SPECIAL EDITION:
INSIDE *WYETH V. NATURAL BIOLOGICS*

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How Trade Secret Litigation Brought Down a "Company Built Upon Misappropriation"

In this special edition of TRENDS, we take you behind the scenes of Wyeth v. Natural Biologics, an eight-year court battle over a decades-old secret chemical process. At stake: billions of dollars and thousands of jobs. Rarely in the U.S. court system has the power of trade secrets to make or break a company's fortunes been so clearly demonstrated.

On one side of this litigation was Wyeth, one of the world's foremost manufacturers of pharmaceuticals, which has sold the drug Premarin for decades as the most popular hormone therapy for menopausal women. Premarin is a natural substance derived from pregnant mares, using a closely guarded secret chemical process known as the Brandon Process, named for the company's manufacturing facility in Brandon, Manitoba. For more than sixty years, no company has ever been able to replicate the Brandon Process. As a billion-dollar drug, Premarin is vital to the economics of Wyeth and its employees.

On the other side was Natural Biologics, a Minnesota-based start-up company that sought to produce a generic version of Premarin, using a chemical process that its CEO, a former agricultural salesman with no scientific training, claimed to have developed from expired Wyeth patents and public records. Had Natural Biologics been successful, it would have deeply cut into the market for Premarin.

Instead, after years of discovery and a 16-day bench trial, Judge Joan Ericksen of the United States District Court for the District of Minnesota, found that Natural Biologics was, "a company built upon misappropriation." She found that the company's CEO had conspired with a former Wyeth scientist to steal the company's secret Brandon Process and had lied repeatedly about his contacts with the ex-employee. Her remedy was bold and complete: she ordered Natural Biologics shut down, ordered the destruction of all research materials and drug supplies at the company, and banned its leaders from ever seeking to re-enter the estrogen replacement market.

Judge Ericksen's order was subsequently upheld in a unanimous ruling by the United States Court of Appeals for the Eighth Circuit.

The litigation turned on a comprehensive document review process designed by Faegre & Benson that unearthed a single phone call on a roster of "redacted" phone records that revealed a contact between the CEO of Natural Biologics and a former Wyeth scientist. Based on this "needle in a

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haystack," the firm was able to obtain unredacted phone records that revealed numerous, lengthy calls between the two men that began to tell the story of the company's deception.

Using a concise, highly effective trial strategy, the litigators at Faegre & Benson were then able to showcase the truth – and the cover-up – behind Natural Biologics.

In this issue, we have included a variety of documents that reveal the facts, strategies, and outcomes in Wyeth v. Natural Biologics:

- Abridged, redacted version of the order by Judge Ericksen that summarizes the facts in the case and orders the company shut down
- Q&A with the leaders of the Faegre & Benson litigation team
- Reprint of the page one story on this litigation that appeared in the National Law Journal
- Introduction to trade secret law
- Members of the litigation team from Faegre & Benson

For more information about this case, or to discuss issues regarding intellectual property litigation, please contact:

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Permanent Injunction: An Abridged Version of the Court Opinion That Shut Down Natural Biologics

NOTE: THE FOLLOWING OPINION HAS BEEN ABRIDGED FOR THIS SPECIAL ISSUE OF TRENDS

UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

Wyeth,

Plaintiff,

v.

Natural Biologics, Inc., and Natural Biologics LLC,

Defendants.

Civ. No. 98-2469 (JNE/JGL)

[ABRIDGED] FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

David J.F. Gross, Esq., Calvin L. Litsey, Esq., Kara L. Benson, Esq., James W. Poradek., Esq., and Michelle Paninopoulos, Esq., Faegre & Benson LLP, and Mark W. Lynch, Esq., Wyeth, appeared for Wyeth.

Richard G. Mark, Esq., Eric J. Rucker, Esq., Kristin L.C. Haugen, Esq., Kurt J. Niederluecke, Esq., and Jason R. Asmus, Esq., Briggs and Morgan, appeared for Defendants Natural Biologics, Inc. and Natural Biologics LLC.

This case came before the Court for trial starting November 12, 2002, and ending November 26, 2002.

NON-CONFIDENTIAL FINDINGS OF FACT

I. Parties

A. Wyeth

1. Wyeth, formerly known as American Home Products Corporation… makes and sells Premarin, a hormone replacement therapy drug. Wyeth makes Premarin from the estrogens found in pregnant mare urine (PMU). The alleged trade secret at issue in this case is the chemical process Wyeth uses to extract estrogens from PMU.

B. Natural Biologics

4. David Saveraid is the founder and President of Natural Biologics.

5. Natural Biologics operates a commercial production facility in Albert Lea, Minnesota, where it extracts natural conjugated estrogens from PMU in the form of a dry bulk product. Natural Biologics, with the assistance of a tablet manufacturer, intends to market a generic form of Premarin.

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II. The Premarin Market

6. Premarin has been sold in the United States since 1942, when the Food and Drug Administration approved it for use in the United States.

7. From 1992 to 2001, gross sales of Premarin in the United States grew from over $500 million to over $2 billion.

From 1992 to 2001, gross sales of Premarin in the United States grew from over $500 million to over $2 billion.

8. Premarin is the only estrogen replacement product on the market that is derived from a natural source.

III. Trade Secret Misappropriation

A. The Brandon Process

11. Wyeth extracts and purifies estrogens found in PMU at its plant in Brandon, Manitoba, [Court describes trade secret process].

B. The Brandon Process is neither generally known nor readily ascertainable

16. The Brandon Process is not patented. In the 1940's and 1950's, Wyeth obtained patents on several methods discovered in connection with its estrogen extraction research. The last patent, the '712 patent', expired in May 1975. Natural Biologics is the only company to claim to have developed a generic equivalent of Premarin based on Wyeth's expired patents.

C. The Brandon Process derives independent economic value from secrecy

21. The Brandon Process is used to make the active ingredient in Premarin. By obtaining the Brandon Process, a prospective competitor would gain a valuable share of the Premarin market.

22. Wyeth's experimentation over the course of several decades led to the development of the Brandon Process. A prospective competitor could not develop a comparable process without a substantial investment of time and money.

D. The Brandon Process is the subject of reasonable efforts to maintain its secrecy

37. The Court finds the testimony of Wyeth's expert witness on security, George Murphy, credible and agrees that, based on all of the evidence and factors discussed in his testimony and report, Wyeth's information protection efforts fell in the "upper end" of the range of reasonableness for corporate security programs.

38. Wyeth subjected the Brandon Process to efforts reasonable under the circumstances to maintain its secrecy.

E. Development of Natural Biologics' process before contacts between David Saveraid and a former Wyeth chemist

[Court discusses David Saveraid's research activities based on Wyeth's expired patents and government waste records.]

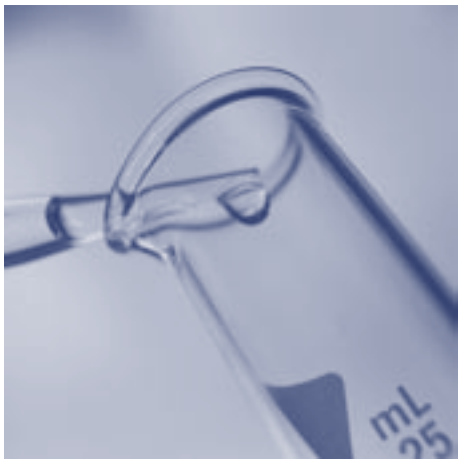
F. Contacts between David Saveraid and a former Wyeth chemist

50. David Saveraid began communicating with Dr. Douglas Irvine (Dr. Irvine), a former Wyeth senior research chemist, in the fall of 1994. Dr. Irvine was one of Wyeth's preeminent authorities on Premarin and the Brandon Process.

55. David Saveraid first called Dr. Irvine on October 31, 1994; that call lasted 38 minutes. David Saveraid called Dr. Irvine again in December 1994. That call lasted 70 minutes. From October 1994 to early 1996, David Saveraid made over 50 calls, lasting more than 1,000 minutes, to Dr. Irvine's home phone and fax numbers. David Saveraid also sent at least three faxes to Dr. Irvine from a hardware store near his home between February and June 1995.

G. Development of Natural Biologics' process after contacts between David Saveraid and Dr. Irvine

57. After learning that Mankato State could not scale up the AURI process [based on an expired Wyeth patent], David Saveraid contacted Dr. Jeffrey Tate (Dr. Tate), the assistant to the director of the Biological Process Technology Institute (BPTI) at the University of Minnesota. The first telephone contact between David Saveraid and Dr. Tate took place on January 24, 1995. Their first meeting took place on February 6, 1995, when David Saveraid toured BPTI's facilities.



58. On February 15, 1995, another meeting at BPTI was held. David Saveraid brought to BPTI a typed protocol for a new process to extract estrogen from PMU; it was the first protocol for estrogen and extraction and purification he had ever typed.

59. David Saveraid provided all of the procedural steps to BPTI.

60. Craig Bremmon, the BPTI pilot plant and laboratory manager turned the process description brought by David Saveraid to the February 15, 1995, meeting into a flow diagram. The flow diagram eventually became a standard operating procedure for the Natural Biologics process. The standard operating procedure is essentially the same as Natural Biologics' current manufacturing process.

63. By letter of March 29, 1995, to David Saveraid, Dr. Tate confirmed the nature of BPTI's work and the results: "following the trial run in which all of the procedural steps you provided were worked out and standard operating procedure (SOP) was agreed upon, our pilot plant personnel have been successfully producing DUE [desiccated urine equine] by the SOP for four weeks."

64. The process protocol that David

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Saveraid brought to BPTI on February 15, 1995, and that was converted into the process that Natural Biologics currently uses, was markedly different from any of the processes previously considered by him.

H. The Brandon Process and Natural Biologics' process are essentially the same

65. The Court finds the testimony of Dr. Miller's comparison of the 1995 Natural Biologics process and the Brandon Process persuasive.

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70. The 1995 Natural Biologics process is essentially the same as the Brandon Process.

I. Disclosure of information about the Brandon Process by Dr. Irvine would be improper

71. Natural Biologics knew it would be improper for David Saveraid to obtain information about the Brandon Process from a former Wyeth employee.

72. David Saveraid knew it would be improper for him to obtain information about the Brandon Process from a former Wyeth employee.

73. Dr. Irvine knew it would be improper for him to disclose information about the Brandon Process to David Saveraid.

J. Natural Biologics' motive for copying the Brandon Process

74. To increase its chances of obtaining FDA approval of a generic version of Premarin, Natural Biologics attempted to copy the Brandon Process. Classification of Natural Biologics' product as a generic would permit Natural Biologics to avoid the time and expense of conducting clinical trials. Financial considerations also motivated Natural Biologics to copy the Brandon Process. Gross sales of Premarin exceeded $2 billion in 2001 in the United States. Natural Biologics believed its entry into the Premarin market as the only generic competitor would have a very small downward pricing effect.

K. David Saveraid's lack of qualifications

75. David Saveraid is the person principally responsible for developing Natural Biologics' process. Before forming Natural Biologics, he had worked most of his career as an agricultural salesman. None of his prior work experience involved chemistry lab work, chemistry processes, extraction processes, or chemistry of any kind. David Saveraid was not qualified to independently develop a process that is essentially the same as the Brandon Process.

M. David Saveraid destroyed records relating to the development of Natural Biologics' process

77. David Saveraid destroyed almost all records relating to the development of Natural Biologics' process after he began communicating with Dr. Irvine. The decision to destroy these records was unreasonable. Natural Biologics destroyed the records in bad faith, attempting to limit damaging evidence against it. Wyeth has been prejudiced by Natural Biologics' document destruction.

Because Natural Biologics' document destruction was unreasonable and intended to limit damaging evidence, and because this action prejudiced Wyeth, the Court finds that David Saveraid's development notes would have revealed that he obtained trade secret information through Dr. Irvine and used that information to develop the 1995 Natural Biologics process.

N. Contacts between David Saveraid and Dr. Irvine reveal that Dr. Irvine disclosed the Brandon Process to David Saveraid

78. The timing and pattern of the telephone calls between David Saveraid and Dr. Irvine reveal that David Saveraid used information from Dr. Irvine to develop Natural Biologics' process.

80. Dr. Irvine concealed his contacts with David Saveraid and denied knowing David Saveraid. Wyeth interviewed Dr. Irvine in January 2000 and February 2001. In those interviews, Dr. Irvine denied any knowledge of David Saveraid, Ken Saveraid, Steven Saveraid, or Natural Biologics, and denied ever meeting or speaking with any of them. Before he made those denials, Dr. Irvine had called David Saveraid to report that he was going to be interviewed by Wyeth's lawyers. Dr. Irvine's concealment of his contacts with David Saveraid reveals that Dr. Irvine discussed the Brandon Process with David Saveraid.

81. Only after Wyeth discovered David Saveraid's phone calls to Dr. Irvine did Dr. Irvine admit that he had numerous telephone conversations with David Saveraid. Dr. Irvine admitted that he introduced himself to David Saveraid as a former Wyeth research chemist, that he discussed the Brandon Process with David Saveraid, and that he engaged in extensive discussions with David Saveraid about the extract and purification of estrogens from PMU.

O. Documentary evidence of Dr. Irvine's involvement in the development of Natural Biologics' process

82. On November 10, 1994, 10 days after he first called Dr. Irvine, David

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Saveraid faxed a letter to Michael Czarny at Salsbury Chemicals. In that letter, David Saveraid wrote: "We have involved a consultant previously involved in the design and development of the innovator drug currently being manufactured in Canada by [Wyeth]." The consultant referred to in the letter is Dr. Irvine.

83. On November 10, 1994, 10 days after he first called Dr. Irvine, David Saveraid faxed a letter to William Tillman at Alpharma. In that letter, David Saveraid wrote: "We have a consultant available with 20 years of experience working in development of the original product now being manufactured by [Wyeth]. He has substantial experience with natural conjugated estrogen bulk and preparation manufacture. He may be of value in expanding our procedure to fit your needs." The consultant referred to in the letter is Dr. Irvine.

P. Natural Biologics concealed and gave false testimony about its contacts with Dr. Irvine

89. Before this litigation, David Saveraid did not tell anybody about his communications with Dr. Irvine. David Saveraid represented to the FDA that a Wyeth chemist was not involved in the development of Natural Biologics' process.

90. David Saveraid continued to conceal his contacts with Dr. Irvine during discovery in this litigation, including on many occasions when he was under oath. After Wyeth requested telephone records, David Saveraid reviewed the records before they were produced and redacted certain calls, including calls to Dr. Irvine. Wyeth's review of the records revealed one page showing several calls to Dr. Irvine that had not been redacted. Production of a full set of unredacted telephone records revealed more than 50 telephone calls from David Saveraid to Dr. Irvine. After reviewing the unredacted records, Wyeth moved to redepose David Saveraid. The Magistrate Judge granted the motion, concluding that David Saveraid had "actively concealed" the calls to Dr. Irvine, had not complied with Court orders, and had given "evasive or false" testimony about his contacts with Dr. Irvine.

91. David Saveraid continued to give false testimony at trial. He falsely testified that he had not violated Court orders, that he had not destroyed evidence, that he had not deceived the FDA, that he did not know until 2001 that Dr. Irvine was a former Wyeth chemist, and that Dr. Irvine had no role in the development of Natural Biologics' process.

Q. No record of development of Natural Biologics' process

92. There is no record showing how Natural Biologics changed the process run at AURI into the process David Saveraid brought to BPTI on February 15, 1995.

95. Natural Biologics' explanation that it pieced together its process from Wyeth's expired patents, waste manifests, and other public information is neither credible nor feasible.

96. Natural Biologics misappropriated the Brandon Process.

IV. Natural Biologics' growth after David Saveraid and Dr. Irvine began communicating

A. Size and assets

97. Before David Saveraid and Dr. Irvine began communicating, David Saveraid had received less than $10,000 in income as an officer of Natural Biologics. Natural Biologics itself had not received any income, had not hired any employees other than David Saveraid, had no private investors, had no office space, had no agreements with third parties to build a plant, had received approximately $10,000 from public entities, and had assets consisting of a leased truck, equipment to collect urine, and improvements to a barn for seven or eight horses.

98. After David Saveraid and Dr. Irvine began communicating, Natural Biologics hired employees, obtained investment money from a private investor, obtained equipment, and built a commercial facility. Natural Biologics is a company built on misappropriation.

B. Natural Biologics' pilot plant

99. After BPTI completed its process runs in the spring of 1995, David Saveraid searched for a facility to begin pilot-scale production, sought analytical results, solicited urine producers, and spoke to pharmaceutical companies about providing them with bulk material.

100. In July or August 1995, David Saveraid met John Albers, the former chief executive officer, President, and Chairman of the Board of Dr. Pepper. Albers is a venture capitalist who has investments in 8 to 10 start-up companies. Albers' investment in each company exceeds $1 million, and his total investment in the companies exceeds.

101. Albers believed that Natural Biologics presented an attractive

investment opportunity. David Saveraid told Albers that Natural Biologics' process came from Wyeth's expired patents and publicly available information about the Brandon plant's waste stream. David Saveraid did not disclose his communications with Dr. Irvine to Albers. Albers did not investigate whether Natural Biologics obtained its process from a former Wyeth employee. In 1995, Natural Biologics received $400,000 from Albers' company, Fairfield Enterprises, to set up a pilot plant and to pay horse ranchers to supply urine.

102. In late 1995, Natural Biologics began assembling a pilot manufacturing facility at the Hormel Institute in Austin, Minnesota. After obtaining space there, Natural Biologics began hiring employees.

103. In April 1996, Natural Biologics began processing batches of urine at the Hormel Institute. Natural Biologics completed processing those batches in May or June 1996.

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VI. Harm to Wyeth

140. If a generic version of Premarin is sold based on material produced by Natural Biologics, Wyeth would lose market share, leading to a decline in revenues, research, and employment. The Court finds the testimony of Dr. Michael Dey, the President of the Women's Health Care Division at Wyeth, regarding the impact on Wyeth to be credible. Wyeth's lost market share would result in decreased revenues. The decreased revenues in turn would result in layoffs of between 3,000 and 4,000 employees and reduced funding for marketing and research of several hundred million dollars.

143. A permanent injunction is necessary to prevent irreparable harm to Wyeth.

144. David Saveraid knew that he risked the loss of his business if he acquired information about the Brandon Process from a former Wyeth employee. Natural Biologics has operated since 1998 knowing that Wyeth sought a permanent injunction. John Albers understood that Natural Biologics would be ordered to shut down if Natural Biologics had engaged in trade secret misappropriation.

145. Unless enjoined from doing so, Natural Biologics would inevitably use the information it learned about the Brandon Process in connection with any business involving extraction of bulk natural conjugated estrogens from urine. Natural Biologics would not be able to undertake future research and development efforts about any other estrogen-extraction process without relying on information gained from Natural Biologics' misappropriation of the Brandon Process.

146. Natural Biologics cannot be trusted to undertake future research and development into extraction processes without relying on information learned from its misappropriation of the Brandon Process.

NON-CONFIDENTIAL CONCLUSIONS OF LAW

[The Court reviews the requirements of trade secret law and its applicability to the facts of this case]

A. Wyeth is entitled to injunctive relief

49. Misappropriation of a trade secret constitutes irreparable harm warranting injunctive relief. Because Natural Biologics misappropriated the Brandon Process and Wyeth will experience irreparable harm in the form of loss of market share, physician relationships, and control over the trade secret unless an injunction issues against Natural Biologics, the Court concludes that Wyeth has demonstrated the prerequisites for injunctive relief.

B. Scope of the injunction

53. Because Natural Biologics would inevitably use information gained from misappropriating the Brandon Process in any research or development related to processes for extracting estrogens from urine, the Court concludes that the scope of the injunction requested by Wyeth is appropriate.

C. Duration of the injunction

55. In its decades-long history, nobody has legitimately replicated the Brandon Process despite its value. The Court therefore concludes that a permanent injunction is appropriate.

In its decades-long history, nobody has legitimately replicated the Brandon Process despite its value. The Court therefore concludes that a permanent injunction is appropriate.

ORDER

Based on the evidence received at trial, the Confidential Findings of Fact, and the Confidential Conclusions of Law, IT IS ORDERED THAT:

1. Natural Biologics, its officers, agents, servants, employees, attorneys, successors, and assigns, and all those persons or entities in active concert or participation with Natural Biologics who receive actual notice of this Order by personal service or otherwise, are PERMANENTLY ENJOINED from:

(a) using for their own benefit or the benefit of any other person or entity, or disclosing to any other person or entity in any manner, whether directly or indirectly, any information or knowledge they have obtained at any time:

(i) about the chemicals, equipment and/or process steps, procedures or methods used by Wyeth at any time, in whole or in part, to remove estrogens from urine and/or produce any material or product consisting in whole or in part of estrogens from urine (collectively, the "Brandon Process");

(ii) about the chemicals, equipment and/or process steps, procedures or methods used by Natural Biologics at any time, in whole or in part, to remove estrogens from urine and/or produce any material or product consisting in whole or in part of estrogens from urine (collectively, the "Natural Biologics process"); and/or

(iii) in connection with any research or development of the Brandon Process and/or the Natural Biologics process.

(b) engaging in the research or development of, or engaging in or utilizing in any manner, whether directly or indirectly, any process, procedure or method for the removal of estrogens from urine and/or the production of any material or product consisting in whole or in part of estrogens from urine;

(c) producing, manufacturing, selling, offering for sale, distributing, importing or exporting any material or product consisting in whole or in part of estrogens from urine; and/or

(d) working for, consulting with, and/or providing services, information, materials or other assistance of any kind to any other person or entity who or which is engaged in the research or development of, or who is engaged in or utilizing in any manner, whether directly or indirectly, any process, procedure or method for the removal of estrogens from urine and/or the production of any material or product consisting in whole or in part of estrogens from urine, or who is engaged in manufacturing,

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selling, offering for sale, distributing, importing or exporting, whether directly or indirectly, any material or product consisting in whole or in part of estrogens from urine.

2. Natural Biologics shall, within 60 days of the date of this Order, file with the Court, under seal, and serve on counsel for Wyeth a list identifying each person and/or entity (together with each such person's and entity's current address and telephone number and, in the case of each entity, the name of the chief executive officer or managing agent of such entity) to whom Natural Biologics has at any time disclosed or provided information and/or documents that describe, in whole or in part, any portion of the Brandon Process and/or the Natural Biologics process and/or to whom Natural Biologics has at any time, directly or indirectly, sold, distributed, furnished or otherwise provided any material or product consisting in whole or in part of estrogens from urine resulting from the Brandon Process.

3. Natural Biologics shall, within 60 days of the date of this Order, withdraw from the U.S. Food and Drug Administration ("FDA") any Drug Master File and file with the Court and serve on counsel for Wyeth proof of such withdrawal. Natural Biologics shall not permit any person or entity to use or rely on any information contained in its Drug Master File in connection with any submission, filing or application to the FDA.

4. Natural Biologics shall, within 120 days of the date of this Order, gather, shred, and destroy all documents or other materials in its possession, custody or control, and use its best efforts to retrieve and to gather, shred, and destroy any documents or other materials from any other person or entity (other than Wyeth) identified in the list required under paragraph 2 above, that contain information about or describe any portion of or analyze (a) the Brandon Process and/or the Natural Biologics process and/or (b) any material or product consisting in whole or in part of estrogens from urine resulting from any Natural Biologics process.

5. Natural Biologics shall, within 120 days of the date of this Order, gather and destroy any conjugated estrogen material or product in its possession, custody or control, and use its best efforts to retrieve and to gather and destroy any conjugated estrogen material or product furnished by Natural Biologics, directly or indirectly, to any other person or entity.

6. Natural Biologics shall, within 130 days of the date of this Order, certify to the Court in writing, under oath, through an officer of Natural Biologics, and serve a copy of such certification upon counsel for Wyeth, that Natural Biologics has complied with all of the requirements of this Order or, if Natural Biologics has not done so, state in such certification the reasons why Natural Biologics has not complied with all of the requirements of this Order.

7. The Second Amended Protective Order Regarding Confidential Information under Fed. R. Civ. P. 26(c) and the Uniform Trade Secrets Act dated September 19, 2002 ("Protective Order") previously entered in this case shall continue to apply to this case and to any information and/or documents produced in this case according to the terms of such Protective Order. The Court's Confidential Findings of Fact and Confidential Conclusions of Law set forth above shall be treated as Super Sensitive Confidential Information under the terms of this Protective Order.

Dated: October, 2003

JOAN N. ERICKSEN

United States District Judge

Winning the Case: Perspectives From the Wyeth Litigation Team

Win Rockwell
Litigation
Counsel

David Gross
Trial Counsel

Cal Litsey
Trial Counsel

Win Rockwell, Cal Litsey, and David Gross of Faegre & Benson were the lead attorneys for Wyeth in its successful litigation to expose trade secret theft by Natural Biologics. Rockwell is a member of the firm's management committee and the former head of its General Litigation group. Litsey is a senior intellectual property litigator. Gross is a nationally known trial lawyer and co-author of The Power Trial Method, published by the National Institute for Trial Advocacy (NITA). They may be reached at wrockwell@faegre.com, clitsey@faegre.com, and dgross@faegre.com.

In this interview for TRENDS, they discuss the forensic investigation and trial strategy underlying the litigation.

TRENDS: Wyeth brought this case believing that their trade secrets had been stolen, but without actual knowledge of how it had been done or who was involved. How did this shape your approach to discovery?

LITSEY: Natural Biologics had destroyed almost all of its records, which made the discovery process very challenging. There was no documented story, nothing to tell us what had really happened. So we had to approach it like forensic detectives, with a lot of careful research and organization, a lot of persistence, and an ability to reassemble the facts from small bits of unrelated information. Our partners Mary Yeager and Bill Roberts were key players in this discovery process. Most of our information came from depositions, too, where your opponents aren't likely to be candid and forthcoming. In fact, as we found out later, they were simply lying.

TRENDS: The phone records turned out to be the needle in the haystack, is that right?

LITSEY: Sure. But most people put their emphasis on the needle. Discovery is all about the haystack. We never would have found that one incriminating unredacted phone record without a thorough, comprehensive, and carefully managed review process. This involved dozens of people and hundreds of hours of time.

TRENDS: Let's talk about the stakes here. Premarin is a billion-dollar product.

ROCKWELL: It's hard to overestimate what was at stake for Wyeth in revenue and jobs. Had Natural Biologics brought a generic version of Premarin to market, Wyeth would have had to lay off thousands of employees and would have lost hundreds of millions of dollars in the first year alone. There was only one option here. To win. To shut the company down.

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TRENDS: That's a big leap of faith for a client to put in any law firm.

ROCKWELL: Absolutely. Every member of our team knew what this case meant to Wyeth. There was a lot of passion here. To Wyeth's credit, they understood they were making an investment in the best people and the best technology. That's what it takes to win the big case.

TRENDS: Are there special challenges in handling a trade secret case, compared to other intellectual property litigation?

LITSEY: One crucial consideration is security. This isn't like a patent case where the material is part of the public record. You need to take great care during the litigation process to keep the trade secret information secure. We researched the technology and implemented a safe room within the firm itself to protect material we gathered during the litigation and we obtained one of the most restrictive protective orders ever entered in federal court. We also had to defend against an all-out assault on Wyeth's efforts to protect their trade secret over the years. Our partners John Connelly and Kara Benson played a major role in stopping this attack.

TRENDS: By the time you went to trial, you had pieced together a lot more of what had happened at Natural Biologics, but you still had gaps where you could infer what had happened, but not necessarily prove it.

GROSS: Exactly. That's the situation you'd expect in a high-stakes trial. You'll never have all the information you want, but you have to craft the most compelling story from what you do have. In this case, the gaps actually helped us make our case, because they underlined the attempts by Natural Biologics to cover up its theft.

The story looks simple now, because we've already told it. But back then, it was just boxes of records and depositions that didn't show a clear picture. We had to craft the most effective story out of the raw information. Did we focus on the science – how Natural Biologics had pursued one scientific process and then changed to something radically different without any rational basis other than theft? Or did we focus on their contacts with a former Wyeth scientist and the fact that they went to great lengths to cover up these contacts?

The more we looked at the two stories, the more we realized they were really just one "before and after" story. Before the head of Natural Biologics began talking to the former Wyeth scientist, he was pursuing a legitimate research path. After he began his discussions with the scientist, he copied Wyeth's process – without conducting any additional research or testing.

TRENDS: What made the story actually work in court?

GROSS: Preparation and speed. We spent enormous time preparing witnesses, working with experts, conducting mock trials, and honing our presentations. But we made the trial itself move quickly – just 16 days. We didn't belabor our cross-examinations. We did Saveraid's cross in one day – highlighting a few of his key contradictions, but not going on and on until it lost impact. We backed up our case with strong, effective animation and computer graphics. The overall effect was quick, punchy and dramatic.

TRENDS: What was your biggest fear?

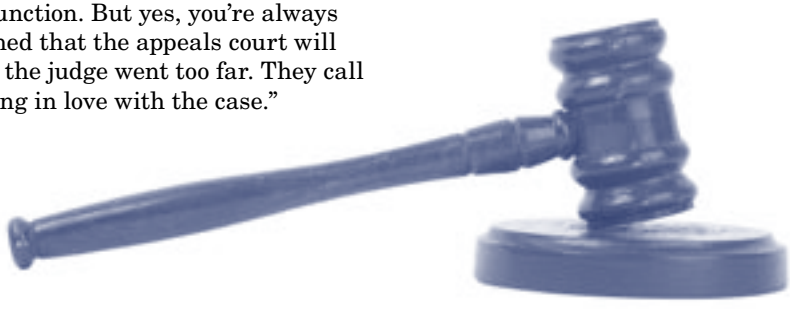
GROSS: We were most worried that Saveraid would come into court and admit that he had lied and apologize. We thought they might confess to the misappropriation and then try to obfuscate the facts by talking about procedural issues, such as statute of limitations. We still would have won, but a confession could have undercut some of the emotional impact. That might have led the judge to consider a less forceful remedy.

TRENDS: The judge ended up issuing a sweeping injunction that shut down Natural Biologics. Did that worry you in the appeal? Did you wonder if you had actually been too successful at trial?

LITSEY: Judge Ericksen wrote a thorough, detailed opinion to back up her injunction. But yes, you're always concerned that the appeals court will believe the judge went too far. They call it "falling in love with the case." How often does a court shut down a company altogether in a trade secret case? Almost never. But the reality is, what's the proper remedy when you prove that a company has been entirely built on misappropriation? You shut them down. This wasn't a large company with a renegade employee who acted without the knowledge of management. This was a start-up company whose CEO deliberately stole a trade secret and then used it to acquire money and resources. There was no company without the theft. That's the way Judge Ericksen saw it. The appellate court agreed.

TRENDS: Tell us about the team effort this kind of large-scale litigation effort demands.

ROCKWELL: You need a highly experienced team that works collaboratively. This isn't a project where one person gets the glory. You can have great people and still fail if they don't have the skills to work together. You need effective management, too. That starts with your partners and associates, but it's not just lawyers. We have paralegal project managers who coordinate complex document and discovery tasks. We have IT staff who lead our technology and database efforts. The key is communicating the big picture, staying focused on the goal, and having a network of lawyers and staff who pay attention to every detail. Every detail counts.



Phone Records Lead to Victory

Wyeth prevails in trade secrets case after key discovery.

By Sue Reisinger

Special to the National Law Journal

For 40 years pharmaceutical giant Wyeth closely guarded the secret process it uses to create a drug called Premarin. So when an upstart Minnesota company named Natural Biologics Inc. began producing the key ingredients of Premarin in 1997, Wyeth thought its trade secret had been stolen.

In an effort to preserve what would become $2 billion in yearly sales of Premarin, Wyeth filed suit in 1998. But it wasn't until a paralegal, poring through thousands of pages of the defendant's edited phone records during discovery made an incriminating finding, that Wyeth began to realize what had happened.

On September 15, U.S. District Judge Joan N. Ericksen in Minneapolis ruled that a theft had occurred. The judge issued a permanent injunction against Natural Biologics that could put the young Minnesota company out of business, since the Premarin ingredient is its only product.

Natural Biologics was granted a stay and has filed a notice of appeal. Its lead defense attorney, Richard G. Mark, said he has never seen a remedy so sweeping as this injunction.

"There was never any direct evidence that in fact trade secret information was passed," said Mark, president of the Minneapolis law firm Briggs & Morgan.

But Ericksen filed a written opinion on October 2 supporting her ruling and ripping the defendant for "brazen and unconscionable conduct [including] destroying evidence, giving false testimony, and improperly redacting evidence." *Wyeth v. Natural Biologics Inc.*, Civ. No. 98-2469.

Most of the case court documents have been sealed to protect the trade secret.

Ericksen's written ruling, along with interviews with attorneys on both sides, reveal details of how Wyeth solved the mystery of the theft.

The story began in 1993 when an agricultural salesman named David Saveraid and his brother, Steve, started Natural Biologics LLC and a related company called Natural Biologics Inc.

Both firms are based in Albert Lea, Minnesota, and the court treats them as one, with David Saveraid as president and the key player in this case.

Saveraid did not return several phone calls and Mark said he did not expect his client to comment.

Production effort

According to court documents, in 1994, Saveraid decided to try to produce the key ingredients of Premarin for use in a generic equivalent—something that several large drug companies like Merck had tried and failed to do for decades.

At the time, Natural Biologics had no income, no employees, one leased truck, some urine-collection equipment and a barn for seven or eight horses, court documents say.

Premarin is a hormone-replacement therapy drug used primarily to treat severe symptoms of menopause and to prevent osteoporosis. Its key

ingredients are natural estrogens found in pregnant mare urine.

The trade secret at issue was a chemical process, called the Brandon Process, which Madison, New Jersey-based Wyeth uses to extract the estrogens.

In 1997, Natural Biologics built a processing plant in Albert Lea, using some of the same vendors that Wyeth had used to build its Brandon processing plant.

In November 1998, before any generic drug had hit the market, Wyeth filed suit based primarily on circumstantial evidence, claiming misappropriation of its trade secret. Wyeth did not seek money damages but asked for an injunction banning Natural Biologics from the field and from ever disclosing the process.

This began a legal battle in which Wyeth's lawyers assembled a forensics evidence team that analyzed thousands of notes, records and scientific documents for months.

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Then came the breakthrough: in February 2001, a paralegal, searching the defendant's phone records, spotted a strange number.

It belonged to Dr. Douglas Irvine, a retired Wyeth scientist who had played a key role in developing and refining the Brandon Process.

The discovery "broke the case open.... It was the classic smoking gun," said David J.F. Gross, Wyeth's co-lead counsel and a partner at Minneapolis-based Faegre & Benson.

Court documents say that in depositions Saveraid and Irvine had denied having had any contact with each other. Irvine could not be reached for comment.

After Wyeth's find, the judge allowed a broader discovery that turned up 17 hours of phone conversations and an exchange of faxes between Saveraid and Irvine that had been concealed.

At that point, "instead of a circumstantial case of misappropriation, we had a direct case of trade secret theft," said Calvin Litsey, co-lead counsel for Wyeth and also a partner at Faegre & Benson.

Defense attorney Mark said that Saveraid and Irvine had legitimate reasons for not revealing the phone calls because they had never discussed trade secret information.

The judge ruled otherwise, saying, "the contacts between David Saveraid and Dr. Irvine coincided with dramatic changes to Natural Biologics' process without any testing or experimentation." In addition, she said Natural Biologics presented no credible record of having developed its own process and Saveraid lacked the necessary chemistry background or other qualifications.

Mark said he was surprised by the judge's sweeping remedy of a permanent injunction. Injunctions in trade secret cases typically last only for the length of time it takes someone to duplicate a process by independent means, he said.

"Our expert said that would be a year to a year and a half," Mark said. "We think the remedy went way beyond what the record will support."

Jerrold Reilly, a partner and trade secret litigator in the Los Angeles office of Jones Day, said courts are reluctant to issue permanent injunctions that put companies out of business, but it is not unprecedented when the facts warrant.

"The judge's key finding was that these people are not to be trusted," Reilly said, "and that finding is copiously supported by the facts. It will be difficult to reverse on appeal."

Also important, Reilly said, was the judge's finding that Natural Biologics' process could cause Wyeth to lose revenue, resulting in layoffs of 3,000 to 4,000 employees and a cut of several hundred million dollars in research spending. At the time, Wyeth sold about $2 billion worth of Premarin annually.

"It's a cautionary tale," said Reilly, who wasn't involved in the litigation. "No matter how badly someone has behaved, it has to stop at the courthouse door."

For Wyeth's lawyers, it's about perseverance. "When litigants try to cover up their bad behavior, they usually leave behind a telltale clue," Gross said. "It's rarely easy to find. If you want to uncover the needle in the haystack, you have to go through the whole haystack."

An Overview of Trade Secret Protection

By Randy Kahnke and Kerry Bundy

Randy Kahnke and Kerry Bundy represent clients in complex commercial and intellectual property litigation and dispute resolution. They may be reached at rkahnke@faegre.com or kbundy@faegre.com.

Can you keep a secret?

That's the challenge for intellectual property owners who rely on trade secret protection to secure their sensitive business assets. Unlike patents, most copyrighted works, and trademarks – which must be publicly disclosed in order to seek recourse from competitors who want to steal them – trade secrets have legal value only to the extent that they stay secret.

File a patent on a new chemical or drug, and you can enjoy exclusive legal rights for about 20 years (often less in practical market terms). As long as you keep trade secrets away from prying eyes, however, they last forever. The trade-off? Once they're out, they're gone. A no-longer-secret trade secret enjoys essentially no legal protection under trade secret laws.

Just about anything can qualify as a trade secret – formulae, computer programs, business methods, database information, customer lists – basically, any knowledge that has independent economic value because other people (such as your competitors) don't know about it and could profit from it if they did. It doesn't necessarily have to be new, different, or unique, as you would expect from patented material and/or even fixed in a tangible form, as with copyrighted works. As long as the information has value to your business because no one else knows about it – and you take reasonable efforts to avoid disclosure – it can qualify as a trade secret.

Pros and Cons

Not surprisingly, there are advantages and disadvantages to using trade secret protection to secure

continued

different types of business assets. Deciding whether to patent certain technology – or keep it under wraps as a trade secret – is often a tough strategic call. Usually, the decision rests on the type of information that needs to be protected.

Most intellectual property owners find the indefinite time limit of trade secret protection appealing, assuming that the information can be maintained in confidence and not easily replicated in the market. For example, say that the knowledge you wish to protect is a manufacturing process. If you patent the process, you get protection for about twenty years. Even though your competitors know exactly what you're doing, they can't copy your process. When your patent expires, however, it's open season on that technology.

By contrast, if you rely on trade secret protection to secure your process, your protection lasts forever, as long as the process remains secret. However, if a competitor is able to replicate the process (without stealing your information), such as through reverse engineering, they're free to do so at any time, and there is usually little or nothing you can do about it.

So the question your business faces is: how vulnerable is your knowledge to being replicated or discovered by others? The answer will shape the kind of IP protection you're likely to seek.

Misappropriation

Unlike patents and copyrights that are governed by federal law, trade secret protection derives primarily from state law. The origins of trade secret doctrine date all the way back to a Massachusetts Supreme Judicial Court decision in 1868, and while numerous courts (including federal courts) have weighed in on specific aspects of trade secret law ever since, no federal civil legislation has ever tackled trade secrets directly. Instead, trade secret laws have been enacted on a state-by-state basis.

Minnesota was the first state to adopt the Uniform Trade Secret Act (UTSA) in 1980, and more than forty other states have since followed suit. The UTSA was adopted in the wake of an increasing reliance by businesses on trade secret protection and a desire to codify common law trade secret principles.

Distilled to its essence, under the UTSA and most state interpretations, the existence of a trade secret is established using a two-fold test. First, you must have knowledge or information that derives independent economic value from not being generally known or readily ascertainable. Second, you must have taken reasonable efforts to maintain the secrecy of the knowledge or information. In that circumstance, the UTSA provides protection by prohibiting the "misappropriation" of trade secrets and providing various remedies, including injunctive relief and damages.

"Misappropriation" covers both obtaining trade secrets through improper means and disclosing or using them without consent. The UTSA also casts a broad net to include not only actual misappropriation (where the theft or disclosure has actually occurred), but also "threatened" misappropriation (which some courts have held to include events such as a key employee bolting to a competitor and putting a trade secret at serious risk of disclosure).

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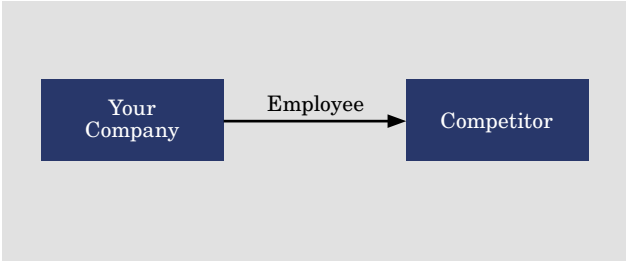
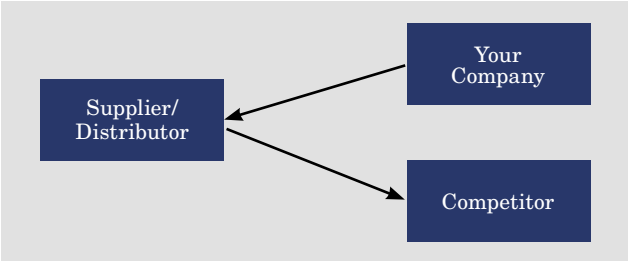
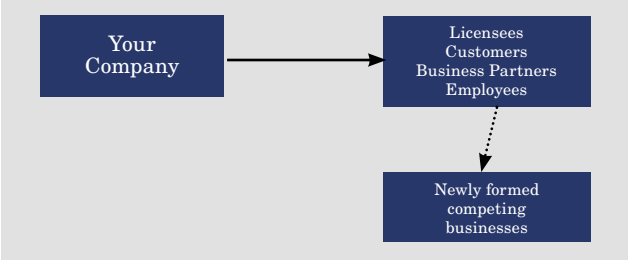
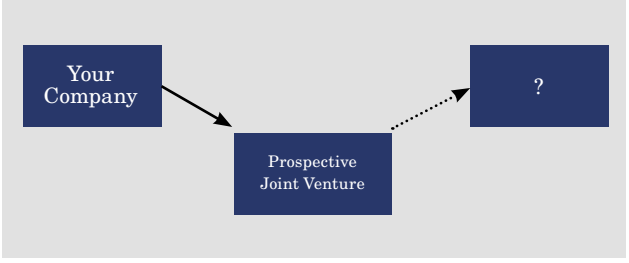
Identifying Risky Relationships





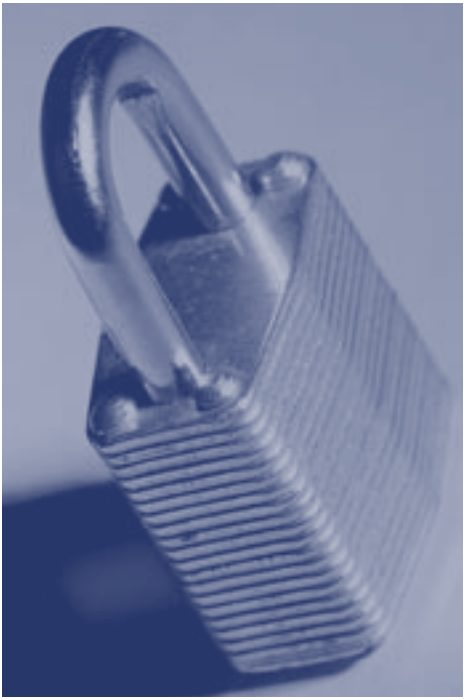




What kinds of actions or circumstances create the greatest risk for trade secret owners? Consider the following:

- One of your employees or independent contractors who has knowledge of your trade secrets leaves to join one of your competitors
- One of your suppliers or distributors also works for a key competitor
- One of your licensees, customers, business partners, or employees decides to start a competing business
- You disclose your confidential information to a prospective business partner, and the deal falls through

This is not an exhaustive list, just a sample of the many ways in which day-to-day business dealings put your trade secrets at risk of misappropriation.



Protecting Your Trade Secrets

How do you take reasonable efforts to protect your trade secrets? Here are a few key steps:

Put it in writing. Consider keeping a written statement of your trade secret security policy. This provides two advantages. First, "unwritten rules" may wind up being laxly or inconsistently enforced within the organization. Second, documented trade secret policies provide evidence in court of the seriousness of the company's efforts to protect its secrets.

Let your employees know. A proper trade secret protection plan should make employees aware of the confidentiality of certain information and, where appropriate, periodically remind them of their obligations to keep that information secure. This would include having employees counter-sign written confidentiality agreements. In addition, companies should consider conducting "exit interviews" with departing employees that include a written reminder of their ongoing responsibility to keep trade secret information secure.

Restrict access. "Sorry, that information is on a need-to-know basis." Where appropriate, keep trade secret information physically separate from nonproprietary information, and restrict access only to those who genuinely require it. Depending on the nature of the intellectual property, this segregation may be as simple as keeping information in a separate filing cabinet, or it may necessitate building an entirely separate and secure facility.

Implement physical security. Consider providing additional security for the information through locked doors, gates, and cabinets. Again, the level of physical security will vary depending on the nature of the information and how the information is used in the business operations.

Consider labeling trade secret documentation. It can be very easy to reproduce, scan, and distribute documents today. Not only should documentation related to trade secret information be treated with special care, but in appropriate circumstances, it may be prudent to label trade secret documents as "SECRET" or "CONFIDENTIAL." A company may also want to educate its employees who have access to such documents about their status, including the sensitivity of and destruction of trade secret documents.

Extend the security procedures to computer systems. Obviously, trade secrets stored in electronic format are particularly susceptible to theft. The entire subject of information systems security may warrant a thorough review by the organization, to minimize the possibility of external "hacking" or internal security breaches. The same care regarding access and labeling that is extended to physical space or documentation, should extend to computer systems where trade secrets are stored.

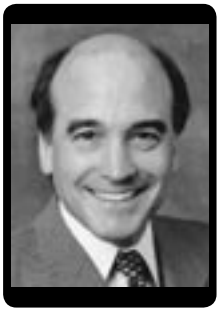
Be mindful of third parties. If business associates, prospective customers, or members of the public have access to facilities in which trade secrets are stored or used, take particular care to avoid inadvertent disclosure. This might include accidents (where documents are left carelessly in open view) or even deliberate but unintentional disclosures (such as tour guides or other employees who inform visitors about the project or process within the facility).

Screen speeches and publications where appropriate. Trade secrets often wind up being disclosed unintentionally at trade shows or in magazine articles, publications, press releases, or speeches. Engineers, marketing executives, mid-level managers, and others may exchange ideas with colleagues or share information publicly because they are unaware of its sensitivity. One tool for reducing this risk is implementing a policy of pre-screening all public communications.

Protect yourself with contracts. The nature of many businesses may require a company to disclose its trade secrets to potential buyers, licensees, joint venture partners, or other outsiders. When engaging in these kinds of third-party transactions, consider monitoring the flow of information carefully and documenting the nature of the trade secrets exposed and the specific limited use to which they may be put. This may include specific confidentiality agreements with the third parties.

When properly identified and secured, trade secrets can often be the most powerful of the various forms of intellectual property protection, given the indefinite lifespan they can offer. Trade secret owners can also obtain swift and dramatic relief in court if they act quickly and have taken care along the way to document and follow their trade secret protection plan. But trade secrets are, by their very nature, fragile. A secret only has value to the extent you can keep it a secret.

Meet the Faegre Legal Team



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