

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO**

Civil Action No.: _____

STEPHEN J. SMITH TRUST, and
STEPHEN J. SMITH, a natural person, individually,

Plaintiffs,

v.

ETHICON, INC.
a New Jersey Corporation.

Defendant.

COMPLAINT AND JURY DEMAND

COME NOW, the Plaintiffs, the Stephen J. Smith Trust (“Smith Trust” and/or collectively “Plaintiffs”) and Stephen J. Smith, a natural person, individually (“Smith” and/or collectively “Plaintiffs”), by and through their attorneys of record, Arthur Lindquist-Kleissler, Esq. of the law firm Lindquist-Kleissler & Company, LLC and Ramon L. Pizarro. Esq., and hereby claim for relief against the Defendant and states as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States of America, Title 35, United States Code, and in particular, in violation of 35 U.S.C. 271, et seq. Plaintiffs have additionally set forth claims for Quantum Meruit, Unjust Enrichment, Breach of Contract, and Promissory Estoppel.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the claims set forth below pursuant to 28 U.S.C. 1331 and 28 U.S.C. 1338(a), 15 U.S.C. 1121, and this Court's pendant jurisdiction. Venue is proper in this district under 28 U.S.C. 1391(c) and 1400. The patent infringement alleged hereunder have been carried out in the United States and within the District of Colorado. Furthermore, the Defendant sells and distributes its products, including the infringing products, throughout Colorado.

THE PARTIES

3. Plaintiff, the Stephen J. Smith Trust is the assignee of the methods and compositions described and claimed in the patents-in-suit. The Stephen J. Smith Trust is managed by Dr. Smith in Colorado.
4. Assignor, Dr. Stephen J. Smith is the inventor of the of the methods and compositions described and claimed in the patents-in-suit, and is the party with whom Ethicon contracted in order to obtain an option for licenses to the methods and compositions described and claimed in the patents-in-suit. Dr. Smith is and has been a resident of Colorado at all times relevant to this Complaint.
5. Defendant, Ethicon, Inc. ("Ethicon"), is a national supplier of medical products, and upon information and belief, is a New Jersey corporation and a wholly-owned subsidiary of the Johnson and Johnson Company, and has a principal place of business at US Route 22 West, PO Box 151, Somerville, New Jersey 08876-0151.

THE PATENT-IN-SUIT

6. The patent-in-suit is United States Letters Patent No. 6,482,431 titled “Method for application and maintenance of medication on body tissue” (“the '431 patent”), which was duly and legally issued on November 19, 2002, to Dr. Stephen J. Smith. A complete copy of this patent is attached hereto as **Exhibit “A”**, and incorporated herein in its entirety by reference.

BACKGROUND

7. Assignor, Dr. Stephen J. Smith, a Dentist, completed his studies as a Doctor of Dental Surgery, at the UCLA School of Dentistry in 1970.
8. As a Dentist, Dr. Smith conceived of the potential dental and medical uses of cyanoacrylates, and began considering and studying, with the possibility of using cyanoacrylates as part of dental surgery procedures.
9. Cyanoacrylates are most commonly known for their use in products such as “super glue.” And are presently used in various “liquid band-aid” ® products.
10. After completing his training as a dentist, Dr. Smith continued to study, practice, and refine the use of cyanoacrylates on volunteer patients, who had given their informed consent to his inventive methods and procedures. Much of the treatment involved trying to develop techniques for applying cyanoacrylates in the restricted and challenging, wet space of a person’s mouth, during dental surgical procedures or for lip or facial lacerations. Over the years, Dr. Smith found that his methods produced many benefits – improved healing, less

bleeding, less post-operative infections, etc.-over known standard techniques.

11. In 1993, Dr. Smith became involved with Project Concern International (Project Concern). Project Concern is a leading international, volunteer based, health organization based in San Diego, California, with a primary goal of providing, support and care crucial to protecting the well-being of children and families. Volunteers through Project Concern programs help save lives of needy families by providing basic health care, teaching how to reduce the spread of infectious disease, and by providing food and access to clean water to communities in need.
12. As part of his involvement with Project Concern, Dr. Smith volunteered to travel to Guatemala to help establish a dental care facility in the remote jungles of Guatemala.
13. When he first made a commitment to volunteer with Project Concern, Dr. Smith did not fully comprehend the severity of the need afflicting the communities helped by Project Concern, but the prospect of helping a community in need appealed to Dr. Smith. Once he arrived in Guatemala City, his trek to the area where he was to perform his work commenced. This trek began over roads and rivers that led into the jungle. Once the end of the road was reached, the trek continued by river in dugout canoe and makeshift boats that provided travel deep into the Guatemalan jungle.
14. Once Dr. Smith reached his destination, he discovered that the clinic that he was assigned to help as a dentist, did not have a physician. Soon, the community discovered that Dr. Smith's training as a doctor of dental surgery, allowed him to

provide desperately needed help to the local residents, and particularly to members of the Kekchi Indian tribe, who constituted the grand majority of the local residents.

15. Accordingly, Dr. Smith's tasks grew from helping to establish a dental clinic, to acting as the local doctor, in emergency situations. As the local doctor, Dr. Smith had to take care of trauma patients, which often included people with deep cuts or other injuries that had to be treated with the few medical and dental instruments and whatever few medications that Dr. Smith had available to him. To address this acute need Dr. Smith provided emergency care using the techniques and methods that he had refined and perfected, in his over twenty years of practice as a Dentist. His experience in using techniques in his practice of dental surgery proved invaluable in these emergency, and potentially life threatening situation.

16. Dr. Smith drew on his experience with cyanoacrylate adhesives and dental surgery and began treating injuries, such as wounds, with cyanoacrylate adhesives, sutures, and medications. Dr. Smith used these adhesives with medications to treat emergency injuries, when no other doctor was available and treatment was required immediately. Dr. Smith also continued to use these methods on dental surgery cases on the Kekchi as he had done for many years in his practice in Colorado. It was through this use in his practice of over twenty (20) years, and used in his volunteer work, that Dr. Smith discovered and continually perfected through continuous improvements, the beneficial effect produced by placing the cyanoacrylate adhesive over the wound treated with the

medication, such as topical anesthetics, used to reduce the pain, or antibacterial agents or hemostatic agents that are used to reduce or stop the bleeding of wounds, as well as other medicaments discussed in the patent-in-suit.

17. Upon returning to the United States, Dr. Smith continued to work with and consider, the effects of medication on tissue, such as the tissue surrounding a wound, and how it would be enhanced by the protection of the medicated tissue by the cyanoacrylate glues.
18. On February 4, 1994, Dr. Smith filed an application for a patent over his inventive methods, techniques, and discoveries. This initial application, titled "Method for application and maintenance of medication on body tissue" which was eventually divided into two applications. One of the division applications was given serial number 08/556,570 (the '570 application), and the other application was given application serial number 08/880,213 (the '213 application).
19. The '570 application became U.S. Patent No. 5,762,955 on June 9, 1998.
20. The '213 application became the parent of several other applications, including the patent-in-suit, the '431 patent.

THE ETHICON AGREEMENT

21. In early 2000, while both the '570 and the '213, applications were pending, Dr. Smith and Ethicon entered into discussions about Dr. Smith's applications. These discussions culminated in an Exclusive Option Agreement, attached hereto as **Exhibit "B"**, which was signed by Dr. Smith on March 1, 2000.
22. The Exclusive Option Agreement granted Ethicon the option to license patents

that descended from the '213 application.

23. Ethicon did not exercise the Exclusive Option Agreement, and allowed the Exclusive Option Agreement to expire on May 29, 2004.

24. On November 27, 2002, Dr. Smith notified Ethicon of the issuance of the patent-in-suit, and that Dr. Smith was of the opinion that Ethicon's marketing and directions of use of Dermabond infringed the patent-in-suit.

25. Ethicon attorney Kent Wissing responded to Dr. Smith's assertions through a voice mail (a transcript of which is attached hereto as **Exhibit "C"**, and referred to here as the "Wissing Transcript"), in which he asserted that that Ethicon was going to "do all of the things we're supposed to do under this agreement" (Wissing Transcript, p. 2, l. 7-8) including to "get the labeling changed" (Wissing Transcript, p. 4, l. 8). He further indicated that Ethicon was "[j]ust continuing with that patent marking [with Dr. Smith's patent] according to the agreement and so forth." Wissing Transcript, p.5, l. 3-4.

26. Ethicon also asserted, through Kent Wessig, that:

... we're not – nobody is backing of this. It's just a matter of getting things together and getting Ethicon to get the labeling changed, and we have to just wrap up some loose ends.

Wessig Transcript, p. 4, l. 6-9.

27. As stated above, Ethicon did not exercise the Exclusion Option Agreement that was then in force. Therefore at the time that Attorney Kent Wissing left this voice mail, the Exclusive Option Agreement needed to be exercised by Ethicon.

28. Dr. Smith relied on Ethicon's promises and waited for Ethicon to carry its promises

of marking the Dermabond product, such that properly marked products would be distributed.

29. Attorney Kent Wessing's duties were soon thereafter assumed by Ethicon Attorney Blossom Loo, who notified Dr. Smith that Ethicon would not do what Ethicon Attorney Kent Wessing said Ethicon would do.

30. The marking of a product with the number of a patent that covers that product is commonly done under 35 U.S.C 287 in order to provide the public with notice of the fact that the product is covered by the patent referred to by the marking.

ETHICON'S INFRINGING ACTIVITIES

31. Ethicon distributes, uses, offers for sale, licensed, marketed, and/or sold products in Colorado and throughout the United States products that induce and instruct others to practice the method claimed in one or more claims of U.S. Patent No. 6,482,431.

32. Ethicon distributes, uses, offers for sale, licensed, marketed, and/or sells in Colorado and throughout the United States products that induce and instruct others to practice the method claimed in one or more claims of U.S. Patent No. 6,482,431.

33. Specifically, Ethicon's Dermabond brand topical skin adhesive is specifically marketed, sold in a manner that willfully induces infringement of the process patented in U.S. Patent No. 6,482,431.

FIRST CLAIM FOR RELIEF

(Patent Infringement of the '431 Patent)

34. Plaintiffs reaffirm and re-allege each and every allegation set forth in paragraphs

1 - 33, inclusive, and incorporate them herein by reference.

35. The '431 patent discloses and claims a method or methods for application and maintenance of medication on body tissue.
36. The Defendant has been, and is, directly or indirectly infringing one or more claims of the '431 patent in violation of 35 U.S.C. 271 (a), (b), (c), and/or (f), by making, using, selling offering to sell or selling, and/or causing other to practice the method claimed in the '431 patent in the United States.
37. The Defendant has willfully assisted and induced the infringement of the '431 patent in violation of 35 U.S.C. 271(b) by instructing others to infringe the '431 patent.
38. The Defendant has derived, and in the future will continue to derive and receive, gains, profits, and advantages from the infringement of the '431 patent in an amount to be proven at trial.
39. The Plaintiffs have been damaged through the Defendant's acts of infringement in a manner that cannot be fully measured or compensated in economic terms and for which there is no adequate remedy at law. The actions of the Defendant have irreparably harmed and will continue to harm the Plaintiffs ability to market, reputation, and good will unless Defendant's acts of infringement are enjoined.
40. The Defendant knew of the '431 patent, knew of the infringement induced by its sale and promotion of the use of Dermabond in an infringing manner, but chose to ignore the Plaintiffs' rights and continue to infringe.
41. As a direct and proximal cause of Defendant's actions, Plaintiffs have been damaged for which they are entitled legal damages and equitable remedies.

SECOND CLAIM FOR RELIEF

(Quantum Meruit)

42. Plaintiffs hereby incorporate paragraphs 1 through 41 by references as though fully set forth herein.

43. Plaintiffs rendered valuable services to Defendant and the Defendant benefited from those services corporately.

44. Defendant accepted the services of Plaintiffs and knew, or should have known, that Plaintiffs expected to be compensated for the reasonable value of such services.

45. Defendant has failed and/or refused to compensate Plaintiffs for the value of those services and consequent benefit conferred upon them.

46. To date, the Plaintiffs have not been compensated for the reasonable value of services provided to the Defendant.

47. Defendant has been unjustly enriched as a result of their failure and/or refusal to compensate Plaintiffs for the services rendered on their behalf.

48. Plaintiffs are entitled to recover from Defendant based upon the theory of quantum meruit and/or based upon the equitable theories of unjust enrichment to the Defendant and/or unjust loss suffered by Plaintiffs, due to Defendant's negligence or intentional and willful conduct.

WHEREFORE, Plaintiffs pray for relief as stated at the conclusion of this pleading.

THIRD CLAIM FOR RELIEF

(Unjust Enrichment)

49. Plaintiffs hereby incorporate paragraphs 1 through 48 above as is fully set forth herein.

50. Defendant had a real and tangible benefit conferred upon them by Plaintiff having provided valuable services to Defendant.

51. The services provided by Plaintiffs were for the benefit of Ethicon, Inc., a New Jersey Corporation.

52. Defendant full enjoyed, appreciated, accepted and retained the benefits of the services provided by Plaintiffs.

53. Defendants' acceptance and retention of the benefits described above, without paying for such services, has unjustly enriched Defendant and it would be inequitable for Defendant to retain the value of the benefits of these services without providing just compensation therefore to the Plaintiff.

54. Defendants' unjust enrichment has caused the Plaintiffs damages and losses for which they should be compensated in an amount to be determined at the time of trial.

55. Plaintiff has additionally been damage due to the fact that he has had to incur attorneys fess and costs in this matter.

WHEREFORE, Plaintiffs pray for relief as stated at the conclusion of this pleading

FOURTH CLAIM FOR RELIEF

(Breach of Contract)

56. Plaintiffs incorporate paragraphs 1 through 55 above as if fully set forth herein.

57. Defendants failed to abide by the verbal contact and agreement for payment of the services provided and has failed to honor the terms thereof.

58. Plaintiffs have been damaged in an amount to be determined at trial.

59. The Plaintiffs are entitled to judgment interest at the rate of 18% per annum.

WHEREFORE, Plaintiffs pray for relief as stated at the conclusion of this pleading

FIFTH CLAIM FOR RELIEF

(Promissory Estoppel)

60. Plaintiffs incorporate paragraphs 1 through 59 above as if fully set forth herein.

61. Defendant promised to pay Plaintiffs for the services, which they contracted.

62. Defendant has not performed on her promise to pay for the services provided, leaving an amount due and owing, together with accruing interest at the rate of 18% per annum, plus, costs and any other items allocable by statute of specific agreement.

63. Plaintiffs were asked by Defendant to provide services for the benefit of Defendant and Plaintiffs reasonably relied upon Defendants' promise to pay for such services.

64. Plaintiffs' reliance on Defendants' promise to pay was reasonable under circumstances.

65. Defendants' actions have caused Plaintiffs damages and losses for which it should be compensated.

WHEREFORE, PLAINTIFFS PRAY THAT:

1. Defendant, its agents, servants, employees, assigns, successors in interest, and all parties in privity therewith be preliminarily and permanently enjoined from the continued infringement of U.S. Patent No. 6,482,431.
2. A judgment be entered finding that Defendant has infringed, induced

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