoslahti and Pierschbacher quickly formed Telios Pharmaceuticals, and obtained patents regarding their discovery of the RGD Peptides (the RGD Patents listed above). Telios was able to raise venture capital to continue its research into the applications of RGD Peptides and simultaneously to enter into agreements with other companies to license their RGD Peptide technology.

In April 1994, Telios contacted Merck in an attempt to reach some type of license agreement with Merck for the use of the RGD Peptides covered by Telios' patents. Merck and Telios began negotiating the terms of a licensing agreement.

In October 1994, the negotiations regarding the RGD Peptides led to Merck's interest in possibly acquiring Telios, specifically because of its interest in the RGD [*7] Patents. Accordingly, Merck and Telios exchanged certain confidential information, including information regarding Telios' RGD Patents. It appears that Merck backed away from its acquisition interest relatively quickly; however, Merck did continue with its negotiations regarding licensing the RGD Patent technology. In November 1994, Merck sent Telios a "letter of intent" regarding the possible license. Part of the due diligence process regarding licensing included Merck investigating whether any of the RGD Patents were subject to third-party rights. On December 6, 1994, Telios sent Merck an offer letter outlining its terms for a license of the RGD Patent technology, which included, *inter alia*, a minimal schedule of further RGD Peptide development.

In April 1995, Telios entered into an acquisition agreement with Integra Life Sciences in which Integra agreed to acquire Telios for a total purchase price of $ 20 million. Integra's acquisition of Telios was finalized in late 1995.

The license negotiations between Merck and Telios/Integra continued until the Spring of 1996 when Merck informed Telios that it was not interested in entering into a licensing agreement for the RGD Peptides [*8] covered by Telios' patents.

**2. Merck and the Scripps Institute**

Separate and apart from Merck's interaction with Telios, Merck entered into an agreement with the Scripps Institute to fund certain projects at the Scripps Institute, including the research of Dr. David Cheresh ("Dr. Cheresh") in 1988 ("the 1988 Agreement"). This agreement expired in late 1994 without any known significant discoveries.

In July 1994, Merck informed Scripps that it would not be renewing the 1988 Agreement to further fund projects at the Scripps institute. Merck did indicate that it might enter into a consulting agreement with Dr. Cheresh, but that would be on a much smaller scale, and only for limited duties, as compared to the 1988 Agreement. Then, on December 30, 1994, Dr. Cheresh published an article in Cell with the results of his RGD Peptide research. See David Cheresh, Integrin [alpha] [v] [beta] [3] Antagonists Promote Tumor Regression by Inducing Apoptosis of Angiogenic Blood Vessels, Cell, December 30, 1994, Vol. 79(7) at 1157; see also, Tr. Ex. 24. Specifically, Dr. Cheresh's December 30, 1994 article indicated that RGD Peptide EMD 66203 -- a cyclic RGD Peptide covered [*9] by Telios' Patents -- blocks the [alpha] [v] [beta] [3] receptors on the surface of cells, and thus inhibits angiogenesis. See Tr. Ex. 24.

Dr. Cheresh's December 30, 1994 article dramatically changed Merck's interest in funding further research at the Scripps Institute, especially with respect to Dr. Cheresh's experiments. Sometime in February 1995, Scripps and Merck began negotiating a new funding agreement ("the 1995 Agreement") in which Merck agreed to fund research at the Scripps Institute conducted by Dr. Cheresh regarding the anti-angiogenesis properties of RGD Peptides. Under the 1995 Agreement, Scripps and Dr. Cheresh were to conduct the necessary experiments to satisfy the biological bases and regulatory Food and Drug Administration ("FDA") requirements for the implementation of clinical trials with HMD 66203 or a derivative thereof. See Decl. Of Alfred Jonczyk ("Jonczyk"), Tr. Ex. 487, P P 5-6. The 1995 Agreement prognosticated that clinical trials of this pharmaceutical would begin in three years. See Tr. Ex. 46, p.356.

Scripps research led to the discovery of EMD 85189 and EMD 121974, both of which are derivatives of EMD 66203. Scripps continued to [*10] experiment on these three chemical compounds to determine which would be the best candidate for clinical development. In 1997, the Scripps research team chose EMD 121974 as the best candidate for clinical development.

**C. Procedural Background**

In the Spring of 1996, Merck informed Telios/Integra that it was no longer interested in entering into a licensing agreement regarding the RGD Patents. In response to this, and on information that Merck, Scripps and Dr. Cheresh were making use of RGD Peptide technology covered by Telios' Patents, Telios/Integra filed suit for patent infringement against Merck, the Scripps Institute and Dr. Cheresh on July 18, 1996. Merck answered that its work regarding the RGD Peptides was protected under the Safe Harbor Rules codified at *35 U.S.C. § 271(e)(1)*, and alleged that Telios' RGD Patents were invalid.

Shortly before trial, Telios/Integra amended its claim for monetary damages and sought only declaratory judgment against Scripps and Cheresh. The case proceeded to trial. After the close of evidence, the Court granted Scripps' and Cheresh's respective motions to dismiss Telios/Integra's claim for declaratory judgment. With [*11] respect to Merck, the jury returned a verdict in favor of Telios/Integra, found that Merck wilfully infringed Telios' RGD Patents, and awarded $ 15 million in damages. See Doc. No. 995.

Merck filed motions for JMOL arguing, *inter alia*, that the accused experiments were protected under *35 U.S.C. § 271(e)(1)*, and that the evidence presented at trial did not support the damages award. The trial court denied Merck's motions for JMOL.

Merck timely appealed the case to the United States Court of Appeals for the Federal Circuit. The Federal Circuit held that Merck's conduct was not protected under *Section 271(e)(1)*, and affirmed the trial court's denial of Merck's motion for JMOL on that issue. The Federal Circuit also held that the trial court correctly construed Telios' patents to include cyclical and linear RGD Peptides.

However, with respect to the $ 15 million damages award, the Federal Circuit found that the award is not supported by substantial evidence in the record. The Federal Circuit reversed the trial court's denial of Merck's motion for JMOL on the issue of damages and remanded the case to this Court to determine: (1) the proper timing the court [*12] should use in calculating the reasonable

royalty, (2) how other license agreements may influence the reasonable royalty calculation in the instant case, (3) other factors which influence the calculation of a reasonable royalty, and (4) the reasonable royalty that Merck would have paid Telios/Integra had the parties entered into a licensing agreement for the RGD Peptide technology.

The parties each briefed the relevant issues remanded to this Court for further determination. On August 27, 2004, the Court conducted a hearing regarding the remand on the issue of a reasonable royalty and took the matter under submission. After careful consideration of the Federal Circuit's opinion in this case, the parties' arguments, the evidence in the record, and the applicable law, the Court issues this Order.

## III. STANDARD OF LAW

### A. Calculation of Damages

[HN1] After finding patent infringement, a jury may award the patentee "damages adequate to compensate for the infringement, but in no event less that a reasonable royalty for the use made of the invention by the infringer." *35 U.S.C. § 284*. The court "may increase the damages up to three times the amount found [*13] or accessed. Id. This permits an injured patentee to enjoy at least a reasonable royalty even when he is unable to show lost profits or to establish a royalty rate. *Integra Life Sciences I, Ltd, v. Merck KgaA, 331 F.3d 860, 869 (Fed. Cir. 2003)*.

[HN2] A reasonable royalty calculation envisions and ascertains the results of a hypothetical negotiation between the patentee and the infringer at a time before the infringing activity began. *Riles v. Shell Exploration & Prod. Co., 298 F.3d 1302, 1311 (Fed. Cir. 2002)* (citing *Hanson v. Alpine Valley Ski Area, Inc., 718 F.2d 1075, 1078 (Fed. Cir. 1983))*. Thus, the reasonable royalty calculus assesses the relevant market as it would have developed before and absent the infringing activity. Although an exercise in approximation, this analysis must be based on "sound economic and factual predicates." *Riles, 298 F.3d at 1311* (citing *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l Inc., 246 F.3d 1336 (Fed, Cir. 2001); Shockley v. Arcan, Inc., 248 F.3d 1349 (Fed. Cir. 2001))*. Royalties, like lost profits, are compensatory damages, not [*14] punitive. See *Riles, 298 F.3d at 1312*.

## IV. ANALYSIS

### A. Determination of Hypothetical Negotiation Date

In its opinion, the Federal Circuit stated that the "first step in the reasonable royalty calculation is to ascertain the date on which the hypothetical negotiation in advance of infringement would have occurred." *Integra, 331 F.3d at 870*. Pursuant to the Federal Circuit raising the issue regarding the hypothetical negotiation date, Merck now argues to this Court that the proper hypothetical negotiation date for purposes of calculating the reasonable royalty rate is August 1994. Merck argues that the first experiment which Plaintiffs challenged as infringing the RGD Patents occurred in August 1994, When Dr. Cheresh conducted a "chick embryo pharmacokenetics" experiment. Merck states that the trial court found this 1994 experiment was the only pre-1995 experiment that was not exempt from infringement under the common law research exemption. Accordingly, Merck argues that August 1994 is the hypothetical negotiation date for purposes of calculating the reasonable royalty in this case.

Integra counters that there has never been a dispute [*15] regarding the fact that the hypothetical negotiation date for a royalty agreement was in 1995, and that it was not until after the Federal Circuit's opinion that Merck asserted a hypothetical negotiation date of August 1994. First, Integra asserts that Merck, Scripps and Cheresh had no agreement to use the RGD Peptides for research regarding anti-angiogenesis pharmaceuticals prior to 1995. Second, Integra points to the declaration of Alfred Jonczyk ("Jonczyk") for support that Merck did not supply Dr. Cheresh with a cyclic -- RGD Peptide for analysis until after August 1994, and that a plan was developed in April 1995 on how to study the potential anti-angiogenesis effects of the relevant peptides. Third, Integra argues that at trial, Merck took the position that it was not until 1995 that experimentation began regarding the possible uses of cyclic -- RGD Peptides as anti-angiogenesis drugs, and that Merck should not now be permitted to assert a different position. Accordingly, Integra urges this Court to find that the hypothetical negotiation date between Merck and Telios/Integra is August 1995.

In determining the date of the hypothetical negotiation, the Federal Circuit instructed [*16] this Court to "clarify [from the record evidence] the proper timing of the reasonable royalty calculus." *Integra, 331*

*F.3d at 870.* In determining the proper timing, it is necessary to determine when Merck first induced infringement of the RGD Patents -- i.e., the time that Merck knew or should have known that they were engaging in conduct which induced another to infringe Telios' RGD Patents. [2] See *Ferguson Beauregard v. Mega Systems, 350 F.3d 1327, 1342 (Fed. Cir. 2003)* (stating that[HN3] to be liable for inducing infringement under *35 U.S.C. § 271(b)*, the patentee must show that the party alleged of inducing infringement took actions to induce direct infringement, and that the party alleged of inducing infringement knew or should have known that such actions would induce direct infringement); see also *Hewlett-Packard Company v. Bausch & Lomb Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990)* (stating that "actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding" inducement).

> 2 Intergra's/Telies' theory of infringement against Merck was premised on Merck's importation into the United States of RGD Peptides covered by Telios' RGD Patents. However, until January 1, 1996, *35 U.S.C. § 271(a)* did not make it unlawful to import into the United States products which infringe U.S. Patents. See *35 U.S.C. § 271(a) (1994 Amendment)*. Accordingly, any theory of infringement against Merck prior to January 1, 1996 must be premised on *35 U.S.C. § 271(b)*, which makes it unlawful for a party to induce another to infringe a U.S. Patent. See *35 U.S.C. § 271(b)*.

[*17] Applying this test to the instant case, the Court must determine when Merck induced Scripps and Dr. Cheresh to make use of the RGD Peptides for research regarding anti-angiogenesis drugs. The evidence presented at trial shows that as of November 29, 1988, Merck and Scripps entered into a collaborative research agreement wherein: (1) Scripps was engaged in scientific biomedical and biochemical research relating to the use of peptides and/or antibodies that perturb cell adhesion and angiogenesis; (2) Merck wanted to provide funding to Scripps related to cell adhesion experiments; and (3) Merck wanted to market any potential pharmaceutical products developed by Scripps. See Tr. Ex. 8. In 1992, Merck and Dr. Cheresh discovered that certain RGD Peptides, including the salt EMD 66203, were selective inhibitors of certain cell receptors. See Decl. of Jonczyk, Tr. Ex. 487, P 3. Although any experiments conducted by Dr. Cheresh prior to 1995, with the exception of one chick embryo pharmacokenetic experiment in August 1994, were held to not infringe Telios' RGD Patents under the common law research exception, these experiments provide evidence that Merck had knowledge that Dr. Cheresh [*18] and Scripps were using RGD Peptide 66203. RGD Peptide 66203 is the cyclic peptide described in Dr. Cheresh December 30, 1994 article regarding the chick embryo pharmacokenetics experiment, and is directly responsible for Merck's renewed interest in funding Dr. Cheresh's research regarding RGD Peptides. See Tr. Ex. 24; see also Doc. No. 1200, pp. 6-7.

With respect to the August 1994 chick embryo pharmacokenetics experiment, in its motion for JMOL of non-infringement, Merck specifically recognized that the August 1994 experiment played a role in drug development, and consequently was not exempted under the basic research exception. See Merck's Motion for JMOL, p. 15, n. 15. The Court granted Merck's motion for JMOL as to all pre-1995 experiments. However, because Merck specifically excluded the August 1994 experiment from its motion for JMOL, that one experiment was included in the alleged infringing experiments which were considered by the jury and found to infringe Telios' Patents. See Tr. Transcript pp. 3390-3391 (granting part IIA of Merck's Motion for JMOL and Denying part IIB of Merck Motion for JMOL). Moreover, that August 1994 experiment was contained in exhibits [*19] that were entered into evidence and were considered by the jury in finding that Merck infringed Telios' Patents. See Ex. ABO; see also Tr. Transcript pp. 3220-3222 (entering Ax. ABO into the record). Accordingly, the evidence in the record supports a finding that the first infringement by Merck occurred in August 1994. [3]

> 3 Although the record shows that during closing argument, Merck's counsel stated "all of the experiments before 1995 have been held to be non-infringing . . . so the only ones you have to consider now are the ones between 1995 and 1998", the Court finds that those passing references which fail to point out the one experiment in August 1994 are not dispositive of the first date of infringement. See Tr. Transcript, pp. 3539:20-3540:5. First, Merck only stated what the Court had held, not what it asserted, thus preserving its rights on that issue. Second, the

overwhelming evidence to the contrary, including Ex. ABO, show that the August 1994 experiment was considered by the jury and found to infringe.

[*20] Based on the evidence in the record, the Court **FINDS** that the date of the hypothetical negotiation between Telios and Merck for a license regarding the technology covered by the RGD Patents is August 1994.

**B. Evidence of a Reasonable Royalty**

The next step in the damages calculation is for the Court to consider the relevant testimony of the parties' witnesses at trial. In considering the parties' expert witnesses, it is important to take into account that the witnesses' testimony at trial assumed a hypothetical negotiation date of at least August 1995.

As reflected in the Federal Circuit's opinion in Integra and Riles, [HN4] royalties are compensatory damages and are designed to make the "patentee whole as opposed to punishing the infringer." *Riles, 298 F.3d at 1312*; see also *Integra, 331 F.3d at 869*. In Riles, the Federal Circuit further stated that "a reasonable royalty determination for purposes of making a damages evaluation must relate to the time infringement occurred, and not be an after-the-fact assessment." *Riles, 298 F.3d 1313* (citing *Hanson v. Alpine Valley Ski Area. Inc., 718 F.2d 1075, 1079 (Fed. Cir. 1983)*. [*21] Of fundamental importance to the damages determination is that it be based on "sound ***economic and factual predicates***." *Riles, 298 F.3d at 1311* (emphasis added). The Federal Circuit has stated that although the damages calculation after a finding of infringement involves "an element of approximation and uncertainty," a "reasonable royalty" will be held valid as long as the award is supported by substantial evidence, is not grossly excessive, and is not based ***"only on speculation and guesswork."*** *Interactive Pictures Corp. v. Infinite Pictures, Inc., 274 F.3d 1371, 1385 (Fed. Cir. 2001)*.

In determining a reasonable royalty, the Court must determine the maximum royalty that a reasonable jury would find is supported by the evidence in the record. See *R&S Redi-Mix v. Sierra Redi-Mix & Contracting Co., 692 F.2d 1245, 1249 (9th Cir. 1982)*.

Here, the Court must analyze the testimony of each party's expert witness together with all other evidence in the record to determine a reasonable royalty based on sound factual and economic factors.

**1. Testimony of Kent Anderson -- Integra's Damages Expert**

Plaintiff Integra called [*22] Kent Anderson ("Anderson") to testify regarding the reasonable royalty that would have been negotiated between Telios and Merck in entering into a license agreement for the RGD Patents. Anderson first generally described the necessity for most royalty calculations to entertain the Georgia Pacific Factors as they represent a "laundry list" of elements that may apply to a determination of a reasonable royalty. [4] See Tr. Transcript pp. 1265:12-1266:7. Anderson further testified that in conducting his reasonable royalty calculation he assumed that no milestone payments would be made until Merck was ready to file an application for an Investigational New Drug ("IND") -- Sealed Tr. Transcript p.9:16-24. Anderson testified that his model ***assumed*** milestone payments of $ 9.5-11 million for each milestone, a five milestone scheme where the first milestone was an IND application, the second milestone was the start of Phase I trials, the third milestone was the start of Phase II trials, the fourth milestone was the start of Phase III trials, and the fifth milestone was final drug approval. See Tr. Transcript pp. 1286:16-25; Ex. 538:12 (Anderson Expert Report). [5]

4 Under *Georgia-Pacific Corp. v. U.S. Plywood Corp., 318 F. Supp 1116, 1120 (S.D.N.Y. 1970)*,[HN5] the following factors may aid in the calculation of a reasonable royalty:

> 1. The royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty.
>
> 2. The rates paid by the licensee for the use of other patents comparable to the patent in suit.
>
> 3. The nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold.
>
> 4. The licensor's established policy and marketing program to maintain his patent monopoly by

not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly.

5. The commercial relationship between the licensor and licensee, such as, whether they are competitors in the same territory in the same line of business; or whether they are inventor and promoter.

6. The effect of selling the patented specialty in promoting sales of other products of the licensee; that existing value of the invention to the licensor as a generator of sales of his non-patented items; and the extent of such derivative or convoyed sales.

[HN6] 7. The duration of the patent and the term of the license.

8. The established profitability of the product made under the patent; its commercial success; and its current popularity.

9. The utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results.

10. The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.

11. The extent to which the infringer has made use of the invention; and any evidence probative of the value of that use.

12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.

13. The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.

[HN7] 14. The opinion testimony of qualified experts.

15. The amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee -- who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention -- would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.

Id.

[*23]

5 The Court should note that the testimony cited was given during voir dire of Dr. Anderson, outside the presence of the jury.

However, there are several flaws in the economic model applied by Anderson in reaching what is a reasonable royalty. First, Anderson used Merck's 1996 projection of worldwide sales for a potential new anti-angiogenesis drug as a starting point for his reasonable royalty calculation. See Tr. Transcript

1331:2-19. However, the use of a later in time projection is tenuous because, as the Federal Circuit stated, given the "rapid development of biotechnological arts, a year can make a great difference in economic risks and rewards." *Integra, 331 F.3d at 870.* Thus, the projections for sales calculated in 1996 could have been vastly greater than what would have been expected in August 1994, when the hypothetical negotiation would have occurred.

Second, Anderson estimated the percentage of Merck's projected United States sales by taking a percentage of the projected worldwide sales for a potential anti-angiogenesis drug. Tr. Transcript pp. 1335:5 -- 1336: [*24] 9. This presents a problem because it is not clear whether Anderson's basis for calculating Merck's U.S. sales for a potential new drug are accurate. [6]

> 6 Only U.S. sales apply to the damages calculation because Interga/Telios did not have patent protection in Europe or the rest of the world for the RGD Peptides in suit.

Third, Merck's projections did not include a worst case scenario for potential sales. Accordingly, Anderson made certain assumptions and developed a model of a worst case scenario. However, this is not based on an any sound economic or factual basis.

Next, Anderson testified that he calculated Merck's expected U.S. profits from an anti-angiogenesis drug to be $ 69 million if Merck experienced no delay in further research and was able to get a drug to market by 2005. Dr. Anderson testified that if Merck experienced a three year delay, projected U.S. profits were $ 29 million. Accordingly, Anderson opined that at most, Merck would be willing to pay $ 40 million for an RGD Peptide license from [*25] Telios (the difference between $ 69 million and $ 29 million); and at a minimum, Telios would accept a zero payment for an RGD Peptide license. Anderson then split the difference to arrive at what he opined was a reasonable royalty. Apparently, this analysis assumed that once drugs are approved as an IND, there is a 20% probability that a drug will make it to market.

However, even under Anderson's split-the-difference approach, his analysis does not take into account the risk on which the Federal Circuit focused. Here, Telios was not taking on any Research and Development Cost ("R&D"), nor was it expecting to incur any costs associated with filing, or other requirements to get the drug to market. Thus, assuming no delay, and assuming that Merck's profits were $ 69 million, to pay Telios $ 20 million, or 28.9 % royalty when Telios is taking no risk seems excessive. That such a royalty is excessive is further supported by reviewing Telios' other RGD Peptide licenses where Telios was to receive between a 5% and 10% royalty of sales for RGD Peptide use. There is also a problem in considering Anderson's testimony regarding potential profits in that the Court held that the infringing incidents [*26] occurred between August 1994 and 1998. This implies that Telios/Integra should not be able to collect damages for any events that took place after November 1998.

Further, Anderson testified that the next-best alternative available to Merck would have been to develop mimetics -- compounds that act like cyclic-RGD Peptides, but which are not RGD Peptides. Anderson testified that he calculated the mimetics program would cost Merck $ 40 million and three to four years to develop, which would prevent it from being first to market. However, Anderson's opinion regarding the mimetics program was based on the statements of one of Telios' principals, and not on independent research or other factual basis. See Tr. Transcript, pp. 1378:13-1380:19. Anderson's testimony that the mimetics program is the next -- best -- alternative does not provide substantial evidence that would support the damages award in this case.

Accordingly, the Court looks to other evidence in its calculation of a reasonable royalty.

**2. Testimony of Bruce Den Uyl -- Merck's Damages Expert**

Defendant Merck called Bruce Den Uyl ("Den Uyl") to testify regarding Merck's calculation of what constitutes a reasonable [*27] royalty for the RGD Patents. Den Uyl also testified that he used the Georgia Pacific factors in evaluating what he believed to be a reasonable royalty in this case. Mr. Den Uyl indicated that some of the relevant factors that he used in his calculation of a reasonable royalty were: (1) Merck would be a non-exclusive licensee of Telios' RGD Patent technology, (2) that the RGD Patent technology would be used in a research setting, not a commercial setting, and (3) that Telios' Patents only applied to the United States market. See Tr. Transcript, p.2797:14 -- 2798:5.

Additionally, Den Uyl testified that at the time the negotiation would have taken place -- assuming August 1995 as the negotiation date -- Merck was merely at the preclinical stage which reduces the probability that Merck would reach the market with a RGD-Peptide anti-angiogenesis drug to 1 in 250. See Tr. Transcript, pp. 2815:9 -- 2816:7. Merck also argues that Den Uyl considered the parties' relative bargaining positions, and Telios' other licensing agreements in calculating the reasonable royalty.

However, it appears that Den Uyl's testimony also contains flaws as to the best measure of damages in this case. [*28] First, Den Uyl failed to consider that Dr. Cheresh's research was based on the use of cyclic RGD Peptides covered by Telios' Patents. As those peptides form the basis of Dr. Cheresh's December 30, 1994 article, Den Uyl does not appear to take into account Merck's enthusiasm for the technology and how Merck radically changed its position regarding further funding of Dr. Cheresh at Scripps for the relevant technology.

Second, Den Uyl does not appear to take into account the fact that without the RGD Patents in the United States, Merck could not begin the process associated with obtaining drug approval in the United States. Even if Merck were to conduct its research in Europe, Merck would have to file applications to get the medication approved in the United States. This process would have to occur sometime before the drug was approved for use in the United States, and might occur while Telios' Patents were still valid, creating the possibility that Merck would infringe Telios' Patents later in time. Additionally, this process might delay Merck's arrival with the new drug to the United States, thus costing Merck market share and reducing Merck's potential profits. Merck would have considered [*29] these options in accessing its potential value for a license of the relevant technology.

Important in considering Den Uyl's testimony is that he based his calculation for a reasonable royalty rate to a large extent on conversations with Merck's Dr. Rohmann. See Tr. Transcript 2884:6 -- 2892:5. However, Den Uyl gave very little weight, if any, to Merck's 1996 projection -- created by Dr. Rohmann -- for potential worldwide sales of a potential RGD Peptide anti-angiogenesis drug. This very contradiction, and Dr. Rhomann's testimony at trial in which he testified that the 1996 projections were missing a great deal of information, lead the trial judge to determine that Dr. Rohmann's testimony that the damages should be limited to $ 40,000 "lacks credibility." See Doc. No. 1165, p.2 (Order Re: JMOL). Accordingly, Den Uyl's reliance on Dr. Rohmann's testimony undercuts the weight of Den Uyl's opinion.

Based on the record in this case, the Court **FINDS** that Den Uyl's calculation of $ 40,000 as a reasonable royalty lacks factual and economic basis, and cannot be adopted as the reasonable royalty calculation in this case.

**3. Genentech Agreement**

In its opinion, the Federal [*30] Circuit specifically referred to a licensing agreement reached between Telios and Genentech ("the Genentech Agreement"). The Genentech Agreement was a collaborative agreement between Telios and Genentech for the development of a cardiovascular drug based on RGD Peptide technology. It was entered into between Telios and Genentech on January 4, 1991 and called for Genentech to pay Telios almost $ 2 million in development costs, and millions of dollars if certain milestones were met in the development of a cardiovascular drug. See Tr. Transcript, pp. 382:12-385:20; see also Def. Ex. 32.

This agreement provides some evidence that Telios had entered into contracts where they would have received milestone payments for very large sums of money if and when those milestones were met. However, contrary to what the Federal Circuit stated, the Genentech Agreement was not contemporaneous, but rather was entered into in January 1991, more than three years before the hypothetical negotiation would have occurred in the instant case. [7] As the Federal Circuit stated in its opinion, "a year can make a great difference in economic risks and rewards" in the biotechnological arts. *Integra, 331 F.3d at 870.* [*31] Because of the three year time span between when the Genentech Agreement was signed and when the hypothetical negotiation would have taken place in this case, the Genentech Agreement does little more than provide evidence that the RGD Patents were valued by the industry in the millions of dollars in 1991 if it led to a marketable drug. Accordingly, the Genentech Agreement's application to the instant hypothetical negotiation, while relevant, is limited.

7 In its opinion, the Federal Circuit stated that the Genentech Agreement was entered into by the parties in 1995. See *Integra, 331 F.3d at 871.* However, this is incorrect; the relevant testimony

and the document memorializing the agreement indicate the Genentech Agreement was entered into in 1991. See Tr. Transcript, pp. 382:12 -- 385:20; see also Def. Ex. 32

**4. Other Telios Agreements**

There are a series of other licensing agreements for use of Telios' RGD Patent technology that were entered into the record. Those agreements range [*32] in time from 1988 to 1996. However, none of those agreements were negotiated in 1994, again limiting the relevance of those agreements for comparison to determine a reasonable royalty.

**5. Other Evidence of Reasonable Royalty**

[HN8] The Federal Circuit has held that in determining a reasonable royalty, the Court may base such calculation on "an established royalty, if there is one, or if not upon a hypothetical royalty resulting from arm's length negotiations between a willing licensor and a willing licensee." *In re Cambridge Biotech Corp., 186 F.3d 1356, 1377 (Fed. Cir. 1999)* (Citations omitted). In In re Cambridge, the Federal Circuit further stated that "When a reasonable royalty' is the measure, the amount may again be considered a factual inference from the evidence, yet there is room for exercise of a common-sense estimation of what the evidence shows would be a reasonable' award." Id.

Here, apart from the expert testimony of Anderson and Den Uyl, there is factual evidence based on the parties' actual negotiation for a license of the RGD Patents. Although they did not enter into a license agreement, the parties did conduct some back and forth negotiation [*33] regarding a license, which provides some factual basis to assist this Court in determining a reasonable royalty. On December 6, 1994, Telios sent Merck a letter outlining its initial terms for a license agreement for the RGD Patents. See Pl's Ex. 398. That letter included the following terms: (1) Merck would pay Telios a reasonable and customary licensing fee, (2) Merck would pay Telios development funding of not less than $ 1.5 million per year for a certain number of years, (3) Merck would assume costs for clinical trials of potential drugs, (4) Merck would pay Telios a series of milestone payments, the first being $ 2 million at the completion of Phase II trials for a drug, and (5) Merck would pay Telios a percentage of royalties from any sales of drugs developed with RGD Peptide technology covered by Telios' patents that make it to market. See id.

There is also evidence that initially, Merck believed that the December 6, 1994 letter sent by Telios to Merck was a good starting point to discuss a potential licensing agreement. See Pl. Ex. 400. However, there is no evidence of any counter-offer by Merck for a potential license. Based on the record before the Court, [*34] there is no evidence that Merck did not intend to enter into a license agreement with Telios/Integra until executives from Telios/Integra traveled to Merck's German headquarters in May 1996 to discuss certain results of animal experiments. During that meeting Telios was told that Merck had decided not to pursue a license with Telios/Integra. See Tr. Transcript, pp. 450:21 -- 452:6.

Although this letter was sent on December 6, 1994, and the hypothetical negotiation date is August 1994, there is no evidence in the record to show that the value of Telios' RGD Patents changed between August 1994 and December 6, 1994. It was not until December 30, 1994, when Dr. Cheresh's article regarding the application of RGD Peptides for anti-angiogenesis purposes came out that there was a change in the market conditions concerning RGD Peptide technology. In fact, the earliest indication that Merck had a renewed interest in Dr. Cheresh's research is December 20, 1994. See Tr. Transcript, pp. 1107-1108. However, there is nothing in the record that shows a significant change between the hypothetical negotiation date of August 1994 and Telios' December 6, 1994 offer letter to Merck.

The [*35] **best evidence** indicates that as of August 1994, Telios was willing to enter into a licensing agreement under the terms indicated in their December 6, 1994 letter to Merck. Starting from that letter, Telios would be entitled to $ 1.5 million per year for development funding. The applicable infringement period was determined by the trial court to be between August 1994 and November 1998, or 51 months of infringement. If the Court were to assume $ 1.5 million for each twelve month period and take a proportional amount for partial years, the calculation of a reasonable royalty for development payments negotiated in August 1994 would be $ 6.375 million. [8]

8 Under the terms of the December 6, 1994 letter, Telios would have received $ 1.5 million for each 12 month period commencing in August 1994 and continuing through July 1998 for a total

of $ 6 million. Additional infringing activities continued through November 1998, or for an additional one-quarter of a year. Accordingly, Telios would have hypothetically received an additional $ 375,000, or one-fourth of the yearly $ 1.5 million for infringing activities from August 1998 through November 1998. Thus, a hypothetical royalty received by Telios for August 1994 through November 1998 from development payments would be $ 6.375 million.

[*36] Although there is evidence that as of the date of trial, Merck was in Phase II of clinical trials for a drug based on the RGD Peptides at issue in this case, there is no evidence that Merck had reached the completion of Phase II which is where the first milestone payment would have been made under the terms of Telios' December 6, 1994 letter. See Tr. Transcript, p. 452:1-6 (Testimony of Dr. Pierschbacher); see also Tr. Transcript, p. 1287:15-1288:1 (Testimony of Anderson ***outside the presence of the jury*** indicating that Merck had completed Phase I trials as of December 1999). Even considering Anderson's testimony regarding the probability of a drug making it to market is approximately 20% once it reaches clinical trials, it would be speculative and not based on any factual or economic basis in the record for the Court to attempt to award any milestone payments, or a percentage thereof.

There is no other factual evidence in the record, either in Telios' December 6, 1994 offer letter to Merck, or elsewhere, to adjust the hypothetical royalty either upward or downward. In awarding Telios/Integra the full amount factually supported by its December 6, 1994 offer letter, [*37] the Court is mindful that the Jury found Merck guilty of willful infringement of Telios' RGD Patents. The reasonable royalty award found by this Court, however, does not include any enhancement for said willful infringement.

Accordingly, based on the evidence available in the record, the Court **FINDS** that the maximum reasonable royalty is $ 6.375 million.

**6. Integra's Purchase Price of Telios**

In its opinion, the Federal Circuit stated that in determining a reasonable royalty, this Court should also consider the $ 20 million price that Integra paid to acquire Telios in 1996. The Federal Circuit stated that the $ 15 million jury award for patent infringement seemed "unbalanced" in light of the Integra's purchase price for Telios.

This fact reinforces a royalty award of $ 6.375 million in this case. First, Telios was founded with the purpose of further developing the RGD Peptide technology covered by the patents in suit. See Tr. Transcript, pp. 375:16-376:3. Thus, the Patented technology represents a large percentage of the value of the company. Second, there is no evidence as to other economic factors that might have affected the price of Telios at the time. Accordingly, [*38] it appears that the royalty of $ 6.375 million is not unbalanced in comparison to the purchase price of Telios, considering the value of Telios' assets was primarily in licensing the RGD Patents for scientific research.

**7. Conclusion -- Calculation of Damages**

Based on the evidence in the record, the Court **AWARDS** a reasonable royalty for the RGD Patents in suit of $ 6.375 million.

**C. Other Considerations Regarding Reasonable Royalty**

Pursuant to the Federal Circuit's opinion in this case, the Court has determined the maximum reasonable royalty to which Telios/Integra is entitled to based on the damages evidence introduced into the record at trial. This has resulted in a reduction in the award from $ 15 million to $ 6.375 million.

The applicable case law requires that [HN9] when a court grants a remittitur, it must make the remittitur conditional on the prevailing party's acceptance of the remittitur with the option of a new trial. See *Hetzel v. Prince William County, Va., 523 U.S. 208, 140 L. Ed. 2d 336, 118 S. Ct. 1210 (1998)*. However, the Federal Circuit appears to have carved out an exception to the requirement of offering the option for a new trial when damages are reduced pursuant [*39] to a motion for JMOL. See *Tronzo v. Biomet, Inc., 236 F.3d 1342, 1351-52 (Fed Cir. 2001)* (holding that where as a matter of law, damages are not supported by the substantial evidence in the record, the trial courts do not commit legal error by not giving the party adversely affected by the reduction in damages the option for a new trial). The Ninth Circuit has tacitly expressed a similar view regarding reduction of damages as a matter of law. See *Club 9, Inc. v. First Security Bank of Idaho, 178 F.3d*

*1299 (9th Cir. 1999)* (unpublished opinion). In Club 93, the Ninth Circuit stated when a reduction in damages results from a *Rule 50* motion for a judgement as a matter of law, rather than a *Rule 59* motion for a new trial, there is no necessity to give the option for a new trial. See id at * 9, n. 23: see also *Telephone * Central Office Telephone, Inc. v. American Telegraph Co., 108 F.3d 981, 993 (9th Cir. 1997)* (reversed on other grounds) (stating that it is constitutionally compatible with the *Seventh Amendment* for a Court to set aside a jury verdict and enter judgment pursuant to *Federal Rule of Civil Procedure 50*).

In this [*40] case, the Federal Circuit reversed Merck's *Rule 50* motion for JMOL. Thus, on remand, this Court has the duty of finding the reasonable royalty supported by substantial evidence in the record. Because there has been a reversal of Merck's *Rule 50* JMOL motion, this Court's determination of a reasonable royalty presents an issue of law as to the highest reasonable royalty supported by the evidence in the record. As such, and in conformity with the Federal Circuit's opinion in *Tronzo*, the JMOL is granted and the verdict regarding a reasonable royalty is reduced to $ 6.375 million with judgment to be entered thereon.

## V. CONCLUSION

*Based on the evidence in the record*, for the reasons contained above and in light of the Federal Circuit's opinion in this case, the Court **FINDS** that the hypothetical negotiation date for a license for the patents in suit is August 1994. Further, based on the available evidence, the Court **AWARDS** Telios/Integra a reasonable royalty of $ 6.375 million as the maximum award of royalties sustainable under the evidence in this case.

**IT IS SO ORDERED**

Dated: September 7, 2004

HON. RUDI M. BREWSTER

United States District [*41] Judge