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U.S. DISTRICT COURT

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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH CENTRAL DIVISION

BRIGHAM YOUNG UNIVERSITY, a Utah Non-Profit Education Institution; and Dr. DANIEL L. SIMMONS, an individual, Plaintiffs, vs. PFIZER, INC., a Delaware Corporation, G.D. SEARLE & COMPANY, a Delaware corporation, G.D. SEARLE LLC, a Delaware Limited Liability Company, MONSANTO COMPANY, a Delaware Corporation; and PHARMACIA CORPORATION, a Delaware Corporation, Defendants.	COMPLAINT JURY TRIAL DEMANDED Case Number (Breach of Contract; Breach of Fiduciary Duty; Correction of Inventorship; Unjust Enrichment; Fraud; Negligent Misrepresentation; Misappropriation of Trade Secrets)

Judge Dale A. Kimball
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I. INTRODUCTION

1. Dr. Daniel L. Simmons, professor at Brigham Young University, discovered the COX-2 enzyme, one of the most important pharmacological discoveries of the last decade. By Monsanto's own admission, the discovery of COX-2 was "critical" to the creation of what Monsanto now touts as its "super aspirin," the COX-2 selective nonsteroidal anti-inflammatory drug ("NSAID"), Celebrex. Celebrex and its second-generation drugs are some of the most commercially successful medications of the last century, with total sales exceeding $20 billion.

2. In early 1991, Dr. Simmons brought his discovery of COX-2 and his project to find a COX-2 selective NSAID to Monsanto. Brigham Young University and Monsanto entered into a "Research Agreement" ("Agreement," attached as Exhibit A) calling for collaborative research, directed by Dr. Simmons, to isolate a COX-2 selective NSAID. The Agreement required that Monsanto notify Brigham Young University of patentable results from the project and provided that Brigham Young University would profit from such patentable results. In breach of that Agreement and acting in bad faith, Dr. Philip Needleman, Monsanto's Chief Scientific Officer, fraudulently terminated the Agreement so that Monsanto could secretly misappropriate Dr. Simmons's discovery and project to develop COX-2 selective NSAIDs for its own gain.

3. With the benefit of Dr. Simmons's discovery and project, Monsanto was the first pharmaceutical company with the capability of systematically testing and identifying a successful COX-2 selective NSAID and, therefore, was the first to market

this type of drug. Monsanto and Dr. Needleman took credit for the remarkable discovery of COX-2, and Monsanto has kept all the profits from the sales of Celebrex, its COX-2 selective NSAID developed from the project, and its various second-generation drugs.

4. Monsanto and its successors fraudulently concealed these facts until recent Monsanto litigation caused them to admit that, before meeting Dr. Simmons, they did not have COX-2 or a COX-2 selective NSAID project and, in fact, were heading down another research path that would never have led to the development of a COX-2 selective NSAID such as Celebrex.

5. The parties entered into a tolling agreement on May 9, 2001, and since then have attempted, without success, to mediate their dispute.

6. Brigham Young University and Dr. Simmons demand a jury trial and seek damages caused by Monsanto's actions, including (1) its failure to notify Brigham Young University of patentable research results obtained from the project and (2) its wrongful taking of Dr. Simmons's COX-2 discovery and his project which enabled Monsanto to be the first to develop a COX-2 selective NSAID.

II. PARTIES

7. Plaintiff Brigham Young University is a private not-for-profit university located in Provo, Utah. Brigham Young University did not use any money from either the state or federal government to fund the research at issue in this Complaint.

8. Plaintiff Dr. Daniel L. Simmons is a professor of biochemistry and chemistry at Brigham Young University. Dr. Simmons holds a Ph.D. from the University

of Wisconsin – Madison. Prior to joining the faculty at Brigham Young University in 1989, he was a Harvard University postdoctoral fellow.

9. Defendant G.D. Searle LLC ("Searle LLC") is a Delaware Limited Liability Company with its principal place of business in Illinois. Searle does business and sells products throughout the United States, including in Utah. Searle LLC is the successor to Defendant G. D. Searle & Company ("Searle Co."). Searle Co. and Searle LLC shall be referred to jointly in this Complaint as "Searle."

10. Defendant Monsanto Co. ("Monsanto") is a Delaware corporation with its principal place of business in St. Louis, Missouri. Monsanto does business and sells products throughout the United States, including in Utah. Monsanto is registered with the Utah Department of Commerce, Corporations Division, as a foreign corporation doing business for profit in Utah.

11. Defendant Pharmacia Corp. ("Pharmacia") is a Delaware corporation with its principal place of business in New Jersey. Pharmacia does business and sells products throughout the United States, including in Utah. Pharmacia is registered with the Utah Department of Commerce, Corporations Division, as a foreign corporation doing business for profit in Utah.

12. Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation with its principal place of business in New York. Pfizer does business and sells products throughout the United States, including in Utah. Pfizer is registered with the Utah Department of

Commerce, Corporations Division, as a foreign corporation doing business for profit in Utah.

13. The Defendants are related as follows: (1) in 1985, Monsanto acquired Searle Co., making Searle Co. its pharmaceutical unit; (2) in April 2000, Monsanto and its Searle Co. unit merged with Pharmacia & Upjohn, Inc. to form Pharmacia; (3) in 2000, Searle Co. changed its corporate form becoming Searle LLC; (4) in 2002, Pharmacia spun off Monsanto's agricultural operations; and finally (5) in April 2003, Pfizer and Pharmacia merged leaving Pfizer in control of Pharmacia and Searle. "Monsanto" as used in this Complaint refers to the defendants collectively unless otherwise designated.

14. On information and belief, Pfizer has assumed Monsanto and Searle's liabilities which arise from the wrongful activities of Monsanto and Searle, described in the body of this Complaint.

15. Alternatively, Monsanto, Searle, and Pharmacia retain some portion of this liability.

16. All Monsanto and/or Searle employees described herein, including but not limited to, Dr. Needleman, Dr. Masferrer, Dr. Seibert, and Dr. Haymore, were at all relevant times acting in the course and scope of their employment. During the early months of Brigham Young University and Dr. Simmons's contacts with Dr. Seibert, she was in transition between Washington University and Monsanto and/or Searle. However,

in all contacts with Brigham Young University and Dr. Simmons, Dr. Seibert was acting as Monsanto and/or Searle's agent. Therefore, liability arising from their dealings with Brigham Young University and Dr. Simmons is attributable to Monsanto and/or Searle and their successors and assigns, (Pharmacia and Pfizer).

III. JURISDICTION AND VENUE

17. This Court retains jurisdiction over this matter pursuant to 28 U.S.C. 1332(a). As stated above, each of the Defendants is a Delaware Corporation or limited liability company with its principal place of business outside the State of Utah; Plaintiffs Brigham Young University and Dr. Simmons are both residents of the State of Utah.

18. The amount in controversy in this action exceeds $75,000, exclusive of interest and costs.

19. Furthermore, this Court retains original subject matter jurisdiction, pursuant to 28 U.S.C. § 1331 over Plaintiffs' Claims arising under 35 U.S.C. § 256.

20. Venue is proper in this Court under 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claims herein occurred within the State of Utah.

21. Furthermore, pursuant to 28 U.S.C. § 1391(c), each of the Defendant corporations is subject to personal jurisdiction in Utah and is, therefore, deemed to reside within this district as stated above in Section II. Each of the Defendant corporations has substantial, continuous, and systematic contacts with the State of Utah.

22. Additionally, the events giving rise to this litigation arise from the Defendants' contacts with the State of Utah.

23. Many of the witnesses who will testify concerning the events giving rise to this litigation are residents of the State of Utah.

IV. FACTS

A. The History Of Pain Medication: NSAIDs And Steroids

1. NSAIDS

24. Aspirin has been used since 1899 for the treatment of inflammation, pain, and fever. Since then, pharmaceutical companies have developed many other drugs which are similar to aspirin. These medications are called non-steroidal anti-inflammatory drugs or NSAIDS.

25. The key to how aspirin and other NSAIDs work is an enzyme commonly called cyclooxygenase or COX. COX produces molecules called prostaglandins, that are responsible for inflammation, pain, and fever. However, prostaglandins also have beneficial effects such as promoting protective mucus secretion in the stomach.

26. NSAIDs work by binding to COX and blocking it from making prostaglandins.

27. While NSAIDs inhibit inflammation, pain, and fever, their frequent use can cause many troubling and dangerous side effects such as gastric distress, ulcers, kidney damage, and even a rare type of asthma. Problematically, NSAIDs indiscriminately prevent the production of all prostaglandins, thus eliminating both the negative effects

(pain, inflammation, and fever) and the beneficial effects (protection of the stomach) resulting in NSAID-induced ulcers that reportedly kill over 16,000 Americans a year.

28. In the 1960s and 1970s, many potent NSAIDs were discovered, including ibuprofen (Motrin or Advil), naproxen (Aleve), sulindac (Clinoril), diclofenac (Voltaren), ketoprofen (Orudis), piroxicam (Feldene), indomethacin (Indocin), and meclofenamate (Meclomen).

29. By the early 1990s, the NSAID market was saturated. Drug companies had little interest in developing yet another NSAID that had the same level of efficacy and carried the same troubling side effects as existing drugs.

2. Steroids

30. Steroids provide an alternative to NSAIDs for treatment of pain and inflammation. Unlike NSAIDs, steroids do not bind to COX to inhibit the production of prostaglandins. Instead, steroids act earlier by preventing the COX gene from producing the COX enzyme. Since 1950, drug companies have made many synthetic anti-inflammatory steroids, including prednisolone, prednisone, betamethasone, and dexamethasone.

31. Anti-inflammatory steroids (sometimes referred to as glucocorticoids) have their own dangerous side effects and can cause a number of ailments, including nausea, bone pain, potassium loss, muscle weakness, thinning skin, glaucoma, depression, hypertension, metabolic disturbances, growth retardation, immune suppression, and adrenal gland shutdown.

32. By the mid 1980s, drug researchers were looking for a way to inhibit pain, inflammation, and fever that did not have the negative side effects associated with either existing NSAIDs or steroids.

B. Drug Researchers Identified One COX With Different Behaviors

33. Until Dr. Simmons's identification of a second COX gene and enzyme, researchers did not understand why COX appeared to act differently under various physiological conditions. For example, researchers observed that COX usually produced a constant level of prostaglandins but, at times, in response to a stimulus like injury or infection, the production of prostaglandins spiked. Researchers developed various theories to try to explain why COX behaved in this way.

34. For example, some laboratories, including Dr. Needleman's, theorized the possible existence of multiple COX "pools," the existence of multiple mRNAs generated from the same COX gene, or even the existence of multiple COX genes.

35. In formulating these theories, researchers, including Dr. Needleman, were hindered because they had not identified or isolated two separate COX genes that produce two separate and distinct COX enzymes. As a result of Dr. Simmons's discovery, scientists now understand that one COX enzyme (now called COX-1) produces the "constitutive" or constant level of prostaglandins, and a second COX enzyme (now called COX-2) produces the "inducible" level of prostaglandins resulting from a stimulus.

C. Monsanto's Steroid-like Research Was Premised On A Single COX Target

36. In 1989, Monsanto hired Dr. Needleman from Washington University in St. Louis as its Chief Scientific Officer. Brigham Young University has recently learned from a review of other Monsanto litigation that about the time of Dr. Needleman's arrival, Monsanto began a research project seeking to find a new and novel steroid-like solution to inflammation and pain.

37. Monsanto and Dr. Needleman were not interested in developing an NSAID-like compound because they thought it would be like the many other NSAIDs already on the market and would have the same side effects. Thus, before Monsanto's collaboration with Dr. Simmons, Monsanto was testing chemicals to develop a steroid-like drug and was eliminating any compound found to have NSAID activity.

38. In other words, Monsanto's steroid-like project assumed that there was no way to make a better or different NSAID (a "super aspirin") because, at the time, Monsanto could not distinguish "constitutive" versus "inducible" COX activities as being distinct targets for potentially selective NSAIDs. Monsanto employees have since indicated in their writings that at the time this steroid-like project was being carried out, Monsanto "doubted that an NSAID selective for the inducible form of Cox could be produced."

D. Dr. Simmons Discovered COX-2

39. By the end of 1988, while working as a Harvard fellow, Dr. Simmons had isolated various messenger ribonucleic acids ("mRNAs") which were induced (or turned on) to relatively high levels by cancer-causing agents. Dr. Simmons, searching for a cancer cure, isolated these mRNAs (called "immediate early" mRNAs) to study their role in the aberrant division of cancer cells.

40. One of the mRNAs Dr. Simmons isolated was named, for laboratory purposes, CEF 147.

41. After coming to Brigham Young University in July 1989, Dr. Simmons, working with his graduate student, Weilin Xie, identified CEF 147's nucleic acid sequence and quickly recognized that it encoded a novel COX, distinguishable from the only COX previously identified. Dr. Simmons named this new COX "mitogen-inducible prostaglandin G/H synthase," a scientifically precise name for the second form of COX. Over time, this became popularly known as "COX-2."

42. Dr. Simmons found that CEF 147 encoded a COX that shared about 60% of the protein sequence identity with the then-known COX and shared all the identifying characteristics of a cyclooxygenase. It was apparent to Dr. Simmons from these and other features that this was a new and different COX.

43. Dr. Simmons immediately understood the significance of his discovery. In October 1989, he submitted a notarized document to the Chairman of the Department of Chemistry at Brigham Young University outlining his discovery. After describing his

research, Dr. Simmons observed that his discovery was likely a very important contribution to pharmacology. He explained that, because there are two different COX enzymes, it would be possible to test for NSAIDs that bind and inhibit one or the other and thus reduce pain, fever, and inflammation without the unwanted side effects. In other words, Dr. Simmons had found a new target (COX-2) to use in developing a potential pain and inflammation blocker. Dr. Simmons also noted in his document that the identification of COX-2 might lead to COX-2 selective NSAIDs with cancer cell antigrowth properties, resulting in new forms of chemotherapy. Both of Dr. Simmons's early predictions proved correct.

44. In 1990, Dr. Simmons performed additional studies on COX-2. He synthesized COX-2 in a test tube and showed that it had many of the critical physical features of COX. He generated an antibody to COX-2 to enable and aid its detection in tissues and cells and cloned mouse COX-1 and COX-2. By early 1991, he had conducted additional experiments measuring the levels of COX-1 and COX-2 expression in tissue and cells, confirming that the COX-1 gene was responsible for the "constitutive" activity of COX and that the COX-2 gene was responsible for the "inducible" activity of COX.

45. In April 1991, Dr. Simmons published his discovery of COX-2 and related findings in the Proceedings of the National Academy of Sciences. However, he did not disclose the nucleic acid sequence of mouse COX-2, reserving this and other proprietary information for an anticipated collaboration with an industrial partner.

E. Dr. Simmons Seeks Collaboration To Develop a COX-2 Selective NSAID

46. In February of 1991, Dr. Barry Haymore, a Monsanto scientist working for Dr. Needleman, came to Brigham Young University to present a seminar on a subject unrelated to COX. According to Dr. Haymore, one of his responsibilities was to scout for new scientific developments that might be of benefit to Monsanto. Dr. Simmons met with Dr. Haymore and told him he had identified COX-2. Dr. Simmons explained the importance of his discovery in the treatment of pain and inflammation, focusing on the possibility of creating a testing system to find an NSAID capable of selectively inhibiting COX-2. Dr. Simmons revealed to Dr. Haymore that he not only had identified COX-2, but had actually cloned COX-2 in both chicken and mouse. Dr. Simmons told Dr. Haymore that he was seeking an industrial collaborator to pursue a project to find, among other things, an NSAID that would selectively inhibit COX-2.

47. Dr. Haymore said he would take Dr. Simmons's discovery directly to Dr. Needleman. Just days later, Dr. Haymore called Dr. Simmons and told him that Monsanto was very interested in Dr. Simmons's COX-2 research and the potential for a business collaboration with Brigham Young University.

48. Dr. Haymore asked Dr. Simmons to come to Monsanto to present a seminar on COX-2. Dr. Haymore also requested that Dr. Simmons send Monsanto certain documentation. Based on Monsanto's representation that it was interested in a business

relationship with Brigham Young University, Dr. Simmons sent the requested materials and agreed to give the seminar at Monsanto.

49. On April 5, 1991, Dr. Simmons made a presentation at Monsanto, describing his discovery of COX-2 and his cloning of COX-2 in chicken and in mouse. He also met with Dr. Needleman and presented Monsanto with a written proposal for collaboration between Brigham Young University and Monsanto.

50. During this same visit, Dr. Simmons went out to dinner with Dr. Haymore and other Monsanto personnel. Dr. Simmons asked them about his patent rights on his COX-2 technology which included his isolated COX-2 and COX-2 cDNA clones, their predicted amino acid sequences and nucleic acid sequences, and his COX-2 antibodies. Dr. Simmons also asked if a method of testing NSAIDs created through his discovery of COX-2 were patentable. They wrongly advised Dr. Simmons that he should not patent these items because any such patent would not be enforceable or defensible.

51. The focus of Dr. Simmons's April 1991 written proposal to Monsanto was the creation of an NSAID that would selectively inhibit COX-2. Also, with Dr. Simmons's methodology, drugs could be found that would selectively inhibit COX-1. The proposal envisioned the creation of drugs that would regulate each COX enzyme separately.

52. The proposal sought Monsanto's collaboration in pursuing the interaction of NSAIDs with COX-2. In addition to some modest initial funding, Dr. Simmons's

proposal sought a full collaboration with Monsanto scientists who could provide NSAIDs for testing and who could provide advice and participate in the project.

53. Dr. Needleman told Dr. Simmons that he was impressed with Dr. Simmons's April 5, 1991, presentation. Dr. Needleman indicated that Monsanto was interested in collaborating with Dr. Simmons and Brigham Young University.

54. On April 11, 1991, six days after Dr. Simmons's seminar and meetings at Monsanto's corporate headquarters, Monsanto sent a proposed research agreement to Brigham Young University.

55. Dr. Needleman personally handled the negotiations between Brigham Young University and Monsanto. Dr. Needleman represented that the research agreement he was offering Brigham Young University was the same agreement Monsanto gave him when he was a professor at Washington University. Dr. Needleman repeatedly assured Dr. Simmons that this agreement fully protected Dr. Simmons and gave Brigham Young University rights to and ownership of the results of the collaborative project with the right of Monsanto to license any technology.

56. From April 21-25, 1991, during a conference in Atlanta, Monsanto scientists Drs. Seibert and Masferrer met with Dr. Simmons at Dr. Needleman's request. During this meeting they told Dr. Simmons that he "had no idea how big" the result of the collaboration between Monsanto and Dr. Simmons would become if Dr. Simmons "worked with" Monsanto. They represented that the collaboration would lead to

tremendous new NSAIDs that would be very profitable to both Brigham Young University and Monsanto.

57. At this same conference, Drs. Seibert and Masferrer expressed excitement over the agreed-upon collaboration and the desire to begin collaborating immediately, requesting that Dr. Simmons begin sending his technology.

58. On April 29, 1991, Dr. Simmons provided Monsanto with his murine (mouse) COX-1 and COX-2 clones and COX-2 antibodies.

59. On May 23, 1991, Dr. Simmons provided Monsanto with a copy of his submitted National Institutes of Health ("NIH") grant proposal containing detailed information about the role of COX-2 in cancer and the potential of COX-2 as a target for anti-cancer therapy.

60. Both the draft Agreement that Brigham Young University received prior to April 29, 1991, and the subsequently signed final Agreement made clear that the parties intended for Dr. Simmons's murine COX-1 and COX-2 clones, COX-2 antibodies, and the information in the NIH grant proposal be covered by the Agreement's Article 4 on Confidential Information.

61. ¶ 4.1 of both the draft and final Agreement included as "CONFIDENTIAL INFORMATION": "proprietary information, including information relating to transformed cells, genes, transformation vectors, transformation, selection and regeneration procedures, media formulations, chemicals, DNA sequences and probes …."

62. In short, ¶ 4.1 described exactly the information Dr. Simmons gave Monsanto with the promise and understanding that the Agreement would cover that information and protect Brigham Young University and Dr. Simmons.

63. Dr. Simmons provided Monsanto with his murine COX-1 and COX-2 clones and COX-2 antibodies and the NIH grant proposal in reliance upon, among others, the following: (1) Monsanto's representation that Brigham Young University would have the same contractual protections that Dr. Needleman had at Washington University, (2) Monsanto and Brigham Young had agreed to a full collaboration, and (3) the understanding that the transmitted technology and information would be covered by the terms of the written confidentiality provisions as reflected in the draft agreement.

64. Monsanto required Dr. Simmons's consent before they could use his trade secrets, including his technology and NIH grant proposal. That consent was granted by the Agreement and included the trade secrets given before signing. If the CONFIDENTIAL INFORMATION/trade secrets exchanged prior to signing were not covered by the Agreement, Monsanto had not otherwise received consent to use them.

F. Brigham Young University and Monsanto Sign The Collaborative Research Agreement

65. By July 8, 1991, Monsanto and Brigham Young University signed the Agreement. Dr. Needleman signed for Monsanto; Associate Academic Vice President J. Bevan Ott signed for Brigham Young University.

66. Paragraph 1.1 describes the "PROJECT" as the "research programs described in Appendix 'A'."

67. Appendix A describes one of the research programs encompassed by the PROJECT in the following terms: "Our laboratory will use the antibodies and cDNA probes that we [Brigham Young University] have generated to COX-1 and COX-2 in chicken, mouse and human to explore the nature of the nonsteroidal anti inflammatory drug (NSAID) interaction with these enzymes." The first listed PROJECT goal is to find a specific COX-1 and COX-2 selective NSAID: "Identification of Isoenzyme-specific Inhibition of Cyclooxygenase (COX) Activity."

68. Appendix A also includes other topics within the scope of the PROJECT including the testing of NSAIDs' interaction with COX in the treatment of cancer and the possible role of COX-2 in wound healing, bone resorption and ovulation.

69. In consideration for Brigham Young University agreeing to disclose Dr. Simmons's discovery and related research results, Monsanto agreed that the collaborative "PROJECT" would be "carried out under the direction of Dr. Daniel L. Simmons."

70. The Agreement required Brigham Young University to "furnish such available laboratory facilities and equipment as it shall determine necessary for the work to be done on this PROJECT."

71. On the other hand, the Agreement required that, "MONSANTO shall furnish prostaglandins, NSAIDs and consulting services to the extent provided in

Appendix 'A' and, in addition shall pay [Brigham Young University] the sum of Fifty-Thousand Dollars ($50,000.00) per year." Appendix A provided that Brigham Young University and Dr. Simmons would "test as many NSAIDs as [they] can obtain."

72. Pursuant to the Agreement, Dr. Simmons would test NSAIDs sent to him by Monsanto in Brigham Young University's laboratory.

73. The Agreement anticipated that Brigham Young University and Monsanto would share confidential scientific information for the purpose of cooperating in the search for a COX-2 selective NSAID. For example:

(a) ¶ 1.2 states: "'MONSANTO INFORMATION' shall mean all technical and biological information and know-how that is received by UNIVERSITY directly or indirectly from MONSANTO...."

(b) ¶ 4.1 states: "In order for the parties to more fully cooperate in this effort, it may be necessary for UNIVERSITY or MONSANTO to disclose to the other party proprietary information, including information relating to transformed cells, genes, transformation vectors, transformation, selection and regeneration procedures, media formulations, chemicals, DNA sequences and probes which information (including MONSANTO INFORMATION) is confidential and proprietary and is hereafter referred to as CONFIDENTIAL INFORMATION."

74. Throughout Dr. Simmons's relationship with Monsanto, he was in frequent contact to update Monsanto with new developments from Brigham Young University's laboratory and also to answer Monsanto's questions in an effort to help them better understand COX-2.

75. Monsanto and Brigham Young University agreed that any shared CONFIDENTIAL INFORMATION could not be used for purposes other than the cooperative effort to find a COX-2 selective NSAID. For example:

(a) ¶ 4.1 states "The parties agree that CONFIDENTIAL INFORMATION will be used only as provided for in this Agreement...."

(b) ¶ 4.1(b) limits "disclosure of CONFIDENTIAL INFORMATION to those personnel who need such access for purposes of this cooperative effort...."

(c) ¶ 4.1(c) states the parties shall "not duplicate or use CONFIDENTIAL INFORMATION in any other manner ...."

76. The Agreement described the PROJECT as being the cooperative effort to develop a COX-2 selective NSAID (or to achieve the other stated objectives) with the use of CONFIDENTIAL INFORMATION.

77. Other provisions of the Agreement confirm that the PROJECT would only be carried out pursuant to the anticipated cooperative effort. For example:

(a) ¶ 1.6 requires Monsanto to furnish prostaglandins, NSAIDs and consulting services to Brigham Young University. It was Brigham Young University's intent and Monsanto's purported intent that Monsanto contribute its considerable technical knowledge to help achieve the PROJECT objectives and that Monsanto could not withhold the most promising NSAIDs for its own secret project.

(b) ¶ 1.3 states "The PROJECT and all work assigned shall be carried out under the direction of Dr. Daniel L. Simmons...." It was Brigham Young University's intent and Monsanto's purported intent that Monsanto could not do PROJECT work outside the cooperative effort and hide the work from Dr. Simmons's direction or knowledge.

(c) ¶ 3.1 contemplates that Brigham Young University and Monsanto may be "joint inventors" of "discoveries and inventions." It was Brigham Young

University's intent and Monsanto's purported intent that they work in a cooperative effort to develop a COX-2 selective NSAID.

(d) ¶ 3.3 states: "In the event that MONSANTO determines that research results obtained from the PROJECT are patentable, it shall notify UNIVERSITY and thereafter indicate to UNIVERSITY its interest in a license under such prospective patents." Monsanto could not seek patents on patentable research results without first notifying Brigham Young University. ¶ 3.5 gave Brigham Young University direct access to Monsanto's attorneys to file and prosecute resulting patent applications. It was Brigham Young University's intent and Monsanto's purported intent that Monsanto could not take Dr. Simmons's CONFIDENTIAL INFORMATION to set up a parallel project, and unilaterally benefit from the patentable results. To do so would deprive Brigham Young University of the agreed-upon consideration.

(e) ¶ 3.4 states that the reasonable royalty would be determined based upon, among other factors, Brigham Young University and Monsanto's "financial and scientific contributions to the research program under which the invention was made." It was Brigham Young University's intent and Monsanto's purported intent that they work in a cooperative effort to develop a COX-2 selective NSAID.

(f) ¶ 3.5 provides that Brigham Young University "shall have the right to designate, at its sole option, either MONSANTO'S Patent Department or a patent attorney in private practice to prepare, file and prosecute patent applications." Monsanto was required to inform Brigham Young University of any patentable research results so that Brigham Young University could exercise its right to protect itself by choosing its own patent counsel or by choosing to use Monsanto's patent attorneys.

(g) ¶ 3.3 and ¶ 3.5 are further bolstered by ¶ 3.6, which states that, "Until such time as MONSANTO notifies UNIVERSITY in writing that it no longer has an interest in a license, or until the expiration of the time specified in paragraph 3.4, MONSANTO agrees to bear the cost for filing and prosecution of patent applications under paragraph 3.5 and the issuance and maintenance of patents thereon." Monsanto was required to notify Brigham Young University of Monsanto's intentions regarding research results from the PROJECT.

78. The above provisions, and the Agreement read in its entirety, establish that although Brigham Young University and Monsanto were assigned certain obligations, they were pursuing a "cooperative effort" to develop a COX-2 selective NSAID and accomplish the other PROJECT aims. Any results of that cooperative effort, regardless of the relative contribution of either Monsanto or Brigham Young University, had to flow through the Agreement. Any attempt by Monsanto to test for and develop COX-2 selective NSAIDs using CONFIDENTIAL INFORMATION outside the PROJECT would breach both the Agreement and Monsanto's fiduciary duty and duty of good faith and fair dealing.

79. Under ¶ 3.3 of the Agreement, if Monsanto determined that research results obtained from the PROJECT were patentable, it was required to notify Brigham Young University. If Monsanto were interested in a license under such patents, Brigham Young University agreed to give Monsanto the right of first refusal for an exclusive license in exchange for payment to Brigham Young University of a reasonable royalty.

80. Dr. Simmons was excited to begin work with Monsanto and based upon Monsanto's representation and the terms of the Agreement, viewed the PROJECT with Monsanto as a full collaboration.

G. Monsanto Assumed a Fiduciary Duty

81. Monsanto assumed a fiduciary duty towards Brigham Young University and Dr. Simmons based on, among others, the following factors:

(a) ¶ 1.6 of the Agreement imposes upon Monsanto a duty to serve as Brigham Young University's consultant.

(b) The Agreement created a joint venture partnership between Brigham Young University and Monsanto by virtue of the parties' explicit mutual intent to each make contributions to the venture; share profits, risks of failure, and losses resulting from the failure to produce results that are marketable; and exert mutual control over the operation of the PROJECT.

(c) Monsanto knowingly received Brigham Young University and Dr. Simmons's CONFIDENTIAL INFORMATION under the Agreement and thereby undertook to maintain this CONFIDENTIAL INFORMATION with exceptional care and skill.

(d) Monsanto assumed a position of trust and confidence over Brigham Young University and Dr. Simmons resulting from Monsanto's expertise and superior knowledge regarding pharmaceutical development, patenting, and marketing.

(e) Monsanto assumed a position of trust and confidence over Brigham Young University because it willingly accepted the contractual obligation that required Monsanto to protect certain of Brigham Young University's financial interests to the potential detriment of Monsanto's own financial interests. For example, Monsanto's duty under ¶ 3.3 of the Agreement to inform Brigham Young University of patentable research results from the PROJECT would limit Monsanto's ability to conduct certain activities without first obtaining a license from Brigham Young University.

(f) ¶ 3.5 of the Agreement gives Brigham Young University the right to choose Monsanto's "patent attorneys to file and prosecute…" patent applications on inventions arising from the PROJECT. Because Brigham Young University was in a prospective attorney/client relationship with Monsanto's patent attorneys, Monsanto owed Brigham Young University a fiduciary duty to treat all CONFIDENTIAL INFORMATION received in a manner that would be in Brigham Young University's best interest.

82. As a result of this fiduciary relationship, Monsanto owed Brigham Young University a duty of loyalty and candor and was required to act in Brigham Young University's best interests.

83. However, as demonstrated below, Monsanto preyed upon Dr. Simmons and Brigham Young University's trust and confidence and breached its contractual and fiduciary duties to Brigham Young University. Evidence that has subsequently come to light demonstrates that no later than early 1992, Monsanto intended to misappropriate the PROJECT and secretly develop its own COX-2 selective NSAID, thus depriving Brigham Young University and Dr. Simmons of the expected professional and economic benefits to which they were entitled.

H. Monsanto and Dr. Needleman Breach the Agreement

1. Monsanto and Dr. Needleman misappropriate Dr. Simmons's research.

84. After collaborating with BYU and Dr. Simmons, Monsanto quickly understood the importance of Dr. Simmons's COX-2 discovery. As a result, Monsanto began to reduce its emphasis on steroid related research and shifted its focus to a search for a COX-2 selective NSAID.

85. By the spring of 1992, Dr. Needleman and Monsanto changed to a COX-2 project looking for an NSAID solution to what they had just learned were two different and distinguishable COX enzymes. Monsanto did not inform Brigham Young University of this change. This was an abrupt and dramatic corporate shift in thinking and approach requiring reallocation of valuable resources and personnel. It took place to further Monsanto's plan to convert the PROJECT for its own gain.

86. It was not long before Monsanto found a promising COX-2 selective NSAID. Between January 8 and 11, 1992, Dr. Simmons and Dr. Seibert attended a seminar in Keystone, Colorado, where Dr. William Galbraith, a scientist working for a joint venture company, made a seminar presentation on a little-known, patented compound – DuP-697.

87. Dr. Galbraith explained that DuP-697 acted to reduce pain and inflammation but did not cause ulcers in test animals. Dr. Galbraith and his company thought that this compound might have some merit but did not understand why it worked because they did not have the tools to distinguish COX-1 and COX-2 activity. DuP-697 had not been marketed because it possessed certain unwanted properties.

88. As a result of Dr. Simmons's discoveries, both Dr. Simmons and Dr. Seibert understood that DuP-697 could potentially be a COX-2 selective NSAID. However, Dr. Simmons believed that, because DuP-697 was under patent, the drug could not be used in the PROJECT.

89. At the Keystone conference, Dr. Galbraith invited Dr. Simmons to speak on COX-2 at Dr. Galbraith's company and Dr. Simmons agreed. On that occasion, Dr. Galbraith asked Dr. Simmons to collaborate on testing DuP-697. Dr. Simmons declined, explaining that he had already agreed to collaborate with Monsanto.

90. Ironically and unbeknownst to Dr. Simmons, by early 1992, Monsanto was planning to test or was already secretly testing DuP-697 against the COX-1 and COX-2

testing system that Monsanto developed using CONFIDENTIAL INFORMATION obtained from Dr. Simmons. The test results confirmed that DuP-697 was its first potential COX-2 selective NSAID.

91. Monsanto also knew (but Dr. Simmons did not know) that it could potentially engineer around the DuP-697 patent. Furthermore, Monsanto believed it could isolate the DuP-697 properties that potentially inhibited COX-2 from its unwanted properties, thereby developing a lead compound for a COX-2 selective drug. By the end of June 1992, Monsanto had made numerous derivatives outside of the original DuP-697 patent.

92. Paragraph 1.6 and related provisions of the Agreement required Monsanto to send DuP-697 and derived compounds to Professor Simmons for testing. Monsanto breached the Agreement, its fiduciary duty to Brigham Young University, and its duty of good faith and fair dealing by not providing these NSAIDs to Brigham Young University and, instead, using them in its secret research.

93. Because Monsanto's testing of DuP-697 and its derivative compounds was part of the PROJECT, ¶ 1.3 required that it be carried out with Dr. Simmons's knowledge and direction.

94. Monsanto's secret research also violated the confidentiality provisions of Article 4 which limits the disclosure (and therefore use) of CONFIDENTIAL

INFORMATION to those "personnel who need such access for purposes of this cooperative effort...," meaning the PROJECT. (See ¶ 4.1(b)).

95. Pursuant to ¶¶ 1.6 and 3.3 of the Agreement, its fiduciary duty, and its prior misrepresentations, Monsanto had a duty to advise Brigham Young University and Dr. Simmons of at least the following patentable results arising from the Project:

(a) The COX-2 gene as described by its nucleic acid sequence;

(b) The COX-2 enzyme as described by its amino acid sequence;

(c) A cell line expressing the COX-2 enzyme;

(d) The method for using the COX-2 gene, enzyme, or cell line for the purpose of constructing a testing system to identify potential COX-2 selective NSAIDs; and

(e) A method of treating pain, inflammation, and fever by selectively inhibiting COX-2 activity in a human host. With Dr. Simmons's ability to test for COX-1 and COX-2 selectivity together with DuP-697 (which Monsanto secretly withheld), Brigham Young University and Dr. Simmons had all the components necessary to obtain a method of treatment patent.

96. These patents would have given Brigham Young University and Dr. Simmons the right to prevent others, without first obtaining a license from Brigham Young University, from testing compounds for COX-2 selectivity, from conducting COX-2 related research, and from developing COX-2 selective NSAIDs for the purpose of commercial exploitation.

97. Monsanto was also required to provide notice of patentability to Brigham Young University, as described above, to correct its previous fraudulent misrepresentation that Dr. Simmons's COX-2 technology should not be patented.

98. Because Dr. Simmons was the first to isolate and purify COX-2 and its underlying gene sequence, his invention would have patent priority over those researchers who later discovered these same patentable phenomena.

99. Had Monsanto given Brigham Young University and Dr. Simmons notice that Dr. Simmons's COX-2 technology was patentable, they would have immediately understood the importance of identifying the human COX-2 enzyme and deriving its nucleic acid and amino acid sequences. Thus, Brigham Young University and Dr. Simmons would have been the first to obtain and own this very valuable and patentable invention.

100. Brigham Young University and Dr. Simmons did not begin to learn that certain of Dr. Simmons's COX-2 related discoveries and technology were patentable until at the earliest, 1999, when he became aware that the University of Rochester had obtained a patent relating to COX-2 technology.

101. Pursuant to ¶ 1.6 and ¶ 3.3 and its fiduciary obligations, Monsanto also had a duty to notify Brigham Young University that Celebrex and its related compounds were "patentable results obtained from the PROJECT."

102. It was vital to Brigham Young University that Monsanto provide these notices of patentability because this was Brigham Young University's first significant biotechnology discovery and Monsanto knew that neither Brigham Young University nor Dr. Simmons understood that Dr. Simmons's COX-2 technology was patentable.

Brigham Young University held no biotechnology patents and had no patent attorneys on staff. Brigham Young University was contractually protected from its lack of familiarity in protecting biotechnology inventions because ¶ 3.3 required Monsanto to notify Brigham Young University of patentability and because ¶ 3.5 gave Brigham Young University access directly to Monsanto's patent attorneys to patent any inventions arising from the PROJECT.

103. Instead of complying with these duties, including Monsanto's duty to notify Brigham Young University of patentable results from the PROJECT, Monsanto breached the Agreement and its fiduciary duties and sought to further its own interests, perpetuate its previous fraudulent misrepresentations, and exclude Brigham Young University and Dr. Simmons from the professional and economic benefits to which they were entitled under the PROJECT.

2. Dr. Needleman and Monsanto terminate the Agreement under fraudulent pretenses.

104. Throughout 1991 and the beginning of 1992, Dr. Simmons and Brigham Young University continued to collaborate with Monsanto. In July 1991, Dr. Simmons sent Dr. William Bradshaw, a colleague, to Monsanto to report on all activities at Brigham Young University and to deliver new developments and information.

105. Dr. Simmons's telephone logs show more than 60 calls to Monsanto during the period the Agreement was in effect. Additionally, he and his laboratory colleagues received many calls from Monsanto. During these calls, Brigham Young University and

Dr. Simmons fully and candidly shared all relevant details of their technology, laboratory results, and accumulated knowledge of COX-1 and COX-2. Monsanto, however, never told Dr. Simmons and Brigham Young University of Monsanto's secret testing of DuP-697 and its derivative compounds.

106. On March 17, 1992, after Monsanto was secretly planning to test, or perhaps had actually tested DuP-697 for COX-2 selectivity, Dr. Needleman (under pretense of not receiving sufficient communications from Dr. Simmons) abruptly announced his intent to terminate the Agreement with Brigham Young University, writing "we should give serious consideration to ending the grant at the end of one year."

107. Dr. Simmons responded on March 20, 1992 with a detailed letter stating that he believed the communication channel was open and functioning as demonstrated by his conversations with members of Dr. Needleman's laboratory. Dr. Simmons also addressed specific questions posed by Dr. Needleman and expressed his desire to remain in an open collaboration with Dr. Needleman's laboratory.

108. Despite Dr. Simmons's response, in a March 23, 1992, letter, Dr. Needleman stated five false and groundless reasons for ending the Agreement and concluded by saying that he regarded the relationship as "an unworkable" collaboration.

109. Because of Monsanto's obvious determination to terminate the Agreement, Brigham Young University sent a letter to Monsanto on March 27, 1992, acknowledging the termination of the Agreement.

110. Brigham Young University sent this letter only because it was fraudulently induced to do so, being completely unaware that Monsanto's true reason for terminating the Agreement was to jettison Brigham Young University so Monsanto could secretly misappropriate the PROJECT.

111. On May 20, 1992, Dr. Simmons wrote Dr. Needleman a letter refuting each of the five reasons Dr. Needleman had cited for termination. Dr. Simmons further expressed his dismay at the PROJECT termination:

> [T]he statements that you made concerning the termination deserve a response, since they are largely in error and are likely due to inadequate or incorrect information communicated to you.

112. Dr. Simmons accompanied the letter with a "post-termination report" to Monsanto describing the results of the PROJECT.

113. Monsanto did not respond to any of Brigham Young University or Dr. Simmons's letters.

114. By terminating the Agreement for fraudulent purposes, Monsanto breached its contractual and fiduciary duties to Brigham Young University and Dr. Simmons and wrongfully attempted to deprive Brigham Young University and Dr. Simmons of the intended benefits of the Agreement. Because Monsanto's termination was fraudulent, the Agreement remained in force and Monsanto was not relieved of its duties under the Agreement.

V. MONSANTO FRAUDULENTLY CONCEALED FROM BRIGHAM YOUNG UNIVERSITY AND DR. SIMMONS ITS BREACHES OF CONTRACTUAL AND FIDUCIARY DUTIES.

115. From the fraudulent termination of the Agreement forward, Monsanto began a campaign to rewrite history by misrepresenting and concealing the true facts concerning its relationship with Brigham Young University. Monsanto concealed that it had secretly taken the PROJECT and CONFIDENTIAL INFORMATION to develop a COX-2 selective NSAID, including Celebrex, because it knew that it had breached the Agreement with Brigham Young University. It also knew that Brigham Young University was entitled to a number of patents resulting from the PROJECT. Monsanto and Dr. Needleman went to great efforts to distance themselves from Brigham Young University and Dr. Simmons and to avoid any reference to reliance on any information or technology received from Brigham Young University or Dr. Simmons.

116. Monsanto's fiduciary relationship with Brigham Young University and Dr. Simmons obligated it to affirmatively "speak the truth." Its affirmative misstatements and deliberate omissions constituted fraudulent concealment. As a result, Brigham Young University and Dr. Simmons did not know, nor reasonably should have known, of their claim until Monsanto's scheme was uncovered.

A. Fraudulent Statements at the Prostaglandin Conference

117. From July 26-31, 1992, Dr. Simmons attended the "International Conference on Prostaglandins and Related Compounds" in Montreal. During the

conference, Dr. Simmons invited Dr. Needleman to lunch. Dr. Needleman accepted. The lunch took place at a Chinese restaurant near the conference center.

118. Dr. Simmons's purpose for setting up the lunch was to persuade Dr. Needleman to reinstate the Agreement or, at a minimum, understand why Monsanto had acted so abruptly. This was Dr. Simmons's first opportunity to meet with Dr. Needleman since Monsanto had terminated the Agreement.

119. During the lunch, Dr. Simmons expressed his frustration that Monsanto had terminated the Agreement and refuted the reasons for termination.

120. Dr. Simmons described the progress Brigham Young University had made, explaining that his laboratory had identified a potential lead compound for a COX-2 selective NSAID. Of course, Dr. Simmons did not know, and Dr. Needleman did not disclose, that Monsanto was secretly testing and developing its own lead compounds derived from DuP-697.

121. Dr. Needleman denied that the reasons for terminating the Agreement were false and represented to Dr. Simmons that Monsanto had done nothing wrong in connection with its relationship with Dr. Simmons or Brigham Young University.

122. Dr. Simmons left the meeting frustrated that Monsanto had terminated the Agreement and feeling that Monsanto had treated him and Brigham Young University poorly. However, Dr. Simmons neither knew nor reasonably could have known that

Monsanto had misappropriated the Project and related CONFIDENTIAL INFORMATION because of Dr. Needleman's misleading conduct.

123. At the end of the Montreal conference, Dr. Masferrer, a Monsanto scientist, approached Dr. Simmons in the foyer of the conference center and asked if he would provide him with RS2 cells, a special cell line used in Dr. Simmons's laboratory.

124. Dr. Simmons responded that, although he had no personal dispute with Dr. Masferrer and was willing to provide the cells to him personally, he was unwilling to provide the cells to Monsanto, explaining that Monsanto had unjustly terminated the Agreement earlier that year.

125. Dr. Needleman was standing nearby. When Dr. Masferrer reported what Dr. Simmons had said, Dr. Needleman looked over towards Dr. Simmons and loudly proclaimed that he (Dr. Needleman) was not dishonest.

B. Further Misrepresentations by Dr. Needleman

126. In March 1997, Dr. Simmons attended a prostaglandin conference in Cannes, France. Dr. Simmons had not seen or spoken to Dr. Needleman since the 1992 conference in Montreal.

127. Dr. Simmons was eating breakfast in the ballroom of the hotel hosting the conference when Dr. Needleman approached and asked if he could join him.

128. Dr. Needleman began the conversation discussing one of the conference presentations. He then turned the discussion to the subject of COX-2 and represented to

Dr. Simmons that he had discovered COX-2 well before Dr. Simmons had and that he had convinced the scientific community of his discovery.

129. Because of Monsanto and Dr. Needleman's systematic fraudulent concealment of the true facts, Dr. Simmons did not have the factual basis, alleged above, to disprove Dr. Needleman's claim. Moreover, Dr. Simmons did not have access to Monsanto's internal scientific documentation that would be needed to expose Dr. Needleman's ongoing deception.

C. Misrepresentations in Patents

130. In at least two Monsanto patents, 5,420,343 dated May 30, 1995, and 5,476,944 dated December 19, 1995, Monsanto fraudulently misrepresented that its cell testing systems were constructed using human or murine COX-1 or COX-2 fragments from "Cayman Chemical, Ann Arbor, Mich."

131. Dr. Simmons has recently learned that these cell systems were not made using COX-1 or COX-2 fragments from Cayman Chemical but in at least one case, were made using the clones Dr. Simmons had provided to Monsanto.

D. Misrepresentations to the Food and Drug Administration

132. On December 1, 1998, Monsanto began making presentations to the Food and Drug Administration (FDA) applying for a special, fast track approval of Celebrex, arguing that the drug was a new class of drugs – a COX-2 selective NSAID.

133. For example, Monsanto presented slides before the FDA showing Celebrex would block COX-2, but not COX-1. Additionally, Dr. Needleman and Monsanto's Dr.

Isakson made statements to the FDA again misrepresenting and concealing Monsanto's true role in the development of Celebrex:

(a) "[W]e watched from the birth of the concept of the COX-2 inhibitors in our laboratories to the fruition and completion of a major clinical trial."

(b) "A second enzyme, a uniquely induced enzyme as we thought in 1990, we named COX-2…"

(c) "Based on the existence of COX-2, we then developed specific COX-2 inhibitors that could go after these rational drug targets but be devoid and spare COX-1 activity."

134. Monsanto omitted Dr. Simmons and Brigham Young University's work, instead misrepresenting that Monsanto had independently discovered and identified COX-2 and given "birth" to the "concept of the COX-2 inhibitors" such as Celebrex.

135. Monsanto's statements were intended to mislead hearers and readers that scientists at Monsanto had independently discovered and identified COX-2. These statements were false, but could not be disproved because they were attributed to the research purportedly carried out "in our [Monsanto's] laboratories."

E. Monsanto's Fraudulent Press Releases and Reports

136. Within a short time after fraudulently terminating the Agreement, Monsanto launched a public relations campaign to convince the world that Dr. Needleman had discovered COX-2. When making this claim, Monsanto failed to disclose that it had no COX-2 selective NSAID testing program before its relationship with Dr. Simmons but, instead, was pursuing its steroid-like project, which to date has

been unsuccessful. This public relations campaign is evidenced by, among others, the press releases detailed below.

137. A July 8, 1996, M2 Press Wire release states: "In the 1980s, Dr. Needleman and other researchers pointed the way toward a potential solution when they discovered that PGs [prostaglandins] are produced by two forms of an enzyme called 'cyclooxygenase' – COX-1 and COX-2." The press release quotes Dr. Needleman, "These early results indicate that Celecoxib may be a medication that can relieve pain and inflammation without putting the patient at risk for gastrointestinal damage;" however, the press release does not mention that Dr. Simmons first identified COX-2 and that Monsanto misappropriated the PROJECT.

138. A 1996 annual report to shareholders, filed with the Securities and Exchange Commission on March 21, 1997, fraudulently gave credit to Monsanto, not Dr. Simmons, for the discovery of COX-2, stating:

(a) "Phil's research team uncovered two types of cyclo-oxygenase - - COX-1 and COX-2."

(b) "[Needleman] … formed a molecular pharmacology group to start the hunt for a new inhibitor that would block the inflammation caused by COX-2, while keeping the stomach protection of COX-1. Celecoxib was born from this work..."

(c) "Phil Needleman is one of the few scientists who may see their dreams through - - all the way from the test tube to a human drug proven safe and effective, and approved for use worldwide. His lifetime commitment to solving the puzzle of inflammation could lead [Monsanto] to one of its biggest breakthrough drugs."

139. These statements in the 1996 annual report to shareholders were intended to mislead its readers that Dr. Needleman and other Monsanto scientists, not Dr. Simmons, identified and discovered COX-2, conceived the idea of a COX-2 selective NSAID project, and pioneered the testing system that led to a COX-2 selective NSAID.

140. Other press releases continued to reflect Monsanto's ongoing propaganda to misrepresent Dr. Needleman's contribution and cover up Dr. Simmons's contribution.

(a) A November 4, 1996, *Biotechnology News Watch* article entitled "Enzyme Inhibitor has potential as therapy for arthritis pain," stated: "Philip Needleman, a scientist with Searle, who spearheaded research into the COX cascade, discovered that two different COX enzymes were at work in the cascade that produces pain in rheumatoid arthritis."

(b) A December 14, 1998, *U.S. News and World Report* article, entitled "Outfoxing Pathways of Pain" stated: "Philip Needleman, ... was instrumental in figuring out in the 1980's that two enzymes help make prostaglandins, dubbed COX-1 and COX-2, and that COX-2 was the driver of the disease's symptoms."

(c) A November 10, 1999, *PR Newswire* article entitled "Celebrex (™) wins Popular Science 'Best Of What's New' Award; Arthritis Treatment Named 'Scientific Advance'" states: "Dr. Needleman first hypothesized the existence of two COX enzymes in the human body: COX-1 helps to regulate normal cell function in the stomach and blood, and COX-2 plays a role in causing pain and inflammation. This discovery led to the development of Celebrex."

(d) A March 10, 2000, *PR Newswire* release entitled "Two Teams Named Winners of Monsanto Science and Technology Award" quotes Dr. Needleman: "It was only the discovery that there are two forms of the COX enzyme - - COX-1 that is present throughout the body and COX-2 that is present at sites of inflammation - - that enabled us to alleviate pain with fewer side-effects. This [Searle] team developed the first selective COX-2 inhibitor, which led to a revolutionary treatment of arthritis for millions worldwide."

(e) A July 11, 2001, statement of Dr. Needleman before the Labor, Health and Human Services, and Education Subcommittee states: "Our studies into the underlying processes that cause the swelling, pain and stiffness of osteo- and rheumatoid-arthritis led to the discovery of a protein-gene called Cox-2 (cyclooxygenase) that is not present in normal stomach or colon tissue but is turned on by tissue injury, inflammation, and various body chemicals released by disease processes."

(f) A February 22, 2002, *PR Newswire* article entitled "Needleman Appointed Science Adviser to Pharmacia Board of Directors and Board Member of Monsanto Company" states: "Needleman is widely credited as the 'father' of the COX-2 inhibitor platform that is revolutionizing the treatment of inflammation-related disease, including Celebrex, the world's leading prescription treatment for arthritis."

(g) A February 22, 2002, *PR Newswire* article entitled "Monsanto Announces Changes to Its Board of Directors" states: "Dr. Needleman has made a number of important contributions in the field of pharmacology, including the discovery of the inflammatory cyclooxygenase-2 (COX-2). This discovery was critical to the development of a new class of arthritis medicines designed to treat the pain and inflammation of osteoarthritis and adult rheumatoid arthritis."

VI. BRIGHAM YOUNG UNIVERSITY BEGINS TO LEARN THE TRUTH

141. Dr. Needleman had represented to investors, elected officials, governmental regulatory agencies, the public, the scientific community and to Dr. Simmons that Monsanto had independently discovered COX-2 and had conceived the concept of a COX-2 selective NSAID. Brigham Young University and Dr. Simmons did not know, nor reasonably should they have known, that Monsanto developed Celebrex from the PROJECT. As demonstrated below, positions taken by Monsanto in Celebrex litigation, and certain limited discovery, revealed to Brigham Young University that Monsanto

misappropriated the PROJECT and used CONFIDENTIAL INFORMATION in developing Celebrex.

142. In mid-1998, the pharmaceutical company Merck contacted Dr. Simmons and asked him to testify in Monsanto's patent infringement litigation against Merck. Merck provided Dr. Simmons with publications in which Dr. Needleman appeared to take sole credit for the discovery of COX-2. Merck also told Dr. Simmons that Monsanto's early COX-2 work had been done with clones derived from mouse. This information raised Dr. Simmons's suspicions because some of the clones Dr. Simmons had first provided to Monsanto in 1991 were from mouse.

VII. BRIGHAM YOUNG UNIVERSITY CONFRONTS MONSANTO

143. By summer of 1998, with his suspicions triggered by the conversations with Merck, Dr. Simmons notified Brigham Young University's General Counsel's office who investigated the matter and then contacted Monsanto's General Counsel's office to inquire about the use of CONFIDENTIAL INFORMATION from the PROJECT in developing Celebrex.

144. Despite Brigham Young University's reasonable inquiries, Monsanto continued to fraudulently deny and conceal that they had taken the PROJECT and used Dr. Simmons's CONFIDENTIAL INFORMATION in developing COX-2 selective NSAIDs.

A. Correspondence

145. When Brigham Young University contacted Monsanto by telephone in late 1998, Monsanto denied having ever worked with Dr. Simmons, or in fact, even knowing who Dr. Simmons was. When confronted with the signed Agreement, Monsanto admitted to working with Dr. Simmons but continued to deny taking the PROJECT.

146. On December 9, 1999, Brigham Young University's in-house counsel, Eugene Bramhall, wrote to William Ide, then General Counsel for Monsanto, setting forth certain of Brigham Young University and Dr. Simmons's concerns regarding Monsanto's conduct.

147. Five weeks later, in a telephone call with Mr. Bramhall, Monsanto's Joe Bullock categorically denied the allegations in Mr. Bramhall's letter.

148. On March 17, 2000, Dale H. Hoscheit, an attorney at the law firm of Banner & Witcoff, Ltd. wrote Mr. Bramhall on Monsanto's behalf.

149. Mr. Hoscheit's letter again denied Mr. Bramhall's allegations and implications, claiming:

(a) Monsanto scientists "... were not successful in obtaining meaningful replication [of Simmons's mouse COX-2]."

(b) Monsanto had obtained another mouse COX-2 cDNA construct from a third-party source.

(c) Monsanto did not obtain "an immediate, significant and unique advance" in this area because of Professor Simmons.

(d) It was not until Monsanto modified another mouse COX-2 construct from a third party source in 1992 that it was able to gain meaningful expression

and Monsanto's testing with mouse COX-2 was based upon that later effort.

150. On or about March 29, 2000, Brigham Young University's counsel and Dr. Simmons sent Monsanto a letter asking fifteen specific questions. Monsanto never squarely addressed these questions in its May 17, 2000, response; however, the parties agreed to meet in Skokie, Illinois, June 1, 2000.

151. During the meeting, Monsanto again fraudulently denied having used Dr. Simmons's CONFIDENTIAL INFORMATION to screen COX-2 selective NSAIDs in general, or Celebrex in particular. Further, Monsanto gave Brigham Young University limited access to Dr. Seibert's notebooks to demonstrate that it had not used Dr. Simmons's research and tools in developing Celebrex. However, Dr. Seibert's notebooks demonstrated the opposite. Dr. Seibert's notebooks evidenced that Monsanto had extensively and successfully used Dr. Simmons's clones. Monsanto refused Brigham Young University and Dr. Simmons's access to the complete notebooks by sealing parts with large metal clips. Monsanto fraudulently misrepresented that the clipped portion related to other, unrelated, confidential projects. In fact, Brigham Young University later discovered that the clipped pages contained the result of Monsanto's NSAID testing for COX-2 selectivity.

152. A notebook entry revealed that Monsanto had tested the COX-2 clones of a UCLA researcher (Dr. Harvey Herschman) without success. (Dr. Herschman had published a separate discovery of COX-2 after Dr. Simmons.) The next entry indicated

that Dr. Seibert planned to continue the work with the old clones or, in other words, those provided by Dr. Simmons. The very next entries in Dr. Seibert's notebooks were clipped so that Dr. Simmons would not read them.

153. Dr. Simmons confronted Dr. Seibert with what he had seen in her notebooks. However, continuing the pattern of fraudulent concealment, Dr. Seibert emphatically stated that Dr. Simmons's clones had not worked and said that Dr. Simmons's clones had led to "18 months of failed experiments." Previously, Monsanto and Dr. Seibert had asserted that Monsanto had used Dr. Simmons's clones for only three months.

B. Tolling Agreement and Mediation

154. In June 2000, Brigham Young University was alerted to Monsanto's fraudulent concealment and investigated further. As the intricate layers of Monsanto's deceptions were laid bare, Brigham Young University only then understood the magnitude of the fraud and related financial harm Monsanto had inflicted. On May 8, 2001, Brigham Young University and Monsanto entered into a tolling agreement preserving Brigham Young University and Dr. Simmons's claims against Monsanto. Since entering the tolling agreement, Brigham Young University has reasonably attempted to mediate this dispute. That effort has failed and this Complaint results.

VIII. COX-2 LITIGATION HAS REVEALED THAT MONSANTO USED DR. SIMMONS'S CONFIDENTIAL INFORMATION TO TEST AND DEVELOP CELEBREX.

155. Celebrex was approved for clinical use by the FDA on December 31, 1998, and was launched for sale shortly thereafter in January 1999. Since the launch of Celebrex, Monsanto has been involved in various lawsuits to protect its Celebrex patent and Monsanto has initiated lawsuits to gain rights over Merck's patents.

156. In May 1999, four months after the launch of Celebrex, Merck launched Vioxx, its own COX-2 selective NSAID. Upon Merck's launch of Vioxx, Searle [Monsanto] announced that it was suing Merck worldwide, contending that Vioxx's structure was covered by a class of Monsanto patents on compounds related to Celebrex.

157. In addition, Searle [Monsanto] was sued by the University of Rochester on April 11, 2000. The University of Rochester claimed that Celebrex violated a University of Rochester COX-2 related patent. About the same time, the Patent Trademark Office ("PTO") initiated an interference action between the University of Rochester and Merck who each held patents on the sequence and use of human COX-2.

158. Because Dr. Simmons was an expert in the COX-2 field, and a witness to the history of COX-2, various parties to these lawsuits approached him and asked him to testify. Merck asked Dr. Simmons to testify as an expert in the Searle [Monsanto] v. Merck litigation in Great Britain. Additionally, Dr. Simmons was asked to testify as a fact witness in the Rochester v. Searle [Monsanto] litigation and as an expert witness in the Rochester v. Merck patent interference action.

A. **The Isakson Statement.**

159. Through Dr. Simmons's participation in these lawsuits, he received information from Monsanto documents contradicting Monsanto's prior statements made to fraudulently conceal Monsanto's wrongdoing.

160. Dr. Simmons promptly informed the Brigham Young University General Counsel's office; and, around October of 2000, Brigham Young University General Counsel ordered copies of transcripts from Monsanto's litigation against Merck from Great Britain.

161. Dr. Simmons was shown orally read pages from a signed witness statement and various trial transcripts of Dr. Peter Isakson, a scientist at Searle [Monsanto] and the head of the COX-2 selective NSAID project. Dr. Isakson had given the statements and trial testimony on August 23, 1999, and October 8 and 11, 1999, respectively. Dr. Isakson made clear in his statement that, before meeting Dr. Simmons, Monsanto was not pursuing a COX-2 selective NSAID project. For example, Dr. Isakson stated:

> [I]n 1991, Monsanto were not looking for a compound with NSAID-like activity as it was doubted that an NSAID selective for the inducible form of COX could be produced.

162. As Dr. Isakson explained, "Dr. Needleman's team was focusing on steroid-related research, rather than non-steroid anti-inflammatory drugs (NSAIDs)."

163. Dr. Isakson also stated in his signed witness statement that compounds with NSAID-like activity were "excluded", and "rejected" from Monsanto's project.

Monsanto only screened for NSAID-like compounds so that it could exclude them from its testing systems: … "If a low concentration of prostaglandin was detected, the test compound was rejected (since it must have exhibited NSAID-like activity)."

164. Dr. Isakson's statements made it clear to Dr. Simmons that Monsanto was not looking for a COX-2 selective NSAID before meeting Dr. Simmons. Monsanto only changed course to pursue a COX-2 selective NSAID after meeting Dr. Simmons and then hid important information from Dr. Simmons and Brigham Young University.

165. Dr. Isakson cryptically testified where Monsanto had developed its cell assays for testing DuP-697: "It was fortuitous that in the course of the [steroid research project] Dr. Seibert and her team had developed a whole cell assay that could be used to test compounds for selective Cox inhibition."

166. "Fortuitous" is an intentionally deceptive rewriting of history. From April 1991 until November/December 1992, the only assay available to Monsanto for distinguishing COX-specific NSAIDs from non-specific NSAIDs was the two cell assay developed by Dr. Seibert. Human fibroblast cells used in Dr. Seibert's assay were characterized for COX-2 expression using probes generated from Dr. Simmons's COX-2 clone beginning as early as June 1991.

B. <u>The Rochester Litigation.</u>

167. Upon information and belief, Searle [Monsanto] made further statements in its litigation against the University of Rochester, that were contrary to Monsanto's fraudulent statements. For example, Brigham Young University has obtained briefs

which were filed by the University of Rochester in 2001 in support of its motion to compel Defendant G. D. Searle & Co., Inc. to produce documents. According to the briefs, Searle [Monsanto] had claimed that "Brigham Young's scientists were the first to identify methods of treatment using selective Cox-2 inhibitors...." Thus, upon information and belief, Searle [Monsanto] had taken the position in the Rochester litigation that Dr. Simmons was the first to identify COX-2 and its potential treatments.

168. For the first time, this information gave Dr. Simmons a reasonable basis for knowing that Monsanto's statements regarding Monsanto's supposed pre-existing COX-2 NSAID discovery program were fraudulent.

169. Dr. Simmons and Brigham Young University learned of the Isakson statement in approximately 2001. Dr. Simmons and Brigham Young University learned of the information from the University of Rochester litigation no earlier than 2004.

IX. CLAIMS FOR RELIEF

COUNT I
(BREACH OF WRITTEN CONTRACT)

170. Brigham Young University and Dr. Simmons incorporate by reference and reallege all other allegations of the Complaint as though set forth in their entirety herein.

(a) ¶ 1.3

171. Pursuant to ¶ 1.3 of the Agreement, among other things, Monsanto agreed that the PROJECT and all work assigned would be carried out under the direction of Dr.

Simmons, the Project Director. The PROJECT included the search for a COX-2 selective NSAID with the use of CONFIDENTIAL INFORMATION.

172. Monsanto breached the contractual duties specified above when it usurped the PROJECT and began conducting research outside of Dr. Simmons's direction.

(b) ¶ 1.6

173. Pursuant to ¶ 1.6 of the Agreement, Monsanto agreed, among other things, to furnish prostaglandins, NSAIDs and consulting services.

174. Monsanto breached the contractual duties specified above when it failed to furnish prostaglandins, NSAIDs, or consulting services to Dr. Simmons and Brigham Young University. For example, Monsanto failed to provide DuP-697 or its derivatives to Brigham Young University even though they had the greatest potential for being COX-2 selective NSAIDs. Monsanto also failed to provide consulting services that would have promoted Monsanto and Brigham Young University's cooperative effort to achieve the Agreement's objectives.

(c) ¶ 3.1

175. Pursuant to ¶ 3.1 of the Agreement, Monsanto agreed, among other things, that title to all discoveries and inventions, whether or not patentable or patented would be determined as follows:

176. If one or more Brigham Young University personnel only are inventors, title shall belong to Brigham Young University;

177. If one or more MONSANTO personnel only are inventors, title shall belong to MONSANTO; and

178. If one or more personnel of Brigham Young University and MONSANTO are joint inventors, title shall belong jointly to Brigham Young University and MONSANTO.

179. Monsanto breached the contractual duties specified above when it failed to inform Brigham Young University of its title to patentable discoveries resulting from the PROJECT in which Brigham Young University was the inventor or, at a minimum, a joint inventor.

(d) ¶ 3.3

180. Pursuant to ¶ 3.3 of the Agreement, among other things, Monsanto owed Brigham Young University a duty to notify Brigham Young University of research results obtained from the PROJECT that were patentable and indicate its interest in a license from Brigham Young University under such prospective patents.

181. Monsanto breached its contractual duties to Brigham Young University by failing to notify Brigham Young University of the patentable research results obtained from the PROJECT.

(e) ¶ 3.4

182. Pursuant to ¶ 3.4 of the Agreement, Monsanto owed Brigham Young University a duty to negotiate in good faith the terms and conditions of a royalty-bearing

license agreement with a right to sublicense on all patented inventions developed in the PROJECT.

183. Furthering its prior breach of failing to notify BYU of patentable results from the PROJECT, Monsanto breached its contractual duties to Brigham Young University by failing to negotiate a royalty for Brigham Young University on such patented inventions resulting from the PROJECT.

(f) ¶ 3.5

184. Pursuant to ¶ 3.5 of the Agreement, Monsanto owed Brigham Young University a duty to allow Brigham Young University to designate, at its sole option, a patent attorney, either from Monsanto or in private practice, to file and prosecute a patent application with regard to any patentable research results obtained from the PROJECT.

185. Monsanto breached its contractual duties to Brigham Young University by keeping from Brigham Young University the patentable research results and unilaterally designating a patent attorney to file and prosecute the patentable results from the PROJECT solely for the benefit of Monsanto. Had Monsanto complied with this provision, Brigham Young University would have been alerted to Monsanto's clandestine actions.

(g) ¶ 3.6

186. Pursuant to ¶ 3.6 of the contract, Monsanto owed Brigham Young University a duty to bear the cost for filing and prosecution of patent applications and issuance and maintenance of patents on Brigham Young University's behalf. Monsanto

also owed a duty to Brigham Young University to promptly communicate its election to not file or prosecute a patent application in adequate time to allow Brigham Young University to take such action if it so desired.

187. Monsanto breached these duties by failing to ever notify Brigham Young University of patentable results obtained from the PROJECT.

(h) ¶ 3.7

188. Pursuant to ¶ 3.7 of the Agreement, Monsanto owed Brigham Young University a duty to, among other things, allow Brigham Young University the right to "retain patent counsel of its own who shall be permitted to review" patent applications and proposed responses to Patent Office actions and to "consult with MONSANTO'S patent attorneys."

189. Monsanto breached its contractual duties under ¶ 3.7 by interfering with Brigham Young University's ability to exercise that right. Had Monsanto complied with this provision, Brigham Young University would have been alerted to Monsanto's clandestine actions.

(i) ¶ 3.11

190. Pursuant to ¶ 3.11 of the Agreement, Monsanto owed Brigham Young University a duty to make reasonable efforts to effect the lawful introduction of licensed products into the market place as early as practicable.

191. Monsanto breached its contractual duties to Brigham Young University by failing to notify Brigham Young University that it had unilaterally patented compounds

obtained through the PROJECT and was bringing them to market unilaterally. Thus, Monsanto also breached its duty to introduce licensed products into the market on Brigham Young University's behalf and for its benefit.

(j) ¶¶ 4.1(a), (b), and (c)

192. Pursuant to ¶¶ 4.1(a), (b), and (c) of the Agreement, among other things, Monsanto owed Brigham Young University a duty to (1) hold any and all CONFIDENTIAL INFORMATION received pursuant to the agreement in confidence and not to disclose such information to third parties without the written consent of the other; (2) limit the disclosure of CONFIDENTIAL INFORMATION to those personnel who need such access for purpose of this cooperative effort and who have undertaken the obligation to restrict the use and disclosure of CONFIDENTIAL INFORMATION to the extent provided by the agreement; and (3) to not duplicate or use CONFIDENTIAL INFORMATION in any other manner.

193. Among other ways, Monsanto breached the contractual duties specified above when, in 1992, Monsanto, unbeknownst to Brigham Young University, shared CONFIDENTIAL INFORMATION with internal Monsanto personnel conducting secret tests on DuP-697 and its derivatives outside and separate from the PROJECT. And, upon information and belief, Monsanto shared confidential material with other, third-party scientists at Washington University.

194. All CONFIDENTIAL INFORMATION that Dr. Simmons provided prior to the formal execution of the Agreement is covered by ¶ 4.1 for the reasons set forth in

¶¶ 55-64 of this Complaint. In the alternative, either Monsanto is estopped from asserting a contrary position because Monsanto made promises to Dr. Simmons that induced his actions, or on implied-in-fact contract existed that the transmitted CONFIDENTIAL INFORMATION would be covered by the Agreement.

(k) ¶ 4.2

195. Pursuant to ¶ 4.2 of the Agreement, once Monsanto obtained a license from Brigham Young University, among other things, it owed Brigham Young University a duty not to furnish any third party, without Brigham Young University's prior written consent, any chemical or biological material, including DNA sequences and vectors, supplied by Brigham Young University under the Agreement.

196. Monsanto breached its contractual duties to Brigham Young University when it sent patent applications to the PTO for publication of patents and patent notices without first obtaining Brigham Young University's prior written consent.

(l) Wrongful Termination

197. Pursuant to ¶ 1.4, the Agreement was to remain in force from August 1, 1991 to July 31, 1993.

198. Monsanto breached its contractual duties to Brigham Young University by fraudulently terminating the Agreement prior to July 31, 1993 under false pretenses. Because Monsanto's termination was wrongful, it did not relieve Monsanto of its duties under the contract.

confidentiality provisions of the Agreement; 5) induced Brigham Young University to share its CONFIDENTIAL INFORMATION as part of a purported cooperative effort when Monsanto's intent was to use it solely for Monsanto's benefit; 6) used the Agreement as a tool to further Monsanto's fraudulent scheme to misappropriate the PROJECT and related CONFIDENTIAL INFORMATION; and 7) otherwise failed to fulfill its obligations and duties under the contract.

204. Monsanto's breach of the duty of good faith and fair dealing caused Brigham Young University damages in the amount to be proven at trial but presently estimated to be significantly in excess of $1 billion.

COUNT III
(BREACH OF FIDUCIARY DUTY)

205. Brigham Young University and Dr. Simmons incorporate by reference and reallege all other allegations of the Complaint as though set forth in their entirety herein.

206. Monsanto assumed a fiduciary duty towards Brigham Young University and Dr. Simmons based on, among other things, the factors described in ¶ 81 of the Complaint.

207. As a result of the fiduciary relationship, Monsanto owed Brigham Young University and Dr. Simmons a duty of loyalty, of candor, of due care and a duty to act in Brigham Young University and Dr. Simmons's best interests.

208. Monsanto breached its fiduciary duty to Brigham Young University and Dr. Simmons by wrongfully and deceitfully taking the PROJECT and CONFIDENTIAL

INFORMATION, using it for Monsanto's economic benefit, and generating billions of dollars in revenue from, among others, the drug Celebrex.

209. Monsanto breached its fiduciary duty to Brigham Young University by failing to advise Brigham Young University of patentable results obtained from the PROJECT.

210. Monsanto breached its fiduciary duty to Brigham Young University and Dr. Simmons by engaging in the other deceitful and wrongful actions described in this Complaint.

211. Monsanto's actions were detrimental to Brigham Young University and Dr. Simmons, because Brigham Young University and Dr. Simmons should have benefited from the results of the PROJECT.

212. Monsanto's breach of fiduciary duty has caused Brigham Young University and Dr. Simmons damages in an amount to be proven at trial.

COUNT IV
(CORRECTION OF INVENTORSHIP UNDER 35 U.S.C. § 256)

(United States Patent Nos. 5,380,738; 5,393,790; 5,418,254; 5,420,343; 5,466,823; 5,476,944; 5,486,534; 5,547,975; 5,563,165; 5,565,482; 5,576,339; 5,580,985; 5,596,008; 5,616,601; 5,620,999; 5,633,272; 5,643,933; 5,663,180; 5,668,161; 5,670,510; 5,670,532; 5,672,626; 5,672,627; 5,686,470; 5,696,143; 5,719,163; 5,736,579; 5,739,166; 5,756,529; 5,756,530; 5,760,068; 5,859,257; 5,886,016; 5,908,852; 5,916,905; 5,935,990; 5,985,902; 6,028,072; 6,034,256; 6,077,850; 6,090,834; 6,156,781; 6,271,253; 6,274,590; 6,395,724; 6,413,960; 6,426,360; 6,432,999; 6,492,390; 6,492,411; 6,492,413; 6,512,121; 6,515,014; 6,586,603; 6,599,934; 6,613,789; 6,613,790; 6,649,636; 6,649,649; 6,673,818; 6,677,364; 6,677,488; 6,696,477; 6,699,884; 6,716,991; 6,753,344; 6,806,288; 6,809,111; 6,822,102; 6,846,818; 6,875,785; 6,951,949; 6,964,978; 7,012,094; 7,030,153)

213. Brigham Young University and Dr. Simmons incorporate by reference and reallege all other allegations of the Complaint as though set forth in their entirety herein.

214. On numerous occasions, Monsanto scientists, including, but not limited to, Bryan H. Norman, Len F. Lee, Jaime L. Masferrer, and John J. Talley, through their patent agents, filed various applications in the United States Patent and Trademark Office (the "PTO") for issuance of one or more United States patents. The PTO eventually granted many of these applications resulting in, but not limited to, the patents listed above. These patents were all based on the work of Dr. Simmons.

215. Based upon his activities, contributions, and inventorship prior to the filing dates of the patent applications underlying the above-listed patents, Dr. Simmons should have been listed as an inventor on each of the patents listed above. Furthermore, he would have been listed as an inventor if Brigham Young University had been accorded its rights in the patenting process as required by, among others, ¶ 3.5 of the Agreement.

216. Dr. Simmons contributed substantially to the conception of each invention forming the subject matter of the above-listed patents by providing the named inventors with data, ideas, insights, materials, and technologies that were not then publicly available and were known only to Dr. Simmons and that were the product of Dr. Simmons's own research and invention. Indeed, each of the inventions forming the subject matter of the above-listed patents would have been impossible without Dr. Simmons's unique contribution at the time of his participation in the inventive process

223. Monsanto accepted and retained the benefit from Brigham Young University and reaped billions of dollars in revenues as a result. For the reasons described in this Complaint, Monsanto has been unjustly enriched by its acceptance of the benefit conferred upon it by Brigham Young University. Under the circumstances, it would be inequitable for Monsanto to retain those benefits.

224. Under applicable law, Brigham Young University is entitled to restitution in the amount of Monsanto's gain, including the profits from all COX NSAIDs.

COUNT VI
(FRAUD)

225. Brigham Young University and Dr. Simmons incorporate by reference and reallege all other allegations of the Complaint as though set forth in their entirety herein.

226. Through their relationship, Monsanto made various misrepresentations to Brigham Young University. These misrepresentations include at least the following:

(a) In 1991, before Brigham Young University entered into the Agreement with Monsanto, Monsanto personnel, including Barry Haymore, misrepresented to Dr. Simmons that he should not get a patent on his COX-2 technology which included his isolated COX-2 and COX-2 cDNA clones, their nucleic acid sequences, and predicted amino acid sequences and his COX-2 antibodies. Upon information and belief, Monsanto and Dr. Haymore were fully aware that Dr. Simmons's discoveries were patentable because of Monsanto's extensive experience in the pharmaceutical and biotechnology industry. Upon information and belief, Monsanto personnel made this misrepresentation and never corrected it because they understood that if Brigham Young University and Dr. Simmons were to patent its COX-related technology, Brigham Young University and Dr. Simmons would be in a position to control and coordinate all future research and discoveries regarding COX-2 to the exclusion of Monsanto (and all others).

(b) Prior to the execution of the July 8, 1991, Agreement, Dr. Needleman, on Monsanto's behalf, misrepresented to Dr. Simmons that Monsanto was giving Brigham Young University the same agreement Monsanto had given Dr. Needleman when he was a professor at Washington University and that the agreement fully protected Dr. Simmons and gave Brigham Young University the right to and ownership of the results of the collaborative project. Dr, Needleman also misrepresented to Dr. Simmons during this same time period Monsanto would enter into a full collaboration with Brigham Young University in which both Monsanto and Brigham Young University would work together in a cooperative effort to develop a COX-2 selective NSAID.

(c) On March 17, 1992, Dr. Philip Needleman sent Brigham Young University a letter on Monsanto's behalf misrepresenting that Brigham Young University had not sufficiently communicated with Monsanto.

(d) On March 23, 1992, Dr. Philip Needleman, on behalf of Monsanto, sent Dr. Simmons a letter indicating that he viewed Monsanto and Brigham Young University's relationship as "an unworkable collaboration." Dr. Needleman misrepresented five issues as the basis for his "annoyance": "(1) that you only supplied us with the first bleed of your chicken based antibody and surely you did your own experiments with superior bleeds; (2) that you never included us in any aspect or discussion of the dexamethasone data while you knew that was a critical scientific interest of ours having discovered the phenomenon; (3) not informing us or sharing the RS-2 cells which could have been an extremely valuable screening tool for us; (4) the slowness with which you have proceeded in testing compounds; and (5) the ease with which you established outside collaborations but with no similar desire with our programs."

(e) Monsanto misrepresented in the Agreement that it would provide NSAIDs to Brigham Young University for testing.

(f) On July 27, 1992, while attending the Montreal prostaglandin conference, Dr. Needleman misrepresented to Dr. Simmons that everything relating to the PROJECT and the termination of the Agreement had been done honestly.

(g) At the March 1997 conference in France, Dr. Needleman misrepresented to Dr. Simmons that he and his laboratory had discovered COX-2 before Dr. Simmons. Monsanto continued to misrepresent its use of

CONFIDENTIAL INFORMATION obtained pursuant to the Agreement and the nature and extent of its own scientific discoveries as described earlier in this Complaint.

(h) In at least two patents, 5,420,343 (May 30, 1995) and 5,476,944 (December 19, 1995) Searle [Monsanto] misrepresented that it had used human or murine COX-1 or COX-2 from "Cayman Chemical, Ann Arbor, Mich." To construct its cell systems as a further fraudulent attempt to distance itself from Brigham Young University and Dr. Simmons.

(i) In various press releases and publications, Monsanto directly misrepresented, or fraudulently allowed the press to misrepresent, that Dr. Needleman, not Dr. Simmons, discovered COX-2 and conceived the concept of COX-2 selective NSAIDs as described above in Section V (E).

(j) On March 21, 1997, in the 1996 annual report to shareholders filed with the Securities and Exchange Commission, Monsanto and Dr. Needleman misrepresented that Dr. Needleman had discovered COX-2; "Philip's research team uncovered two types of cyclooxygenase – COX-1 and COX-2.

(k) In late 1998, Monsanto misrepresented to the FDA its role in the discovery of COX-2 and the conception of COX-2 selective NSAIDs.

227. The misrepresentations in ¶ 226 (h)-(k) were not made directly to Brigham Young University or Dr. Simmons but illustrate a portion of Monsanto's campaign to misrepresent facts to its investors, elected officials, governmental regulatory agencies, the public and to the scientific community of which Dr. Simmons was a part.

228. In addition to the direct misrepresentations Monsanto made to Brigham Young University, Dr. Simmons, and the public, Monsanto made misrepresentations to Brigham Young University by way of fraudulent omissions.

229. As a party to a business transaction with and related duties running to Brigham Young University, Monsanto was obligated to disclose:

(a) Matters known to Monsanto by virtue of the fiduciary duty described above;

(b) Matters that Monsanto knew Brigham Young University would need to understand in order to make Monsanto's other statements not misleading;

(c) Subsequently acquired information that Monsanto knew would make previous statements untrue or misleading;

(d) Untrue statements Monsanto originally thought Brigham Young University would not rely on, when Monsanto realized that Brigham Young University was in fact relying on them;

(e) Facts basic to the Agreement that Monsanto knew Brigham Young University was mistaken about and that Monsanto knew Brigham Young University expected it to disclose based on their relationship; and

(f) All material information that the Agreement, including ¶ 1.6 and ¶ 3.3, obligated Monsanto to disclose to Brigham Young University.

230. Therefore, Monsanto was under a duty to disclose to Brigham Young University and Dr. Simmons at least the following:

(a) Monsanto secretly began a parallel project seeking a COX-2 inhibiting NSAID with the use of the CONFIDENTIAL INFORMATION.

(b) Monsanto tested DuP-697 and found it to be COX-2 selective and a potential lead compound in the search for a COX-2 selective inhibitor.

(c) Brigham Young University could have applied for various patents, including those described in ¶ 95 of this Complaint. Contrary to its obligation to do so, Monsanto failed to correct its prior misrepresentations.

(d) Monsanto and Dr. Needleman did not intend to enter into a collaborative project with Brigham Young University that would provide Brigham Young University with the rights to and ownership of the results of the PROJECT, but intended to use the Agreement as a method of taking the PROJECT and CONFIDENTIAL INFORMATION for its own use and economic benefit.

(e) Monsanto terminated the Agreement with Brigham Young University not because Dr. Simmons was uncommunicative or for the other stated reasons, but because Monsanto intended to use CONFIDENTIAL INFORMATION to create COX-2 selective NSAIDS while excluding Brigham Young University from the economic benefits to which they were entitled under the Agreement.

231. All of the misrepresentations and omissions listed above were material to the status of the research PROJECT between Monsanto and Brigham Young University.

232. The respective Monsanto representatives knew the statements were false when they made them. In the case of omissions, Monsanto knew it had omitted disclosing material information to Brigham Young University and Dr. Simmons. Monsanto intended and reasonably contemplated that Brigham Young University and Dr. Simmons would rely, either directly or indirectly, on the misrepresentations and omissions by not pursuing their economic rights resulting from the PROJECT.

233. Brigham Young University was unaware that Monsanto's misrepresentations were false until years later when Dr. Simmons discovered, through Monsanto's litigation, that Monsanto had not independently identified or isolated COX-2 and did not have its own project to search for a COX-2 selective NSAID prior to Dr. Simmons bringing it to them. Rather, Monsanto made misrepresentations designed to deceive Brigham Young University and Dr. Simmons, terminate the relationship with Brigham Young University, deny Brigham Young University and Dr. Simmons of their rightful professional and economic expectancies, and thwart their reasonable and diligent actions to uncover the truth.

234. Brigham Young University and Dr. Simmons reasonably and justifiably relied upon the truth of Monsanto's misrepresentations, had a right to rely thereupon, and were unaware of the truth because of Monsanto's concealment and misleading conduct.

235. As a consequence of Brigham Young University and Dr. Simmons's justifiable reliance upon Monsanto's misrepresentation, Brigham Young University and Dr. Simmons have been caused damage in an amount to be proven at trial.

COUNT VII
(NEGLIGENT MISREPRESENTATION)

236. Brigham Young University and Dr. Simmons incorporate by reference and reallege all other allegations of the Complaint as though set forth in their entirety herein.

237. Throughout their relationship, Monsanto made various misrepresentations and omissions to Brigham Young University and Dr. Simmons as more extensively enumerated in COUNT VI (Fraud), above.

238. In the alternative to the above alleged fraud claim, Brigham Young University and Dr. Simmons allege that Monsanto made the misrepresentations and omissions negligently.

239. Monsanto had a pecuniary interest in its relationship with Brigham Young University and Dr. Simmons relating to Dr. Simmons's isolation and identification of COX-2 and the related technology. Monsanto supplied Brigham Young University and Dr. Simmons false information for guidance in their business transaction.

240. Monsanto was in a superior position over Brigham Young University to know the material facts regarding, among other things, whether Dr. Simmons's technology was patentable, whether other results obtained from the PROJECT were patentable, how Monsanto used Dr. Simmons's CONFIDENTIAL INFORMATON, and whether Dr. Needleman had in fact discovered COX-2.

241. Monsanto carelessly or negligently made false representations and omissions.

242. Monsanto expected Brigham Young University and Dr. Simmons to rely and act upon Monsanto's representations and omissions.

243. Brigham Young University and Dr. Simmons did reasonably rely on Monsanto's representations and omissions, and Brigham Young University and Dr. Simmons suffered losses as a result.

COUNT VIII
(VIOLATION OF THE UNIFORM TRADE SECRET ACT, UTAH CODE ANN. § 13-24-2 ET SEQ)

244. Brigham Young University and Dr. Simmons incorporate by reference and reallege all other allegations of the Complaint as though set forth in their entirety herein.

245. At the time Dr. Simmons made his April 5, 1991, presentation at Monsanto, and during the course of all subsequent dealings with Monsanto, Dr. Simmons and Brigham Young University maintained "trade secrets" related to their COX-2 discovery and research. These "trade secrets" included, but were not limited to, Dr. Simmons and Brigham Young University's COX-2 mRNA, nucleic acid sequences, mRNA samples

containing COX-2 mRNA, complete COX-1 and COX-2 clones, assays for determining COX-2 selectivity and all other technical direction, and advice and information provided by Dr. Simmons and others who worked with him at Brigham Young University over the telephone and in person during the course of their cooperative effort.

246. Each "trade secret" held by Dr. Simmons and Brigham Young University derived independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who could obtain economic value from its disclosure or use. Specifically, Dr. Simmons and Brigham Young University's COX-2 mRNA sequence, COX-1 and COX-2 clones and antibodies, and assays for determining COX-2 selectivity could be used to develop a COX-2 selective NSAID. But this discovery's value would be minimized if these "trade secrets" were disclosed.

247. Therefore, Dr. Simmons and Brigham Young University took reasonable efforts to maintain the secrecy of the "trade secrets." These efforts included refraining from publishing the murine COX-2 nucleic acid sequence and refusing to deliver his murine COX-1 and COX-2 clones and antibodies to Monsanto until Brigham Young University and Monsanto orally agreed that the CONFIDENTIAL INFORMATION would receive the protection of the confidentiality provisions contained in the draft agreement provided to Brigham Young University. In fact, Dr. Needleman repeatedly

represented that Brigham Young University would receive the same protection he had received at Washington University in connection with dealing with Monsanto.

248. Monsanto willfully and maliciously and in bad faith misappropriated Dr. Simmons and Brigham Young University's "trade secrets" by disclosing and using them without express or implied consent despite the fact that Monsanto acquired the "trade secrets" under circumstances giving rise to a duty to maintain their secrecy and limit their use. Specifically, by July 8, 1991, the Agreement obligated Monsanto to protect Dr. Simmons and Brigham Young University's CONFIDENTIAL INFORMATION that was comprised of its "trade secrets." Additionally, both before the Agreement was put in force and after it was terminated, Dr. Simmons and Brigham Young University's express statements or implied terms made clear that Monsanto was not to use these "trade secrets" outside of the collaborative effort. Alternatively, on information and belief, Monsanto used improper means, including fraudulent inducements, to acquire knowledge of the "trade secrets."

249. Dr. Simmons and Brigham Young University acted reasonably and diligently and could not have discovered Monsanto's misappropriation through the exercise of due diligence before Dr. Simmons's reading of the Peter Isakson statement.

250. Dr. Simmons and Brigham Young University should be awarded attorney fees, injunctive relief, damages comprising actual loss, unjust enrichment, or a reasonable royalty for Monsanto's unauthorized use of the "trade secrets." Additionally, due to the

malicious and willful character of Monsanto's misappropriation, Dr. Simmons and Brigham Young University should be awarded punitive damages.

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants as follows:

A. For actual damages in an amount to be proven at trial or motion, including damages to Brigham Young University and Dr. Simmons;

B. For a directive to issue to the Commissioner of the United States Patent and Trademark Office instructing said Commissioner to issue a certificate of correction in connection with the patents listed in Count IV above attesting to the fact that Dr. Simmons was erroneously omitted as an inventor on that patent and correcting that error by including Professor Simmons among the listed inventors.

C. For prejudgment and post-judgment interest as allowed pursuant to statutory and common law;

D. For punitive damages in an amount to be determined at trial;

E. For attorneys' fees, costs, and expenses of litigation as may be allowed pursuant to statutory and common law; and

F. For such other relief as the Court deems just and proper.

DATED this ____ day of October 2006.

OFFICE OF THE GENERAL COUNSEL

By _____
David B. Thomas (Utah Bar No. 3228)
BRIGHAM YOUNG UNIVERSITY

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CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTION ON THE REVERSE OF THE FORM.)

I(a) PLAINTIFFS
Brigham Young University and Dr. Daniel L. Simmons

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF (EXCEPT IN U.S. PLAINTIFF CASES)

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)
David B. Thomas, Office of the General Counsel
Brigham Young University, A-350 ASB, Provo, UT 84602
801-422-4722 (see attachment)

DEFENDANTS
Pfizer, Inc., G. D. Searle LLC, G.D. Searle & Company, Monsanto Company; and Pharmacia Corporation

FILED
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2006 OCT 18 A 9:05
U.S. DIST. COURT DISTRICT OF UTAH
BY DEPUTY CLERK

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT New York
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION (PLACE AN " X" IN ONE BOX ONLY)

- ☐ 1 U.S. government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (For Diversity Cases Only)

(PLACE AN X IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT)

	PTF	DEF		PTF	DEF
Citizen of This State	☒1	☐1	Incorporated or Principal Place of Business in This State	☐4	☐4
Citizen of Another State	☐2	☐2	Incorporated and Principal Place of Business in Another State	☐5	☒5
Citizen or Subject of a Foreign Country	☐3	☐3	Foreign Nation	☐6	☐6

IV. NATURE OF SUIT (PLACE AN X IN ONE BOX ONLY)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholder Suits
- ☒ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury--Med Malpractice
- ☐ 365 Personal Injury--Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence Habeas Corpus
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Others
- ☐ 550 Civil Rights

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 RR & Truck
- ☐ 650 Airline Regs
- ☐ 660 Occupational Safety -Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt. Reporting Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSHD Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS--Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 810 Selective Service
- ☐ 850 Securities/ Commodities/Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900 Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (PLACE AN X IN ONE BOX ONLY)

☒ Original Proceeding	☐ 2 Removed from State Court	☐ 3 Remanded from Appellate Court	☐ 4 Reinstated or Reopened	☐ 5 Transferred from another district (specify)	☐ 6 Multidistrict Litigation	☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 U.S.C. 1332(a)

Brief description of cause: breach of contract

VII. REQUESTED IN COMPLAINT

CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND$

Check YES only if demanded in complaint:
JURY DEMAND: ☒YES ☐ NO

VIII. RELATED CASE(S) IF ANY (See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE 10/18/06

SIGNATURE OF ATTORNEY OF RECORD

Judge Dale A. Kimball
DECK TYPE: Civil
DATE STAMP: 10/18/2006 @ 09:06:04
CASE NUMBER: 2:06CV00890 DAK

Co counsel representing plaintiffs in this action

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