

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

CLONTECH LABORATORIES, INC.,            )  
  )  
                  Plaintiff,                    )  
  )  
                  v.                            )        C.A. No. 98-750-SLR  
  )  
INVITROGEN CORPORATION                 )  
(formerly Life Technologies, Inc.)     )  
  )  
                  Defendant.                 )

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**OPINION**

Wilmington, Delaware  
Dated: May 20, 2003

**ROBINSON, Chief Judge**

**I. INTRODUCTION**

On December 22, 1998, plaintiff Clontech Laboratories, Inc. ("Clontech") filed suit against defendant Invitrogen Corporation (formerly Life Technologies, Inc. or "LTI") alleging false marking pursuant to 35 U.S.C. § 292. (D.I. 1) Plaintiff's complaint was subsequently amended to include allegations of violation of the Sherman Act, 15 U.S.C. §§ 1, 2, and the Delaware Deceptive Trade Practices Act ("DTPA"), 6 Del. C. § 2531 et seq. (D.I. 83, 137) The case was then temporarily stayed pending the outcome of related litigation in the United States District Court for the District of Maryland. (D.I. 139) From October 7 to October 10, 2002, the court held a bench trial on the issues. The following are the court's findings of fact and conclusions of law pursuant to Fed. R. Civ. P. 52(a). This court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338.

**II. FINDINGS OF FACT**

**A. The Parties**

1. Plaintiff Clontech is a California Corporation with its principal place of business in Palo Alto, California. (D.I. 199) Clontech has developed and sold products for genomics as well as protein detection analysis and cellular biology. (D.I. 208 at 553) Clontech has also produced cDNA libraries using reverse transcriptase ("RT") and sold kits used to make cDNA. (D.I. 208 at 554)

2. In 1999, Clontech was acquired by Becton, Dickinson and Company, a medical devices and technology company. (D.I. 208 at 552-53)

3. Defendant Invitrogen, formerly Life Technologies, Inc. ("LTI"), is a Delaware Corporation with its principal place of business in Carlsbad, California. (D.I. 199) Invitrogen also produces and sells products in the genomics and molecular biology field.

#### **B. The Technical Background**

4. **Reverse transcriptase.** The technology at issue in this case relates to an enzyme known as reverse transcriptase or "RT." RT has been used as an important tool in molecular biology and recombinant DNA technology since the early 1980's. (D.I. 206 at 176-77) A principal use of RT is in the cloning of DNA molecules.

5. The RT enzyme consists of a polypeptide chain, i.e., a chain of amino acids. (D.I. 206 at 63-4, D.I. 207 at 365-66) The linear RT polypeptide corresponds to the linear DNA sequence which encodes the RT. (D.I. 206 at 67) In its natural form, however, the RT polypeptide is not linear but, instead, resembles a ball of string. (Id.)

6. RT in its native form or "wild-type" may be isolated from viruses such as the Moloney-Murine Leukemia Virus ("MMLV").

(D.I. 206 at 62) The wild-type RT has two primary activities: (1) DNA polymerase activity; and (2) RNase H activity. (D.I. 206 at 63-4)

7. DNA is a molecule comprised of two strands of nucleotide bases configured in a double helix formation. (PX 504; D.I. 206 at 63) In order to clone a DNA molecule to create a cDNA molecule, each strand of the DNA must be synthesized. (D.I. 206 at 64-5)

8. The DNA polymerase activity in RT enables the RT enzyme to utilize a mRNA molecule as a template to synthesize a complementary strand of DNA. (D.I. 206 at 64) This reaction, known as first-strand synthesis, results in a DNA/RNA hybrid molecule. (Id.)

9. In order to allow for the synthesis of the second strand of complementary DNA, the mRNA template must be removed. (D.I. 206 at 64-5, D.I. 207 at 328) The RNase H activity of the RT enzyme degrades the mRNA template in the DNA/RNA hybrid molecule which allows the DNA polymerase activity to synthesize a complementary second strand of DNA, called second-strand synthesis, resulting in a cDNA molecule. (Id.)

10. In the 1980s, scientists theorized that if one could eliminate the RNase H activity from RT, they might be able to synthesize cDNA more efficiently. (D.I. 206 at 177-78) However,

before one could attempt to alter the RT's inherent activities or create mutants of the wild-type RT, it was necessary to obtain a cloned DNA sequence for the wild-type RT. (D.I. 206 at 65, 178)

11. By at least 1984, research scientists successfully cloned the MMLV wild-type RT gene. (DX 12, 13, 14, 15; D.I. 206 at 179) Once the wild-type RT was successfully cloned, researchers then had to determine which amino acids in the RT gene were responsible for the RNase H activity. (D.I. 209 at 663-65) This area is known as the "active site." (Id.) By at least 1988, it was well-known in the scientific community where the specific RNase H region or active site of RT was. (DX 14; D.I. 209 at 667-68)

12. By at least 1987, scientists had created RT mutants with reduced RNase H activity. (D.I. 206 at 74, 179, D.I. 209 at 727)

13. **Invitrogen's patents.** On April 30, 1987, Dr. Michael Kotewicz and Dr. Gary Gerard submitted a Invention Disclosure Form ("IDF") to the management at LTI, Invitrogen's predecessor. (PX 10; D.I. 206 at 72) The IDF was entitled "Reverse transcriptase lacking Ribonuclease H activity; RNase H- RT." (PX 10) Drs. Kotewicz and Gerard described their invention as "an altered reverse transcriptase protein that has the polymerizing activity of the native enzyme, but is missing the RNase H

activity.” (PX 10, ¶ 2; D.I. 206 at 179) The inventors achieved this result by “deleting a portion of the RT gene.” (Id.) This type of mutation is called a “deletion mutation.” (PX 10, ¶ 9; D.I. 209 at 669)

14. Several days prior to filing a patent application on their invention, an article was published by Drs. Kotewicz, Gerard and others, disclosing the details of the invention thereby forfeiting the right to file for patent protection outside of the United States. (DX 16; D.I. 206 at 172-74) It was the usual practice at LTI to obtain both foreign and U.S. patent rights on its inventions. (D.I. 209 at 974-95)

15. On January 13, 1988, Drs. Kotewicz and Gerard filed a U.S. patent application on their RNase H- RT invention. (PX 447; D.I. 206 at 92) During prosecution, the inventors distinguished their invention over the prior art disclosing enzymes with reduced RNase H activity by stating that none of the prior art exhibited, inter alia, “substantially no RNase H activity,” as defined in the application. (PX 3 at 764-768; D.I. 206 at 95)

16. The application ultimately issued as U.S. Patent No. 5,244,797 (“the ‘797 patent”) on September 14, 1993, entitled “Cloned Genes Encoding Reverse Transcriptase Lacking RNase H Activity.” (PX 1; ‘797 patent)

17. The ‘797 patent is directed to “a gene which encodes

reverse transcriptase having DNA polymerase activity and substantially no RNase H activity." (PX 1; '797 patent, col. 2, ll. 49-51) Claim 1 of the '797 patent claims:

A polypeptide having DNA polymerase activity and substantially no RNase H activity wherein said polypeptide may be used for the preparation of full length cDNA without significant degradation of the mRNA template during first strand synthesis wherein said polypeptide is encoded by a nucleotide sequence derived from an organism selected from the group consisting of a retrovirus, yeast, Neurospora, Drosophila, primates and rodents.

'797 patent, col. 19, ll. 17-25.

18. The '797 patent defines the term "substantially no RNase H activity" as "reverse transcriptase purified to near homogeneity and having an RNase H activity of less than 0.001 pmoles [<sup>3</sup>H](A)<sub>n</sub> solubilized per μg protein with a [<sup>3</sup>H](A)<sub>n</sub>•(dT)<sub>n</sub> substrate in which the [<sup>3</sup>H](A)<sub>n</sub> has a specific radioactivity of 2,200 cpm/pmole." '797 patent, col. 9, ll. 14-19.

19. The RNase H activity must be measured at 20 minutes in a 50 μl reaction volume. ('797 patent, col. 13, ll. 47-58; PX 121, 123)

20. Invitrogen also owns U.S. Patent No. 5,405,776 ("the '776 patent") entitled "Cloned Genes Encoding Reverse Transcriptase Lacking RNase H Activity." (PX 7; '776 patent) The '776 patent was a division of the '797 patent and is directed to "a gene which encodes reverse transcriptase having DNA

polymerase activity and substantially no RNase H activity.”

(’776 patent, Abstract)

21. Invitrogen also owns U.S. Patent No. 5,668,005 (“the ’005 patent”) entitled “Cloned Genes Encoding Reverse Transcriptase Lacking RNase H Activity.” (PX 5; ’005 patent) The ’005 patent was a continuation of the ’776 patent and is directed to “a gene which encodes reverse transcriptase having DNA polymerase activity and substantially no RNase H activity.” (’005 patent, Abstract)

22. Invitrogen also owns U.S. Patent No. 6,063,608 (“the ’608 patent”) entitled “Cloned Genes Encoding Reverse Transcriptase Lacking RNase H Activity.” (PX 13; ’608 patent) The ’608 patent was a continuation of the ’005 patent and is directed to “a gene which encodes reverse transcriptase having DNA polymerase activity and substantially no RNase H activity.” (’608 patent, Abstract)

### **C. Invitrogen’s Products at Issue**

23. Invitrogen produces and sells H- RT products known as SuperScript (“SS”) and SuperScript II (“SSII”). (D.I. 199) SS was introduced in 1989. (PX 460) The SS product is a truncated form of the MMLV RT enzyme created by deleting a portion of the MMLV RT enzyme responsible for RNase H activity. (D.I. 199) That is, SS is a deletion mutation of the MMLV RT. (D.I. 206 at

66, 70, D.I. 207 at 344)

24. SSII is a mutated form of the MMLV RT enzyme created by introducing three point mutations in the nucleotide sequence of the MMLV RT at points responsible for RNase H activity. (D.I. 206 at 70-1) That is, SSII is a point mutation of the MMLV RT. (D.I. 207 at 344)

25. Invitrogen also produces and sells kits that contain SSII and cDNA libraries that were made using SSII. (D.I. 199, D.I. 208 at 553-54)

#### **D. Testing RNase H Activity**

26. Two tools scientists may use to measure RNase H activity are solubilization assays and gel assays. (D.I. 206 at 179-80) Solubilization assays measure RNase H activity by determining how much of a substrate is solubilized by a specific enzyme over a specific time period. (Id. at 123-24) This may be accomplished by using a radioactive substrate. (Id. at 125) The higher the substrate's specific radioactive activity, the more sensitive the assay is to the presence of RNase H activity. (Id. at 127-28)

27. When the assay is performed, RNase H activity will "cut" the substrate into pieces. (Id. at 124) These cut pieces will then be solubilized if they are small enough, i.e., between approximately 1 and 16 base pairs long. (Id. at 125) The

solubilized material is then collected and because of the radioactivity of the substrate, can be measured using a scintillation counter. (Id. at 125-26) The scintillation counter measures the radioactivity of solubilized substrate and determines how much radioactivity per mass of substrate is emitted. (Id. at 126) This is measured in counts per minute per picomole of substrate. (Id.) The higher the number, the greater the RNase H activity.

28. Solubilization assays are sensitive to small cuts in the substrate, i.e., between approximately 1 and 16 base pairs long because the small pieces may be solubilized. Solubilization assays are not sensitive to larger cuts, such as 100 base pairs, because these pieces are too large to be soluble. (D.I. 206 at 124)

29. Gel assays measure RNase H activity in a different way. Gel assays look at the mRNA to determine whether or not RNase H activity is present. (D.I. 206 at 180) In a gel assay, the substrate is again radioactive. (Id.) When the reaction is performed, the assay runs the mRNA through a gel matrix to determine whether or not the mRNA remains intact or if it is cut. (Id.) If the mRNA is cut, larger molecules migrate slower through the gel while smaller pieces migrate more quickly. (Id.) Viewing the matrix using radiographic techniques, scientists can

see whether or not the mRNA remained intact, evidencing a lack of RNase H activity, or whether it was cut, evidencing RNase H activity.

30. Gel assays are more sensitive to larger cuts in the substrate. Smaller cuts may be too small to be seen migrating through the gel matrix. (D.I. 209 at 705-7)

**E. The RNase H Activity of SuperScript and SuperScript II**

31. **The 1990 test results.** In a July 1990 status report, Dr. Gerard reported that the SuperScript RT had a 20,000 fold reduction in RNase H activity compared to the wild-type RT. (PX 34)

32. **The 1991 solubilization assay.** On March 6, 1991, Dr. Gerard performed a solubilization assay testing the RNase H activity of numerous mutant RTs, including SS and SSII, as well as the wild-type enzyme. (PX 273; D.I. 206 at 132) The solubilization assay was performed with a substrate having 2220 counts per minute per picomole. (PX 273; D.I. 206 at 134) Measurements were taking at zero hours, one hour and two hours. (PX 273; D.I. 206 at 136)

33. Dr. Gerard measured the RNase H activity of SS to be 0.008089 picomoles solubilized per hour per microgram of substrate. (PX 273; D.I. 206 at 138) He also measured the RNase H activity of SSII to be 0.01062 picomoles solubilized per hour

per microgram of substrate. (Id.)

34. Dividing these values by three to extrapolate to 20 minutes, yields values of 0.0027 picomoles solubilized per hour per microgram of substrate for SS and 0.0035 picomoles solubilized per hour per microgram of substrate for SSII. (D.I. 209 at 720)

35. Based on this data, Dr. Gerard concluded that SS had a 15,752 fold reduction in RNase H activity compared to the wild-type RT. (PX 273; D.I. 206 at 147) He also concluded that SSII had RNase H activity 1.31 times greater than SS. (PX 273; D.I. 206 at 148) At the time he performed this experiment, Dr. Gerard believed the data to be accurate. (D.I. 206 at 148)

36. Dr. Gerard also converted the RNase H activity measure from the 1991 assay from picomoles solubilized per hour per microgram of substrate to units of "specific activity." (D.I. 206 at 151-52) He concluded that SS had a specific activity of 0.0013 units/mg. and SSII had a specific activity of 0.0018 units/mg. (PX 224, 225) Comparatively, the wild-type RT had a measurement of 30 units/mg. (Id.)

37. This data was subsequently relied on in LTI publications stating that the RNase H activity of the wild-type is reduced 20,000 fold for SS and 10,000 fold for SSII. (PX 42) However, LTI subsequently stated in its literature that its SS

and SSII products exhibited a 1,000,000 to 10,000,000 ( $10^6$  to  $10^7$ ) fold reduction in RNase H activity compared to the wild-type. (PX 43, 298, 299, 314; D.I. 208 at 526)

38. **The 1996 tests.** In October 1996, Dr. Gerard performed a number of assays testing the RNase H activity of SS, SSII, and the wild-type RT. He performed a solubilization assay and concluded that SS and SSII lacked RNase H activity. (DX 25; D.I. 206 at 196-97) He also conducted a number of gel assays and reached the same conclusion. (DX 25, 26, 28; D.I. 206 at 198-200)

39. **The 2000 solubilization assay.** In early 2000, Dr. Gerard performed another solubilization assay under the supervision of Invitrogen's expert Dr. James Champoux. (DX 29; D.I. 207 at 255-58, D.I. 209 at 674-75) This test was performed using a substrate having 2324 counts per minute per picomole and measurements were taken at 20 minutes in 50  $\mu$ l reaction volume as required by the '797 patent. (DX 29; D.I. 207 at 260, 267-8)

40. Under these conditions, Dr. Gerard measured the RNase H activity for SSII at 0.0162 picomoles solubilized per hour per microgram of substrate. (DX 29; D.I. 207 at 268) He also measured the RNase H activity for SS at 0.0444 picomoles solubilized per hour per microgram of substrate. (Id.) The RNase H activity of the wild-type RT was 144.18 picomoles

solubilized per hour per microgram of substrate. (DX 29)

41. This test was performed by Dr. Gerard for the purpose of determining whether or not SS and SSII met the "substantially no RNase H activity" limitation of the '797 patent. (D.I. 207 at 261) This term was defined by Dr. Gerard as a co-inventor of the '797 patent and the methodology utilized in the 2000 experiment was the methodology contemplated and disclosed by Dr. Gerard for measuring RNase H activity when he filed the patent application. (D.I. 206 at 92-3, 113-14, 116-17; See '797 patent) As a co-inventor, Dr. Gerard is uniquely qualified to determine whether or not an RT enzyme falls within the scope of his own definition using his self-defined methodology.

#### **F. The Marking of Invitrogen's Products**

42. Invitrogen manufactures both SS and SSII in lots. (D.I. 208 at 452) After the lots are manufactured, the liquid enzyme is placed into a tube. (Id. at 453) The tube is then labeled and put into a plastic container with a product insert called a product profile sheet. (PX 128, DX 122; D.I. 208 at 453) The filled container then gets sealed and frozen. (D.I. 208 at 453)

43. In April 1992, prior to the issuance of the '797 patent, LTI began stating that there was a "patent pending" covering SS and SSII in its product profile sheet and catalogs.

(PX 299, 315; D.I. 208 at 571)

44. After issuance of the '797 patent, LTI marked the product profile sheets of SS, SSII, kits including SSII, and cDNA libraries with the '797 patent. (PX 128, DX 122; D.I. 199, D.I. 201) LTI also marked its SS products with the notation "and foreign equivalents" indicating that LTI's products were also covered abroad by equivalent foreign patent rights. (PX 97; D.I. 206 at 171-73)

45. When LTI's intellectual property counsel realized that LTI was precluded from filing for foreign equivalents to the '797 patent due to the previously published article, the "and foreign equivalents" language was voluntarily removed from LTI's materials. (D.I. 209 at 806)

46. LTI has marked the product profile sheets of the SS and SSII products with at least the '797 patent since June 9, 1994. (PX 113, 128; D.I. 208 at 453) LTI has marked the packaging of a number of its products with at least the '797 patent since May 27, 1999. (PX 113, 294)

47. LTI also indicated in its catalogs, limited label licenses, instruction manuals, promotional materials and on its website that its SS-related products were covered by its patents. (PX 224-25, 298-99, 303-07, 313, 341, 343, 349-51; D.I. 208 at 519, 523-25, 527, 531-34, 537-38, 541-42)

48. Mark Berninger, LTI's Director of Intellectual Property and Technology Acquisition until 1994, was responsible for notifying people in the marketing department when new patents issued. (D.I. 209 at 793) The marketing department would then change the labels on the products to reflect coverage under the newly issued patent. (Id.)

49. Prior to marking the SS products with the '797 patent, Mr. Berninger did not perform an analysis or look at any data to determine whether or not the SS products were covered by the '797 patent, nor did he ask outside patent counsel to perform an analysis. (D.I. 209 at 798) Rather, he assumed the products were covered by the patent because he believed the patents were specifically directed at the company's H- RT products. (Id. at 797)

#### **G. Invitrogen's Patent Enforcement Actions**

50. In July 1994, after LTI began marking its SS and SSII products with the '797 patent, it adopted a strategic plan with respect to its cDNA products which included the strategy to "[a]ggressively use our existing patent positions to force competitors out of the market if possible, or to at least slow them down." (PX 101; D.I. 208 at 574)

51. Promega, a research supply company, introduced an H- RT product at the end of 1991 which it sold between 1991-1994.

(D.I. 207 at 300-01) In January 1994, Promega was informed by LTI that the '797 patent issued. (Id. at 304) By October of 1994, LTI had refused to license its '797 patent to Promega and sent a cease and desist letter. (Id.) Within a month after the letter, LTI sued Promega for patent infringement. (PX 388; D.I. 207 at 304) Promega withdrew from the H- RT market by the end of 1994.

52. In March 1995, Promega entered into an agreement with LTI which provided that Promega would not make or sell H- RT in the U.S. and LTI would dismiss its lawsuit. (D.I. 207 at 309-10)

53. Stratagene, another seller of molecular biology tools, introduced an H- RT product in 1993. (D.I. 207 at 278) In April 1995, LTI sued Stratagene for patent infringement. (Id. at 292) Stratagene and LTI reached an agreement in which Stratagene would no longer sell its H- RT product. (Id.)

54. In December 1996, LTI sued Clontech for infringement of the '797 and '005 patents in the United States District Court for the District of Maryland. (D.I. 208 at 625)

55. By 1997, LTI had a 100% market share of the H- RT market in the United States. (PX 358; D.I. 208 at 491-92)

56. In July 1999, after a bench trial, the District Court held that the '797 and '005 Invitrogen patents were unenforceable due to inequitable conduct. (D.I. 208 at 539) After this

decision, LTI took steps to cease marking its products with these patents. (Id.)

57. After the Maryland District Court's decision, both Promega and Stratagene reentered the H- RT market. (D.I. 207 at 294, 311)

58. On September 21, 2000, the United States Court of Appeals for the Federal Circuit reversed the Maryland District Court's decision and remanded the case back to the District Court for further proceedings. Life Technologies, Inc. v. Clontech Labs, Inc., 224 F.3d 1320 (Fed. Cir. 2000).

59. In January 2001, Invitrogen sued New England Biolabs ("NEB"), a competitor in the H- RT market, for patent infringement. (PX 387, tab 2) In settling the lawsuit, NEB agreed not to manufacture or sell H- RT products in the U.S. for the term of Invitrogen's patents. (Id.)

60. In February 2001, Invitrogen sued Display Systems Biotech ("DSB"), another competitor in the H- RT market, for patent infringement. (PX 387, tab 5) DSB similarly settled and agreed not to sell H- RT products in the U.S. (Id.)

61. In September 2001, Invitrogen sued Toyobo Co., Ltd., a supplier of H- RT to Clontech, for patent infringement. (PX 391; D.I. 208 at 564) Toyobo also settled its lawsuit and agreed to withdraw from the H- RT market.

## **H. The Coverage of Invitrogen's Patents**

62. The specific amino acid sequence of the RT mutant which ultimately became the SuperScript product was not explicitly disclosed in the patents in suit. (D.I. 206 at 119-20)

63. Each of the patents in suit contain the "substantially no RNase H activity" limitation as defined in the patents as "reverse transcriptase purified to near homogeneity and having an RNase H activity of less than 0.001 pmoles [<sup>3</sup>H](A)<sub>n</sub> solubilized per µg protein with a [<sup>3</sup>H](A)<sub>n</sub>•(dT)<sub>n</sub> substrate in which the [<sup>3</sup>H](A)<sub>n</sub> has a specific radioactivity of 2,200 cpm/pmole."

64. In 1991, Dr. Gerard measured the RNase H activity of SS to be 0.008089 picomoles solubilized per hour per microgram of substrate and concluded that SS had a 15,752 fold reduction in RNase H activity compared to the wild-type RT. (PX 273; D.I. 206 at 138, 147). This amount of RNase H activity is outside the scope of the "substantially no RNase H activity" limitation in the patents in suit. Therefore, Invitrogen's SS product is not covered by the patents in suit.

65. This conclusion was confirmed by Dr. Gerard's 2000 solubilization assay in which he measured the RNase H activity for SS at 0.0444 picomoles solubilized per hour per microgram of substrate. (DX 29; D.I. 207 at 268) This test was specifically performed to determine whether or not the RNase H activity of SS

was within the limitations of the claims of the patents in suit.

66. In 1991, Dr. Gerard measured the RNase H activity of SSII to be 0.01062 picomoles solubilized per hour per microgram of substrate and concluded that SSII had RNase H activity 1.31 times greater than SS. (PX 273; D.I. 206 at 138, 148) This amount of RNase H activity is outside the scope of the "substantially no RNase H activity" limitation in the patents in suit. Therefore, Invitrogen's SSII product is not covered by the patents in suit.

67. This conclusion was confirmed by Dr. Gerard's 2000 solubilization assay in which he measured the RNase H activity of SSII at 0.0162 picomoles solubilized per hour per microgram of substrate. (DX 29; D.I. 207 at 268) This test was specifically performed to determine whether or not the RNase H activity of SS was within the limitations of the claims of the patents in suit.

68. None of Invitrogen's patents in suit are directed to cDNA libraries. (D.I. 206 at 105-7) Therefore, Invitrogen's cDNA libraries are not covered by the patents in suit.

#### **I. Invitrogen's Basis for Marking its Products and Literature**

69. Invitrogen began marking its SS and SSII products with "patent pending" as early as April 1992. At this time the only data Invitrogen had on the RNase H activity was Dr. Gerard's 1991 solubilization experiment data. This data indicated that the

RNase H activity of these products was outside the scope of the pending claims of the application for the '797 patent.

Therefore, Invitrogen had no basis for marking its SS and SSII products with the "patent pending" notation.

70. After the '797 patent issued Invitrogen marked its SS and SSII products, kits including SSII, and cDNA libraries with the '797 patent. LTI also marked its SS products with the notation "foreign equivalents." At this time, the only data Invitrogen had on the RNase H activity was Dr. Gerard's 1991 solubilization experiment data. This data indicated that the RNase H activity of these products was outside the scope of the claims of the '797 patent. Therefore, Invitrogen had no basis for marking its products with the '797 patent.

71. Invitrogen was also unable to file foreign equivalents to the '797 because of its publication prior to the filing of the application for the '797 patent. Therefore, Invitrogen had no basis for marking its products with the "and foreign equivalents" notation.

72. Invitrogen began indicating that its SS and SSII products exhibited a  $10^6$  to  $10^7$  fold reduction in RNase H activity compared to the wild-type as early as April 1992. At this time the only data Invitrogen had on the RNase H activity was Dr. Gerard's 1991 solubilization experiment data. This data

indicated that the reduction of RNase H activity of SS and SSII compared to the wild-type was on the order of 10,000 to 20,000 fold. Therefore, Invitrogen had no basis for marking its SS and SSII literature with the "reduction of 10<sup>6</sup> to 10<sup>7</sup>" notation.

### III. CONCLUSIONS OF LAW

#### A. False Marking

1. 35 U.S.C. § 292 states that:

(a) Whoever, without the consent of the patentee, marks upon, or affixes to, or uses in advertising in connection with anything made, used, offered for sale, or sold by such person within the United States, or imported by the person into the United States the name or any imitation of the name of the patentee, the patent number, or the words "patent," "patentee," or the like, with the intent of counterfeiting or imitating the mark of the patentee, or of deceiving the public and inducing them to believe that the thing was made, offered for sale, sold, or imported into the United States by or with the consent of the patentee; or

Whoever marks upon, or affixes to, or uses in advertising in connection with any unpatented article, the word "patent" or any word or number importing that the same is patented, for the purpose of deceiving the public; or

Whoever marks upon, or affixes to, or uses in advertising in connection with any article, the words "patent applied for," "patent pending," or any word importing that an application for patent has been made, when no application for patent has been made, or if made, is not pending, for the purpose of deceiving the public --

Shall be fined not more than \$500 for every such offense.

(b) Any person may sue for the penalty, in which event

one-half shall go to the person suing and the other to the use of the United States.

2. Section 292 is penal in nature and must be strictly construed. See Mayview Corp. v. Rodstein, 620 F.2d 1347, 1359 (9th Cir. 1980); Brose v. Sears, Roebuck & Co., 455 F.2d 763, 765 (5th Cir. 1972); Accent Designs v. Jan Jewelry Designs, 827 F. Supp. 957, 968 (S.D.N.Y. 1993); Johnston v. Textron, 579 F. Supp. 783, 795 (D.R.I. 1984). 35 U.S.C. § 292(b), while penal, is not a criminal statute. Filmon Process Corp. v. Spell-Right Corp., 404 F.2d 1351, 1355 (D.C. Cir. 1968).

3. When strictly construed, § 292 requires that four elements be established to sustain a finding of a violation: (1) a marking importing that an object is patented (2) falsely affixed to (3) an unpatented article (4) with intent to deceive the public. Mayview Corp., 620 F.2d at 1360; California Medical Prods. v. Tecnol Medical Prods., 921 F. Supp. 1219, 1261 (D. Del. 1995).

4. Plaintiffs have the burden to prove that a defendant acted with the specific intent to deceive the public. If a defendant then comes forward with evidence of good faith, this may rebut a showing of actual intent to deceive the public. M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., 205 F. Supp. 2d 306, 318 (D.N.J. 2002); Sadler-Cisar, Inc. v. Commercial Sales Network, Inc., 786 F. Supp. 1287, 1296 (N.D. Ohio 1991).

5. As in other areas of the law, reasonable inferences may properly be drawn from established facts in order to prove intent to deceive. Sadler-Cisar, 786 F. Supp. at 1296. While the statute requires intent to deceive, an intent to deceive the public will not be inferred if the facts show no more than that the erroneous patent marking was the result of mistake or inadvertence. Blank v. Pollack, 916 F. Supp. 165, 173 (N.D.N.Y. 1996); Laughlin Prods. v. Ets, Inc., 2002 U.S. Dist. LEXIS 21393, \*17-18 (N.D. Tex. 2002); Roman Research, Inc. v. Caflon Co., Inc., 210 U.S.P.Q. 633 (D. Mass. 1980).

6. In this case, the first factor of a false marking analysis, defendant's "marking importing that an object is patented," is undisputed. Defendant does not argue that it did not mark its products at issue with its patents. Thus, the court concludes this factor is met.

7. The second and third factors of the analysis are closely related and require that the marking was "falsely affixed" to "an unpatented article." The court has found that defendant's SS, SSII and cDNA library products are not covered by any of the patents with which it marked these products. Therefore, the court concludes that factors two and three of the false marking analysis are met.

8. Defendant argues that even if its products are not

literally covered by the patents in suit, they are covered under the doctrine of equivalents. However, defendant cites no cases, nor has the court found any, that hold that the doctrine of equivalents is applicable to a false marking analysis. Furthermore, there is no evidence in the record that any of LTI's employees considered its products substantially covered or equivalently covered by the patents. While the doctrine of equivalents may be relevant in an infringement analysis, the court concludes that it does not apply in the context of a false marking claim.

9. Therefore, the gravamen of plaintiff's false marking claim is whether or not defendant marked its products "with intent to deceive the public." Based on the evidence of record, the court concludes that defendant has falsely marked its products with an intent to deceive the public since February 2000.

10. Prior to February 2000, the only data LTI possessed indicating that its products were not covered by the patents in suit was from Dr. Gerard's 1991 solubilization assay. Although this data indicated that neither SS nor SSII met the "substantially no RNase H activity" limitation of what would become the '797 patent, the data was collected two years prior to the issuance of the '797 patent and the test was not specifically

performed to determine whether or not LTI's products would meet the limitations of the claims that would eventually issue in the '797 patent.

11. Furthermore, every witness employed by LTI during this time period testified that they believed that LTI's products at issue were covered by the '797 patent and they believed the patent was directed at LTI's H- RT products. These witnesses were unfamiliar with the patent laws and, other than Dr. Gerard, not cognizant of the results of the 1991 tests. Plaintiff did not impeach the credibility of these witnesses or persuasively show deceptive intent of any LTI employee either directly or by reasonable inference.

12. The court concludes that prior to February 2000, LTI marked its products with a reckless indifference for the truth of the matter asserted. Had the company acted in a reasonably prudent manner, its employees should have realized that its 1991 data contradicted its patent marking and should have investigated further prior to marking its products. It is unclear in the case law whether or not a reckless indifference can serve as evidence of specific intent to deceive the public. See M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., 205 F. Supp. 2d 306, 318 (D.N.J. 2002); Laughlin Prods. v. Ets, Inc., 2002 U.S. Dist. LEXIS 21393, \*17-18 (N.D. Tex. 2002); Blank v. Pollack, 916 F.

Supp. 165, 173 (N.D.N.Y. 1996); Johnston v. Textron, 579 F. Supp. 783, 795 (D.R.I. 1984). Rather, two district courts have held that there is not intent to deceive when employees, unfamiliar with the patent system, mistakenly mismark a product with a patent with an honest belief that the patent covers the product. Blank, 916 F. Supp. at 173; Laughlin, 2002 U.S. Dist. LEXIS 21393 at \*18.

13. In accordance with these decisions and strictly construing § 292, the court concludes that LTI's actions prior to February 2000 do not rise to the level of an intent to deceive the public.

14. However, in late January and early February of 2000, LTI instructed Dr. Gerard to perform another solubilization assay for the express purpose of determining whether or not its H- RT products met the "substantially no RNase H activity" of the patents in suit. The data from this testing also demonstrated that LTI's products were not covered by the patents in suit. At the very least, these tests put LTI on notice that its products were not covered by the patents in suit and any good faith belief LTI had that its products were covered by the patents was lost. At this point, LTI's failure to correct its mistaken mismarking of its products rose to the level of deceptive intent. See Blank, 916 F. Supp. at 173 (concluding that after learning that a

patent may not actually cover a marked product, a defendant's good faith belief is lost).

15. Therefore, the court concludes that after February 2000, defendant falsely marked its products in violation of 35 U.S.C. § 292.

16. The court concludes that LTI's marking of its H- RT products with the phrase "foreign equivalents" was a good faith mistake which LTI corrected on its own after it found out about it. It was routine practice for LTI to seek foreign rights on its invention and in the case of the patents in suit, an inadvertent publication of an article a few days prior to filing precluded LTI from seeking foreign rights. Therefore, there was no deceptive intent in marking its products with "and foreign equivalents."

#### **B. Antitrust Violations**

17. Plaintiff argues that defendant's conduct violates § 1 of the Sherman Act, 15 U.S.C. § 1. To establish an antitrust violation under § 1 of the Sherman Act, plaintiff must prove: (1) the existence of a conspiracy, combination, or contract; (2) a restraint on trade; and (3) an effect on interstate commerce. See Weiss v. York Hosp., 745 F.2d 786, 812 (3d Cir. 1984); Marian Bank v. Electronic Payment Servs., Inc., 1997 U.S. Dist. LEXIS 21021 at \*65 (D. Del. Dec. 30, 1997).

18. The lynchpin of plaintiff's argument is that defendant's false marking induced its competitors to agree to abandon the H- RT market in the United States. It asserts that this activity is clear evidence of a conspiracy, combination, or contract furthering an unreasonable restraint on trade.

19. Although plaintiff asserts that defendant's alleged false marking forced competitors out of the market, the evidence shows that it was defendant's enforcement of its patent rights that convinced its competitors to leave the market. There is no evidence that it was the marking of defendant's products that convinced any of LTI's competitors to cease producing H- RT in the United States.

20. Each of the parties against whom TI asserted its patent rights had the opportunity to challenge LTI's patents in court and chose not to do so. It was the strategic decisions of LTI's competitors that prompted them to leave the H- RT market, not the marking of LTI's products. Therefore, the court concludes that defendant has not violated § 1 of the Sherman Act.

21. Plaintiff next argues that defendant's conduct violates § 2 of the Sherman Act, 15 U.S.C. § 2. To establish monopolization or attempted monopolization in violation of § 2 of the Sherman Act, plaintiff must prove: (1) possession of monopoly power in a relevant market (or a dangerous probability

of achieving monopoly power); (2) a specific intent to monopolize; and (3) that defendants engaged in predatory or anticompetitive conduct. See Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 122 L. Ed. 2d 247, 113 S. Ct. 884 (1993).

22. Again, the lynchpin of plaintiff's argument is that defendant's false marking was sufficient evidence of predatory or anticompetitive conduct cognizable under § 2 of the Sherman Act. As discussed above, the court has concluded that defendant's false marking was not the conduct that caused its competitors to leave the H- RT market, rather, it was defendant's vigorous enforcement of its patents rights. As the enforcement of its valid patent rights may not be the basis for liability under antitrust law absent a showing of fraud or that the litigation was a sham, the court concludes that defendant has not violated § 2 of the Sherman Act. See CSU, L.L.C. v. Xerox Corp., 203 F.3d 1322, 1326 (Fed. Cir. 2000) ("[a] patent owner who brings suit to enforce the statutory right to exclude others from making, using, or selling the claimed invention is exempt from the antitrust laws, even though such a suit may have an anticompetitive effect, unless the infringement defendant proves one of two conditions.").

### **C. Delaware Deceptive Trade Practices Act**

23. Plaintiff argues that defendant's conduct violates the

Delaware Deceptive Trade Practices Act ("DTPA"), 6 Del. C. § 2531 et seq. Plaintiff alleges violations of subsections 2532(a)(5),

(a)(7), (a)(9) and (a)(12) of the Act, which state:

(a) A person engages in a deceptive trade practice when, in the course of a business, vocation, or occupation, that person:

(5) Represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have, or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have;

\* \* \*

(7) Represents that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;

\* \* \*

(9) Advertises goods or services with intent not to sell them as advertised;

\* \* \*

(12) Engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.

The Act codifies the Uniform Deceptive Trade Practices Act, which in turn, codifies the common law of unfair competition.

Del. Solid Waste Auth. v. E. Shore Env'tl., Inc., 2002 Del. Ch.

LEXIS 34 at \* 15 (Del. Ch. March 28, 2002).

24. Plaintiff argues that defendant's false marking, public statements that its SS and SSII products exhibited a  $10^6$  to  $10^7$

fold reduction in RNase H activity compared to the wild-type and that its products were protected by "foreign equivalents," violates the aforementioned sections of the DTPA. In support of its argument, plaintiff notes that under the DTPA intent to deceive and other common law fraud elements are not required. Rather, the DTPA is violated when a company engages in one of the prohibited actions set out in § 2532(a).

25. The court concludes that plaintiff has standing under the DTPA to bring the present action. "The DTPA prohibits unreasonable interference with the promotion and conduct of another person's business." Grand Ventures v. Whaley, 632 A.2d 63, 65 (Del. 1993). "The Act specifically makes unnecessary proof of competition between the parties, monetary damages or intent to deceive." Id. In this case, plaintiff and defendant were both competitors in the H- RT market and plaintiff could reasonably expect to be damaged by defendant's false representations as required by 6 Del. C. § 2533(a).

26. However, the court further concludes that with respect to plaintiff's allegations of violation of the DTPA for false marking, it has failed to come forward with evidence of bad faith and, therefore, its claims are preempted by the federal patent laws. See Moore N. Am., Inc. v. Poser Bus. Forms, Inc., 2000 U.S. Dist. LEXIS 14651 at \*22 (D. Del. Sept. 29, 2000) (citing

Hunter Douglas, Inc. v. Harmonic Design, 153 F.3d 1318, 1336 (Fed. Cir. 1998).

27. With respect to the "and foreign equivalents" notation and the "10<sup>6</sup> to 10<sup>7</sup> fold reduction" notation in defendant's literature, the court concludes that these acts do violate the DTPA. Therefore, pursuant to § 2533(a), defendant is enjoined from marking its literature with these notations. Since the court has concluded that defendant's actions were not willful or done in bad faith, this is not an exceptional case under § 2533(b) and an award of attorneys' fee is not warranted.

#### **IV. CONCLUSION**

For the reasons stated, defendant's actions since February 2000 constitutes false marking under 35 U.S.C. § 292, defendant has not violated the Sherman Act, 15 U.S.C. § 1 et seq., and defendant has violated the Delaware Deceptive Trade Practices Act, 6 Del. C. § 2531 et seq. An appropriate order shall issue and judgment shall be entered accordingly.