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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.	**BYU AND DR. SIMMONS'S MOTION FOR DISCOVERY SANCTIONS** Case Number: 2:06CV-890 DAK Judge Dale A. Kimball Magistrate Judge Brooke C. Wells

Based on the facts detailed in BYU and Dr. Simmons's Response to Pfizer's Third Supplemental Certification Regarding Discovery Efforts and Memorandum In Support of Motion for Discovery Sanctions, filed contemporaneously herewith, BYU and Dr. Simmons hereby move for discovery sanctions as detailed therein.

RESPECTFULLY SUBMITTED this 14th day of January 2009.

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CERTIFICATE OF SERVICE

I hereby certify that on the 14th day of January, 2009, I electronically filed the foregoing BYU and Dr. Simmons's Motion for Discovery Sanctions with the Clerk of the United States District, District of Utah Central Division, using the CM/ECF system which sent notification of such filing to the following:

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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.	**BYU AND DR. SIMMONS'S RESPONSE TO PFIZER'S THIRD SUPPLEMENTAL CERTIFICATION REGARDING DISCOVERY EFFORTS AND MEMORANDUM IN SUPPORT OF MOTION FOR DISCOVERY SANCTIONS** **[REDACTED]** Case Number: 2:06CV-890 DAK Judge Dale A. Kimball Magistrate Judge Brooke C. Wells

TABLE OF CONTENTS

Page

Table Of Contents i

Introduction 1

Factual Background 6

I. In Order To Prove Its Central Defense, Pfizer Withholds Key Documents. 6

II. Pfizer Is Intentionally Withholding A Critical Document Marked As An Exhibit At A Needleman Deposition Attended By Pfizer's Chicago Counsel O'Malley. 11

A. Mr. O'Malley Saw And Heard Testimony About The Unproduced $10 M/Day Exhibit. 11

B. BYU Gave Pfizer A $10M Per Day Head Start For Celebrex. 13

C. Mr. O'Malley Knew The $10M/Day Exhibit Was Relevant To This Litigation. 14

D. Pfizer Should Have Produced The $10M/Day Exhibit In Response To BYU's First Request For Production. 15

E. Mr. O'Malley Intentionally Withholds The $10 M/Day Exhibit. 21

F. Despite BYU's Requests, Pfizer And Its Chicago Counsel Still Have Not Produced The Needleman Exhibits. 24

III. Pfizer Failed To Produce Documents, Transcripts, And Depositions From All Relevant Litigations. 26

IV. Pfizer And Its Chicago Counsel Have Misrepresented Pfizer's Discovery Since February 2007. 34

V. Before The Court's Order Causing Pfizer To Find Over 300 Samples, Pfizer Claimed Four Times That It Could Not Locate Responsive Biological Materials. 36

A. Pfizer's 9 October 2007 Claim That Pfizer Had Been Unable To Locate Any Biological Materials Was A Misrepresentation. 41

B. Pfizer's Statements To This Court That BYU's Biological Materials Did Not Work And Were Discarded Were Misrepresentations. 41

C. Pfizer's 7 January 2008 Claim That Pfizer Used Up BYU's Biological Materials During The Mediation Was A Misrepresentation. 42

D. Pfizer's Chicago Counsel Did Not Adequately Inform Mr. Hauser Of His Duties. 43

E. Mr. Hauser Testified That He Did Not Contact Key Individuals With Regard To His Search For Biological Materials. 44

F. Pfizer Did Not Adequately Search For Plasmids. 45

G. Pfizer Did Not Search For Antibodies. 47

H. Pfizer Did Not Search All Of Its Freezers Likely To Contain Responsive Biological Material. 48

I. Pfizer Did Not Appear To Search For Documents Relating To Biological Materials This Court Ordered It To Produce. 50

J. Mr. O'Malley, Pfizer's Chicago Counsel, And Pfizer Failed To Produce Court-Ordered Documents. 51

VI. Pfizer Claims That It Produced All Relevant Scientific Notebooks. 53

A. Monsanto Scientific Notebooks Are A Crucial Source Of Evidence In This Litigation. 53

B. Pfizer Has Always Misrepresented Its Production Of Scientific Notebooks. 55

C. Pfizer Still Fails To Produce Relevant Scientific Notebooks And Lists Of All Scientific Notebooks. 60

1. Monsanto, Searle, and Pfizer's internal policies require near permanent retention of scientific notebooks. 61

(a) Pfizer told the Court its scientific notebooks never leave Pfizer's archives. 61

(b) Pfizer has a legal obligation to retain its scientific notebooks. 61

(c) Because Monsanto, Searle, and Pfizer all have policies to keep and index scientific notebooks, Pfizer's claims that it cannot find crucial notebooks are not credible. 63

2. Pfizer has not produced information one would expect to be available from its document database. 64

(a) Pfizer likely uses a database for its scientific notebooks like the TAB database that Pharmacia used. 64

(b) Pfizer has still not produced Monsanto's internal index of notebooks and the relevant parts of Searle's index. 68

3. Pfizer failed to produce at least five specific scientific notebooks. 69

(a) Pfizer still has not produced sets of relevant scientific notebooks assigned to Reitz, Warren, or McWilliams 70

(b) Pfizer has not produced three other specific Court-ordered scientific notebooks. 81

VII. BYU Believes Pfizer's Spoliated Documents Will Disprove Pfizer's Central Defense That BYU's Clones Did Not Work. 82

1. The Raz letters prove Dr. Simmons's clones and reagents worked. 83

2. The Seibert email proves Dr. Simmons's clones and reagents worked. 84

3. The Blue slide proves Dr. Simmons's clones and reagents worked. 85

4. Monsanto's draft publications give BYU credit for its valuable trade secrets. 85

VIII. Pfizer Continues To Withhold Important Financial Information. 88

IX. Pfizer Continues To Disregard The Court's Order With Inappropriate Redactions And Newly Asserted Privilege Claims. 95

A. Pfizer's Early Productions Contained Unexplained Redactions. 96

B. Pfizer Claimed That Its Unexplained Redactions Were Based On Relevance. 97

C. BYU Continued Questioning Pfizer's Unexplained Redactions And Filed Its Motion To Compel 98

D. The Court Ordered Pfizer To Remove Its Relevance Objections And Log Any Privilege Redactions. 100

E. After The Court's Order, Pfizer Changed The Bases For Its Redactions From Relevance To Privilege—But Did Not Produce Its Redacted Scientific Notebooks. 100

F. Pfizer's New Privilege Claims Concealed At Least One Relevant, Non-Privileged Document. 101

G. Ms. Schneider Represented To The Court That Pfizer Had Produced The "get the Simmons effect" Page. 102

H. Pfizer's Third Supplemental Certification Maintains Pfizer's Newly Asserted Privilege Claims. 103

X. Pfizer Still has Not Produced Minutes From At Least 31 Board Meetings Between 1991 and 1993. 104

XI. Pfizer Seeks An *Ex Parte* Decision From The PTO Regarding BYU's Inventorship Claim Based On Incomplete Evidence. 108

XII. Pfizer Made Material Misrepresentations To The Court And BYU Regarding Its Discovery And Compliance With The Court's Discovery Order. 114

A. Pfizer Misrepresented To This Court At Least Eight Times That Its Document Production Was Complete. 114

B. Pfizer Misrepresented To This Court At Least Seven Times That It Had Completely Disclosed All Documents Regarding Previous COX-2 Litigation. 115

C. Pfizer Misrepresented To This Court At Least Five Times Regarding Its Production Of Biological Materials And Related Documents. 117

D. Pfizer Misrepresented To This Court At Least Seven Times Facts Regarding Scientific Notebooks. 117

E. Pfizer Misrepresented To This Court At Least Two Times That It Disclosed To BYU All Pfizer Board Meeting Minutes. 118

F. Pfizer Misrepresented To BYU At Least Seven Times That Its Document Production Was Complete. 119

G. Pfizer Misrepresented To BYU At Least Two Times That It Had Completely Disclosed All Documents Regarding Previous COX-2 Litigation. 120

H. Pfizer Misrepresented To BYU At Least Four Times That It Had Disclosed All Biological Materials. 120

I. Pfizer Misrepresented To BYU At Least Four Times That It Had Produced All Scientific Notebooks. 121

J. Pfizer Made At Least Three Misrepresentations To BYU Regarding Redactions. 122

Motion For Sanctions 123

Argument 123

I. Legal Standard. 124

II. Under *Ehrenhaus*, Pfizer's Answer Should Be Stricken. 124

A. Pfizer's Conduct Has Significantly Prejudiced BYU. 125

B. Pfizer Has Significantly Interfered With The Judicial Process. 126

C. Pfizer Is Culpable For Its Misconduct. 126

D. Pfizer Ignored This Court's Warnings. 127

E. Lesser Sanctions Are Ineffective. 128

III. Other Necessary Sanctions. 129

A. Spoliation Instruction. 129

B. Contempt Of Court. 131
C. Depositions Regarding Discovery Compliance. 131
D. Damages Jury Instruction. 132
E. The Court Should Make An In Camera Inspection. 132
Prayer 134
Certificate Of Service 136

INTRODUCTION

Even though BYU sued Pfizer on 18 October 2006 and served its First Request for Production of Documents on 13 February 2007, and even though this Court ordered Pfizer to provide BYU with a "full and complete production" on 26 March 2008, Pfizer has still not completed its document production.

Despite BYU's efforts, Pfizer continues to knowingly withhold key documents that Pfizer's Chicago counsel have direct and personal knowledge about—including depositions and exhibits, scientific notebooks, internal corporate documents, financial documents, biological materials, and other critical materials that this Court has ordered Pfizer to produce.

During the more than two year span of this case—and the more than $1 million expense of lawyer and paralegal time—Pfizer has misrepresented and misdirected, either in writing or in open Court, facts about its production at least 50 times, including at least 30 times directly to this Court. Pfizer's conduct is intentional and willful.

In making these claims, BYU is mindful that it must document and support these serious allegations. This document is lengthy because BYU feels it must set forth the supporting facts.

BYU is also cognizant of this Court's 29 July 2008 admonition:

> [I]n reviewing the pleadings I sense a rising tone of frustration between the parties, and I just would remind you all that we are going to and do operate under the Utah Rules of Professionalism and Civility.[1]

The Court's sense that BYU is increasingly frustrated is correct.

[1] Motions Hearing Transcript, 29 Jul 08, 5:11-15, Ex. 1.

Pfizer's pattern of production follows a consistent model. First, Pfizer claims that its production in a particular area is complete. When BYU points out the inaccuracy of that claim, Pfizer responds by claiming that BYU's assertions are "absurd." Thereafter, Pfizer acknowledges that its production is incomplete and then produces additional documents. During this process, Pfizer and its Chicago counsel also turn the Federal Rules of Civil Procedure on their head by repeatedly suggesting that if BYU can identify a document that Pfizer has not produced, Pfizer will produce it. Now, despite the Court's Order, Pfizer is refusing to produce even documents that BYU has identified, documents like deposition exhibits that are probably accessible from the Chicago offices of Pfizer's counsel.

On 4 and 5 March 2008, Richard O'Malley, Pfizer's long-time counsel, who, by BYU's count, has participated in over 77 depositions of Pfizer deponents, sat in a conference room in St. Louis, Missouri, where Dr. Philip Needleman, Pfizer's Head Scientist relating to Celebrex, gave a deposition in *In Re: Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation,* Case No. M:05-CV-01699 CRB MDL No. 1699 (U.S.D.C., N.D. Cal., San Fran. Div.) ("MDL"). At page 33 of the transcript, a non-Bates labeled document was put in front of Dr. Needleman, marked as Exhibit 1, and counsel labeled the document with a handwritten Bates label.[2] Notwithstanding this document is responsive to various BYU document requests and BYU's numerous specific requests, Pfizer has not produced this document nor listed it on any privilege log.

[2] Dep. of Dr. Philip Needleman, 4 Mar 08, Celebrex Marketing Sales Practices Product Liability Litigation, BYU-PFE 211315 at 347-48, 33:18-34:21, Ex. 2 (emphasis added).

BYU believes it has found a version of Exhibit 1 on the internet. If BYU has the correct document, Exhibit 1 appears to be a four-page document authored by Dr. Needleman, in consult with Pharmacia's Director of Research Operations, Michael J. Montague, entitled "From a twinkle in the eye to a blockbuster drug: the story of Celebrex holds lessons for R&D leaders everywhere."[3]

Exhibit 1 is particularly relevant because it makes key admissions regarding this case:

- For each day the drug development is accelerated, there is $1 Million added to the Company's sales figures. **For Celebrex this figure could approach $10 Million per day**.
- **COX-2 could be just the right target for a major drug** to meet a significant medical need.
- **With the help of a CEO** who recognized the importance of having a critical mass of scientists focused on a problem, **we mobilized 50 molecular and cell biologists [and] 1/3 of all the medicinal chemists at Searle.**.[4]

Mr. O'Malley, who heads Pfizer's defense in this litigation, saw exhibit 1, did not produce it to BYU, and now—even after BYU has identified and requested these exhibits in writing—has not produced it or the other 47 exhibits marked in that deposition.

During a phone conference on 23 December 2008, Mr. O'Malley reaffirmed the misrepresentation he made to this Court that Pfizer has "produced every non-privileged, responsive document it has located…."[5] That is simply not true, and Pfizer's counsel knows it.

But it does not end there. On 24 December 2008, BYU learned through a news article on the internet that a California jury in *Ischemia Research & Educ. Found., et al. v. Pfizer Inc., et*

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[3] "From a twinkle in the eye to a blockbuster drug: the story of Celebrex® holds lessons for R&D leaders everywhere," authored by Philip Needleman, published in Research-Technology Management, Vol. 44, No. 6, 1 Nov 2001, pp. 38-41, Ex. 3.

[4] *Id.*

[5] Defendants' Third Supplemental Certification Concerning Discovery Efforts, 15 Oct 08, Dkt. No. 157.

al., No. 1 04 CV 026653 (Cal. Super. Santa Clara Cty.) ("IREF") returned a verdict against Pfizer.[6] IREF involved selective COX-2 inhibitors.

Through various telephone calls and an actual visit by an Associate General Counsel of BYU to look at the publicly available file, BYU confirmed that Mr. O'Malley was involved in the IREF litigation and attended the deposition of Dr. Needleman on Pfizer's behalf. Pfizer has not produced that deposition of Dr. Needleman. After identifying the deposition to Pfizer and Mr. O'Malley, Mr. O'Malley continues to reaffirm his representation that Pfizer has produced every non-privileged document it's located.

According to the news article that BYU read regarding the IREF verdict, the jury found Pfizer liable for misappropriation of trade secrets. From BYU's cursory review of the public files in San Jose, it appears that the Court in IREF instructed the jury that Pfizer had spoliated documents—similar to what BYU believes Pfizer has done in this litigation.

Notwithstanding BYU's requests for the MDL and IREF Needleman exhibits and the IREF deposition, and notwithstanding the fact that Mr. O'Malley was physically present at both the IREF and MDL depositions of Dr. Needleman and must certainly have ready access to those documents, Pfizer has not produced the IREF transcript nor any of the exhibits to either Needleman deposition. Yet Mr. O'Malley persists in his misrepresentation to BYU and reaffirms Pfizer's certification to this Court that Pfizer

> **[i]dentified for BYU the various other COX-2 related litigation** matters and, to the extent they are relevant to this case, **produced the production documents, pleadings, depositions (including exhibits**), expert reports, witness statements, and hearing transcripts from these matters [and]

[6] Law.com: Pfizer Hit With $38 Million Jury Verdict in IP Case, 12/29/2008, at http://www.law.com/jsp/law/LawArticleFriendly.jsp?id=1202426997770, Ex. 4.

> produced **every** non-privileged, **responsive document** it has located.[7]

It appears that Pfizer has decided to defy this Court's Order and not produce relevant documents. It appears that Pfizer has decided, just as in IREF, that it would rather withhold or destroy documents than produce them as required by this Court's Order and the Federal Rules of Civil Procedure. Without the information Pfizer is withholding, BYU's "ability to prepare [its] case [is] crippled."[8] Further, "[b]y **destroying the best evidence relating to the central issue** in the case, [Pfizer] has **inflicted the ultimate prejudice upon [BYU]**."[9]

Knowing that it has not given BYU key and relevant documents, on 15 October 2008, Pfizer filed a Patent Reissue Application with the PTO wherein it seeks to obtain a decision for use before this Court that suggests that Dr. Simmons did not make a significant contribution to various Celebrex-related patents that derived from the trade secrets Pfizer misappropriated from BYU. This is an *ex parte* proceeding. And Pfizer, hoping to gain a tactical advantage in this case, invited BYU to allow Pfizer to submit an incomplete factual record. When BYU said it would not participate, but would not interfere if Pfizer agreed it would not attempt to offer any PTO finding as evidence in this case, Pfizer refused.

BYU cannot participate in such a process because Pfizer is withholding scientific notebooks, biological materials, board meeting minutes, financial documents, and other critical information that BYU believes will prove its significant contribution in the development of the patents at issue in this litigation.

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[7] Defendants' Third Supplemental Certification Concerning Discovery Efforts, 15 Oct 08, Dkt. No. 157 at 3, 5 (emphasis added).

[8] *Grange Mut. Cas. Co. v. Mack*, 270 Fed. Appx. 372, 2008 WL 744723 (C.A.6 Ky.); *see also Klein-Becker v. Collagen Corp.*, 2008 WL 4699804 (D. Utah) ("[the party] cannot proceed in this litigation without the requested information.").

[9] *Arista Records v. Tschirhart*, 241 F.R.D. 462, 465 (W.D. Tex. 2006) (emphasis added).

Though the Rules do not require it and the Court has not ordered it, BYU has provided Pfizer and this Court with specific information regarding the material that BYU knows either exists or has been destroyed that Pfizer has not provided. This process of identification by BYU has been both burdensome and expensive and is not how the Rules are intended to operate. Even after BYU's efforts, Pfizer continues to knowingly withhold key documents.

As another example, when BYU pressed the question of biological materials, Pfizer's Chicago counsel gave this Court various stories explaining why it had not produced any: they didn't work, Pfizer discarded them, and Pfizer used them up in the mediations between BYU and Pfizer. Then, only after this Court's Order, Pfizer produced more than 300 vials of responsive biological materials. Still missing, though, are the corresponding notebooks that describe the work involved in developing many of those 300 vials. Even so, Pfizer has now certified that its production is complete.

Portions of this Brief cover subjects, with important new details, that this Court has already heard. Much of this brief, though, covers new subjects like the MDL, IREF, and PTO proceedings. For the Court's benefit and organizational convenience, BYU submits this Brief with a Table of Contents, tabs reflecting the subject matter being discussed and, in the electronic PDF, navigational hyperlinks. Though BYU acknowledges that Pfizer has produced millions of documents, as it appears Pfizer has done in numerous litigations, Pfizer is withholding critical documents that relate to this litigation.

FACTUAL BACKGROUND

I. IN ORDER TO PROVE ITS CENTRAL DEFENSE, PFIZER WITHHOLDS KEY DOCUMENTS.

Pfizer's central defense to BYU's claims is encapsulated in its counsel's 29 July 2008 misrepresentation to this Court that

> we **didn't get Simmons' COX-2 clones to work**. Now, that's true … . **Simmons had nothing to do with the creation of Celebrex**.[10]

In order to prove its central defense, Pfizer withholds documents that reveal BYU and Dr. Simmons's significant contribution to Pfizer's development of COX-2 selective inhibitors, including the multi-billion dollar drug Celebrex.

Even in the face of this Court's Order, Pfizer continues to withhold key documents that disprove its central defense. However, BYU has found a few documents that prove Pfizer's central defense is not true and that Pfizer is not producing key documents.

For example, Pfizer's documents prove that Dr. Simmons was the first to discover and isolate COX-2:

Pfizer's documents also prove that Dr. Simmons, pursuant to a Research Agreement, provided Pfizer with COX-1 and COX-2 clones, antibodies, and other trade secrets:

Pfizer's documents further prove that it had a head start in its development of Celebrex:

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[10] Motions Hearing Transcript, 29 Jul 08, 50:5-12, Ex. 5 (emphasis added).

[11] Message points on history of Needleman/Searle and COX-2 science, 20 Jul 00, BYU-PFE 553590, Ex. 6 (emphasis added).

[12] Ltr. from D. Hoscheit to E. Bramhall, 17 Mar 00, BYU-PFE 002906 *et seq*, Ex. 7 (emphasis added); *see also* Ltr. from D. Simmons to K. Seibert and J. Masferrer, 29 Apr 91, BYU-PFE 087023, Ex. 8.

> It's going to be a dogfight … **We've been fortunate to have a head start**.[13]

The deposition exhibit that Pfizer is withholding, and that BYU recently found, proves the head start in developing Celebrex that BYU provided was worth $10 million a day:

> [F]or each day that [drug] development is accelerated, there is $1 million added to the company's sales figure. **For Celebrex, this figure could approach $10 million per day**.[14]

Given these documents, Pfizer's primary defense in this litigation is an attack on the quality of Dr. Simmons's biological materials and other trade secrets. Despite the fact that this claim is not supported by its documents, Pfizer has repeatedly told the Court that BYU's materials did not work:

> It's our view that **Dr. Simmons' clones didn't work**, so there was a minimal amount of research with them and then **they were discarded**.[15]

Before Pfizer or its counsel even looked for responsive biological materials, Pfizer claimed at least four times to this Court and BYU that it did not have any of Dr. Simmons's biological materials to produce:

> **Pfizer has** to date **been unable to locate any biological materials** requested in plaintiffs' document requests.[16]

> **Pfizer did have certain biological materials** ... However, Pfizer had only very small quantities of those materials [at] that time and **those materials were utilized** to obtain sequence data during the mediation.[17]

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[13] Langreth, Richard. "Merck's Health Hinges on Sales of Arthritis Pill." Wall St. J., 14 Apr 1999, nat'l. ed.: B1, Ex. 9 (emphasis added); *see also* PFC00256260.

[14] "From a twinkle in the eye to a blockbuster drug: the story of Celebrex® holds lessons for R&D leaders everywhere," authored by Philip Needleman, published in Research-Technology Management, Volume 44, Number 6, 1 Nov 01, pp. 38-41, Ex. 3.

[15] Motion to Compel Hearing Transcript, 19 Mar 08, 58:14-16, Ex. 10 (emphasis added).

[16] Ltr. from L. Schneider to L.R. Williams, 9 Oct 07, Ex. 11 (emphasis added).

[17] Ltr. from L. Schneider to L.R. Williams, 7 Jan 08, Ex. 12 (emphasis added).

> **[O]riginal biological materials** that Pfizer used to sequence Dr. Simmons' clones … **no longer exist** [and that] the freezer in which the sample was stored malfunctioned and **the sample was inadvertently discarded**.[18]

Then, at the hearing on 19 March 2008, Pfizer's Chicago counsel told this Court:

> we later learned that, in fact, there have been some left that were put in **the freezer that malfunctioned**.[19]
>
> * * *
>
> [I]t's our view that **Dr. Simmons' clones didn't work**, so there was a minimal amount of research with them and then **they were discarded**.[20]

Though BYU did not know it at the time, when Pfizer made these claims, Pfizer possessed over 300 vials of responsive biological material—including at least eight vials labeled with Dr. Simmons's name—that Pfizer found after a "two or three days"[21] it did not conduct until after this Court's Order.

Contrasting (1) Pfizer's four different stories about biological materials and (2) Pfizer's subsequent discovery of the 300 responsive vials after this Court's Order, it seems as though Pfizer and its Chicago counsel would rather make misrepresentations than produce responsive material until they have no other choice.

Pfizer's misrepresentations began with its production of documents from the *Pfizer, Inc. et al. v. Teva Pharmaceuticals USA, Inc.*, Case No. 04-754 (3CL), U.S.D.C. (NJ) ("*Teva*") litigation—when Pfizer specifically misrepresented the production, contents, and completeness of *Teva*.

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[18] Defendants Memorandum In Opposition To Motion To Compel Immediate Production of Documents, 25 Jan 08, Dkt. No. 69 at 8 (emphasis added).

[19] Motion To Compel Hearing Transcript, 19 Mar 08, 55:1-2, Ex. 13 (emphasis added).

[20] *Id*. at 58:14-16 (emphasis added).

[21] Scott Hauser 30(b)(6) Deposition, 10 Jun 08, 188:7, Ex. 14.

Only after BYU spent almost a year requesting a complete production from Pfizer, and several hundred thousand dollars, and filed a motion with this Court did Pfizer finally admit that "the *Teva* **production** … **is apparently incomplete**."[22]

Pfizer intended to mislead BYU by claiming *Teva* was complete because *Teva* did not include the Raz letters, the Blue slide, or the Seibert email—all critical documents proving that Dr. Simmons's clones worked, that Pfizer used them, and that Dr. Simmons provided a substantial contribution to Pfizer's development of COX-2 selective inhibitors, including Celebrex. And, as with its claims regarding biological materials, Pfizer has never explained how it is that key documents remained missing until BYU identified these lapses.

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* * * *

[22] Ltr. from L. Schneider to L.R. Williams, 16 Jan 08, Ex. 15 (emphasis added).

II. PFIZER IS INTENTIONALLY WITHHOLDING A CRITICAL DOCUMENT MARKED AS AN EXHIBIT AT A NEEDLEMAN DEPOSITION ATTENDED BY PFIZER'S CHICAGO COUNSEL O'MALLEY.

A. Mr. O'Malley Saw And Heard Testimony About The Unproduced $10 M/Day Exhibit.

On 4 and 5 March 2008, Richard F. O'Malley, Jr., a Senior Partner from Pfizer's Chicago counsel, who has by name, bar number, and *pro hac vice* appeared on Pfizer's pleadings, discovery, and all other filings in this litigation, sat in a conference room in St. Louis, Missouri representing Pfizer at Dr. Needleman's deposition in the MDL Litigation.

As described briefly in the introduction, Exhibit 1 in the deposition, a document marked without a Bates label, is a presentation Dr. Needleman, then a Senior Executive Vice President and Chief Scientist at Pharmacia, Pfizer's predecessor-in-interest, created in collaboration with Pharmacia's Director of Research Operations, Michael J. Montague, and presented in May 2001 entitled "From a twinkle in the eye to a blockbuster drug: the story of Celebrex® holds lessons for R&D leaders everywhere."[23] BYU had not previously known about, heard about, or become aware of this document until it read the deposition, called various counsel, and then was guided to what BYU believes is a duplicate, or near duplicate, of Exhibit 1.

In Exhibit 1, Dr. Needleman and Pfizer make the following statements and admissions:

- [F]or each day that [drug] development is accelerated, there is $1 million added to the company's sales figure. **For Celebrex, this figure could approach $10 million per day**.
- **COX-2 could be just the right target** for a major drug to meet a significant medical need.

[23] "From a twinkle in the eye to a blockbuster drug: the story of Celebrex® holds lessons for R&D leaders everywhere," authored by Philip Needleman, published in Research-Technology Management, Vol. 44, No. 6, 1 Nov 01, pp. 38-41, Ex. 3.

- **[W]ith the help of a CEO** who recognized the importance of having a critical mass of scientists focused on a problem, **we mobilized 50 molecular and cell biologists [and] one-third of all the medicinal chemists** at Searle.[24]

Consistent with Pfizer's fraudulent concealment of Dr. Simmons's role in bringing his COX-2 discovery to Monsanto, BYU's critical role is completely omitted.

Dr. Needleman, on Pfizer's behalf, actually quantifies, in dollars per day, the advantage of moving quickly during drug development and being first to market:

> **For each day [drug] development is accelerated**, there is $1 million added to the company's sales figure. **For Celebrex[R], this figure could approach $10 million per day.**[25]

On 4 March 2008, Mr. O'Malley, who is the most senior Pfizer Chicago counsel BYU has interacted with, heard Dr. Needleman questioned about Exhibit 1:

Q. REDACTED

A. REDACTED

* * *

Q. REDACTED

A. REDACTED

Q. REDACTED

A. REDACTED

Q. REDACTED

A. REDACTED

Q. REDACTED

[24] *Id.* (emphasis added).

[25] *Id.* (emphasis added).

* * *

A. REDACTED

Q. REDACTED

A. REDACTED.[26]

B. BYU Gave Pfizer A $10M Per Day Head Start For Celebrex.

On 4 April 1999, Pfizer's Chairman and Chief Executive Officer, William C. Steere, admitted in a Wall Street Journal article about the upcoming marketing battle between Pfizer's Celebrex and Merck's Vioxx that:

> It's going to be a dogfight. … **We've been fortunate to have a head start.**[27]

Pfizer's head start resulted from Dr. Simmons's discovery and sequencing of COX-2, his identification of COX-2 as a target, his COX-2 clones and other reagents, his expertise, and the Research Agreement with Monsanto, detailing a collaborative plan to create COX-2 specific NSAIDs.

Though Pfizer has stated at least three times in this litigation, including twice to this Court, that Dr. Simmons's COX-2 clones did not work,[28] Dr. Simmons's COX-2 clones did work. Pfizer's own documents, including documents that Pfizer did not produce until its later productions, after BYU identified missing documents in Pfizer's earlier production, prove that Dr. Simmons's clones worked.[29]

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[26] Dep. of Dr. Philip Needleman, 4 Mar 08, Celebrex Marketing Sales Practices Product Liability Litigation, BYU-PFE 211315 at 347-48, 33:18-34:21, Ex. 2 (emphasis added).

[27] Langreth, Richard. "Merck's Health Hinges on Sales Of Arthritis Pill." Wall St. J., 14 Apr 1999, nat'l. ed.: B1, Ex. 9 (emphasis added); *see also* PFC00256260.

[28] Ltr. from L. Schneider to L.R. Williams, 22 Oct 07, Ex. 16; Motion to Compel Hearing Transcript, 19 Mar 08, 58:14-16, Ex. 10; and Motions Hearing Transcript, 29 Jul 08, 50:5-12, Ex. 5.

[29] Dr. Needleman's 1991 letters to Dr. Amiram Raz, S00664940 and S00664738 REDACTED

Pfizer's documents also prove BYU's materials gave Pfizer a head start. On 17 March 2000, Pfizer's counsel, Dale Hoscheit, wrote a letter to BYU indicating that

REDACTED

* * *

REDACTED

By Pfizer's own admission, BYU provided Monsanto with at least a 12-month head start; according to Dr. Needleman's presentation at $10 million per day, that head start was a quantifiable benefit to Pfizer of some $3.65 billion.

C. Mr. O'Malley Knew The $10M/Day Exhibit Was Relevant To This Litigation.

On 25 January 2008, just 39 days before Dr. Needleman's deposition, Mr. O'Malley and his team filed Pfizer's Response to Plaintiffs' Motion to Compel Immediate Production of Documents with this Court. Pfizer and Mr. O'Malley's Response represented to this Court that Pfizer committed to search for and produce every responsive document:

> **Pfizer's commitment to search for and produce additional responsive documents** for each category of documents described

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REDACTED , Ex. 17; Dr. Seibert's 1992 email to Dr. Needleman, S00663784-85 REDACTED , Ex. 18; and a slide prepared by Pfizer referred to as the "Blue slide", S00504065.367 (showing that Monsanto was using Dr. Simmons's COX-1 and COX-2 clones for "REDACTED" "REDACTED," and "REDACTED"), Ex. 19.

[30] Ltr. from D. Hoscheit to E. Bramhall, 17 Mar 00, BYU-PFE 002960, Ex. 7 (emphasis added).

> in BYU's Motion to Compel **renders many of BYU's claims moot or premature.**[31]

But notwithstanding Pfizer's commitment to the Court, Pfizer has not yet produced Exhibit 1 to Dr. Needleman's 4 and 5 March 2008, deposition—the $10M/day Needleman exhibit.

D. <u>Pfizer Should Have Produced The $10M/Day Exhibit In Response To BYU's First Request For Production.</u>

On 10 January 2008, BYU filed its Motion to Compel with this Court. Though BYU did not then know about the $10M/day Needleman exhibit, BYU's motion addressed at least four requests for production to which the $10M/day Needleman exhibit is responsive. For example, BYU's Request No. 8 sought:

> All laboratory and scientific notebooks, **internal memoranda**, notes from research meetings **and other documents summarizing**, constituting, **concerning, referring, or relating to any COX-related research by Monsanto** including, but not limited to, any product to develop a COX-1 or COX-2 selective NSAID, or any COX-related cancer research.[32]

BYU's Request No. 20 sought:

> All internal or publically available **financial information** referring or **relating to [Pfizer's] sales of Celebrex** or other COX-2 inhibiting NSAIDs, including, but not limited to, documents that report or reflect income, profits, net profits, revenue, total sales, unit sales, costs of goods sold or other related direct or indirect expenses.[33]

BYU's Request No. 29 sought:

> All documents relating to Monsanto's **organizational division of resources and manpower,** specifically as between the "DIP Project" and any project(s) **to find a COX-2 selective NSAID**

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[31] Defendants' Memorandum in Opposition to Motion to Compel Immediate Production of Documents, 25 Jan 08, Dkt No. 69 at 2 (emphasis added).

[32] Plaintiffs' First Request for Production of Documents, 12 Jan 07, Ex. 20 at 10 (emphasis added).

[33] *Id.* at 15 (emphasis added).

> during the years 1990 to 2003, including, but not limited to, department budgets, timesheets, organizational memoranda, reports, management reports, or corporate documents.[34]

BYU's Request No. 39 sought:

> **All documents relating to any COX-related litigation including**, but not limited to, communications, notes, briefs, memoranda, **deposition transcripts**, interrogatory responses, expert witness testimony and reports, or electronic media.[35]

In its Memorandum in Support of Motion to Compel Immediate Production of Documents, BYU further described the categories of documents BYU requested and that Pfizer had not produced. Specifically, BYU described the following:

- "**[R]esearch scientists create** emails, reports, memos, **presentations** and other documents **related to their research**. These have largely not been produced."
- "Internal documents will set forth Pfizer's … corporate strategy as it relates to development of COX-2 selective drugs …."
- "BYU requested **internal financial information** sufficient to identify the **revenue** and costs attributable to Pfizer's COX-2 related drugs."
- "BYU has asked repeatedly for **deposition transcripts and the exhibits marked** at those depositions from prior litigation."[36]

BYU's Motion to Compel Production and Supporting Memorandum were not the first times BYU identified to Pfizer these categories of documents that Pfizer was withholding.

On 12 January 2007, BYU sent its Request for Production of Documents to Pfizer.

On 14 February 2007, Pfizer responded that "**the bulk of Pfizer's production** will consist of … **[*Teva*]**."[37]

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[34] *Id.* at 18 (emphasis added).

[35] *Id*. at 20 (emphasis added).

[36] Plaintiffs' Memorandum in Support of Motion to Compel Immediate Production of Documents, 10 Jan 08, Dkt. No. 58 at 3-4 (emphasis added).

[37] Pfizer Response to Plaintiffs' First Request for Production of Documents, 14 Feb 07, Ex. 21 at 3-4 (emphasis added).

On 28 February 2007, BYU wrote Mr. O'Malley:

> We are concerned that you are significantly limiting your production to only those documents you produced in [*Teva*] … we do not believe the *Teva* production includes all (or some) of the documents relating to areas such as: **presentations, speeches**, or conferences made or **engaged in by Monsanto and its scientists regarding COX**, DIP, or NSAIDS.[38]

On 17 July 2007, Pfizer produced over 2 million pages of documents referred to as the *Teva* Production. The *Teva* production did not include what would become the $10M/day Needleman exhibit or Needleman's deposition in IREF. Nor did it include what would become Exhibits 2-48 of the 4 and 5 March 2008 Needleman deposition.

On 16 August 2007, BYU wrote Mr. O'Malley and Lisa Schneider, addressing

> the inadequacy of **Pfizer's document production** … [I]t is evident that Pfizer's attempt to cut corners on discovery **has not uncovered relevant documents** Plaintiffs have requested.[39]

On 24 August 2007, BYU wrote Ms. Schneider:

> **Pfizer … has yet to provide BYU** and Dr. Simmons **with a meaningful production** resulting **from an independent collection effort** undertaken in connection with this case.[40]

On 3 October 2007, Ms. Schneider misrepresented to BYU

> categories of information which we are in the process of collecting/reviewing/producing and a date by which we expect to complete production of each such category of information … **[I]f a general category of information is not listed below, it is because we have produced all responsive documents or because we have been unable to locate any responsive documents**.[41]

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[38] Ltr. from L. Beus to R. O'Malley, 28 Feb 07, Ex. 22 (emphasis added).

[39] Ltr. from L.R. Williams to L. Schneider and R. O'Malley, 16 Aug 07, Ex. 23 (emphasis added).

[40] Ltr. from L.R. Williams to L. Schneider, 24 Aug 07, Ex. 24 (emphasis added).

[41] Ltr. from L. Schneider to L.R. Williams, 3 Oct 07, Ex. 25 (emphasis added).

Ms. Schneider then listed 15 categories of documents, one of which was "**Custodian collections** per prior communications."[42]

BYU would expect that the $10M/day Needleman exhibit, a presentation Dr. Needleman gave while he was a Senior Executive Vice President and Chief Scientist at Pharmacia, including any drafts, notes, supporting information, and correspondence supporting the presentation, would be included in Dr. Needleman's "custodian collection" from Pfizer.

Not so.

Ms. Schneider indicated that all custodian collections would be produced by "October 31, 2007."[43] But Pfizer did not produce the $10M/day exhibit by 31 October 2007, or ever.

On 9 October 2007, BYU wrote Ms. Schneider seeking "a full explanation of why Pfizer expects that all responsive documents are included in the *Teva* production."[44] BYU also asked Ms. Schneider to "verify whether Pfizer has produced all the documents that relate to **Monsanto's research projects and its strategies to develop COX-related products**."[45]

On 22 October 2007, Ms. Schneider wrote BYU misrepresenting that "notebooks, minutes and **reports were all collected in connection with the Rochester litigation** and therefore would have been produced in the *Teva* document production."[46]

On 29 October 2007, Ms. Schneider wrote BYU specifically misrepresenting that Pfizer's production of "**custodian collections**" was "**done**."[47] Pfizer still had not produced the $10M/day Needleman exhibit.

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[42] *Id.* (emphasis added).

[43] *Id.*

[44] Ltr. from L.R. Williams to L. Schneider, 9 Oct 07, Ex. 26.

[45] *Id.* (emphasis added).

[46] Ltr. from L. Schneider to L.R. Williams, 22 Oct 07, Ex. 16 (emphasis added).

[47] Ltr. from L. Schneider to L.R. Williams, 29 Oct 07, Ex. 27 (emphasis added).

On 9 November 2007, BYU advised Ms. Schneider that "Pfizer is not relieved of its duty to provide a **complete production of responsive documents**."[48]

On 15 November 2007, Ms. Schneider indicated that

> we do not understand your 'condition' that 'Pfizer is not relieved of its duty to provide a complete production of responsive documents.' Pfizer has conducted a good faith search for documents, has kept BYU informed as to precisely what Pfizer does and does not agree to produce, and has followed-up on all of BYU's expressed concerns. **We are at a lack to understand what more BYU expects from Pfizer**.[49]

On 20 November 2007, Ms. Schneider wrote BYU misrepresenting that

> [a]s of yesterday … **all responsive documents located by Pfizer after a reasonable search have been produced** to BYU with three exceptions.[50]

The three exceptions described by Ms. Schneider do not include the $10M/day Needleman exhibit and, summarized generally, were (1) Pfizer's "production of original notebooks;" (2) documents from "the Merck interference;" and (3) "additional contracts … in response to your most recent document request."[51]

On 21 December 2007, BYU wrote Ms. Schneider indicating that

> **[o]ver the course of the past year, BYU has repeatedly attempted to obtain full discovery** of all relevant scientific notebooks and other documents, but to no avail.[52]

BYU specifically quoted from its First Request for Production No. 8 seeking

> **all … internal memoranda, notes from research meetings and other documents summarizing, constituting, concerning, referring, or relating to any COX-related research** by

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[48] Ltr. from L.R. Williams to L. Schneider, 9 Nov 07, Ex. 28 (emphasis added).

[49] Ltr. from L. Schneider to L.R. Williams, 15 Nov 07, Ex. 29 (emphasis added).

[50] Ltr. from L. Schneider to L.R. Williams, 20 Nov 07, Ex. 30 (emphasis added).

[51] *Id.*

[52] Ltr. from L.R. Williams to L. Schneider, 21 Dec 07, Ex. 31 (emphasis added).

> Monsanto including, but not limited to, **any project to develop a COX-1 or COX-2 selective NSAID** ….[53]

On 7 January 2008, Ms. Schneider wrote BYU misrepresenting that "**Pfizer continues to believe that it has [at] all times acted in good faith** throughout the course of discovery in this matter."[54]

On 10 January 2008, three days later, BYU filed its Motion to Compel Production.

On 16 January 2008, six days later, Pfizer confessed that "the *Teva* **production … is apparently incomplete**."[55]

On 25 January 2008, nine days later, Pfizer filed its Memorandum in Opposition to Motion to Compel Immediate Production of Documents with this Court misrepresenting that

> during the *Rochester* litigation, Pfizer performed a good faith search of its files for virtually all technical documents related to COX-2 and produced hard copies of those documents during that litigation. The breadth of Pfizer's document production in the *Rochester* litigation is evident from the document requests propounded by the University of Rochester during that litigation. For example, **Rochester's Request 1 sought** '**[a]ll documents** concerning, recounting, **referring to, summarizing, analyzing or relating to the identification and/or development of Celebrex** as a cox-2 inhibitor.'[56]

Although Dr. Needleman made his $10M/day presentation four months after Rochester's First Request for Production of Documents, Pfizer had a continuing duty in that litigation to produce responsive documents. The $10M/day presentation is a responsive document that Pfizer should have produced in the *Rochester* litigation.

Pfizer also indicated in its Opposition that it was

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[53] *Id.* (emphasis added).

[54] Ltr. from L. Schneider to L.R. Williams, 7 Jan 08, Ex. 12 (emphasis added).

[55] Ltr. from L. Schneider to L.R. Williams, 16 Jan 08, Ex. 15 (emphasis added).

[56] Defendants' Memorandum in Opposition to Motion to Compel Immediate Production of Documents, 25 Jan 08, Dkt. 69 at 3 (emphasis added).

> **in the process of searching for and producing materials in response to most categories of documents set forth in BYU's motion**. Pfizer will produce these materials to BYU promptly and on a rolling basis.[57]

E. Mr. O'Malley Intentionally Withholds The $10 M/Day Exhibit.

As described above, on 4 March 2008, 39 days after Pfizer's Chicago counsel filed its Opposition, Mr. O'Malley sat in a deposition where the $10M/day Needleman exhibit was marked and distributed. Neither Mr. O'Malley, nor anyone on his team, produced that exhibit to BYU. Mr. O'Malley still has not produced the $10M/day exhibit. Nor has Mr. O'Malley produced any of the other 47 exhibits marked at the 4 and 5 March 2008 Needleman deposition, drafts of the $10M/day exhibit, notes from Dr. Needleman's collaboration with Montague, or documents reflecting the help Dr. Needleman received from Monsanto's CEO "mobiliz[ing] 50 molecular and cell biologists [and] one-third of all the medicinal chemists at Searle."[58]

On 19 March 2008, only two weeks after Mr. O'Malley attended the Needleman deposition representing Pfizer and saw the $10M/day presentation with no Bates label marked as an exhibit, Mr. O'Malley's partner, Ms. Schneider, appeared on behalf of Pfizer and represented to this Court that, during the *Rochester* litigation she

> was **personally involved in that collection effort** and I can tell you we've searched the files of over 150 custodians likely to have any documents regarding COX-2 …. We collected everything that had anything to do with COX-2 from the majority of those witnesses. We then reviewed those documents and produced them for purposes of the University of Rochester case.
>
> **We did follow-up searches. You know, as the litigation progressed**, as we learned there might be some missing documents, we contacted additional custodians. We searched those

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[57] *Id.* at 6 (emphasis added).

[58] "From a twinkle in the eye to a blockbuster drug: the story of Celebrex® holds lessons for R&D leaders everywhere," authored by Philip Needleman, published in Research-Technology Management, Vol. 44, No. 6, 1 Nov 2001, pp. 38-41, Ex. 3.

> custodian's files, we searched the central files' repository, and **we believe we got the vast majority of documents that relate to COX-2 in the Rochester case**.
>
> * * *
>
> I mean **everything has been produced**.[59]

But Ms. Schneider didn't produce Needleman's $10M/day presentation.

On 26 March 2008, as described above, the Court ordered that Pfizer provide

> **a complete production**, after a full search for all documents in Defendants' possession, custody or control, responsive **to BYU's First Request for Production of Documents**.[60]

The Court also ordered Pfizer to

> produce all internal correspondence, including email, memoranda, meeting minutes, **reports** (including those to Board of Directors) and **other corporate documents referring or relating to plaintiffs'** DIP and **COX II projects**.[61]

On 27 May 2008, Mr. O'Malley and his team filed Defendants' Certification Concerning Discovery Efforts with this Court. Mr. O'Malley and his team represented with regard to financial documents that "**Pfizer has already begun its production** of responsive documents."[62]

On 29 July 2008, Mr. O'Malley appeared in front of this Court on Pfizer's behalf regarding Pfizer's Certification Concerning Discovery Efforts. Appearing with Mr. O'Malley were his partner, Ms. Schneider, as well as Pfizer's Utah counsel, Messrs. George Haley and David Parkinson. BYU wants to be clear that it makes no suggestion that either Mr. Haley or Mr. Parkinson was aware of the $10M/day Needleman exhibit or Mr. O'Malley and Pfizer's Chicago counsel's failure to produce it in this litigation.

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[59] Motion to Compel Hearing Transcript, 19 Mar 08, 42:6-22; 46:10, Ex. 32 (emphasis added).

[60] Order Granting BYU's Motion to Compel Immediate Production of Documents, 26 Mar 08, Dkt. No. 106 at 1 (emphasis added).

[61] *Id.* at 5 (emphasis added).

[62] Defendants' Certification Concerning Discovery Efforts, 27 May 08, Dkt. No. 117 at 23 (emphasis added).

Mr. O'Malley sat at counsel's table while Mr. Haley represented to this Court that:

> **We have been trying hard to produce all of the documents** that the plaintiffs have requested, and one of the problems that we have is we have a lawsuit that's filed in 2006 dealing with issues that occurred in 1989, 1990 to, you know, through 1992, **it's hard to find things**. The effects of the discovery is not to be perfect, but it's **to do a good-faith job** and make a reasonable search, and **we've done much more than that. We've bent over backwards**, we've spent a tremendous amount of time **responding to Your Honor's Order**.
>
> * * *
>
> And to have the suggestion be that we are hiding documents, removing documents from production, and that we are violating the order is frankly offensive. **We have done what it takes**.[63]

Mr. O'Malley also allowed Mr. Haley to say that any suggestion that

> [Pfizer's lawyers] have not behaved ethically or done our duties as lawyers in complying with a court order **is simply not fair or accurate**.
>
> * * *
>
> **We've done our best, judge**, no one's trying to cheat, we're bending over backwards.[64]

But neither Pfizer, nor its Chicago counsel, produced the $10M/day presentation or the other 47 exhibits marked in Mr. O'Malley's presence at the 4 and 5 March 2008 Needleman deposition.

Finally, on 15 October 2008, two-and-a-half months after the hearing and after producing over 4 million more pages of documents, Pfizer, with Mr. O'Malley listed as counsel, filed its Third Supplemental Certification Concerning Discovery Efforts claiming to this Court that Pfizer:

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[63] Motion To Compel Hearing Transcript, 19 Mar 08, 48:16-49:1; 49:21-25; 50:24-51:1; 70:3-4, Ex. 33 (emphasis added).

[64] *Id* .

> has … **[i]dentified for BYU the various other COX-2 related litigation matters and**, to the extent they are relevant to this case, **produced** the production documents, pleadings, **depositions (including exhibits)**, expert reports, witness statements and hearing transcripts **from these matters**.[65]

Pfizer's representation to this Court is false because Pfizer has never produced the $10M/day Needleman exhibit to BYU.

F. Despite BYU's Requests, Pfizer And Its Chicago Counsel Still Have Not Produced The Needleman Exhibits.

On 24 December 2008, BYU wrote Mr. O'Malley and Ms. Schneider specifically identifying the $10M/day exhibit and requesting that they produce all of the exhibits.

Rather than promptly produce the exhibits, on 29 December 2008, Ms. Schneider suggested that BYU rely on Google searches:

> we certainly did not intentionally withhold this document and, in fact, produced abstracts with a similar title no less than six times. *See e.g.,* BYU-PFE-ARC 1002590338; S00675830; BYU-PFE 653110; Needle-P 10000008149; Needle-P 10000007350. And, **a simple Google search using the terms "Needleman" and "twinkle" promptly pulls up the entire article.**[66]

First, the abstracts to which Pfizer's Chicago counsel referred are not abstracts[67] and do not mention the daily value of a head start, the importance of a target, or the internal importance the COX-2 project had at Monsanto that required the CEO's involvement. If BYU had relied on the so-called abstracts, Pfizer and its Chicago counsel would have succeeded in intentionally misdirecting BYU regarding a highly relevant document.

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[65] Third Supplemental Certification Concerning Discovery Efforts, 15 Oct. 08, Dkt. No. 157 at 3 (emphasis added).

[66] Ltr. From L. Schneider to L. Beus, 29 Dec 08, Ex. 34 (emphasis added).

[67] BYU-PFE-ARC 1002590338; S00675830; BYU-PFE 650301; BYU-PFE 653110; Needle-P 10000008149; Needle-P 10000007350, Ex. 35.

Second, Ms. Schneider's suggestion that BYU rely on Google searches to discover relevant documents is not contemplated by the Federal Rules of Civil Procedure. Further, such a search is unlikely to discover the other 47 exhibits marked at the deposition, some of which are described as Needleman correspondence.

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III. PFIZER FAILED TO PRODUCE DOCUMENTS, TRANSCRIPTS, AND DEPOSITIONS FROM ALL RELEVANT LITIGATIONS.

BYU recently learned from news reports that a California jury in the IREF litigation returned a verdict against Pfizer for misappropriation of trade secrets regarding testing of the COX-2 drug, Bextra.[68] BYU also learned from these same reports that Pfizer was accused of spoliating documents in IREF.

Because BYU was surprised that Pfizer had not produced any documents from a litigation that seemed so similar to this one, BYU's counsel called counsel for IREF and discovered that Dr. Needleman had been deposed in the IREF litigation and answered questions regarding COX-2 and COX-2 inhibitors that are relevant to this litigation. BYU also learned that the Court in the IREF litigation provided the jury with a spoliation instruction that Pfizer had destroyed documents. In spite of its Certification to this Court, Pfizer has still not produced any documents from the IREF litigation.

A review of the discovery history reveals that Pfizer and its Chicago counsel intentionally misrepresented and misdirected BYU regarding the IREF litigation.

On 12 January 2007, Plaintiffs requested

> **All documents relating to any COX-related litigation** including, but not limited to, communications, notes, briefs, memoranda, **deposition transcripts**, interrogatory responses, expert witness testimony and reports, or electronic media.[69]

Additionally, on 4 May 2007, BYU sought, through its Interrogatory No. 1, that Pfizer

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[68] Law.com: Pfizer Hit With $38 Million Jury Verdict in IP Case, 12/29/2008, at http://www.law.com/jsp/law/LawArticleFriendly.jsp?id =1202426997770, Ex. 4.

[69] Plaintiffs' First Request for Production of Documents, 12 Jan 07, Ex. 20 at 20 (emphasis added).

> **identify the court, parties, and case number for all COX-related litigation to which Pfizer has been a party**, subpoenaed, or otherwise involved.[70]

BYU defined COX-related litigation as

> **any and all litigation** or other legal proceedings (including arbitrations) in any jurisdiction **in which one or more of the Defendants is or has been a party**, including a third party, including, but not limited to, litigation between G.D. Searle and the University of Rochester, Pfizer and Teva Pharmaceuticals ltd, G.D. Searle and Merck, any and all class action litigation; any and all international proceedings **wherein "COX" was relevant to the litigation**; and any interference action or other proceeding initiated by the Patent and Trademark Office ("PTO").[71]

In response to BYU's interrogatory, on 5 June 2007, Pfizer named, with brief descriptions, at least 18 litigations by case name and number, including a 140-page exhibit purporting to be "a list of Celebrex and/or Bextra cases submitted to the N.D. Cal. on December 1, 2005."[72]

As one of the 18 specifically listed cases, Pfizer listed IREF. In describing the IREF litigation, Pfizer stated only that it was one of "a number of cases against it **involving other claims related to the prescription medicines Celebrex and Bextra**."[73] Pfizer did not tell BYU that those "other claims" included Pfizer's misappropriation of trade secrets. Instead, Pfizer lumped the IREF case into a category of "other claims" which included *Public Citizen Health Research Group v. Food & Drug Admin., G.D. Searle & Co.*, No. 99-CV-0177 (D.D.C.).

On 26 March 2008, the Court ordered Pfizer to produce

> documents produced in the litigation, pleadings, depositions (including exhibits), expert reports, witness statements and hearing

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[70] Plaintiffs' First Set of Interrogatories to Defendant Pfizer, Inc., 4 May 07, Ex. 36 at 6 (emphasis added).

[71] *Id.* at 2 (emphasis added).

[72] Defendant Pfizer, Inc.'s Response to Plaintiffs' First Set of Interrogatories, 5 Jun 07, Ex. 37 at 5.

[73] *Id.* at 6 (emphasis added).

> transcripts **from other COX-2 related litigation matters to the extent they are relevant in this case**.[74]

After the Court's Order, on 18 April 2008, Ms. Schneider wrote BYU's local counsel, Mark Bettilyon, misrepresenting several aspects of IREF:

> Under the terms of Judge Wells' March 26 Order, "Pfizer is also required to produce documents … **from other COX-2 related litigation** [other than *Teva*, *Merck*, and *Rochester*] matters to the extent they are relevant in this case."
>
> * * *
>
> Lastly, **Pfizer has previously disclosed two other cases in which it was a defendant where plaintiffs alleged claims related to Celebrex and Bextra. See *Ischemia Research & Education Foundation, et al. v. Pfizer* *Inc., et al.,*** No. 1 04 CV 026653 (Cal. Super. Santa Clara Cty.) ("IREF"); *Public Citizen Health Research Group v. Food & Drug Admin., G.D. Searle & Co.,* No. 99-CV-0177 (D.D.C.).
>
> As **Pfizer** has previously stated, it **does not believe that the subject matter of any of these cases is relevant to the claims of BYU or Dr. Simmons …. In *IREF*, the plaintiffs seek damages related to the alleged improper use of an epidemiological database during a Bextra clinical trial**. Lastly, *Public Citizen Health Research Group*, sought to enforce a FOIA request with regard to Celebrex and Bextra regulatory documents.
>
> **None of these issues are germane to the claims of BYU or Dr. Simmons**. Nevertheless, and without admitting that any of the materials related to these cases are relevant, **Pfizer will produce the custodial files that were produced, transcripts, and exhibits from the depositions or trial testimony in the above-listed cases of any witness who is listed on either party's initial disclosures or on either party's identification of planned deposition witnesses in this case**.
>
> In addition, despite our belief that the production materials from these other litigations are not relevant, Pfizer is willing to produce—at BYU's option and expense—all of the electronic documents that Pfizer produced in these cases in the form in which they were previously produced. **Thus far, Pfizer has produced**

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[74] Order Granting BYU's Motion to Compel Immediate Production of Documents, 26 Mar 08, Dkt. No. 106 at 2 (emphasis added).

> **more than 42 million pages of documents, plus dozens of clinical trial databases and other electronic data in the product liability MDL proceedings alone. Many of these same documents have also been produced in the shareholder litigations, as well as in the *IREF* matter**. As a result, if Plaintiffs opt to have Pfizer reproduce all of these documents, **Plaintiffs will receive tens of millions of pages of documents, many of which are overlapping**.[75]

In the same letter, Ms. Schneider promised that Pfizer would produce

> **transcripts and exhibits from the depositions or trial testimony in [IREF or other COX-related litigation] of any witness** who is listed on either party's initial disclosures or on either party's identification **of planned deposition witnesses in this case**,[76]

Pfizer has never produced the Needleman deposition from the IREF litigation.

On the same date, 18 April 2008, Mr. Bettilyon responded:

> Generally speaking, the types of legal proceedings which are relevant are the types of cases not mentioned at all in your letter, including any **intellectual property matters concerning COX II**, including legal proceedings involving the defendants and any of their competitors, such as Merck.
>
> In our conversation you indicated that you would compile a list of these types of legal proceedings and provide that to us. In that summary, **please also provide a brief description of each matter**.[77]

Mr. Bettilyon, without knowing it, described the IREF litigation when he wrote "intellectual property matters concerning COX II." However, relying on Pfizer's description of the IREF litigation and not wanting Pfizer to produce "42 million pages of documents," BYU did not yet understand that IREF was relevant.

On 30 May 2008, Mr. Bettilyon wrote Ms. Schneider again:

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[75] Ltr. from L. Schneider to M. Bettilyon, 18 Apr 08, Ex. 38 (emphasis added).

[76] *Id.* (emphasis added).

[77] Ltr. from M. Bettilyon to L. Schneider, 18 Apr 08, Ex. 39 (emphasis added).

> Finally, **we ask that you** fully comply with the Court's Order and **provide to us a complete list of all "COX-2 related litigation matters to the extent that they are relevant in this case."** To date, **we have never seen a complete list of such litigation matters**. We would ask that you provide, in one place, all of these litigation matters, so that there is no misunderstanding regarding this issue.[78]

On 26 June 2008, Mr. Bettilyon wrote Ms. Schneider to request sample pleadings from the categories of litigation Pfizer identified in its response to BYU's Interrogatory No. 1:

> With respect to the following categories, **could you please provide us with one or two sample complaints, answers and counterclaims**?
>
> A. Shareholder claims related to the prescription medicines Celebrex and Bextra.
>
> B. Consumer fraud claims related to the prescription medicines Celebrex and Bextra.
>
> C. **Cases involving other claims related to the prescription medicines Celebrex and Bextra**.[79]

Category C is the category in which Pfizer placed the IREF litigation on 5 June 2007, in its response to BYU's interrogatory.

Then, on 29 July 2008, Pfizer failed to specifically produce documents from the *IREF* litigation:

> **You have asked for sample complaints, answers and counterclaims from** (1) a shareholder claims case; (2) a consumer fraud case; and (3) **either the Ischemia Research & Education Foundation case or the Public Citizen Health Research Group case. ... The answer and complaint for the Public Citizens case will be produced shortly**.[80]

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[78] Ltr. from M. Bettilyon, to L. Schneider 30 May 08, Ex. 40 (emphasis added).

[79] Ltr. from M. Bettilyon to L. Schneider, 26 Jun 08, Ex. 41 (emphasis added).

[80] Ltr. from L. Schneider to M. Bettilyon, 29 Jul 08, Ex. 42 (emphasis added).

Unlike the *IREF* litigation, the *Public Citizens* case does not appear to deal with trade secret misappropriation and destruction of evidence issues similar to those in this litigation.

On 15 October 2008, Pfizer and its Chicago counsel told this Court that they had

> [i]dentified for BYU the various **other COX-2 related litigation matters and, to the extent they are relevant to this case, produced the production documents, pleadings, depositions (including exhibits)**, expert reports, witness statements and hearing transcripts from these matters.[81]

On 23 December 2008, in a phone conference with BYU's counsel, Mr. O'Malley and Ms. Schneider reaffirmed Pfizer's certification. Ms. Schneider stated:

> Obviously, **we believe we have produced all relevant documents in this case**.

And Mr. O'Malley reaffirmed:

> **I stand by our representations to the Court that we have produced all relevant documents**.

Shortly after the 23 December 2008 phone conference, BYU's counsel learned that the IREF litigation was relevant to this litigation, that Dr. Needleman had been deposed in the IREF litigation, and that, at his deposition, Dr. Needleman was asked about the discovery of COX-2 and COX-2 inhibitors, and that IREF involved similar spoliation issues—all issues that, unlike Pfizer's Chicago counsel told BYU, "are germane to the claims of BYU."

Because Pfizer did not respond to BYU's requests regarding IREF documents, BYU sent counsel to San Jose, California, to examine the public record attached to the IREF litigation. While examining the IREF public record, BYU's counsel confirmed, in addition to trade secret misappropriation, (1) the IREF plaintiffs also accused Pfizer and Pharmacia of destruction of documents and (2) that spoliation is a factor in the case.

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[81] Third Supplemental Certification Concerning Discovery Efforts, 15 Oct 08, Dkt. No. 157 at 3 (emphasis added).

From the IREF public record, counsel was able to learn that Pfizer had filed a motion *in limine* (Motion *in Limine* #8) to preclude IREF's reference at trial to Pfizer's spoliation. It appears from the public record that the motion *in limine*, the response, and perhaps even the court's order addressing those motions, were filed under seal, and therefore not available in the public record. The public record consisted of nearly 150 large binders of pleadings filed with the court; however, counsel's search of that record was conducted under time pressures associated with the availability of the record at the court and with traveling to California for only one day. The California court would only allow counsel to copy 25 pages from the record on any given day. It appears that most of the documents regarding spoliation were filed under seal; however, available in the public record were portions of plaintiffs' trial brief, summarizing plaintiffs' spoliation argument.

According to plaintiffs' trial brief, the IREF litigation involves the misappropriation of trade secrets from the IREF plaintiffs' databases, "some of the most important databases in the world pertaining to the characteristics, treatment, and outcomes of patients undergoing coronary artery bypass graft (CABG) surgery."[82] Plaintiffs further alleged that, on occasion, drug companies asked to use those databases in the development and commercialization of drugs through clinical trials.[83] In 1999, Pfizer approached IREF for help in getting the drug Bextra approved for use in the treatment of acute pain, potentially a huge market for Pfizer.[84] However, the IREF plaintiffs allege that when the companies were unable to reach an agreement for the licensing of plaintiffs' databases, Pfizer maliciously approached one of the plaintiffs' employees,

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[82] *See* Plaintiffs Trial Brief, Case No. 1-04-CV-026653, *Ischemia Research and Education Foundation v. Pfizer, Inc.*, 19 Oct 07, Ex. 43 at 26 (emphasis added).

[83] *Id*.

[84] *See Id.* at 1-2.

Dr. Ping Hsu, and conspired with him to secretly search plaintiffs' databases, without plaintiffs authorization.[85] Again, according to the plaintiffs' trial brief:

> Hsu—without telling his superiors and without authorization—repeatedly accessed and conducted unauthorized studies of Plaintiffs' Databases, creating subsets of patients who matched the characteristics of the patients enrolled in the Pfizer CABG studies. [citation to statement of facts omitted.] Hsu would then query and study those subsets to answer questions relevant to issues being faced at the same time in Pfizer's CABG II study.[86]

Similar to the allegations in BYU's case, the above allegations involve misappropriation of trade secrets for the development of Pfizer's COX-2 inhibitors. IREF's trial brief also contained allegations of Pfizer's willful suppression of evidence:

> [W]hen counsel for Plaintiffs advised Pfizer of a possible legal action and requested that Pfizer preserve certain files and media, Pfizer also deliberately destroyed evidence and potential evidence and failed to preserve the files of key witnesses in this case, including former Pfizer employees, Dr. Snabes and Dr. Robert Anders.[87]

Plaintiffs in the IREF litigation found themselves in a similar position to that of BYU – *i.e.*, Pfizer had destroyed or lost important evidence:

> Defendants, particularly Pfizer, are likely to argue that there is a purported absence of physical files, copies of files, or other information or data reflecting the communication or transfer of information from Plaintiffs' Databases to Pfizer. This situation is largely the result of Defendants' destruction of evidence in this case, which Plaintiffs intend to show at trial. Plaintiffs will produce evidence relating to Defendant Pfizer and Hsu's spoliation of electronic records. Because of Defendants' intentional or reckless spoilative activity, Plaintiffs intend to seek a jury charge that is appropriate under California law, and which includes mention of an adverse evidentiary inference. With respect to Pfizer, Plaintiffs are not seeking to limit evidence, and have not filed a motion in

[85] *See Id.* at 3-4.

[86] *Id.* at 4.

[87] *Id.* at 6-7.

> limine for an evidentiary finding. Nonetheless, at the close of evidence, Plaintiffs intend to seek an adverse inference concerning Pfizer's wanton and reckless omissions which led to the destruction of evidence.[88]

Likewise, in this case, Pfizer has engaged in a pattern of destroying biological materials and otherwise losing or destroying lab notebooks, sets of notebooks, financial information, e-mails, and board minutes. BYU anticipates that Pfizer will argue that these missing documents leave a hole in BYU's case, just as Pfizer apparently attempted to argue in IREF.

Pfizer will likely argue that any inferences or evidence from the IREF litigation are irrelevant here. However, BYU is entitled to show at trial that Pfizer has engaged in a systematic litigation strategy of willfully tampering with evidence. As mentioned above, it appears that many records in the IREF litigation are filed under seal and are not available in the public record. However, Pfizer should have notified BYU, long ago, that issues raised in the IREF litigation are relevant to this litigation; and, Pfizer should have produced any relevant documents to BYU from the IREF litigation. So that Plaintiffs can establish these points at trial, this Court should enter an order requiring Pfizer to give BYU full access to the IREF litigation files, including those files which were filed under seal.

IV. PFIZER AND ITS CHICAGO COUNSEL HAVE MISREPRESENTED PFIZER'S DISCOVERY SINCE FEBRUARY 2007.

The foregoing are not the only examples, though they are egregious, of Pfizer and its Chicago counsel's misrepresentations. As BYU describes below, Pfizer and its attorneys, including Mr. O'Malley, have been misrepresenting Pfizer's production and the relevant documents in its possession since 14 February 2007, when Pfizer responded to BYU's First Request for Production of Documents.

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[88] *Id.* at 25.

Given Pfizer's history in this case, BYU cannot believe Pfizer's claims, especially its claim that:

> **Pfizer has produced every non-privileged, responsive document it has located as a result of these extensive searches** (which were conducted by a team of individuals, including Pfizer employees, Pfizer contractors, and Pfizer outside counsel.[89]

In the following seven sections, BYU outlines some of Pfizer and its counsel's other misrepresentations.

* * * *

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* * * *

[89] Third Supplemental Certification Concerning Discovery Efforts, 15 Oct 08, Dkt. No. 157 at 5 (emphasis added).

V. BEFORE THE COURT'S ORDER CAUSING PFIZER TO FIND OVER 300 SAMPLES, PFIZER CLAIMED FOUR TIMES THAT IT COULD NOT LOCATE RESPONSIVE BIOLOGICAL MATERIALS.

BYU provided Pfizer with biological materials, including clones, antibodies, other reagents, and other trade secrets that provided Pfizer with the $10M/day head start described above. To minimize the importance of Dr. Simmons's contribution, Pfizer told this Court that Pfizer "discarded" Dr. Simmons's biological materials because they did not work:

> It's our view that **Dr. Simmons' clones didn't work, so** there was a minimal amount of research with them and then **they were discarded.**[90]

Then, on 21 May 2008, approximately two months after this Court's Order, Pfizer identified eight vials whose label includes "Simmons." Pfizer also identified over 295 more vials not specifically labeled "Simmons," but responsive to BYU's requests because they contain COX-1 or COX-2 biological materials.[91]

Pfizer's production, coming only after misrepresentations and a court order, demonstrates again that Pfizer's claims cannot be trusted and that Pfizer's litigation strategy relies on withholding critical evidence.

Pfizer's production further demonstrates that it was not only able to cause Dr. Simmons's clones to replicate, but also that Pfizer wanted to replicate Dr. Simmons's clones. Had Dr. Simmons's clones not worked or been otherwise not valuable, as Pfizer now claims, Pfizer would not have duplicated and stored for approximately 17 years the clones and other reagents.

Further, as described below, Pfizer's notebooks indicate that Pfizer used and reproduced many more of Dr. Simmons's materials than it has identified.

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[90] Motion To Compel Hearing Transcript, 19 Mar 08, 58: 14-16, Ex. 44 (emphasis added).

[91] Ltr. from J. Spanbauer to K. Ricker, 21 May 08, Ex. 45 (emphasis added).

On 12 January 2007, BYU requested

> **all recombinant constructs and clones** (including but not limited to **plasmids** or viruses) of **murine COX-1 and COX-2** as well as samples of all **antibodies against COX-2** obtained by Monsanto from Dan Simmons or from other sources between 1989 and 1995.[92]

On 14 February 2007, Pfizer, with Mr. O'Malley's name on the Response, responded that it would investigate

> **whether responsive material exist** in Defendants' possession, … and will respond to the request at the conclusion of such investigation.[93]

On 28 February 2007, BYU wrote Mr. O'Malley indicating that

> We do not believe the *Teva* production includes all (or some) of the documents relating to areas such as: … documents or other material regarding recombinant constructs and clones of murine COX-1 and COX-2 and antibodies against COX-2 obtained by Monsanto from Dr. Simmons and other sources between 1989 and 1995.[94]

On 16 August 2007, BYU wrote Mr. O'Malley and Ms. Schneider indicating that

> **Pfizer has produced no** documents relating to scientific information, data, and **biological materials** Dr. Simmons sent to Monsanto or any information relating to the specific clones used by Monsanto in their development of COX-2 selective NSAIDs. … **Pfizer's production is incomplete**.[95]

On 20 August 2007, Ms. Schneider wrote BYU misrepresenting that

> **Pfizer has been searching for**, collecting and reviewing documents responsive to requests [for biological materials][96]

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[92] Plaintiffs' First Request for Production of Documents, 12 Jan 07, Ex. 20 at 21 (emphasis added).

[93] Pfizer Response to Plaintiffs' First Request for Production of Documents, 14 Feb 07, Ex. 21 at 38 (emphasis added).

[94] Ltr. from L. Beus to R. O'Malley, 28 Feb 07, Ex. 22 (emphasis added).

[95] Ltr. from L.R. Williams to L. Schneider and R. O'Malley, 16 Aug 07, Ex. 23 (emphasis added).

[96] Ltr. from L. Schneider to L.R. Williams, 20 Aug 07, Ex. 44 (emphasis added).

On 3 October 2007, Ms. Schneider again wrote BYU misrepresenting

> categories of information which we are in the process of collecting/reviewing/producing and a date by which we expect to complete production of each such category of information … **if a general category of information is not listed below, it is because we have produced all responsive documents or because we have been unable to locate any responsive documents**.[97]

Ms. Schneider then listed 15 categories of documents, none of which described biological materials or related documents.

On 9 October 2007, Ms. Schneider wrote to BYU misrepresenting that "**Pfizer has** to date **been unable to locate any biological materials** requested in plaintiffs' document requests."[98]

Because BYU mediated this dispute with Pfizer on 31 January 2006 in Chicago, Illinois—a mediation that BYU President Dr. Cecil Samuelson personally attended—on 28 November 2007, BYU wrote Ms. Schneider:

> We understand that **Pfizer had [BYU's] biological materials during the mediation.** Please explain why no biological materials presently exist?[99]

On 7 January 2008, more than two months later, Ms. Schneider wrote to BYU stating that

> **Pfizer did have certain biological materials** …. However, Pfizer had only very small quantities of those materials [at] that time and **those materials were utilized** to obtain sequence data during the mediation.[100]

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[97] Ltr. from L. Schneider to L.R. Williams, 3 Oct 07, Ex. 25 (emphasis added).

[98] Ltr. from L. Schneider to L.R. Williams, 9 Oct 07, Ex. 11 (emphasis added).

[99] Ltr. from L.R. Williams to L. Schneider, 28 Nov 07, Ex. 46 (emphasis added).

[100] Ltr. from L. Schneider to L.R. Williams, 7 Jan 08, Ex. 12 (emphasis added).

On 25 January 2008, Mr. O'Malley, Pfizer's Chicago counsel, and Pfizer filed Pfizer's Memorandum in Opposition to BYU's Motion to Compel in which Pfizer misrepresented to this Court that

> **original biological materials** that Pfizer used to sequence Dr. Simmons' clones … **no longer exist** [and that] the freezer in which the sample was stored malfunctioned and **the sample was inadvertently discarded**.[101]

Then, on 19 March 2008, in front of this Court, Ms. Schneider claimed that

> [i]t's our view that **Dr. Simmons' clones didn't work**, so there was a minimal amount of research with them and then **they were discarded**.[102]

Pfizer and Pfizer's Chicago counsel's statements to this Court and to BYU were not true.

On 19 March 2008, the Court asked BYU if it was "contemplating any **argument or investigation into spoliation**."[103] BYU responded that it was.

On 26 March 2008, among other things, this Court ordered Pfizer to

> produce **all biological materials and reagents** used in Defendants screen for COX II selective compounds.[104]

On 21 May 2008—two months after Pfizer stated to this Court that it did not have any of Dr. Simmons's clones and two months after the Court asked BYU about investigating spoliation—Pfizer claimed to have

> **conducted an extensive search for cyclooxygenase-related biological materials** that remain in Pfizer's possession, custody or

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[101] Defendants Memorandum In Opposition To Motion To Compel Immediate Production of Documents, 25 Jan 08, Dkt. No. 69 at 8 (emphasis added).

[102] Motion To Compel Hearing Transcript, 19 Mar 08, 58: 14-16, Ex. 10 (emphasis added).

[103] *Id.* at 31: 3-5 (emphasis added).

[104] Order Granting BYU's Motion to Compel Immediate Production of Documents, 26 Mar 08, Dkt. No. 106 at 4 (emphasis added).

> control [including] biological materials that it received from Professor Simmons.[105]

Pfizer's "extensive search," according to Pfizer's 30(b)(6) deposition testimony, seems to have been carried out by only one employee—Scott Hauser—lasted only "**two or three days**,"[106] and yielded eight Eppendorf tubes with "Simmons" on the label, including one labeled "**Simmons's mouse COX-1/COX-2**" and one labeled "**Simmons mCOX-2** in bluescript C75 mitogenic COX-2."[107]

Additionally, Pfizer identified 295 other vials with samples of biological material, including several mCOX-2 clones.[108]

On 10 June 2008, BYU deposed Scott Hauser, Pfizer's 30(b)(6) designee to testify about, among other things, Pfizer's "search for biological materials and related information."[109] Mr. O'Malley defended Hauser's deposition. BYU learned that Pfizer and its Chicago counsel had no basis for its previous four claims about not having biological materials—claims that all proved false. Further, BYU learned that Pfizer's "two or three day" search did not include talking to key scientists—key scientists who Pfizer knew had actually received and used Dr. Simmons's clones and antibodies—or checking every freezer likely to have biological materials.

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[105] Ltr. from J. Spanbauer to K. Ricker, 21 May 08, Ex. 45 (emphasis added).

[106] Scott Hauser 30(b)(6) deposition, 10 Jun 08, 188:3-9, Ex. 14 (emphasis added).

[107] *Id.* at 99:21-100:6 (emphasis added).

[108] Ltr. from J. Spanbauer to K. Ricker, 21 May 08, Ex. 45.

[109] Ltr. from L. Schneider to M. Bettilyon, 13 May 08, Ex. 47 (emphasis added); *see also* Scott Hauser 30(b)(6) deposition, 10 Jun 08, 6:13-14 ("identification of any **biological materials relating to COX-1 and 2**."), Ex. 14 (emphasis added).

A. Pfizer's 9 October 2007 Claim That Pfizer Had Been Unable To Locate Any Biological Materials Was A Misrepresentation.

Mr. Hauser testified that the first time he was asked to look for any of Dr. Simmons's clones in this case was in April 2008, six months after Ms. Schneider's claim that Pfizer had been "unable to locate any biological materials" and after the Court's order:

> Q. When was the first time that you were asked to look for any clones in this case?
>
> * * *
>
> A. I don't have an exact date. It was **mid April**.
>
> Q. Of this year?
>
> A. **Yes**.[110]

Mr. Hauser further testified regarding when he had been asked to search for biological materials and how long it took him to find them:

> Q. You hadn't been asked to find anything in October of 2007, had you?
>
> A. I had not, no.
>
> Q. Okay. **How long did it take you** to find these biological materials?
>
> * * *
>
> A. W ell, **two or three days**.[111]

B. Pfizer's Statements To This Court That BYU's Biological Materials Did Not Work And Were Discarded Were Misrepresentations.

Mr. Hauser described the biological material from Dr. Simmons that he found in Pfizer's possession:

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[110] *Id.* at 105:11-20 (emphasis added).

[111] *Id.* at 187:24-188:7 (emphasis added).

> Well, for instance, in regards to these, I mean the original DNAs that we still have of Dr. Simmons' clones are labeled whatever they were, mCOX-1, mCOX-2 and the vector that we received them, you know, I think with a notation that said Simmons or something.
>
> They are not the original tubes. There was probably a finite number in there, and we would have retransformed and made another working stock, which were the tubes that we produced in this document. But we continued to refer to them as, you know, mCOX-1 from Simmons, for instance.[112]

Thus, Pfizer successfully used and replicated Simmons's clones to make more stocks as they continued to work with them.

C. Pfizer's 7 January 2008 Claim That Pfizer Used Up BYU's Biological Materials During The Mediation Was A Misrepresentation.

On 7 January 2008, Ms. Schneider wrote that

> **Pfizer did have certain biological materials** …. However, Pfizer had only very small quantities of those materials [at] that time and **those materials were utilized to obtain sequence data** during the mediation.[113]

At his deposition, Mr. Hauser confirmed that he was aware of some sequencing work done with BYU's COX-1 and COX-2 clones in 2000, in preparation for a meeting with BYU:

> Q. Okay. So you were asked in 2000 to **resequence these clones?**
>
> * * *
>
> A. **Yes**.
>
> Q. And did you do that?
>
> A. I did not. **Elizabeth [Harding] did**.[114]

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[112] *Id.* at 165:17-166:4 (emphasis added).

[113] Ltr. from L. Schneider to L.R. Williams, 7 Jan 08, Ex. 12 (emphasis added).

[114] Scott Hauser 30(b)(6) deposition, 10 Jun 08, 104:14-22, Ex. 14 (emphasis added).

Hauser further testified that he had never been told that Dr. Simmons's clones were all used up in the 2000 sequencing. Instead, Mr. Hauser testified that he thought Dr. Simmons's clones were still viable:

> Q. Okay. Now, were you ever told that the – that Dr. Simmons' clones were all used up in the 2000 sequencing?
>
> A. **No**. I never had any follow-up conversation about them.
>
> * * *
>
> Q. Okay. Do you think there are probably viable clones in the tubes?
>
> * * *
>
> A. DNA is pretty stable. **I would imagine we could resurrect those clones**. I don't know that for a fact, no.
>
> Q. Okay. But **more likely than not** they could be resurrected?
>
> A. **I would imagine.**[115]

D. <u>Pfizer's Chicago Counsel Did Not Adequately Inform Mr. Hauser Of His Duties.</u>

Mr. Hauser testified that he did not "recall seeing"[116] the Court's Order. He further testified that he did not know what was needed to comply with the Court's Order, explaining "**[a]s far as what I need to do, I don't have a firm understanding for that**."[117]

Mr. Hauser also testified that he didn't understand his duty to preserve potential evidence:

> Q. Okay. Before [April or May of 2008], **did you have an understanding regarding your duties to preserve**

[115] *Id.* at 107:11-108:14 (emphasis added).

[116] *Id.* at 78:8-11.

[117] *Id.* at 214:13-15 (emphasis added).

> **biological materials** or information relating to this lawsuit with BYU?
>
> A. **I don't specifically remember** being told that one way or another.[118]

E. Mr. Hauser Testified That He Did Not Contact Key Individuals With Regard To His Search For Biological Materials.

Mr. Hauser testified that in order to comply with the Court's Order, he

> **started by contacting** … [his] **colleagues** … who are still with the company **who were present during the time** we did this work to ask them what reagents they were aware of that were still around, where they may be located, and how we could initiate a search…."[119]

These colleagues included Elizabeth Harding, Nick Staten, Gerry Casperson, Bev Reitz, Jim Gierse, and Mark Moffatt.

Hauser testified that he did not know if any of them looked in notebooks to ensure that BYU was getting all of the responsive biological materials.[120] Further, Hauser testified that Staten "was **not involved in the COX project**, but as a person occupying the lab space … at the time."[121]

Dr. Simmons sent his biological materials to Monsanto on 29 April 1991.[122] Drs. Karen Seibert and Jaime Masferrer directed Monsanto's work with Dr. Simmons's clones and antibodies. However, even though Mr. Hauser "**worked with [Karen Seibert] on COX-2** related projects,"[123] Mr. Hauser "**did not**" contact Seibert to ask her if she had any information

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[118] *Id.* at 160:10-15 (emphasis added).

[119] *Id.* at 7:10-17 (emphasis added).

[120] *Id.* at 46:15-47:4.

[121] *Id.* at 7:19-22 (emphasis added).

[122] Ltr. from D. Simmons to K. Seibert and J. Masferrer, 29 Apr 91, BYU-PFE 087023, Ex. 8.

[123] Scott Hauser 30(b)(6) deposition, 10 Jun 08, 35:16-21, Ex. 14 (emphasis added).

about where biological materials may be stored because "**it did not occur to [him]** that she would have any knowledge or memory of what may or may not be around."[124]

Similarly, even though Mr. Hauser knew that Jaime Masferrer was involved "in **COX-2 development efforts**,"[125] Mr. Hauser did not contact Jaime Masferrer because "**it did not occur to [him]** that [Masferrer] would be able to identify any biological reagents [Pfizer] might have."[126]

Further, Mr. Hauser testified that he did not ask anyone what biological materials they might have discarded:

> Q. Okay. Did you discuss with anyone else **what they threw away**?
>
> A. **No**.
>
> Q. Okay. So the context of your work for preparing for this deposition, **you did not ask anyone what they might have discarded**?
>
> A. Not specifically.[127]

F. <u>Pfizer Did Not Adequately Search For Plasmids.</u>

BYU requested "all … plasmids" from Pfizer relating to COX-1 and COX-2. According to a Beverly Reitz scientific notebook that Pfizer still has not produced, Monsanto scientists used plasmids "REDACTED"[128] in their COX-1 and COX-2 research. Hauser testified that Monsanto researchers assigned specific numbers to each plasmid created at

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[124] *Id.* at 35:8-36:16 (emphasis added).

[125] *Id.* at 37:10-38:17 (emphasis added).

[126] *Id.* at 37:14-16 (emphasis added).

[127] *Id.* at 158:4-10 (emphasis added).

[128] MON001768, Ex. 48 (emphasis added).

Monsanto. These numbers begin with the prefix pMON—which stands for "plasmid from Monsanto."[129] Hauser further testified:

> **pMON numbers were assigned to researchers** in blocks of 100 sequentially. It was up to [researchers] to decide what plasmid needed to have a pMON designation and to **record them in [their] notebooks**….[130]

And although Mr. Hauser testified that it

> **would have been possible** [to] go back to researchers and say, 'what pMON numbers were assigned to you when you were working on that COX-2 project?' and just go check those numbers, … **it didn't occur to** Mr. Hauser to find the relevant pMON numbers.[131]

For example, in the same Reitz notebook that Pfizer has still not produced, Reitz writes that pMON 23902 contains mCOX-1 and that pMON 23903 contains mCOX-2.[132] Ms. Reitz also noted that she would "REDACTED"[133]

Further, Mr. Hauser testified that a document Pfizer produced listing eight pMON numbers, including 23902 and 23903, reflected "**biological samples** with those pMON numbers **[that] at one point in time existed**:"[134]

> Q. Okay. But you'll acknowledge that it appears very likely, given your knowledge of Exhibit 25 [PFC01212081], that at one point in time **there were biological samples that had been assigned those pMON numbers**?
>
> A. Correct.
>
> Q. Okay. And you haven't found those?

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[129] Scott Hauser 30(b)(6) deposition, 10 Jun 08, 23:19-24:2, Ex. 14 (emphasis added).

[130] *Id.* at 24:16-22 (emphasis added).

[131] *Id.* at 25:21-26:7 (emphasis added).

[132] MON001767, Ex. 49.

[133] MON001787, Ex. 50 (emphasis added).

[134] PFC01212081, Ex. 51 Scott Hauser 30(b)(6) deposition, 10 Jun 08, 121:12-19, Ex. 14 (emphasis added).

A. **I haven't found them**, but I would say to you that they – I cannot speak to 23900 and 901, where they have gone, they've dried up, been discarded or what.

* * *

So I haven't found them. They did exist at one time.[135]

Even though biological samples with those eight COX-related pMON numbers existed at one time, Mr. Hauser only located biological samples from three of the eight pMON numbers. Mr. Hauser did not find vials relating to pMONs 23902, 23903, 23905, 23911, or 23913.[136]

Mr. Hauser further testified that he is not "confident that **every pMON number** in that time frame **that's relevant to COX-2**" was provided to BYU.[137]

Mr. Hauser also testified that he did not know if there would "be a **record that would show what blocks** [of pMON numbers] **were assigned** to different researchers."[138]

Mr. Hauser testified that he "**didn't decide where to start looking**" in scientific notebooks for pMON numbers but instead relied on counsel "through phone conversations with **Mr. Spanbauer [one of Pfizer's Chicago counsel], who was in possession of the copies of the notebooks**."[139]

G. Pfizer Did Not Search For Antibodies.

When asked about his searches to respond to BYU's Request No. 43 for antibodies, Mr. Hauser testified:

Q. Did you find any antibodies at all?

A. **I did not look for antibodies**.

---

[135] *Id.* at 122:12-123:7 (emphasis added).

[136] *Id.* at 120:3-121:1.

[137] *Id.* at 30:13-19 (emphasis added).

[138] *Id.* at 24:24-25:6 (emphasis added).

[139] *Id.* at 43:3-6 (emphasis added).

* * *

A. **I didn't see [BYU's Request for Production]. I didn't realize antibodies was on it**. And my search was limited to the things enclosed in that letter because that was my understanding what we were to find.

Q. Okay. So **you did not look at BYU's document production request** before you went out and did your searching?

A. **I don't recall seeing this**.

Q. Okay. And **you didn't search for antibodies**?

A. **I did not**.

Q. Okay. If you were to search for antibodies, **where would you look**?

A. I would begin with talking to the – to **people that would probably have been involved in this work at the time**.

* * *

Q. **You didn't know** that [Monsanto received antibodies from Dr. Simmons]?

A. No. **I had no idea**.[140]

H. Pfizer Did Not Search All Of Its Freezers Likely To Contain Responsive Biological Material.

Mr. Hauser testified that during the relevant time period "**Monsanto had two sites where we did research**, Chesterfield Village and Creve Coeur."[141]

Mr. Hauser testified that he was "in Chesterfield"[142] and that Karen Seibert's laboratory was "on the Creve Coeur campus"[143] where "there were some screening activities taking

[140] *Id.* at 77:13-78:24 (emphasis added).

[141] *Id.* at 33:22-24 (emphasis added).

[142] *Id.* at 33:10-12.

[143] *Id.* at 33:16-18.

place"[144] or researchers were "running some type of assays."[145] All of this work "related to COX-2."[146]

Even though Monsanto was conducting COX-2-related work at both the Creve Coeur and Chesterfield facilities, Mr. Hauser did not search the freezers at Creve Coeur.[147]

When Pfizer acquired Pharmacia, Mr. Hauser believes

> that virtually **every freezer in the place moved up, down**, around, **as Pfizer restructured** itself and new—and groups were phased out and new groups started. I think that there was a—there was a **tremendous upheaval of space** that people occupied.[148]

Even though Mr. Hauser was aware of the upheaval and does not know if "**freezers moved in and out** to other locations,"[149] Mr. Hauser also does not know what freezers were moved from Pfizer's Creve Coeur facility nor does he know what was in those freezers.[150] Mr. Hauser also did not search all of the freezers in Pfizer's Chesterfield facility and he does not even know how many freezers are in the Chesterfield facility.[151]

Mr. Hauser also testified that he had not searched a third facility, the Newstead facility, for relevant materials:

> Q. **What's currently at the Newstead site**?
>
> A. **I don't know**.

---

[144] *Id.*

[145] *Id.* at 34:22-35:6.

[146] *Id.* at 33:16-18.

[147] *Id.* at 49:20-50:1.

[148] *Id.* at 60:19-61:19 (emphasis added).

[149] *Id.* at 61:24-62:5 (emphasis added).

[150] *Id.* at 63:12-20.

[151] *Id.* at 64:20-65:17.

> Q. Okay. **Do you know if any freezers from Creve Coeur or Chesterfield might have been sent to the Newstead site**?
>
> A. **I don't**.
>
> Q. **Who** would know?
>
> A. **I don't know**.[152]

I. Pfizer Did Not Appear To Search For Documents Relating To Biological Materials This Court Ordered It To Produce.

On 26 March 2008, among other things, the Court ordered Pfizer to produce

> **complete documentation relating to the chain of custody** or any other documents related to the loss of all biological materials and requests provided to Defendants by Dr. Simmons including any insurance claims.[153]

Mr. Hauser testified that he is "**not clear as to what a chain of custody document** would be or that anything like that **would even exist**."[154]

He also testified that he was "**not specifically aware prior to today** that he needed to look for chain of custody documents."[155]

At the very least this would include notebook pages.

The Court also ordered Pfizer to

> **produce all other responsive documents relating to biological materials,** including (1) its **retention policies** for biological materials, (2) **a list of all biological materials** that were used by Monsanto relating to its COX II projects, and (3) **all documents relating to testing of any COX II related biological materials**.[156]

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[152] *Id.* at 64:20-65:17 (emphasis added).

[153] Order Granting BYU's Motion to Compel Immediate Production of Documents, 26 Mar 08, Dkt. No. 106 at 4 (emphasis added).

[154] Scott Hauser 30(b)(6) deposition, 10 Jun 08, 70:14-18, Ex. 14 (emphasis added).

[155] *Id.* at 71:3-6 (emphasis added).

[156] Order Granting BYU's Motion to Compel Immediate Production of Documents, 26 Mar 08, Dkt. No. 106 at 4-5 (emphasis added).

Mr. Hauser testified that he didn't "know anything about that part of the order" and that he was **not "aware of any others that have done work" relating to that part of the Court's Order**.[157]

J. Mr. O'Malley, Pfizer's Chicago Counsel, And Pfizer Failed To Produce Court-Ordered Documents.

As demonstrated above, Mr. O'Malley defended Pfizer's 30(b)(6) deposition and heard testimony that Pfizer's designee (1) did not thoroughly search for biological materials and (2) did nothing with regard to searching for or gathering documents the Court specifically ordered Pfizer to produce.

Since Mr. Hauser's deposition, Pfizer has not produced any Court-ordered documents

> relating to the **chain of custody** or any other documents related to the loss of all biological materials and reagents provided to Defendants by Dr. Simmons including any insurance claims, … documents of all **repairs and malfunctions of freezer, labs** from 2000 to the present in any facility in which Dr. Simmons biological material were stored, along with **policies and procedures regarding maintenance** of lab freezers, … all documents in Defendants' possession, custody or control that **reflect Defendants' work with Dr. Simmons' reagents** and other biological and intellectual property, [or] all other responsive **documents relating to biological materials** including (1) its **retention policies** for biological materials, (2) a **list of all biological materials** that were used by Monsanto relating to its COX II projects and (3) all **documents relating to testing** of any COX II related biological materials.[158]

On 17 July 2008, Mr. Spanbauer wrote BYU indicating that, after Mr. Hauser's deposition, Mr. Hauser conducted "additional searches [and interviewed additional Pfizer

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[157] Scott Hauser 30(b)(6) deposition, 10 Jun 08, 74:8-20, Ex. 14 (emphasis added).

[158] Order Granting BYU's Motion to Compel Immediate Production of Documents, 26 Mar 08, Dkt. No. 106 at 4-5 (emphasis added).

personnel]."[159] Mr. Spanbauer also indicated that, after talking with Ben Zweifel, Mr. Hauser located two tubes containing COX-1 antibody and two tubes containing COX-2 antibody.[160]

Pfizer's follow-up letter demonstrates that Pfizer will withhold critical material even in the face of a Court Order. If BYU had not deposed Mr. Hauser and asked the correct questions, Pfizer would not have identified the 17 July 2008 antibodies.

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* * * *

* * * *

[159] Ltr. from J. Spanbauer to K. Ricker, 17 Jul 08, Ex. 52.

[160] *Id.*

VI. PFIZER CLAIMS THAT IT PRODUCED ALL RELEVANT SCIENTIFIC NOTEBOOKS.

A. Monsanto Scientific Notebooks Are A Crucial Source Of Evidence In This Litigation.

On 22 October 2007, Ms. Schneider wrote BYU indicating that

> **[R]esults of research** performed at pharmaceutical companies are **commonly recorded in lab notebooks**.[161]

Because research results are recorded in those lab notebooks or scientific notebooks, all COX-2 related scientific notebooks from Monsanto and Searle during the relevant time period—especially from 1991 to 1993—are, as Ms. Schneider indicated, crucial sources of evidence in this litigation.

Also underscoring the importance of scientific notebooks in this litigation was Mr. Hauser's deposition testimony that scientific notebooks are an important source of information regarding biological materials—an important source that Mr. Hauser did not consult:

> Q. Well, I guess a question for you, Mr. Hauser, is you've been asked to provide all the biological materials, and it appears from this e-mail that **there were cDNA probes that were being created as of September of 1991**.
>
> And my question for you is, how are we going to find those cDNA probes?
>
> * * *
>
> A. **I don't know, without** having a conversation with someone and **going through notebooks**, what this involved or what maybe was generated if any exists.[162]
>
> * * *

[161] Ltr. from L. Schneider to L.R. Williams, 22 Oct 07, Ex. 16 (emphasis added).

[162] Scott Hauser 30(b)(6) deposition, 10 Jun 08, 147:4-17, Ex. 14 (emphasis added).

I would agree that **a notebook would be a reasonable place to determine what biological reagents would have been generated.**[163]

* * *

A. I would say that **that would require a rather extensive review of a lot of notebook pages** to see what other clones may have arisen from those, and we do not physically go through the notebooks and try to cross-reference everything.[164]

Q. --How would you go about then searching for derivatives of his clones that are in your possession?

* * *

A. I believe you would have to systematically sequence everything we've generated.

Q. Okay. Would there be any other way of doing it?

A. Well, one could, I'm sure, **spend a considerate amount of effort in the notebooks** to backtrack and see if it were notated, you know, what the parent clone was.[165]

* * *

Q. What are your -- what pMON blocks of numbers were assigned to you personally?

A. W ell, **I would have to go back to all my other notebooks to remember**. Obviously, the ones that I was working on at the time frame of these were the 23,900 block. I have worked within other ones, but I would have to go -- I mean I don't recall. **I would have to go back to my notebooks**.[166]

* * *

[163] *Id*. at 81:7-9 (emphasis added).

[164] *Id*. at 100:12-16 (emphasis added).

[165] *Id.* at 101:21-102:13 (emphasis added).

[166] *Id.* at 173:21-174:5 (emphasis added).

> Q. **Do you know if [Seibert] used pMON numbers** that had been assigned to others besides you?
>
> A. No, I don't know. **We would have to go through [Seibert's] notebooks.**[167]
>
> * * *
>
> I don't know when [Siebert] left the lab. We could probably **trace that through when her notebook stopped**.[168]

Both Pfizer's Chicago counsel and Pfizer concede the importance of the scientific notebooks to this litigation. However, Pfizer has still failed to produce specific notebooks, and sets of notebooks, that BYU knows about and has requested, and Pfizer has failed to produce any index of notebooks that would indicate exactly what notebooks are still missing.

B. <u>Pfizer Has Always Misrepresented Its Production Of Scientific Notebooks.</u>

On 12 January 2007, in Request No. 8 of Plaintiffs' First Request for Production of Documents, Plaintiffs requested

> **[a]ll laboratory and scientific notebooks** … relating to any COX-related research by Monsanto.[169]

On 14 February 2007, Pfizer responded to Request No. 8 of Plaintiffs' First Request for Production:

> **Defendants will produce all nonprivileged documents produced** … **in** the case captioned ***Pfizer Inc. v. Teva Pharmaceuticals USA Inc***.[170]

On 28 February 2007, BYU informed Mr. O'Malley that *Teva* would be insufficient.

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[167] *Id.* at 175:9-12 (emphasis added).

[168] *Id.* at 200:11-13 (emphasis added).

[169] Plaintiffs' First Request for Production of Documents, 12 Jan 07, Ex. 20 at 10 (emphasis added).

[170] Pfizer Response to Plaintiffs' First Request for Production of Documents, 14 Feb 07, Ex. 21 at 14-15(emphasis added).

> As we have reviewed your response to our Request for Production of Documents, we are concerned that **you are significantly limiting your production** to only those documents you produced in *Pfizer Inc. v. Teva Pharmaceuticals USA Inc.*, No. 04-754 (D.N.J.) … **we do not believe the *Teva* production includes all** (or some) of the documents relating to areas such as: … **[s]cientific or laboratory notebooks**.[171]

On 9 October 2007, BYU identified specific notebooks missing from Pfizer's production:

> In Pfizer's production, **I have found reference to at least three apparently relevant scientific notebooks that Pfizer did not produce.** Those notebook numbers are GDS-2771, 4,051,201, and 4,873,301. Please produce those notebooks and all other responsive notebooks immediately.
>
> * * *
>
> **Pfizer produced incomplete scientific notebook sets**, including notebooks with missing pages, **from** Dr. Karen Seibert, Gwen Krivi, Beverly Reitz, **Tom Warren**, Jean Pegg, and David Creely. Additionally, many fragments of scientific notebooks have been produced which do not contain adequate context to allow effective review.
>
> * * *
>
> In addition to '[n]otebooks mentioned in prior correspondence,' **BYU requested *all* responsive and relevant notebooks**. Please confirm that Pfizer will produce all responsive documents.[172]

On 22 October 2007, Ms. Schneider wrote that

> **I am not aware of any request that specifically seeks "all responsive and relevant notebooks"** and I note that you did not identify any such request. To the extent you believe document request 8 covers this topic, please review Pfizer's response to that request, in which **Pfizer agreed to produce the Teva production documents**. Please also review my letter of September 21 in which I responded to your September 6 letter regarding notebooks. **I see no need to address this issue yet again**.[173]

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[171] Ltr. from L. Beus to R. O'Malley, 28 Feb 07, Ex. 22 (emphasis added).

[172] Ltr. from L.R. Williams to L. Schneider, 9 Oct 07, Ex. 26 (emphasis added).

[173] Ltr. from L. Schneider to L.R. Williams, 22 Oct 07, Ex. 16 (emphasis added).

On 25 October 2007, BYU wrote Ms. Schneider:

> Your October 22, 2007, letter makes clear that we are at an impasse with respect to any responsive relevant scientific notebooks that are not produced by October 31, 2007. **You apparently take the position that you will not search for responsive relevant notebooks unless we provide you with specific notebook numbers**, as I did in paragraph 10 of my October 9, 2007 letter. That is not workable.
>
> * * *
>
> Further review of Pfizer's production to date indicates that in addition to what we have asked for previously, **other responsive and relevant notebooks are missing** as follows:
>
> * * *
>
> Jean Pegg ... **Tom Warren** ... **Bev Reitz** ... Gwen Krivi ... Rodney Combs ... **Jaime Masferrer** ... **Joe Bullock** ....
>
> * * *
>
> Again, **this is a partial list intended only to illustrate that Pfizer has not adequately searched for responsive notebooks.** It is not our responsibility to do this work. … To the extent Pfizer does not comply (by producing complete copies of all relevant responsive notebooks by October 31, 2007), we are at an impasse and will file a motion to compel on November 2, 2007. [174]

On 8 November 2007, Ms. Schneider stated:

> [W]e desire to put an end to BYU's repeated complaints about the notebook production.
>
> * * *
>
> **Pfizer currently maintains a database that contains certain information concerning laboratory notebooks.** … We are willing to search that database for all notebooks prior to 1996 that contain the following words 'cox,' 'cyclooxygenase,' 'DIP' and 'dexamethasone induced protein.' **As a back-up to ensure the relevant notebooks are not missed in this search**, we are also willing to search for: (1) a limited number of additional key terms

[174] Ltr. from L.R. Williams to L. Schneider, 25 Oct 07, Ex. 53 (emphasis added).

> identified by BYU and (2) all notebooks from 1988-1995 for particular custodians of your choosing.[175]

On 9 November 2007, BYU wrote Ms. Schneider:

> In an attempt to avoid more delay, **BYU has no choice but to move forward with your proposal** under the following conditions. One, that the search and production of these notebooks can happen in a timely manner. Two, that the vast majority of notebooks BYU seeks are 'still in existence and locatable after a reasonable search.' Three, as described above, **Pfizer is not relieved of its duty to provide a complete production of responsive documents**. Four, that all notebooks identified in prior correspondence (including our latest correspondence of October 25, 2007) are produced in electronic form, as per your previous agreement.[176]

On 15 November 2007, Ms. Schneider claimed:

> I must note that **your assertions** that we 'are still a long way from obtaining even close to full production of highly relevant scientific notebooks' **is blatantly false. The notebooks produced to BYU are the same notebooks produced in at least two other litigations** and were obtained **as a result of a good faith investigation** looking for all notebooks pertaining to Searle/Monsanto/Pharmacia's COX-2 efforts.[177]

On 20 November 2007, Ms. Schneider noted that

> As of yesterday … **all responsive documents located by Pfizer after a reasonable search have been produced to BYU** with three exceptions … we are still discussing the production of original notebooks. Although we have already produced most of these notebooks, to eliminate any objections to the redactions and any complaints of missing notebooks **we have begun the process of searching for and collecting those notebooks again** for an inspection.[178]

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[175] Ltr. from L. Schneider to L.R. Williams, 8 Nov 07, Ex. 54 (emphasis added).

[176] Ltr. from L. R. Williams to L. Schneider, 9 Nov 07, Ex. 28 (emphasis added).

[177] Ltr. from L. Schneider to L.R. Williams, 15 Nov 07, Ex. 29 (emphasis added).

[178] Ltr. from L. Schneider to L.R. Williams, 20 Nov 07, Ex. 30 (emphasis added).

On 21 December 2007, BYU wrote Ms. Schneider:

> **The following scientific notebooks are referenced in other documents** (identified in parenthesis by Bates number), **but have never been produced**: 4,051,201 (PFC00678414); 4,873,301 (PFC00678414); 4,918,701 (PFC00646613); 5,303,901 (PFC0001222621); GDS-3173 (PFC01527181); unknown scientific notebooks number (PFC01527177); GDS-2288 (PFC00386621). Please produce these notebooks immediately.
>
> * * *
>
> Every time BYU provides assistance, **Pfizer attempts to shift its burden of production to BYU**. Pfizer has an obligation to conduct a thorough and complete review of all scientific notebooks and other documents and immediately produce those which are relevant to this litigation.
>
> * * *
>
> On October 29, 2007, BYU wrote that 'we do not have a complete set of the data notebooks prepared by Karen Seibert during her stay at Washington University.' **Pfizer still has not responded to that letter.**
>
> * * *
>
> On October 29, 2007, BYU requested additional laboratory notebooks of Jaime Masferrer, Karen Seibert, Kathleen Leahy, Ben Zweifel, Michael Holtzman, Phil Needleman, Aubrey Morrison, Peter Isaakson and Bill Stinson. **Those notebooks still have not been produced**.[179]

On 30 January 2008, BYU wrote Pfizer indicating that

> [document number] PFC01218409 reflects Casperson's work with mCOX-1 constructs 'in pMON1440 from D McW.' To date, **Pfizer has provided only one scientific notebook for Casperson** (PFC1218365) **and none for Diana McWilliams**. Further, Pfizer has provided few other documents reflecting these individuals COX-related research.[180]

[179] Ltr. from L.R. Williams to L. Schneider, 21 Dec 07, Ex. 31 (emphasis added).

[180] Ltr. from L.R. Williams to L. Schneider, 30 Jan 08, Ex. 55 (emphasis added).

On 4 February 2008, less than a month after BYU filed its Motion to Compel, Pfizer conceded that

> It does appear from the descriptions in these spreadsheets that there **may be notebooks of relevance** which **have not yet been produced to you.**[181]

Since Pfizer's 4 February 2008 admission, Pfizer has produced another approximately 2,532 scientific notebooks—approximately 1,729 of those are dated prior to 1991 or after 1995 and are mostly irrelevant. But Pfizer still has not produced at least five specific critical scientific notebooks that BYU knows about and that the Court ordered Pfizer to produce. Additionally, Pfizer has failed to produce any notebooks from scientists like Tom Warren. And because, as discussed more thoroughly below, Pfizer has not produced any Monsanto or Searle indices of scientific notebooks for the critical time period, BYU does not know how many notebooks Pfizer is still withholding.

C. Pfizer Still Fails To Produce Relevant Scientific Notebooks And Lists Of All Scientific Notebooks.

In spite of its Third Supplemental Certification, Pfizer still fails to produce at least five COX-2-related scientific notebooks that BYU has identified. Additionally, Pfizer claims to have lost indices of scientific notebooks kept by both Monsanto and Searle. And since Pfizer is apparently unable to reproduce the information on those indices, it is impossible for BYU to accurately determine exactly how many other notebooks Pfizer has not yet produced.

Pfizer's failure to produce these notebooks is especially troubling given the policies Monsanto, Searle, and Pfizer all have regarding maintaining notebooks and Pfizer's own representations to this Court.

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[181] Ltr. from L. Schneider to L.R. Williams, 4 Feb 08, Ex. 56 (emphasis added).

1. Monsanto, Searle, and Pfizer's internal policies require near permanent retention of scientific notebooks.

(a) Pfizer told the Court its scientific notebooks never leave Pfizer's archives.

On 19 March 2008, Pfizer's attorney, Ms. Schneider, told the Court that because the scientific notebooks are

> legal documents that in many cases are **maintained in archives for legal purposes**[, t]o ask Pfizer to take those original lab notebooks, ship them here to Salt Lake I think is not a reasonable request.[182]

Ms. Schneider further noted that "Pfizer [was] going to **strenuously object to taking original lab books out of archives**."[183] In fact, the idea of shipping original scientific notebooks out of the archives was so sensitive, that Ms. Schneider suggested that Pfizer

> could **submit affidavits** from somebody at Pfizer explaining **why they would not let their original lab notebooks go out** of the archives area.[184]

In spite of Pfizer's willingness to provide an affidavit regarding why its scientific notebooks should not be allowed out of Pfizer's archive area, Pfizer still has not provided any explanation for why at least five COX-2 related notebooks and whole sets of notebooks, like Tom Warren's, are missing from its archives. Instead, Pfizer has simply certified that it "has produced every non-privileged, responsive document it has located …."[185]

(b) Pfizer has a legal obligation to retain its scientific notebooks.

Pharmaceutical companies such as Monsanto, Searle, and Pfizer must comply with FDA regulations regarding scientific notebooks. 21 CFR § 58 prescribes good laboratory practices for

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[182] Motion to Compel Transcript, 19 Mar 08, 51:24-52:2, Ex. 57 (emphasis added).

[183] Motion to Compel Ruling, 19 Mar 08, 9:25-10:1, Ex. 58 (emphasis added).

[184] *Id.* at 4:23-5:1(emphasis added).

[185] Defendant's Third Supplemental Certification Concerning Discovery Efforts, 15 Oct 08, Dkt. No. 157 at 5.

all non-clinical laboratory studies, like those Monsanto, Searle, and Pfizer perform, involved in submitting "applications for research or marketing permits for **products regulated by the Food and Drug Administration, including** food and color additives, animal food additives, **human and animal drugs** …."[186]

Section 58.3(d) defines non-clinical laboratory studies as "in vivo [live] or in vitro [petrie dish/test tube] experiments in which test articles are studied prospectively in test systems under laboratory conditions to determine their safety."[187] Monsanto's studies of compounds using BYU's trade secrets in its process of developing Celebrex are non-clinical laboratory studies.

Further, section 58.190 requires that Pfizer store, index, and be able to easily retrieve its records and data:

> (a) **All raw data, documentation, protocols, final reports, and specimens** (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids) generated as a result of a nonclinical laboratory study **shall be retained**.
>
> (b) **There shall be archives for orderly storage and expedient retrieval** of all raw data, documentation, protocols, specimens, and interim and final reports.
>
> * * *
>
> (e) Material retained or referred to in the archives shall be indexed to permit expedient retrieval.[188]

Good Laboratory Practices Regulations underscore how important it is for laboratories to maintain this data and explain why laboratories such as Monsanto, Searle, and Pfizer have strict policies in place regarding their maintenance of scientific notebooks.

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[186] 21 CFR § 58.1 (emphasis added).

[187] 21 CFR § 58.3(d).

[188] 21 CFR § 58.190 (emphasis added).

(c) Because Monsanto, Searle, and Pfizer all have policies to keep and index scientific notebooks, Pfizer's claims that it cannot find crucial notebooks are not credible.

In addition to the FDA regulations described above, Monsanto, Searle, and Pfizer all recognize the importance of safeguarding scientific notebooks. As a result, all three companies require that scientific notebooks be carefully maintained. Had Monsanto, Searle, and/or Pfizer followed their own policies, all of the relevant notebooks would have been readily available for production.

For example, Monsanto's Records Management Manual, dated April 1994, states that notebooks must be kept for 25 years following their date of issue and, prior to their destruction, the notebooks must be microfilmed:

REDACTED

Further, key COX-2 researcher at Monsanto and Pfizer's Vice-President of Discovery Research, Karen Siebert testified that it was Monsanto's policy that

REDACTED

Thus, even if the physical notebook has been destroyed, which should not happen for 25 years from the date of issue, copies of the notebooks should be available from these stored records.

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[189] Monsanto's Records Management Manual, April 1994, MON001557-633 at 620, Ex. 59 (emphasis added).

[190] Aff. of Dr. Karen Seibert, *G.D. Searle & Co. v. Novopharm Ltd*., 3 Oct 05, PFC01579754-774 at 760 (exhibits omitted), Ex. 60 (emphasis added).

Similarly, Searle's policy stated:

REDACTED

And Pfizer, Monsanto and Searle's successor-in-interest, has a similar policy:

REDACTED

REDACTED

Pfizer's policy is to keep all scientific notebooks.

2. <u>Pfizer has not produced information one would expect to be available from its document database.</u>

(a) <u>Pfizer likely uses a database for its scientific notebooks like the TAB database that Pharmacia used.</u>

On 8 November 2007, Ms. Schneider informed BYU that

> **Pfizer currently maintains a database that contains certain information concerning laboratory notebooks**. For example, the database includes a field called 'description' that contains descriptions such as 'completed Monsanto notebook number 4,898,901 containing brefeldin A on fetal fibroblast cox activity test date 9/91-9/91' and 'completed Monsanto notebook 5,281,801 containing cellular assay for COX-1 and COX-2; ELISA for PGE2; covering compounds SC18057.'[193]

[191] Searle Laboratory Notebook Instructions, BYU-PFE-LNB-K 1000012909, Ex. 61 (emphasis added).

[192] Pfizer Laboratory Lab Book Instructions, BYU-PFE-LNB-E 1000391706, Ex. 62 (emphasis added).

[193] Ltr. from L. Schneider to L.R. Williams, 8 Nov 07, Ex. 54 (emphasis added).

Ms. Schneider's letter informed BYU of what it already suspected, that Pfizer keeps a searchable database of its scientific notebooks and—as confirmed at the 19 March 2008 hearing—many of its other documents.

> Pfizer strenuously objects to giving [BYU] access to the database. This is not a database of solely COX-2 related matters. **It is a database of Pfizer's entire archive system**. There are variety of fields in there.[194]

In Pfizer's 30(b)(6) deposition, Ms. Owen, Pfizer's designee regarding document production, testified:

> Q. Can you tell me **what databases exist at Pfizer** that would contain information concerning scientific notebooks or related documents?
>
> A. The **records center has a database** that contains the information that has been archived, and **it includes information about notebooks**.[195]
>
> * * *
>
> Q. For example, with respect to a scientific notebook, what information would I find in the records center regarding a specific scientific notebook?
>
> A. I believe that **there is a field that indicates it's a lab notebook.**[196]
>
> * * *
>
> Q. Okay. Let's talk about fields. You say one of the fields would be what kind of document it is, correct?
>
> A. Or records it is, right. I mean, it may be a box – **the database is just a database to track the information** that Pfizer has on what's been sent to archives. It's not going to give you every word on every piece of paper that's in there. It's not a scanned version of everything in the box so you

[194] Motion to Compel Transcript, 19 Mar 08, 51:4-8, Ex. 63 (emphasis added).

[195] Kathy Owen 30(b)(6) deposition, 10 Jun 08, 77:11-16, Ex. 64 (emphasis added).

[196] *Id.* at 81:2-7 (emphasis added).

> can do any kind of keyword searches and get everything that's in there.[197]

However, on 14 April 2008, Ms. Schneider limited the scope of the database:

> I think **there might be come [sic] confusion about the scope of the database**. The database **does not contain an extensive subject matter listing** of all of the information in the notebooks, **nor does it contain any sort of OCR information from the notebooks**. Rather, when notebooks are placed in the archives, the individual transmitting the notebook keys in certain information about the notebook. **The accuracy and completeness of the information in the database is dependent upon the information keyed in by the person who transmitted the notebook to archives.**[198]

BYU does not know specifics about Pfizer's database. But, in its investigation, BYU found a company called TAB, a company that provides software for information management, that Pharmacia, Pfizer's predecessor-in-interest, used for document management.

According to its website, TAB

> has more than a 50-year history of innovation and is the global leader in **records and information management systems for vital documents** where **immediate access** to information is critical.[199]

Also on its website is a "case study" in which TAB shows how Pharmacia implemented TAB's FileTracker software.[200]

The case study quotes Lynne Palmer, Pharmacia's Facilities and Purchasing Manager, describing the process of implementing TAB's software and the results:

> We **implemented** a network version of **TAB's FileTracker software** with Tabquik labeling. We used the software to publish a company records classification plan integrated with retention

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[197] *Id.* at 83:14-24 (emphasis added).

[198] Ltr. from L. Schneider to M. Bettilyon, 14 Apr 08, Ex. 65 (emphasis added).

[199] http://www.tab.com/about.aspx, Ex. 66 (emphasis added).

[200] http://www.tab.com/ecms.aspx/resources/Pharmacia.pdf, Ex. 67.

> standards. We designed a selection of six standard colour-coded file and binder labels, which are meaningful to all of our records series. **We converted files, implemented file tracking, and developed audit reports**.
>
> **We did virtually the same thing at the document level**, i.e., classification plan, **standards, retention,** barcode labels, **document tracking, auditing and reports**. We also went through the same process for inactive records, but this time we implemented **right down to the storage box level for all departments**.
>
> For the pilot project, we deployed TAB's FileTracker software in our Medical department to track the lifecycle of files and critical documents. **We can quickly find any document**, which makes it easy to **comply with both our company and external regulatory requirements**. We made excellent use of FileTracker's nesting capabilities. **We can identify documents within files, and files within boxes**, to track items by both **their assigned and their current locations**.
>
> FileTracker has made the set-up and retrieval of records significantly easier. The query and reports function means that **we can audit documents and files versus regulatory and corporate standards**, and ensure that all the requirements are continually being met. Now, seeing the end result, **I look forward to fully implementing FileTracker in other departments**, as well as linking FileTracker to our electronic records.[201]

The case study also identifies three needs that Pharmacia had that TAB was able to fulfill:

- Seamless system for filing large volumes of documents for each project at each stage of research and development.
- **The ability to quickly retrieve documents to comply with both company and external regulatory requirements.**
- Finding a knowledgeable document company who could deliver a system for their specific needs.[202]

Further, the case study describes Pharmacia as being

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[201] *Id.* (emphasis added).

[202] *Id*. (emphasis added).

> **committed to excellence in records management**. **Maintaining a high level of documentation is imperative in the pharmaceutical industry.** At each stage of research and development, volumes of documentation, research data, study protocols, development history, and many other records must be created and preserved. The product approval process is rigorous.[203]

Some of the records created and preserved during the "research and development" stage are scientific notebooks. BYU does not know whether Pfizer uses a TAB database or not—Pfizer has produced no records regarding its document database. However, BYU would expect that Pfizer, like its predecessor Pharmacia, retains millions of documents in its work as a pharmaceutical corporation and would similarly be able to "identify documents within files, and files within boxes, to track items by both their assigned and their current locations."

However, as described below, Pfizer has not produced or otherwise explained its loss of at least five critical scientific notebooks—or whole sets of notebooks—that BYU has specifically identified. Neither has it produced an index of the notebooks that it assigned to specific investigators during this period so that BYU can verify the accuracy of Pfizer's claims.

Pfizer's claims that it cannot identify the scientific notebooks it assigned, the researchers to whom it assigned them, and the notebooks' present location—especially in light of federal regulations and Pfizer's own internal policies—is not credible.

(b) Pfizer has still not produced Monsanto's internal index of notebooks and the relevant parts of Searle's index.

21 C.F.R. § 58.190(e) requires covered laboratories to index all the material they keep in archives. Both Monsanto and Searle kept an index of all the scientific notebooks they issued. Pfizer admitted that Monsanto kept such an index when its attorneys claimed "we have **not yet**

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[203] *Id*. (emphasis added).

located a log of Monsanto notebooks."[204] Though Pfizer did produce an incomplete version of a document it purports to be Searle's scientific notebook index, the Searle index that Pfizer produced does not include any notebooks Searle issued for the COX-2 project during the relevant time period.[205] These missing indices keep track of basic information relevant to this litigation such as to whom and on what date Monsanto issued its scientific notebooks. Without these indices, BYU cannot identify, by number or by investigator, all the missing notebooks. Pfizer has not offered any explanation for why these indices are conspicuously incomplete, or whether Pfizer used its database to create replacement indices.

Given the importance of maintaining an index of scientific notebooks, BYU does not understand how these indices could apparently disappear at a time when they are relevant to the current litigation. It is particularly troubling that Pfizer will not produce this information given the "REDACTED " an "REDACTED "[206] According to Pfizer's counsel in the *Merck Frosst Canada* litigation—a matter Merck brought against, among others, Searle and Pfizer in 1999:

REDACTED

3. Pfizer failed to produce at least five specific scientific notebooks.

Despite Pfizer's own admissions concerning the importance of its scientific notebooks, it has failed to produce at least five notebooks directly relevant to this litigation that this Court

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[204] Ltr. from L. Schneider to M. Bettilyon, 9 Sep 08, Ex. 68 (emphasis added).

[205] Pfizer List of Specific Notebooks Searched For Or Produced In Response to March 26, 2008 Court Order, BYU-PFE 268135-75, Ex. 69.

[206] Transcript of Motions Hearing, *Merck Frosst Canada & Co. v. G.D. Searle & Company, et al.,* 12 Feb 02, 25:1-8 (BYU-PFE 008193 at 217-218), Ex. 70.

[207] *Id*. at 26:14-21 (emphasis added).

ordered it to produce. Neither has Pfizer provided either the Court or BYU with an explanation for its failure to locate and produce these notebooks.

(a) Pfizer still has not produced sets of relevant scientific notebooks assigned to Reitz, Warren, or McWilliams.

The Court ordered that Pfizer "produce … all relevant scientific notebooks and related documentation from the following Pfizer researchers … Beverly Reitz … Tom Warren … Diana McWilliams."[208] Pfizer still has not produced these sets of notebooks.

During this litigation, the New Monsanto, not Pfizer, produced to BYU a key notebook assigned to Reitz. Despite its clear policy mandating that Pfizer preserve notebooks, Pfizer still has not offered any explanation for why it is unable to produce this Reitz notebook or a microfilm copy. The Reitz notebook led BYU to other relevant notebooks that Pfizer has not produced because the notebook indicates that researchers Warren and McWilliams performed research, including the insertion of mouse and human COX clones into BHK cells, prior to the Fall of 1993.

Specifically, on 16 March 1993, under the heading "[redacted]" Reitz described cloning of human COX-2 into BHK cells done by Warren: "[redacted]"[209]

Reitz's notebook entry indicates that Warren (1) performed COX-2 work during the relevant time period and (2) had the skill set necessary to insert mouse COX-2 into BHK cells. Even though Warren worked for Pfizer at least through 2006—and may still work for Pfizer—Pfizer has yet to provide BYU with a single Warren notebook.

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[208] Order Granting BYU's Motion to Compel Immediate Production of Documents, 26 Mar 08, Dkt. No. 106 at 3.

[209] Beverly Reitz Notebook No. 5296801 at 822, MON001941, Ex. 71 (emphasis added).

As another example, Seibert's notebook, 4,956,601, includes an unnumbered page between pages 4,956,623 and 4,956,624. On that page, the following notation in handwriting other than Seibert's states: REDACTED [210] Following this notation is a reproduction of results from the "Northern Analysis," also known as a "Northern Blot."

A Northern Blot is used by researchers to test different kinds of cells for specific genetic material. For example, after BYU discovered COX-2 and identified it as a target for Monsanto, Monsanto researchers conducted Northern Blots on several kinds of cells to identify what cells produced COX-2 under what kinds of conditions. Specifically, "Synovial Fibroblasts" are a type of cell that BYU's trade secrets allowed Monsanto to understand was rich in COX-2 after it is treated with the chemical IL-1.

According to the unnumbered page in Seibert's notebook, it appears that a Northern Blot was conducted on synovial fibroblasts treated with IL-1. It also appears that Monsanto notebook page 4,695,681 records some part of that research. BYU specifically asked Pfizer to produce the notebook containing page 4,695,681 on 12 October 2007.[211] Pfizer never responded to BYU's request and still has not produced that notebook, nor has Pfizer offered an explanation for why it has not produced the notebook.

On the next numbered page of Seibert's notebook, 4,956,624, dated 22 January 1992, Seibert wrote "REDACTED" in a list titled "REDACTED."[212] "REDACTED" likely

[210] Karen Siebert Notebook No. 4956601 at 623-624, 650, 660, PFC01549702-704, 766, 790, Ex. 72 (emphasis added).

[211] Ltr. from D. Bart Dewey to L. Schneider, 12 Oct 07, Ex. 73.

[212] Karen Siebert Notebook No. 4956601 at 623-624, 650, 660, PFC01549702-704, 766, 790, Ex. 72.

refers to "synovial fibroblasts" and "REDACTED" likely refers to Tom Warren. On page 4,956,650 in this notebook, Seibert records that she "REDACTED [redacted]" and that "REDACTED." Further, on page 4,956,660, Seibert records that she "REDACTED."[213]

Seibert's notebook entries confirm Warren's work on Monsanto's COX-2 project and the likelihood that Warren would have kept scientific notebooks.

Given Seibert's notation that Warren was connected to synovial fibroblast cell research and the unnumbered page, written in different handwriting, with results from research using synovial fibroblast cells, it appears likely that Warren wrote the unnumbered page that Seibert placed in her notebook and referred to a specific page in Warren's notebook containing research related to the synovial fibroblast cells. Despite this Court's Order, Pfizer has not produced that notebook.

Without Warren's highly relevant notebook or notebooks, BYU is unfairly prejudiced because it will not be able to effectively question Warren about his participation in the events surrounding Pfizer's misappropriation of BYU's trade secrets.

Further, BYU is prejudiced because Pfizer will continue to withhold evidence of BYU's direct contribution to and participation in Monsanto's COX-2 project as part of Dr. Simmons's partnership with Monsanto—the project that led to Celebrex.

Similarly, McWilliams's name appears several times in relevant notebooks and it appears that her work was integral to Monsanto's in vitro assays for the COX-2 project. Specifically,

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[213] *Id.* (emphasis added).

Reitz states in her notebook entry on 2 November 1993, that '[redacted]'[214]

This research is important because Monsanto likely used BYU's trade secrets, including its mouse COX clones. In fact, Pfizer's only source of mCOX-1 was from Dr. Simmons.

But the earliest notebook Pfizer has produced for McWilliams was created on 23 February 1994—a year after the Reitz entry.[215] Without the McWilliams' notebooks reflecting her work with BHK cells, BYU will not have the evidence from these notebooks necessary to ask McWilliams questions about her specific work with BYU's trade secrets and will be unfairly prejudiced in its prosecution of this litigation.

McWilliams and Warren's work, and, therefore, notebooks reflecting that work, with BHK cells in COX-1 and COX-2 and inserting human COX-2 into BHK cells is especially important to this litigation because of the Rangwala chart described below and discussed at length at the 29 July 2008 hearing. Because one-third of the missing data supporting the Rangwala chart was done with BHK cells, the missing Warren and McWilliams notebooks are directly relevant to the data contained in the Rangwala table—and therefore Monsanto's work with BYU's trade secrets. By not producing these notebooks, Pfizer acknowledges that it has either lost or destroyed sets of relevant notebooks. Pfizer's actions merit a spoliation instruction.

In its hearing memorandum and also at the last hearing, BYU identified a table created by Monsanto researcher Shaukat Rangwala that contains highly relevant mouse COX data for which Pfizer has produced no supporting data. Rangwala's mouse COX-1 data must have been

[214] Beverly Reitz Notebook No. 5296801 at 840, MON001952, Ex. 74 (emphasis added).

[215] Beverly Reitz Notebook No. GDS-3592, PFC01577755-56, Ex. 75.

produced using Dr. Simmons's mCOX-1 clone because, as Pfizer admits, it never had another source for mouse COX-1.[216]

Rangwala's mouse COX-2 data also likely resulted from the use of Dr. Simmons's mCOX-2 clone because Pfizer's data does not match the data it generated using Dr. Herschman's clone and, in one case, because the Herschman data was not available until 16 days after Rangwala inserted the table into his notebook. Rangwala's table is further evidence that, after terminating BYU and prior to the receipt of Dr. Herschman's clones, Monsanto used Dr. Simmons's mouse COX clones to establish expression systems and has hidden the evidence of that work to avoid liability to BYU.

It is important to note that the Rangwala chart and the work it reflects is not just something that appears in one place in Rangwala's notebook and was later forgotten. The Rangwala chart appears to have been an important collection of data that was used to justify Monsanto's pursuit of the COX-2 program that BYU provided to Monsanto in April 1991.

For example, in a document entitled '[redacted]" dated 9 September 1992 by a fax line, Dr. Isakson, the Project Leader, reports that

[redacted]

Dr. Isakson's description of what had happened by 9 September 1992 and what was underway is exactly what the Rangwala chart reflects.

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[216] Ltr. to D. Thomas from D. Hoscheit, 17 May 00, BYU-12-0088, Ex. 76.

[217] BYU-PFE 042356-57, Ex. 77 (emphasis added).

According to Pfizer's own documents, the Rangwala chart was perpetuated and promulgated through corporate documents with regard to Monsanto's COX-2 project.[218] It was an important chart for which Pfizer has not produced the missing supporting data shown in the Rangwala chart. Instead, after unsuccessfully attempting to explain the absence of data supporting Rangwala's chart at the hearing, Pfizer's Second Supplemental Certification made another attempt by claiming that the data in Rangwala's chart was not as shown in the officially counter-signed notebook page, but that it was (1) averaged, (2) multiplied, (3) incorrectly recorded with regard to dates, (4) incorrectly recorded with regard to species, (5) incorrectly recorded with regard to the length of the assay, and (6) summed data from other investigators' notebooks that have been produced.

The following graphic is adapted from a visual BYU provided the Court at the 29 July 2008 hearing and matches Pfizer's explanations to the data they purportedly explain:

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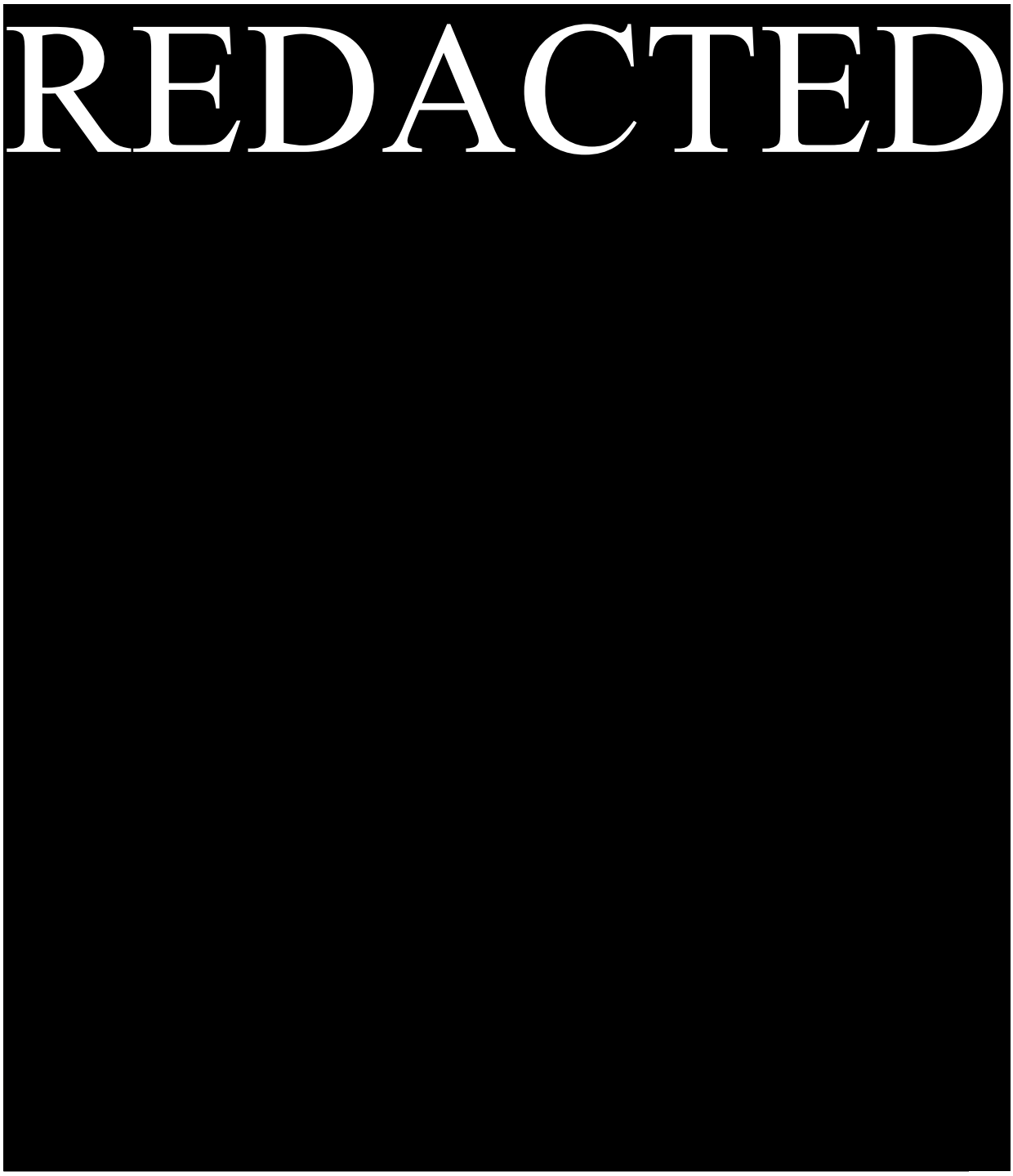
[218] *See, e.g.,* BYU-PFE 355255, Ex. 78, BYU-PFE 348554-556, Ex. 79, BYU-PFE 141355 at 423, Ex. 80, and Dep. of Gwen Krivi, *University of Rochester v. G.D. Searle & Co., et al.*, 30 Apr 02, 153:15-154:19 (BYU-PFE 118302 at 340-41), Ex. 81.


REDACTED

First, Pfizer claims that support for Rangwala's insect data can be found by multiplying values it selects from Seibert's mouse COX-1 and mouse COX-2 insect expression results by three:

REDACTED

But its rationale for doing so is scientifically flawed. Pfizer claims that Rangwala multiplied Seibert's results because Seibert used a 10 minute assay whereas Reitz used a 30 minute assay. Pfizer's claim assumes that prostaglandin synthesis increases linearly over time, after exposure to arachidonic acid, up to 30 minutes. Pfizer has provided no support for that claim, which, in fact, is false because cyclooxygenase is 'REDACTED REDACTED.'[220] Therefore, either a 10 or 30 minute assay would produce nearly the same amount of prostaglandins. Thus, multiplying Seibert's results would not 'REDACTED' them to Reitz's results but would, instead, be made up scientific data.

Further, Pfizer's multiplication of the data cannot be true because the data listed in the columns is for a 10 minute assay, not a 30 minute assay. For Pfizer's artificial adjustment of the assay results through arithmetic manipulation to make any sense, Rangwala would have had to divide the BHK data by three in order to fit the table heading 'REDACTED.'

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[219] Defendants' Second Supplemental Certification Concerning Discovery Efforts, 12 Aug 08, Dkt. No. 147 at 10 (emphasis added).

[220] T.E. Eling, *et. al*, Prostaglandin H-Synthase Xenobiotic Oxidation, Annual Reviews of Pharmacology and Toxicology, 1990, at 5, Ex. 82.

Next, Pfizer claims that, despite (1) the title of Rangwala's table: '[redacted] ' Rangwala was actually comparing the expression of recombinant human COX-1 and mouse COX-2 in COS cells.

[redacted]

Pfizer does not explain the utility of such an inter-species comparison. Nor does Pfizer realize that the purported substitution of human COX-1 in the data column for mCOX-1 COS systems would also mean that human COX-1 was used in the BHK and insect expression systems also listed in the column headed '[redacted].' If that is Pfizer's claim, its explanations for the COX-1 data in BHK and insect cells would be invalid because (1) the documents it references clearly refer to mouse COX-1 and (2) references to expression of human COX-1 in BHK and insect cells in the notebooks Pfizer produced were not available until months after the creation of the Rangwala chart.[222]

Next, Pfizer asks BYU and this Court to accept that the mCOX-2 data was rounded to the nearest tenth but that the purported hCOX-1 value was averaged instead of rounded to the nearest tenth:

[redacted]

[221] Defendants' Second Supplemental Certification Concerning Discovery Efforts, 12 Aug 08, Dkt. No. 147 at 8 (emphasis added).

[222] *See* PFC00646762 (April 8, 1993, Monsanto's David Creely creates a plasmid, pMON23953 (hCOX-1 in PVL1393) appropriate for insertion of hCOX-1 into insect cells and a plasmid, pMON23952 (hCOX-1 in 3360B) appropriate for inserting hCOX-1 into BHK cells, Ex. 83.

REDACTED

Pfizer's explanation does not make sense. In the notebook Pfizer relies on, BYU found three results for mCOX-2 expression in COS cells—0.17, the result Pfizer suggests was rounded to 0.2. The other two results are 6.4 and no detectable data, or 0.

Specifically, page 4,956,691 of Dr. Seibert's notebook indicates a control value of 6.4 for expression of mCOX-2 in COS cells.[224] Page 4,956,699 of the same notebook indicates two more control values for expression of mCOX-2 in COS cells: 0.17 and no detectable data.[225]

Pfizer's suggestion that three data points of 0, 0.17, and 6.4 could culminate in a result rounded to 0.2 is not credible. The average of .17, 6.4 and 0 is 2.19—more than ten times Pfizer's .2. Besides, no scientist would average three such disparate results. Pfizer's explanation appears to be manufactured.

With respect to COX expression in BHK cells, Pfizer claims that Rangwala used data recorded by Bev Reitz 16 days after Rangwala's notebook entry. To support that claim, Pfizer suggests that Rangwala created his table on or after 22 October 1992, and then taped it into a conveniently-sized gap on a page recording his 6 October 1992, notebook entry. Because the data in Rangwala's notebook immediately following the table is also dated 9 October 1992, it is evident that Rangwala was doing experiments on a continual basis throughout October and recording it sequentially. Thus, in order to paste the chart on 6 October 1992 for data created by Reitz on 22 October 1992, as Pfizer suggests, Rangwala would have needed to know the exact size of his chart at least 16 days before he created it. Moreover, he would have needed to violate

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[223] Defendants' Second Supplemental Certification Concerning Discovery Efforts, 12 Aug 08, Dkt. No. 147 at 8 (emphasis added).

[224] PFC01512483, Ex. 84.

[225] PFC01512491, Ex. 85.

both Monsanto's notebook policy and federal scientific recording guidelines, which each require that research be appropriately dated.[226] Specifically, Monsanto's notebook policy states:

7. REDACTED

8. REDACTED

Finally, Pfizer also claims that Reitz's BHK data was used in Rangwala's chart: "REDACTED "[228] This perfect match is 15 widely ranging numbers in Reitz's notebooks that are all less than 20 for mouse COX-1 and eight numbers for mouse COX-2 that are less than five. Virtually unlimited data could match the <20 and <5 described in Rangwala's table, including data created prior to 6 October 1992, using Dr. Simmons's mouse COX clones. Moreover, Reitz's assay was for 30 minutes, not the 10 minutes shown in the chart.

Pfizer's explanations are not credible, give further evidence that critical scientific notebooks are missing, and that Pfizer and its Chicago counsel will go to great lengths to withhold relevant documents.

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[226] Monsanto's Guidelines for Research Records, PFC01582628-42, Ex. 86.

[227] *Id*. at PFC01582633 (emphasis added).

[228] Defendants' Second Supplemental Certification Concerning Discovery Efforts, 12 Aug 08, Dkt. No. 147 at 9-10.

(b) Pfizer has not produced three other specific Court-ordered scientific notebooks.

Additionally, Pfizer has not produced three other specific notebooks, identified by number, the Court ordered Pfizer to produce. Though Pfizer claims it has "[p]roduced legible, unredacted (except for privilege) copies of every notebook in its possession, custody or control which it has located,"[229] Pfizer has not produced notebooks 4,051,201; 4,873,301; or 4,695,201—all relevant notebooks the Court ordered Pfizer to produce.

By way of background, BYU found several notebooks, identified by number, in other relevant scientific notebooks. Specifically, Seibert wrote the notebook numbers 4,051,201 and 4,873,301 in her personal notebook from August 1993.[230] Because Seibert played a major part in the COX-2 project, any notebook she is involved with has a high likelihood of being relevant. Pfizer is unable to explain where these notebooks are, to whom they were issued, or what they contain.

Further, Pfizer produced only eight pages of notebook 4,695,201 dated May 1991. Monsanto assigned this notebook to Patrick M. Sullivan, a Monsanto scientist who is listed as an author on the paper "Tyrosine kinase inhibitors prevent cytokine-induced expression of iNOS and COX-2 by human islets."[231]

In a 20 July 1992 page from her Notebook No. 4,956,601, Karen Seibert indicates that "REDACTED."[232] Because Monsanto assigned this notebook in May 1991, right after Monsanto began working

[229] Defendant's Third Supplemental Certification Concerning Discovery Efforts, 15 Oct 08, Dkt. No. 157 at 3.

[230] Karen Seibert Personal Notebook No. 13, Aug 93, PFC00678414, Ex. 87.

[231] BYU-PFE-ARC 1001476975-81, Ex. 88.

[232] Karen Seibert Notebook No. 4,956,601, 20 Jul 92, PFC91548749, Ex. 89 (emphasis added).

with BYU's trade secrets, and Seibert describes utilizing Sullivan's COS cells in 1992, this notebook is likely to contain highly relevant information crucial to BYU's case.

But, as with the other missing notebooks, Pfizer offers no explanation for why these notebooks are missing or where they last were.

Pfizer's claims are not credible. If BYU had not insisted, Pfizer would never have produced several relevant scientific notebooks. Even after the Court's Order, however, Pfizer still has not produced specific notebooks, including the whole set of Tom Warren's notebooks and Reitz's notebooks regarding her creation of BHK cells using Dr. Simmons's materials.

VII. BYU BELIEVES PFIZER'S SPOLIATED DOCUMENTS WILL DISPROVE PFIZER'S CENTRAL DEFENSE THAT BYU'S CLONES DID NOT WORK.

The biological material and notebooks Pfizer has failed to produce are most obviously relevant to the issue of whether BYU's COX-2 clones and other trade secrets worked.

On 22 October 2007, early in this discovery dispute, Pfizer tried to justify the small amount of relevant documents it was producing:

> If your concern lies more with Pfizer's alleged use of Dr. Simmons clones, it is not surprising that Pfizer does not have a similarly vast quantity of documents concerning Dr. Simmons' clones. **As Pfizer has told Dr. Simmons since the late 1990's, Pfizer was unable to get Dr. Simmons' COX-2 clones to work**.[233]

Ms. Schneider, Pfizer's counsel, repeated this misrepresentation at the 19 March 2008 hearing stating:

> [i]t's [Pfizer's] view that **Dr. Simmons' clones didn't work**.[234]

And, at the 29 July 2008 hearing, Pfizer's local counsel, Mr. Haley, once again made the same representation:

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[233] Ltr. from L. Schneider to L.R. Williams, 22 Oct 07, Ex. 16 (emphasis added).

[234] Motion to Compel Hearing Transcript, 19 Mar 08, 58:14-15, Ex. 10 (emphasis added).

> **[W]e didn't get Simmons' COX-2 clones to work**.[235]

Pfizer and its counsels' statements put them in the "unenviable position of making representations that ultimately could not be substantiated."[236]

Pfizer cannot dispute that its only source of mCOX-1 was BYU and Dr. Simmons.

> **Professor Simmons also provided Monsanto with a clone for mCOX-1 … since Professor Simmons' clone of COX-1 was handy,** [a] co-worker **used it** for his PCR work in order to amplify the COX-1 gene.[237]

Neither can Pfizer dispute that its only source of mCOX-2 prior to 24 August 1992 was BYU and Dr. Simmons.

> By the end of 1991, Dr. Seibert essentially ceased to work with the **Simmons' mCOX-2 clone**. Dr. Seibert's notebook page of **August 24, 1992** reports receipt of **another mCOX-2 clone** from another independent source.[238]

Monsanto's scientific notebooks record receipt of Dr. Herschman's mouse COX-2 clone on 24 August 1992.[239] That means Monsanto used only BYU and Dr. Simmons's COX-2 clone for at least 12 months.

1. <u>The Raz letters prove Dr. Simmons's clones and reagents worked.</u>

On 19 November 2007, Pfizer produced two letters that Dr. Needleman wrote to Dr. Amiram Raz in 1991. In the letters, Needleman credits Dr. Simmons with providing:

REDACTED

[redacted]

[235] Motions Hearing Transcript, 29 July 08, 50:8-9, Ex. 5 (emphasis added).

[236] Motion to Compel Hearing Transcript, 19 Mar 08, 46:1-3, Ex. 90.

[237] Ltr. from D. Hoscheit to D. Thomas, 17 May 00, BYU-12-0088-89, Ex. 76 (emphasis added).

[238] *Id.* (emphasis added).

[239] Karen Seibert Notebook No. 4956601 at 690, 24 Aug 92, PFC01549856, Ex. 91.

REDACTED

These letters are direct evidence, written by Dr. Needleman, that Dr. Simmons's COX-2 clones worked.

Pfizer produced the Raz letters, dated 1991, in the *Rochester* litigation at S00664940 and S00664738. But, in this litigation, even after Pfizer claimed in February and October of 2007 that

> **documents prior to June 1995 'produced' in the Rochester litigation were likewise produced in the Teva litigation. Your assertion that the statement is somehow untrue … is absurd**.[241]

Pfizer did not produce the 1991 Raz letters until 19 November 2007. And then, Pfizer only produced the Raz letters as deposition exhibits, not as part of the *Rochester* production. Pfizer did not produce the Raz letters as part of the *Rochester* production until 7 July 2008.

2. <u>The Seibert email proves Dr. Simmons's clones and reagents worked.</u>

Similarly, Pfizer did not produce, until 7 July 2008, an email Dr. Seibert wrote Needleman dated 24 March 1992 stating that "REDACTED",[242] Like the Raz letters, the Seibert email disproves Pfizer's claims about Dr. Simmons's COX-2 clones and proves that BYU's clones did work.

Though Pfizer also produced the Seibert email, dated 1992, in the *Rochester* litigation, at S00663784-85, Pfizer did not produce the Seibert email to BYU until 23 May 2008 as part of Dr. Needleman's custodial production. And Pfizer did not produce the 1992 Seibert email as part of the *Rochester* production until 7 July 2008, eight months after it called BYU "absurd" for suggesting that

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[240] Raz ltrs, S00664940 and S00664738, Ex. 17 (emphasis added).

[241] Ltr. from L. Schneider to L.R. Williams, 7 Jan 08, Ex. 12 (emphasis added).

[242] Seibert email, S00663784-85, Ex. 18 (emphasis added).

> **documents prior to June 1995 'produced' in the Rochester litigation [had not been] produced in the Teva litigation**.[243]

Moreover, Pfizer has yet to produce the Needleman letter to which Seibert is responding.

3. <u>The Blue slide proves Dr. Simmons's clones and reagents worked.</u>

Further, on 19 November 2007, Pfizer produced the Blue slide, a document likely created in mid-1992, indicating that Monsanto was using Dr. Simmons's COX-1 and COX-2 clones for '[redacted]' '[redacted]," and '[redacted]."[244]

Pfizer also produced the Blue slide—a pre-1995 document—in the *Rochester* litigation at S00504065.367. However, Pfizer produced it to BYU only as a deposition exhibit on 19 November 2007—after Pfizer had already claimed to have produced all pre-1995 documents from *Rochester*. Pfizer did not produce it as part of the *Rochester* production until 28 July 2008, more than eight months after Pfizer claimed to have produced all pre-1995 documents it produced in Rochester.

4. <u>Monsanto's draft publications give BYU credit for its valuable trade secrets.</u>

An August 1993 Monsanto draft article, produced to BYU as part of *Teva*, reflects its successful use of Dr. Simmons's biological materials and trade secrets. The 1993 draft states that [redacted]." This same draft article detailed how Monsanto had removed the coding region of the COX-1 and COX-2 cDNA and had reengineered the cDNA's ends for the purpose of inserting them into '[redacted]"—a way of isolating a gene or part of a gene for further scientific study. The expression vectors were then introduced into cell systems that

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[243] Ltr. from L. Schneider to L.R. Williams, 7 Jan 08, Ex. 12 (emphasis added).

[244] Blue Slide, S00504065.367, Ex. 19.

would cause them to produce large quantities of COX-1 and COX-2 enzymes and prostaglandins.[245] The insertion process described in the drafts was a process that fit only Dr. Simmons's COX-2 clones, not Dr. Herschman's clone:

REDACTED

A subsequent Monsanto draft article similarly describes the successful use of Dr. Simmons's mouse COX-1 and COX-2 cDNAs in the creation of expression vectors:

REDACTED

Although this draft article also attributed mouse COX clones to Dr. Simmons, it omits the description of the cloning process described in the first draft article.

The second draft article was subsequently published, with a different title, in PNAS (Proceedings of the National Academy of Sciences) in December 1994. Karen Seibert's published paper was "communicated" by Dr. Needleman and is clearly descended from the first and second drafts because, although the title is changed, the abstract and published articles are almost identical. However, the published PNAS article removes attribution to Dr. Simmons from otherwise identical language stating instead: "[t]he coding regions of mouse COX-1 and COX-2 were subcloned in the baculovirus expression vector pVL1393 (Invitrogen)."[248]

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[245] August 1993 Draft Article, PFC00652108, Ex. 92 (emphasis added).

[246] *Id.* at PFC00652110.

[247] Monsanto Draft Article, PFC00652146-152, Ex. 93 (emphasis added).

[248] Pharmacological and biochemical demonstration of the role of cyclooxygenase 2 in inflammation and pain, Proc.Natl.Acad.Sci. USA, Vol. 91, pp. 12013-12017, Dec. 94, PFC00388780-784 at 781, Ex. 94.

Pfizer argues that it does not matter how Pfizer produced the Raz letters, the Seibert email, or the Blue slide, only that Pfizer did finally produce them.

> THE COURT: But how is it that there could be such large holes?
>
> MS. SCHNEIDER: Well, I don't think there are such large holes, Your Honor. They point to things and they say you didn't produce the Raz letter. We did produce the Raz letter. That's the only reason they know that the Raz letter exists. We produced it in the context of deposition exhibits. They argue that we didn't produce deposition exhibits in the Teva litigation. **We never agreed to produce deposition exhibits in the Teva production. We said that will be a separate production**.
>
> THE COURT: **Aren't we playing semantic games in that regard**?
>
> MS. SCHNEIDER: **No**, I don't believe so, Your Honor. I mean everything has been produced. [249]

But what matters is that Pfizer's 22 October 2007, claim that "documents prior to June 1995 'produced' in the *Rochester* litigation were likewise produced in the *Teva* litigation," documents like the Raz letter, the Seibert email, and the Blue slide, was false.

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[249] Motion to Compel Hearing Transcript, 44:21-45:10, Ex. 95 (emphasis added).

VIII. PFIZER CONTINUES TO WITHHOLD IMPORTANT FINANCIAL INFORMATION.

As described above, Dr. Needleman and Pfizer calculated the value of each day of head start for Celebrex's availability on the market at $10 million. However, Pfizer has not produced any financial documents—documents that must exist—to support its corporate conclusions.

Similarly, Pfizer has not produced any other financial information that BYU requested and that this Court ordered it to produce.

On 12 January 2007, at Request No. 20, Plaintiffs requested:

> **All internal or publicly available financial information referring or relating to your sales of Celebrex or other Cox-2 inhibiting NSAIDs**, including, but not limited to, **documents that report or reflect income, profits, net profits, revenue, total sales, unit sales, cost of goods sold or other related direct or indirect expenses**.[250]

On 14 February 2007, Pfizer responded:

> **Defendants agree to produce sufficient financial information** to show income, profits, net profits, revenue, total sales, unit sales, costs of goods sold or other related direct or indirect expenses for Celebrex and Bextra.[251]

On 6 September 2007, BYU wrote Ms. Schneider reiterating its Request:

> **Pfizer agreed to 'produce sufficient financial information** to show income, profits, net profits, revenue, total sales, unit sales, cost of goods sold or other related direct or indirect expenses for Celebrex and Bextra.'[252]

On 5 November 2007, Pfizer produced only six pages it described as "Profit and Loss Statements for Celebrex and Bextra."

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[250] Plaintiffs' First Request for Production of Documents, 12 Jan 07, Ex. 20 at 12 (emphasis added).

[251] Defendants' Response to Plaintiffs' First Request for Production of Documents, 14 Feb 07, Ex. 21 at 25 (emphasis added).

[252] Ltr. from L.R. Williams to L. Schneider, 6 Sep 07, Ex. 96 (emphasis added).

On 18 January 2008, BYU again wrote Ms. Schneider, Mr. O'Malley's partner:

> **Your recent discovery does not cure Pfizer's deficiency** with respect to BYU's motion. BYU still seeks relief regarding the other categories of documents identified in its Motion, many of which will be dated January 1992 or later. For example, in addition to documents pre-dating 1992, BYU's Motion sought the following categories of documents that will include documents created after 1991:
>
> **Financial Documents**: **financial documents related to Pfizer's revenue from drugs developed through Dr. Simmons's technology and project**. All such documents would be post-January, 1992.[253]

On 9 April 2008, in an attempt to assist Pfizer and its Chicago counsel in identifying the documents BYU requested in February 2007—the documents the Court ordered Pfizer to produce—BYU identified as examples 14 categories of documents that BYU expects Pfizer possesses:

> 1. Monthly sales of Celebrex and Bextra (gross and net) measured by dollars and volume from 1998 to present. To reconcile gross and net sales, BYU also needs detailed breakdowns of the items netted from gross sales….
>
> 2. Monthly Celebrex and Bextra product line profitability statements or reports. Such reports should include at a minimum: the sales numbers listed in 1 above, and a detailed cost breakdown listing costs for direct material, direct labor, manufacturing overhead components, indirect labor, depreciation, laborer insurance costs, production utilities, supplier or subcontractor costs, and others….
>
> 3. Monthly costs beyond those identified and included in costs of goods sold that are historically attributed and allocated to Celebrex and Bextra. Such costs are traditionally referred to as 'selling, general and administrative costs….'
>
> 4. Annual Celebrex and Bextra operating profits and pretax profits….

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[253] Ltr. from L.R. Williams to L. Schneider, 18 Jan 08, Ex. 97 (emphasis added).

5. Total monthly R&D expenditures for each Defendant, not broken down by project, from 1987 to the present.

6. Total monthly R&D expenditures for DIP and Cox-2 projects (if any) from 1987 to the present….

7. Cox-related market studies and analyses from 1987 to the present….

8. Sales projections and forecasts for any selective COX-2 inhibitor whether or not released, from 1987 to present.

9. All license agreements from 1989 to 1999 based upon which Pfizer has paid a royalty to a third party….

10. Monthly NRx and TRx data (in electronic form) for the Cox-2, analgesic and NSAID markets from 1987 to the present.

11. Expert reports and all related drafts and other documents submitted by any party in any COX-related litigation, as limited by paragraph B6 of the Court's March 26, 2008 Order.

12. Press releases announcing sales of Celebrex or Bextra.

13. Celebrex and Bextra marketing material.

14. Analysis and documents relating to the pricing of Celebrex and Bextra. [254]

On 23 April 2008, Pfizer's Chicago counsel wrote BYU suggesting that

> [i]n significant respects, however, **the categories of information sought in your April 9, 2008 letter far exceed what was originally requested in Plaintiffs' document request** seeking financial information.[255]

Pfizer's counsel then promised that

> **[p]ending any alternate resolution to the issues identified above, and subject to the objections and issues raised above**,

[254] Ltr. from L.R. Williams to N. Wyland, 9 Apr 08, Ex. 98.

[255] Ltr. from N. Wyland to L.R. Williams, 23 Apr 08, Ex. 99 (emphasis added).

> Defendants will search for and produce documents (to the extent such documents exist) [256]

regarding some of the categories BYU identified.

Although BYU believes the 14 categories it outlined for Pfizer in its 9 April 2008 letter are all categories of documents BYU requested in its First Request for Production of Documents, in another effort to facilitate Pfizer's production of financial documents, on 2 May 2008, BYU sent Pfizer Plaintiffs' Fifth Request for Production of Documents which listed the same categories of information set forth in BYU's 9 April 2008 letter. On 18 July, 24 September, and 10 October 2008, Pfizer sent documents it represented were responsive to BYU's requests for financial information. A review of Pfizer's produced documents shows Pfizer's production to be nothing more than a data dump.

Unable to decipher the information contained in Pfizer's "financial documents," BYU retained accounting consultants to review the documents. These consultants report that the financial documents produced by Pfizer contain pages of ledger entries with no way to decipher what the information means. As one of BYU's accounting consultants analogized, trying to reconstruct Pfizer's financials from the information produced would be like putting a puzzle together without knowing what the picture on the front of the box looks like and without having all of the pieces. An impossible and unduly burdensome task.

To date, Pfizer has produced very little meaningful financial information responsive to BYU's clear requests. Specifically, BYU has received incomplete and unclear information regarding:

- Monthly sales of Celebrex and Bextra (gross and net) measured by dollars and volume from 1998 to the present, including documents sufficient to reconcile gross and net sales;

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[256] *Id.*

- Monthly Celebrex and Bextra product line profitability statements or reports. Such reports should include at a minimum: the sales numbers listed above, any detailed cost breakdown listing cost for direct material, direct labor, manufacturing overhead components, indirect labor, depreciation, labor insurance costs, production utilities, supplier or subcontractor, and others;

- License agreements relating to Defendants' inflammation research from 1989 to 1999 based upon which Defendants paid a royalty to a third party, including:

  - The actual licensing agreements;
  - The royalty amount paid by year for each licensing agreement; and
  - The product sales of the product upon which the royalty was paid;

- Expert reports and all related drafts and other documents submitted by any party in any COX related litigation as noted by paragraph B6 of the Court's 26 March 2008 Order;

- Press releases announcing sales of Celebrex or Bextra;

- Documents sufficient to identify monthly NRx and TRx data (in electronic form) for the COX-2, analgesic and NSAID markets from 1989 to the present.

And BYU has not found any documents in Pfizer's production containing the following information:

- Monthly costs beyond those identified and included in costs of good sold that are historically attributed and allocated to Celebrex and Bextra which may include:

  - Sales costs, including commissions;

  - Promotional and marketing costs;

  - Royalty payments;

  - Distribution costs;

  - R&D; and

  - Other costs not captured in Costs of Good Sold;

- Annual Celebrex and Bextra operating profits and pre-tax profits for the United States and foreign countries, by country and region;

- Total monthly R&D expenditures for each Defendant not broken down by project;

- Total R&D expenditures for the DIP and COX-2 projects (if any) for each Defendant including:
    - R&D reports to management; and
    - R&D reports to the Board of Directors;
- All COX-related market studies and analysis from 1989 to the present including:
    - Market opportunity;
    - Competitors;
    - Market size;
    - Market share;
    - Market potential;
    - Competitive products; and
    - Product comparisons;
- Sales projections and forecasts for any selective COX-2 inhibitor, whether or not released, from 1989 to the present; and
- Documents related to the pricing of Celebrex and Bextra, including price-selling policies, policies, and documents created pursuant thereto related to Defendants' rationale in setting the price for Celebrex and Bextra over time.

The fact that Pfizer has failed to produce any of the above-requested documents is further evidence of its willful violation of this Court's Order and the Federal Rules of Civil Procedure. These documents must exist.

As early as 1994, Monsanto disclosed in its annual report the importance of the COX-2 inhibitor project stating:

REDACTED

REDACTED

Surely, this disclosure would not make it into the public report of a multi-billion dollar company without some type of underlying financial analysis by the company. The types of internal financial documents that should exist related to a COX-2 inhibitor project would include at least the following:

- Annual management reports;
- R&D management reports;
- Product development management reports;
- Sales and marketing management reports;
- Board of Directors reports; and
- R&D reports devoted to COX-2 Inhibitors.

Defendants' failure to produce meaningful or complete internal documents related to the financial analysis or forecasting of COX-2 inhibitor sales is staggering. In fact, its own documents evidence the existence of summarized financial data. For example, a document bates numbered BYU-PFE 544492 through BYU-PFE 544496 titled 'REDACTED ' includes a schedule[258] that provides a sales forecast for Celebrex from 1999 through 2002. However, at the top of the schedule it states that these numbers are an 'REDACTED !" Surely, if a document exists which shows numbers as an 'REDACTED " Pfizer must possess documents that contain actual calculations used internally by the company. Another example, at BYU-PFE 255253 through BYU-PFE 255416, is a document titled 'REDACTED " which contains relevant requested financial data, but only for the third quarter of 2004. No other data like this for other periods have been produced. To date, Pfizer has intentionally flaunted the Court's Order and failed to produce any such documents.

[257] Monsanto 1994 Annual Report, p. 38, BYU-PFE 167982-049, Ex. 100.

[258] BYU-PFE 544495, Ex. 101.

IX. PFIZER CONTINUES TO DISREGARD THE COURT'S ORDER WITH INAPPROPRIATE REDACTIONS AND NEWLY ASSERTED PRIVILEGE CLAIMS.

On 26 March 2008, the Court ordered Pfizer

> [t]o **remove any redactions not based on privilege** from the scientific notebooks and related documentation already provided to BYU.[259]

In spite of the Court's Order, Pfizer continues using redactions and improper privilege claims to hide relevant scientific notebooks and documents. Pfizer's redactions and privilege claims cover scientific data and strategic business decisions that are relevant to its central defense—that Dr. Simmons's biological materials and other trade secrets did not work. Some redacted and/or withheld information is from the critical 1991-mid-1992 time period when Monsanto only had Dr. Simmons's recombinant COX-2 technology.

As explained below, Pfizer previously claimed these pages were irrelevant. However, when faced with a Court Order, Pfizer now claims that the pages reflect responsive information communicated to its patent attorneys and are, therefore, privileged. Pfizer makes this claim in spite of the Research Agreement's clear mandate that BYU would control the patent process with respect to the COX-2 project:

> **With respect to prospective patent rights** referred to in paragraph 3.3, 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.[260]

Based on the Research Agreement, all COX-2 project-related Monsanto communications with internal or outside patent counsel should have been done on behalf of, and shared with,

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[259] Order Deeming Moot BYU's Motion For Re-Designation With Modifications, 26 Mar 08, Dkt. No. 105 at 2-3 (emphasis added).

[260] Research Agreement § 3.5, 1 Aug 91, BYU-18-3243, Ex. 102 (emphasis added).

BYU. Instead, Monsanto excluded BYU and now withholds documents (that it previously claimed were irrelevant) because the documents are allegedly communications with patent attorneys related to the COX-2 project.

In light of Pfizer and its Chicago counsel's history of misrepresentations, BYU does not believe Pfizer's new claims of privilege. Further, Pfizer's privilege claim with respect to BYU violates the Research Agreement's provision that COX-2 project patent work would be performed on BYU's behalf and with counsel approved by BYU. Therefore, BYU respectfully requests that the Court review the remaining redactions to Pfizer's scientific notebooks in camera.

Pfizer's long history of abusing redactions is outlined below.

A. Pfizer's Early Productions Contained Unexplained Redactions.

Almost immediately after Pfizer produced its FDA and *Teva* productions, BYU noted that Pfizer's production contained numerous redactions with no indication that redactions had been made for privilege and without any log explaining the redactions. BYU wrote Pfizer on 16 July 2007:

> In our preliminary review of the regulatory documents Pfizer produced on June 13, 2007, **we have discovered a number of redactions**. These include several complete pages reading only: 'REDACTED. Chemistry, Manufacturing & Control Information for Litigation Preparation.' **Pfizer did not provide any privilege log** describing the withheld documents with any particularity or indicating what privilege Pfizer is asserting with respect to these missing sections.[261]

On 30 August 2007, BYU followed up its 16 July 2007 letter and provided a list of over 900 documents containing unexplained redactions.[262] BYU explained the problem in detail:

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[261] Ltr. from A. Anderson to L. Schneider, 16 Jul 07, Ex. 103 (emphasis added).

[262] Ltr. from L. Beus to L. Schneider, 30 Aug 07, Ex. 104 (emphasis added).

- PFC01579781 reads simply: "Pages PFC00290821 to PFC00290834 have been redacted"

- PFC01564189 is a transmittal record wherein the entire body of the document is redacted with no explanation

- PFC00339562 discusses test results for a class of COX-2 inhibitors, yet the "Issues" section is partially redacted with no explanation.[263]

B. Pfizer Claimed That Its Unexplained Redactions Were Based On Relevance.

On 21 September 2007, Ms. Schneider wrote BYU:

> Finally, in response to your request regarding redactions, it is safe to say that **if the redactions are not recorded in the Teva privilege log, they were made because the underlying information pertains to research on products other than COX-2 inhibitors**.[264]

On 3 October 2007, Ms. Schneider provided further arguments in support of Pfizer's redactions. She claimed with respect to the FDA production that

> **the only redactions** are for patient information, chemistry, manufacturing and control ('CMC') information and personal information such as social security numbers.[265]

With respect to Pfizer's *Teva* production, Ms. Schneider admitted that documents had been redacted for reasons other than privilege and claimed that

> [s]ome documents were redacted because **they contain information unrelated to COX-2**.[266]

BYU was concerned with Pfizer's statement given the *Rochester* Court's Decision and Order dated 28 March 2002:

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[263] *Id.*

[264] Ltr. from L. Schneider to L.R. Williams, 21 Sep 07, Ex. 105 (emphasis added).

[265] Ltr. from L. Schneider to A. Anderson, 3 Oct 07, Ex. 106 (emphasis added).

[266] *Id.* (emphasis added).

REDACTED

* * *

REDACTED

One of Pfizer's unexplained redactions (and one of its subsequent baseless claims of privilege) was a Dr. Seibert notebook page dated approximately 27 August 1991 stating "get the Simmons effect."[268]

C. BYU Continued Questioning Pfizer's Unexplained Redactions And Filed Its Motion To Compel.

BYU wrote Pfizer again on 9 October 2007, explaining the scope of the problem:

> 96 of the 447 scientific notebooks Pfizer produced contain redactions. Many of these redactions are surrounded by COX-2 related material.[269]

BYU asked that Pfizer either comply with FRCP 26(b)(5)(A) by describing any redactions made on the basis of privilege or produce the redacted portions of each scientific notebook by the end of October 2007.[270]

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[267] Decision and Order, 28 Mar 02, BYU-PFE077427 at 453, Ex. 107 (emphasis added).

[268] SM264805-806, Ex. 108.

[269] Ltr. from L.R. Williams to L. Schneider, 9 Oct 07, Ex. 108.

[270] *Id.*

Instead, on 22 October 2007, Pfizer again admitted that its redactions were based on relevance, rather than any claim of privilege, but refused to produce additional notebooks:

> In our view, locating **redactions in only 96 of 447 scientific notebooks shows that Pfizer did not over-redact**. The mere fact **that the redacted pages are surrounded by COX-2 related material does not mean the redactions are related to COX-2**. I am quite confident you routinely work on multiple matters on the same day, just as Pfizer scientists do. Finally, your request that we reproduce 351 notebooks by the end of the month, regardless of the topics contained in those notebooks, is unreasonable, particularly given that the vast quantity of these notebooks are of little to no relevance in this litigation. **We are entitled to and intend to rely on the redactions made during the *Teva* litigation**.[271]

In light of Pfizer's continued refusal to produce or claim privilege over scientific notebooks assigned to researchers working on the COX-2 project during the critically relevant 1991-1995 time periods, BYU filed its motion to compel, which included a request that the Court compel Pfizer to produce

> **unredacted copies of all notebooks** issued researchers working on the COX-2 or DIP projects between 1990 and 1995, as well as all reports, emails, memos or other documents **authored by these scientists regarding COX-1, COX-2, and DIP research**.[272]

Almost six months after its initial complaints about Pfizer's unexplained redactions, on 12 February 2008, BYU again wrote regarding "the continuing problem with unexplained redactions."[273] BYU identified redactions in 12 researchers' notebooks. Such redactions included notes concerning business/strategy meetings in Dr. Seibert's personal notebooks. For example, BYU's 9 October 2007 letter identified that Pfizer had redacted Dr. Seibert's

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[271] Ltr. from L. Schneider to L.R. Williams, 22 Oct 07, Ex. 16 (emphasis added).

[272] Motion to Compel Immediate Production of Documents, 10 Jan 08, Dkt. No. 58 at 6 (emphasis added).

[273] Ltr. from L.R. Williams to L. Schneider, 12 Feb 08, Ex. 109.

notebooks as follows: "REDACTED"[274] and "REDACTED"[275]

D. The Court Ordered Pfizer To Remove Its Relevance Objections And Log Any Privilege Redactions.

On 26 March 2008, the Court ordered Pfizer to

> **remove any redactions not based on privilege from the scientific notebooks** and related documentation already provided to BYU.
>
> **provide privilege logs**, within 60 days, for redactions based on privilege that are not already identified on its privilege logs and to provide updated privilege logs if Pfizer redacts information based on privilege in future discovery.[276]

E. After The Court's Order, Pfizer Changed The Bases For Its Redactions From Relevance To Privilege—But Did Not Produce Its Redacted Scientific Notebooks.

Pfizer failed to comply with the Court's Order to remove redactions or provide privilege logs within 60 days. BYU raised the issue again in its brief prepared for the 29 July 2008 hearing and identified 10 specific redactions of scientific notebooks that Pfizer had not explained:

- REDACTED
- REDACTED
- REDACTED
- REDACTED

[274] PFC00678613-615, Ex. 110.

[275] PFC01589046-9047, Ex. 111.

[276] Order Deeming Moot BYU's Motion for Re-Designation With Modifications, 26 Mar 08, Dkt. No. 105 at 2-3 (emphasis added).

- REDACTED
- REDACTED
- REDACTED
- REDACTED
- REDACTED and
- REDACTED[277]

In response to the Court's Order, on 24 July 2008, Pfizer sent BYU a supplemental privilege log listing each of the 10 notebooks BYU mentioned in its brief to the Court.[278] Each of the notebooks listed on the Privilege Log is described as privileged in some version of the following:

> Handwritten notes memorializing confidential communications with patent counsel, J. Bulock, **reflecting legal advice regarding patent prosecution**.[279]

F. Pfizer's New Privilege Claims Concealed At Least One Relevant, Non-Privileged Document.

Despite Pfizer's newly asserted privilege claims, BYU had independently discovered that one of the documents on Pfizer's 24 July 2008, privilege log was not privileged and was relevant because it referred to Dr. Simmons, stating "get the Simmons effect." BYU described the continuing redaction problem at the 29 July 2008 hearing and displayed the "get the Simmons effect" document for the Court.

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[277] Plaintiffs' Memorandum for July 29, 2008 Hearing, 21 Jul 08, Dkt. 136 at 34-35.

[278] Ltr. from N. Kopinski to L.R. Williams (with attached Privilege Log), 24 Jul 08, Ex. 112.

[279] *Id.* (emphasis added).

G. Ms. Schneider Represented To The Court That Pfizer Had Produced The "get the Simmons effect" Page.

In response to the Court's questioning, Ms. Schneider claimed that the "get the Simmons effect" document had been produced the day before:

> THE COURT: **What about the exhibit** that Mr. Williams showed **that had been redacted** in one litigation and was privileged **but it had been produced in the other litigation and clearly made reference to the Simmons COX-2.**
>
> MR. HALEY: Right. And the -- under the Merck litigation, if you go back and you look at it, that's all under the patent that was filed by the lawyer which we claim to be privileged under work-product doctrine that it was a privileged document -- it was inadvertently produced in the Merck litigation, when they talked about the waiver points, I understand it, going out, right?
>
> MS. SCHNEIDER: **My understanding is that went out yesterday and they should have received it this morning in un-redacted form**.[280]

BYU waited until 5 August 2008, but did not receive the un-redacted "get the Simmons effect" page. Thereafter, BYU wrote Pfizer explaining that Pfizer had not produced an unredacted copy of the "get the Simmons effect" page, but had instead produced a 28 July 2008 privilege log claiming that the "get the Simmons effect" page was privileged on the grounds that it contained "[h]andwritten notes memorializing confidential communications with patent counsel, L. Swaney, reflecting legal advice regarding patent prosecution."[281] BYU then demanded that Pfizer correct Ms. Schneider's misrepresentation to the Court.

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[280] Motions Hearing Transcript, 29 Jul 08, 65:10-25, Ex. 113 (emphasis added).

[281] Ltr. from L.R. Williams to D. Parkinson, 5 Aug 08, Ex. 114.

Only then, on 7 August 2008, over a week after her misrepresentation to this Court, did Pfizer correct Ms. Schneider's misrepresentation and produce a copy of the "get the Simmons effect" page to BYU.[282]

H. Pfizer's Third Supplemental Certification Maintains Pfizer's Newly Asserted Privilege Claims.

On 15 October 2008, Pfizer stood by its new privilege claims, claiming that it had

> **[P]roduced legible, unredacted** (except for privilege) copies of every notebook in its possession, custody or control which it has located and which is even arguably responsive to BYU's discovery requests, resulting in the production of over 2700 notebooks.[283]

Based on its new privilege claims, Pfizer has continued to withhold notebook pages that are apparently relevant and over which no logical claim of privilege can be asserted, including those listed in BYU's brief for the 29 July 2008 hearing. In light of Pfizer's history of misrepresentations and the "get Simmons effect" page, BYU questions the legitimacy of Pfizer's newly asserted privilege claims.

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[282] Ltr. from N. Kopinski to L.R. Williams, 7 Aug 08, Ex. 115.

[283] Defendants' Third Supplemental Certification Concerning Discovery Efforts, 15 Oct 08, Dkt. No. 157.

X. PFIZER STILL HAS NOT PRODUCED MINUTES FROM AT LEAST 31 BOARD MEETINGS BETWEEN 1991 AND 1993.

In light of the $10M/day Needleman document, Monsanto's CEO was clearly personally involved in the COX-2 project:

> Taking a leap of faith after I joined Monsanto, and **with the help of a CEO who recognized the importance of having a critical mass of scientists focused on a problem, we mobilized 50 molecular and cell biologists** to clone and express the human genes for both forms of the enzyme and to set up high-throughput assays looking for active compounds with differential activities against the two enzymes. **We also mobilized one-third of all the medicinal chemists at Searle** to synthesize candidate compounds, **creating an intense, highly-focused effort**.[284]

As a publicly traded Fortune 500 company with all the attendant reporting requirements, it is incredible to believe that the mobilization of resources Dr. Needleman describes, with the CEO's involvement, would not have been approved by, or at least presented to, the Board of Directors.

Pfizer's attempt to minimize the relevance of the board meetings is just another misrepresentation:

> As of July '93, the **COX-2** Celebrex, whatever you want to call it, **isn't in the top ten research projects**. Go to the next page. This is the high potential research projects, the next ten, it's not there either. **It's not in the top 20**. So of course they wouldn't be talking about it in the board meeting. It's not even in the top 20 projects at Pfizer, they're working on a lot of things, because it wasn't that big a deal then. **And you would never expect that level of detail to be presented to a board meeting**.[285]

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[284] "From a twinkle in the eye to a blockbuster drug: the story of Celebrex® holds lessons for R&D leaders everywhere," authored by Philip Needleman, published in Research-Technology Management, Vol. 44, No. 6, 1 Nov 01, pp. 38-41, Ex. 3 (emphasis added).

[285] Motions Hearing Transcript, 29 Jul 08, 69:14-24, Ex. 116 (emphasis added).

BYU understands that Celebrex was one of Monsanto's most successful drugs. It is not credible to believe that Monsanto's Board of Directors was not receiving reports regarding Monsanto's investment in the project.

On 12 January 2007, BYU requested:

> **All documents relating to Monsanto's organizational division of resources and manpower**, specifically as between the 'DIP Project' and any project(s) to find a COX-2 selective NSAID during the years 1990-2003, **including, but not limited to, department budgets, timesheets, organizational memoranda, reports, management reports, or corporate documents**.[286]

On 9 October 2007, BYU wrote Ms. Schneider asking that she:

> Please verify whether Pfizer has produced all the documents that relate to Monsanto's research projects and its strategies to develop COX-related products. For example, **Pfizer did not produce committee minutes, notes, executive summaries, funding requests, memoranda, or similar documents dated earlier than 1992. Although Pfizer produced a handful of such documents from 1992, BYU believes that many more should exist**. Please confirm that Pfizer produced all documents that relate to Monsanto's research project and its strategies to develop COX-related products.[287]

On 26 March 2008, the Court ordered Pfizer to produce "**all … meeting minutes**, reports (including those to Boards of Directors) … **referring or relating to plaintiff's DIP and COX II projects**."[288]

On 24 July 2008, more than four months after the Court's order, Pfizer produced 3,930 pages described as "Monsanto materials related to the Board of Directors." Among those almost 4,000 pages, Pfizer produced minutes and supporting documents from only five Monsanto board

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[286] Plaintiffs' First Request for Production of Documents, 12 Jan 07 at 18, Ex. 20 (emphasis added).

[287] Ltr. from L.R. Williams to L. Schneider, 9 Oct 07, Ex. 26 (emphasis added).

[288] Order Granting BYU's Motion to Compel Immediate Production of Documents, 26 Mar 08, Dkt. No. 106 at 5.

meetings: three from 1991,[289] one board meeting from 1992,[290] and one board meeting from 1993.[291] None of the minutes Pfizer produced contains any discussion of COX-2.

After the Court's Order to produce all board meeting minutes, BYU asked Pfizer during its 30(b)(6) deposition about Monsanto's board; Pfizer's witness testified that she did not even know if Monsanto had a board of directors between 1991 and 1993:

> Q. Was there a board of directors of Monsanto in 1990 through 1993?
>
> A. I don't know.
>
> Q. **Have you ever asked that question**, whether there was a board of directors at Monsanto?
>
> A. **No**.[292]

In its post-hearing production of over 4 million pages, Pfizer has not produced any more board meeting minutes.

But, according to Pfizer's own documents, in 1993 and 1994, Monsanto's Corporate Law Department transmitted four boxes of 1991 and 1992 "REDACTED [redacted]"[293] for at least 28 meetings to the Monsanto Records Center. According to Pfizer's documents, the "REDACTED [redacted]"[294]

Pfizer has only produced minutes for five of the meetings—a total of 20 pages from the four boxes of minutes and back-up material Pfizer sent to its record center.

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[289] BYU-PFE 209124; BYU-PFE 209127; and BYU-PFE-BM_002780, Ex. 117.

[290] BYU-PFE-BM_001551, Ex.118.

[291] BYU-PFE 209139, Ex. 119.

[292] Dep. of Kathy Owens, 10 Jun 08, 125:13-18, Ex.120 (emphasis added).

[293] BYU-PFE-BM_002277, BYU-PFE-BM_001538, Ex. 121 (emphasis added).

[294] *Id*.

Pfizer's representation regarding board minutes is not credible given the personal involvement the $10M/day document indicates that Monsanto's CEO had with regard to the COX-2 project.

Again, without explanation for why it has still not produced almost four boxes of relevant documents, Pfizer states only that it "has produced every non-privileged, responsive document it has located as a result of … extensive searches."[295]

It is not believable that Monsanto's Board of Directors did not discuss the COX-2 project that produced one of the most successful prescription drugs in history. It also seems implausible that a mobilization chart involving "50 molecular and cell biologists" would not have required board approval.

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[295] Defendants' Third Supplemental Certification Concerning Discovery Efforts, 15 Oct 08, Dkt. No. 157 at 5.

XI. PFIZER SEEKS AN *EX PARTE* DECISION FROM THE PTO REGARDING BYU'S INVENTORSHIP CLAIM BASED ON INCOMPLETE EVIDENCE.

On 15 October 2008, the same day Pfizer filed its Third Supplemental Certification with this Court, Pfizer sent BYU 141 pages it described as "a reissue application which Pfizer recently filed in the PTO pertaining to the '068 patent."[296]

On 16 October 2008, Ms. Schneider wrote Mr. Bettilyon suggesting that:

> As part of our effort to comply with the 37 C.F.R. § 1.56, **we would like to submit all of the pleadings, discovery requests and responses** (including any documents cited in BYU's response to our interrogatory concerning BYU's claims for correction of inventorship) **and transcripts of depositions taken to date** (including exhibits) **to the PTO**.[297]

Because Pfizer continues to withhold critical documents, BYU was concerned that Pfizer's submission of the documents described in its letter would be an incomplete record upon which any decision from the PTO regarding Pfizer's reissue application would be based.

37 C.F.R. § 156 states in part that:

> **Each individual** associated with the filing and prosecution of a patent application **has a duty of candor and good faith in dealing with the Office**, which includes a **duty to disclose** to the Office **all information** known to that individual **to be material** to patentability.

It is almost poetic, given Pfizer's history, that Pfizer would now be concerned with its duty of candor.

On 31 October 2008, BYU raised its concerns with Pfizer that Pfizer's reissue application was really a parallel proceeding in which BYU's participation would be limited:

> Candidly, Dr. Simmons and BYU believe that Pfizer's motivation for seeking to submit their documents to the PTO is to begin a **parallel proceeding**, in which BYU and Dr. Simmons's

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[296] Ltr. from L. Schneider to L.R. Williams, 15 Oct 08, Ex. 122.

[297] Ltr. from L. Schneider to M. Bettilyon, 16 Oct 08, Ex. 123 (emphasis added).

participation is very limited, **that may inappropriately impact BYU and Dr. Simmons's correction of inventorship claims in the District Court**. The PTO is not the proper forum from which to obtain any kind of opinion that will impact a correction of inventorship dispute.

Not only can Pfizer not cure its prior deceptive conduct during the patent prosecutions via its reissue application, but given Pfizer's lack of candor and continued denial that Dr. Simmons provided any useful technology to Monsanto—in the face of overwhelming evidence to the contrary—**any decision from the PTO regarding Pfizer's Reissue Application will be based on an incomplete record**.

BYU and Dr. Simmons's ability to participate in the reissue application proceedings is limited because the proceedings under 35 U.S.C. § 251 do not allow any input from a party other than the applicant—Pfizer. According to the Manual of Patent Examining Procedure at § 1404, BYU and Dr. Simmons's participation in the reissue application would be limited to filing a protest. However, according to 37 C.F.R. § 1.291, even if BYU and Dr. Simmons attempted to protest Pfizer's application, not only would Pfizer have to consent to the protest, but their ability to participate in the proceedings 'ends with the filing of the protest ….'

These limitations mean that, if BYU and Dr. Simmons either consent to Pfizer's request to submit their confidential documents as part of the reissue proceeding or submit the documents as part of a protest, they will not have the ability to control the presentation of the documents or the supporting evidence or even argue their merit.

If BYU and Dr. Simmons either consent to Pfizer's request or protest Pfizer's application, Pfizer will have effectively precluded BYU and Dr. Simmons from adequately protecting their interests and may then be able to disingenuously use any PTO decision Pfizer obtains—and any real or perceived relation it has to inventorship—**to support its argument against BYU and Dr. Simmons's correction of inventorship claims**. Consequently, BYU and Dr. Simmons cannot consent to Pfizer's submission of its confidential documents from this litigation to the PTO.[298]

[298] *Id.*.

However, because BYU believes it has an interest in the patent at issue in Pfizer's reissue application, BYU did not categorically refuse to consent to Pfizer's request. Instead, BYU asked for more information regarding Pfizer's plans and suggested that Pfizer stipulate to the accuracy of BYU's position with regard to Dr. Simmons's collaboration with Monsanto regarding the patent issue.

On 25 November 2008, Ms. Schneider wrote BYU refusing BYU's suggestion:

> [I]t is important to note that (1) **Pfizer's efforts to submit the materials from this litigation to the PTO is in no way an admission that these materials are material to patentability** – rather, it is simply a recognition that someone (like BYU) may claim down the road that they are material; (2) Pfizer does not believe that Dr. Simmons is an inventor of the claimed inventions of any of the patents listed in the Complaint, including the '068 patent; and (3) **your assertions that Pfizer intends to submit this material for some sort of nefarious purpose are incorrect**.[299]

Although Ms. Schneider denied any "nefarious purpose," she did not offer any further explanation for Pfizer's desire to submit the documents to the PTO except to explain that:

> Pfizer intends only to submit the materials as part of an Information Disclosure Statement. Should the PTO raise questions or concerns concerning these materials, we will respond to those questions or concerns.[300]

On 8 December 2008, BYU responded to Ms. Schneider:

> **[I]t appears to us that Pfizer is merely forum-shopping in an attempt to obtain support for its position in an *ex parte* proceeding before a tribunal which will not have the benefit of full discovery and even-handed access to both sides of the issues.**
>
> As noted in my letter dated December 1, 2008, Pfizer has failed to provide adequate answers to the questions and concerns raised in my letter of October 31, 2008. Your letter of December 4, 2008, also failed to include any further information. In the absence of

[299] Ltr. from L. Schneider to L. Beus, 25 Nov 08, Ex. 125 (emphasis added).

[300] *Id.*

> such answers, BYU and Dr. Simmons continue to object to any use of their confidential information during the reissue proceedings—especially in light of Pfizer's continued refusal to explain why BYU's information must be disclosed to the PTO.[301]

BYU further indicated that:

> [I]t is apparent that Pfizer intends to use an *ex parte* proceeding before the PTO to create the illusion that the PTO has somehow considered and rejected Dr. Simmons's claim of inventorship. Because reissue proceedings are *ex parte,* **BYU understands that Pfizer will argue (1) that only Pfizer has the right to meaningfully participate in those proceedings; (2) that only Pfizer has the right to respond to the questions or positions of the PTO; (3) that only Pfizer has the right to meet and discuss the application directly with the patent examiner (largely off the record)**; (4) that only Pfizer will select which documents relating to joint inventorship should and should not be presented to the examiner; and (5) that only Pfizer has the right to abandon or appeal reissue proceedings if dissatisfied with the PTO's decisions.[302]

BYU then identified for Pfizer one more time the critical documents Pfizer still has not produced in this litigation without which any decision from the PTO would necessarily be based on an incomplete record.

Finally, BYU suggested that Pfizer stay its proceedings in front of the PTO in favor of this litigation:

> If, as Pfizer apparently claims, there are 'no significant overlapping issues between the application and the litigation' then **Pfizer should affirm and stipulate that the reissue proceedings will have no effect on the inventorship claims of Dr. Simmons and BYU**. If, on the other hand, Pfizer believes the two matters do overlap, we ask that Pfizer agree to stay the reissue proceeding, in favor of the District Court case, as the PTO recommends.[303]

Then, on 16 December 2008, Ms. Schneider wrote BYU:

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[301] Ltr. from L. Beus to L. Schneider, 8 Dec 08, Ex. 126 (emphasis added).

[302] *Id.*

[303] *Id.*

> We have advised you that **Pfizer has made no determinations regarding how, or whether, it will use any resulting PTO decision in the ongoing litigation**, but that Pfizer will not argue that any resulting PTO decision will preclude BYU from raising the question of inventorship in the district court litigation.[304]

Pfizer further stated that:

> **Pfizer does not consent to a stay of the reissue proceedings … Pfizer cannot stipulate that the 'reissue proceedings will have no effect on the inventorship claims of Dr. Simmons and BYU.'** Pfizer cannot anticipate whether the PTO will determine that materials from the litigation are material, nor can Pfizer anticipate whether the PTO will raise the inventorship question.[305]

On 22 December 2008, BYU indicated to Pfizer that Paragraphs 13 and 22 of the Protective Order in this litigation prohibit Pfizer from submitting the documents it seeks to present to the PTO:

> No party or person **shall make any other use of any such PROTECTED INFORMATION, including** but not limited to use for commercial or competitive purposes or use **in any other legal proceeding**, except as permitted by order of the Court.
>
> * * *
>
> All materials designated as **PROTECTED INFORMATION shall be used for the purposes of this litigation only**. [306]

By this time, BYU had learned that Pfizer had not produced the $10M/day Needleman exhibit, despite its certification to the contrary. This only strengthened BYU's position that any submission of documents Pfizer made to the PTO would be incomplete and misleading. BYU identified the $10M/day Needleman exhibit to Pfizer in its 22 December 2008 letter, but Pfizer

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[304] Ltr. from L. Schneider to L. R. Beus, 16 Dec 08, Ex. 127 (emphasis added).

[305] *Id.*

[306] Protective Order, 5 Jun 07, Dkt. No. 43 at ¶¶ 13, 22 (emphasis added).

has failed to produce either that exhibit or any of the other exhibits marked at the 4 and 5 March 2008 Needleman deposition.

On 23 December 2008, BYU and Pfizer's Chicago counsel held a meet and confer via telephone during which Pfizer claimed, among other things, that it had not done an economic analysis of the '068 patent at issue in the reissue proceedings, that it would not stay the PTO proceedings, and, as described above, both Mr. O'Malley and Ms. Schneider claim to have produced every relevant document in this litigation.

During the meet and confer, BYU proposed to Pfizer's Chicago counsel that the parties submit the inventorship issue to Judge Kimball in the District Court of Utah, without a jury, prior to the PTO's *ex parte* proceeding. On 24 December 2008, BYU wrote Mr. O'Malley and Ms. Schneider repeating:

> BYU's offer of yesterday that **we are willing to have Judge Kimball decide the inventorship issue, without a jury, prior to the PTO's *ex parte* proceeding on your reissue application**. I can only assume that your outright rejection of this proposal indicates your desire to unfairly undermine BYU's position in this litigation.[307]

On 7 January 2009, Pfizer filed its Motion for Leave From and Modification To The Protective Order. BYU will respond to it formally in a separate response.

Pfizer's refusal to stay the *ex parte* proceeding before the PTO and allow Judge Kimball to decide the inventorship issue, even without a jury, indicates Pfizer's intention to circumvent the correct forum for deciding BYU's claims and suggests a motive for Pfizer's continued withholding of critical documents in this litigation.

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[307] Ltr. from L.R. Beus to R. O'Malley and L. Schneider, 24 Dec 08, Ex. 128 (emphasis added).

XII. PFIZER MADE MATERIAL MISREPRESENTATIONS TO THE COURT AND BYU REGARDING ITS DISCOVERY AND COMPLIANCE WITH THE COURT'S DISCOVERY ORDER.

As detailed above, Pfizer has misrepresented to both the Court and to BYU what responsive documents and materials it possesses. Though some of Pfizer's misrepresentations are more obviously blatant than others, BYU lists below most of the misrepresentations it has identified and the category of information to which they pertain:

A. Pfizer Misrepresented To This Court At Least Eight Times That Its Document Production Was Complete.

On 15 October 2008, Pfizer represented in its Third Supplemental Certification Concerning Discovery Efforts that it

> has … **[i]dentified for BYU the various other COX-2 related litigation matters and**, to the extent they are relevant to this case, produced the production documents, pleadings, **depositions (including exhibits)**, expert reports, witness statements and hearing transcripts **from these matters**.
>
> * * *
>
> [Pfizer] hereby certifies that **its production in response to BYU's First Request for Production is now complete**.[308]

On 18 July 2008, Pfizer stated that

REDACTED

On 29 July 2008, Pfizer stated to the Court that:

> **[w]e have been trying hard to produce all of the documents** that the Plaintiffs have requested.… **We've bent over backwards**,

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[308] Defendants' Third Supplemental Certification Concerning Discovery Efforts, 15 Oct 08, Dkt. No. 157 (emphasis added).

[309] Defendants' Supplemental Certification Concerning Discovery Efforts, 18 Jul 08, Dkt. No. 137 (emphasis added).

> we've spent a tremendous amount of time responding to **your Honor's Order**.
>
> * * *
>
> **[w]e've done our best, Judge,** no one's trying to cheat, we're bending over backwards.[310]

On 19 March 2008, Lisa Schneider, counsel for Pfizer, stated to the Court that she

> was personally involved in that [Rochester] collection effort and I can tell you we've searched the files of over 150 custodians likely to have any documents regarding COX-2 … I mean, **everything has been produced**.[311]

On 25 January 2008, Pfizer claimed that its commitment to search for and produce additional responsive documents renders many of BYU's claims moot. On this same date, Pfizer also stated that

> during the Rochester litigation, **Pfizer performed a good faith search of its files** for virtually all technical documents related to COX-2 **and produced hard copies of those documents during that litigation**.[312]

B. <u>Pfizer Misrepresented To This Court At Least Seven Times That It Had Completely Disclosed All Documents Regarding Previous COX-2 Litigation.</u>

On 15 October 2008, Pfizer's counsel, Mr. O'Malley, represented to the Court in Pfizer's Third Supplemental Certification Concerning Discovery Efforts that it completely

> **identified for BYU the various other COX-2 related litigation matters and**, to the extent they are relevant to this case, **produced** the production documents, pleadings, **depositions (including exhibits)**, expert reports, witness statements, and hearing transcripts **from these matters**.[313]

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[310] Motions Hearing Transcript, 29 Jul 08, 48:16-49:1; 70:3-4, Ex. 33 (emphasis added).

[311] Motion to Compel Hearing Transcript, 19 Mar 08, 42:6-22; 46:10, Ex. 32 (emphasis added).

[312] Defendants' Memorandum in Opposition to Motion to Compel Immediate Production of Documents, 25 Jun 08, Dkt. No. 69 at 3 (emphasis added).

[313] Defendants' Third Supplemental Certification Concerning Discovery Efforts, 15 Oct 08, Dkt. No. 157 at 3 (emphasis added).

On 15 October 2008, Pfizer stated that it

> has **produced all documents produced in the Rochester, *Merck* and *Teva* litigation matters**.[314]

On 12 August 2008, Pfizer stated that its

REDACTED

On 18 July 2008, Pfizer stated that

REDACTED

* * *

REDACTED

* * *

REDACTED

On 27 May 2008, Pfizer stated that

> **[t]o the extent [prior litigation documents] are in our possession**, custody or control, …. Pfizer's production is complete, as **Pfizer has either produced or made available for inspection all such documents**.[317]

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[314] *Id.*

[315] Defendants' Second Supplemental Certification Concerning Discovery Efforts, 12 Aug 08, Dkt. No. 147 at 11 (emphasis added).

[316] Defendants' Supplemental Certification Concerning Discovery Efforts, 18 Jul 08, Dkt. No. 137 at 12-13 (emphasis added).

[317] Defendants' Certification Concerning Discovery Efforts, 27 May 08, Dkt. No. 117 at 6 (emphasis added).

C. Pfizer Misrepresented To This Court At Least Five Times Regarding Its Production Of Biological Materials And Related Documents.

On 12 August 2008, Pfizer stated that its "REDACTED [redacted]"[318]

On 27 May 2008, Pfizer stated it

> **has produced all documents in [its] possession**, custody or control **that reflect Defendant's work with Dr. Simmons' reagents and other biological and intellectual property** as well as all documents relating to testing of any COX II related biological materials.
>
> * * *
>
> **has produced all documents relating to the chain of custody of biological materials** and reagents provided by Professor Simmons.[319]

On 19 March 2008, Ms. Schneider, Pfizer's counsel, represented to this Court that

> **Dr. Simmons' clones didn't work**, so there was a minimal amount of research with them and then **they were discarded.**[320]

On 25 January 2008, Pfizer stated in its Memorandum In Opposition To Motion To Compel Immediate Production of Documents that

> **[o]riginal biological materials** that Pfizer used to sequence Dr. Simmons's clones … **no longer exist** [and that] the freezer in which the sample was stored malfunctioned and **the sample was inadvertently discarded**.[321]

D. Pfizer Misrepresented To This Court At Least Seven Times Facts Regarding Scientific Notebooks.

On 15 October 2008, Pfizer stated that it

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[318] Defendants' Second Supplemental Certification Concerning Discovery Efforts, 12 Aug 08, Dkt. No. 147 at 11 (emphasis added).

[319] Defendants' Certification Concerning Discovery Efforts, 27 May 08, Dkt. No. 117 at 20, 22 (emphasis added).

[320] Motion to Compel Hearing Transcript, 19 Mar 08, 58:14-16, Ex. 10 (emphasis added).

[321] Defendants' Memorandum in Opposition to Motion to Compel Immediate Production of Documents, 25 Jan 08, Dkt. No. 69 at 8 (emphasis added).

> has **produced legible, unredacted (except for privilege) copies of every notebook in its possession**, custody, or control which it has located and is even arguably responsive to BYU's discovery requests.[322]

In Pfizer's 12 August 2008 Second Supplemental Certification regarding the Rangwala chart found in Rangwala's notebook, Pfizer represented to this Court that it

- REDACTED
- REDACTED
- REDACTED
- REDACTED

On 28 July 2008, Pfizer represented to this Court that it "**didn't get Simmons' COX-2 clones to work**."[324]

Pfizer previously made the same assertion, when it represented to the Court on 19 March 2008 that "it is [Pfizer's] view that **Dr. Simmons' clones didn't work**."[325]

E. Pfizer Misrepresented To This Court At Least Two Times That It Disclosed To BYU All Pfizer Board Meeting Minutes.

On 15 October 2008, Pfizer stated in its Third Supplemental Certification Concerning Discovery Efforts that it

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[322] Defendants' Third Supplemental Certification Concerning Discovery Efforts, 15 Oct 08, Dkt. No. 157 at 3 (emphasis added).

[323] Defendants' Second Supplemental Certification Concerning Discovery Efforts, 12 Aug 08, Dkt. No. 147 at 8, 9, 12 (emphasis added).

[324] Motions Hearing Transcript, 29 Jul 08, 11:10-12, Ex. 129 (emphasis added).

[325] Motion to Compel Hearing Transcript, 19 Mar 08, 58:14-16, Ex. 10 (emphasis added).

> Produced all internal correspondence referring or relating to Pfizer's DIP and COX-2 projects.[326]

On 29 July 2008, Pfizer represented to this Court that

> As of July '93, the **COX-2** Celebrex, whatever you want to call it, **isn't in the top ten research projects**. Go to the next page. This is the high potential research projects, the next ten, it's not there either. **It's not in the top 20**. So of course they wouldn't be talking about it in the board meeting. It's not even in the top 20 projects at Pfizer, they're working on a lot of things, because it wasn't that big a deal then. **And you would never expect that level of detail to be presented to a board meeting**.[327]

F. <u>Pfizer Misrepresented To BYU At Least Seven Times That Its Document Production Was Complete.</u>

On 15 October 2008, Mr. O'Malley, counsel for Pfizer, stated in a letter to Plaintiffs that

> **Pfizer has produced every non-privileged, responsive document** it has located as a result of these extensive searches.[328]

On 7 January 2008, Ms. Schneider wrote BYU indicating that

> **[d]ocuments prior to June 1995 'produced' in the Rochester litigation were likewise produced in the Teva litigation. Your assertion that the statement is somehow untrue … is absurd.**[329]

On 20 November 2007, in a letter to Plaintiffs' counsel, Ms. Schneider stated that

> **[a]ll responsive documents located by Pfizer** after a reasonable search **have been produced** to BYU with three exceptions.[330]

On 15 November 2007, in a letter to Plaintiffs' counsel, Ms. Schneider stated that "Pfizer has conducted a **good faith search for documents**…."[331]

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[326] Defendants' Third Supplemental Certification Concerning Discovery Efforts, 15 Oct 08, Dkt. No. 157 at 4 (emphasis added).

[327] Motions Hearing Transcript, 29 Jul 08, 69:14-24, Ex. 116 (emphasis added).

[328] Defendants' Third Supplemental Certification Concerning Discovery Efforts, 15 Oct 08, Dkt. No. 157 at 5 (emphasis added).

[329] Ltr. from L. Schneider to L.R. Williams, 7 Jan 08, Ex. 12 (emphasis added).

[330] Ltr. from L. Schneider to L.R. Williams, 20 Nov 07, Ex. 30 (emphasis added).

[331] Ltr. from L. Schneider to L.R. Williams, 15 Nov 07, Ex. 29 (emphasis added).

On 29 October 2007, in a letter to Plaintiffs' counsel, Ms. Schneider stated that Pfizer's production of "**custodian collections**" was "**done**."[332]

On 22 October 2007, in a letter to Plaintiffs' counsel, Ms. Schneider stated that

> **[n]otebooks, minutes and reports were all collected in connection with the Rochester litigation** and therefore would have been produced in the Teva document production.[333]

On 22 October 2007, in a letter to Plaintiffs' counsel, Ms. Schneider indicated that "**[a]ll custodian collections would be produced by October 31, 2007**."[334]

G. <u>Pfizer Misrepresented To BYU At Least Two Times That It Had Completely Disclosed All Documents Regarding Previous COX-2 Litigation.</u>

On 18 April 2008, in a letter to Plaintiffs' counsel, Ms. Schneider stated that Pfizer

> **does not believe that the subject matter of any of these cases (IREF) is relevant to the claims of BYU or Dr. Simmons.**[335]

On 28 November 2007, Pfizer stated that

> **[w]e searched our files for all deposition transcripts and exhibits** from the University of Rochester v. Searle litigation. We did not locate any of the seven depositions transcripts you identified in your letter.[336]

H. <u>Pfizer Misrepresented To BYU At Least Four Times That It Had Disclosed All Biological Materials.</u>

On 21 May 2008, Mr. Spanbauer stated that Pfizer has

> **conducted an extensive search for cyclooxygenase-related biological materials** that remain in Pfizer's possession, custody or control [including] biological materials that it received from Professor Simmons.[337]

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[332] Ltr. from L. Schneider to L.R. Williams, 29 Oct 07, Ex. 27 (emphasis added).

[333] Ltr. from L. Schneider to L.R. Williams, 22 Oct 07, Ex. 16 (emphasis added).

[334] *Id.*

[335] Ltr. from L. Schneider to M. Bettilyon, 18 Apr 08, Ex. 38 (emphasis added).

[336] Ltr. from L.R. Williams to L. Schneider, 28 Nov 07, Ex. 46 (emphasis added).

[337] Ltr. from J. Spanbauer to K. Ricker, 21 May 08, Ex. 45 (emphasis added).

On 7 January 2008, in a letter to Plaintiffs' counsel, Ms. Schneider stated that

> Pfizer **did have certain biological materials** … **However**, Pfizer had only very small quantities of t**hose materials [at] that time and those materials were utilized to obtain sequence data during the mediation**.[338]

On 9 October 2007, in a letter to Plaintiffs' counsel, Ms. Schneider stated that

> **Pfizer has** to date **been unable to locate any biological materials** requested in Plaintiffs' document request.[339]

On 20 August 2007, in a letter to Plaintiffs' counsel, Ms. Schneider stated that

> **Pfizer has been searching for**, collecting and reviewing documents responsive to requests [for biological materials].[340]

I. Pfizer Misrepresented To BYU At Least Four Times That It Had Produced All Scientific Notebooks.

On 20 November 2007, in a letter to Plaintiffs' counsel, Ms. Schneider stated that

> **[a]ll responsive documents located by Pfizer after a reasonable search have been produced to BYU** with three exceptions.[341]

On 15 November 2007, in a letter to Plaintiffs' counsel, Ms. Schneider stated that

> **[t]he Notebooks produced to BYU are the same notebooks produced in at least two other litigations and were obtained as a result of a good faith investigation** looking for all notebooks pertaining to Searle/Monsanto/Pharmacia's COX-2 efforts.[342]

On 22 October 2007, in a letter to Plaintiffs' counsel, Ms. Schneider stated that

> **[n]otebooks, minutes and reports were all collected in connection with the Rochester litigation** and therefore would have been produced in the Teva document production.[343]

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[338] Ltr. from L. Schneider to L.R. Williams, 7 Jan 08, Ex. 12 (emphasis added).

[339] Ltr. from L. Schneider to L.R. Williams, 9 Oct 07, Ex. 11 (emphasis added).

[340] Ltr. from L. Schneider to L.R. Williams, 20 Aug 07, Ex. 44 (emphasis added).

[341] Ltr. from L. Schneider to L.R. Williams, 20 Nov 07, Ex. 30 (emphasis added).

[342] Ltr. from L. Schneider to L.R. Williams, 15 Nov 07, Ex. 29 (emphasis added).

[343] Ltr. from L. Schneider to L.R. Williams, 22 Oct 07, Ex. 16 (emphasis added).

In that same letter, Ms. Schneider also stated

> **[a]s Pfizer has told Dr. Simmons since the late 1990's, Pfizer was unable to get Dr. Simmons' COX-2 clones to work.**[344]

J. <u>Pfizer Made At Least Three Misrepresentations To BYU Regarding Redactions.</u>

On 3 October 2007, Ms. Schneider provided further arguments in support of Pfizer's redactions. She claimed with respect to the FDA production that

> **the only redactions** are for patient information, chemistry, manufacturing and control ('CMC') information and personal information such as social security numbers.[345]

With respect to Pfizer's *Teva* production, Ms. Schneider admitted that documents had been redacted for reasons other than privilege and misrepresented that:

> [S]ome documents were redacted for because **they contain information unrelated to COX-2**.[346]

On 21 September 2007, in a letter to Plaintiffs' counsel, Ms. Schneider stated that

> **[i]f the redactions are not recorded in the Teva privilege log, they were made because the underlying information pertains to research on products other than COX-2 inhibitors.**[347]

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[344] *Id.*

[345] Ltr. from L. Schneider to A. Anderson, 3 Oct 07, Ex. 106 (emphasis added).

[346] *Id.* (emphasis added).

[347] Ltr. from L. Schneider to L.R. Williams, 21 Sep 07, Ex. 105 (emphasis added).

MOTION FOR SANCTIONS

Based on the foregoing Response to Defendants' Third Supplemental Certification Concerning Discovery Efforts, BYU moves for sanctions as provided for by FRCP 37(b) including (1) striking Pfizer's Answer; (2) ordering that Pfizer pay BYU's costs and fees incurred in discovering Pfizer's discovery abuses; (3) entering a spoliation instruction that all the documents Pfizer has destroyed or otherwise withheld support BYU's contention that Dr. Simmons's COX-2 clones worked; (4) holding Pfizer in contempt of Court; (5) allowing depositions of witnesses, including, among others, its attorneys, Mr. O'Malley and Ms. Schneider, for deposition to explain its discovery abuses; and (6) entering a jury instruction that, in the event BYU proves at trial that Dr. Simmons's contribution to Pfizer's development of Celebrex provided Pfizer with a head start and/or first to market advantage, that BYU's damages for the head start Dr. Simmons's biological materials and other trade secrets provided Pfizer should be calculated at, at least, $10 million per day.

As set forth in detail below, these sanctions are both just and related to the particular claims at issue in the Order to provide discovery.

ARGUMENT

As demonstrated above, for the past two years, Pfizer has demonstrated a regular, consistent, and repeated unwillingness to comply with its discovery obligations—including this Court's Order—and produce relevant documents. Under Rule 37, Pfizer's conduct merits severe sanctions. Without such sanctions, given Pfizer's history, it seems as though Pfizer's misconduct will only continue, thereby prejudicing BYU's right to a fair trial on the merits of its claim. For all of these reasons, BYU respectfully requests the Court invoke the provisions of Rule 37 and sanction Pfizer for its misconduct.

I. LEGAL STANDARD.

Under Rule 37 of the Federal Rules of Civil Procedure, the Court has discretion to impose a wide variety of sanctions for Pfizer's failure to abide by the Court's 26 March 2008 Order Granting BYU's Motion to Compel Immediate Production of Documents. Such sanctions include, but are not limited to:

> i **Directing that the matters embraced in the order or other designated facts be taken as established** for purposes of the action, as the prevailing party claims.
>
> iii **Striking pleadings in whole** or in part.
>
> vii **Treating as contempt of court the failure to obey any order** except an order to submit to a physical or mental examination.[348]

The Court has discretion to impose any such sanctions that are "just and related to the particular claim which was at issue in the order to provide discovery."[349] These sanctions are not exclusive of each other, and the court may impose several of those sanctions simultaneously.[350]

II. UNDER *EHRENHAUS*, PFIZER'S ANSWER SHOULD BE STRICKEN.

Because striking a party's pleading is severe, the Tenth Circuit, in *Ehrenhaus*, provided guiding factors, not a "rigid test," for a Court to consider: (1) the degree of actual prejudice to BYU; (2) the amount of interference with the judicial process; (3) Pfizer's culpability; (4) whether the Court warned Pfizer in advance of the severe sanction; and (5) the efficacy of lesser sanctions.[351]

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[348] Fed. R. Civ. P. 37(b)(2)(A).

[349] *Ehrenhaus v. Reynolds*, 965 F.2d 916, 921 (10th Cir. 1992) (upholding dismissal of action as sanction against plaintiff's failure to abide by discovery order after considering relevant factors).

[350] *Guidry v. Continental Oil*, 640 F.2d 523, 533 (5th Cir. 1981) (Rule 37 sanctions "are flexible and, within reason, may be applied in as many or varied forms as the Court desires by exercising broad discretion in light of the facts of each case").

[351] *Ehrenhaus*, 965 F.2d at 920.

Here, under the *Ehrenhaus* factors, Pfizer's discovery misconduct warrants having its Answer stricken. As demonstrated by the MDL Needleman exhibits and the IREF Needleman deposition and exhibits, Pfizer shows no signs of correcting any of its discovery misconduct despite the Court's 26 March 2008 Order. Because Pfizer's actions are willful[352] and calculated to protect the profits of its wildly successful line of COX-2 selective inhibitor drugs, and because the Court has previously warned Pfizer in its Order and the hearings to correct its discovery practice, lesser sanctions are not effective to ensure compliance.

Moreover, Rule 37(b) expressly provides that

> [i]nstead of or in addition to the orders above, **the court must order the disobedient party, the attorney advising the party, or both to pay the reasonable expenses, including attorneys' fees**, caused by the failure.[353]

In the present case, these monetary sanctions must be awarded.

A. <u>Pfizer's Conduct Has Significantly Prejudiced BYU.</u>

In *Ehrenhaus*, the moving party was prejudiced by "**delay and mounting attorneys' fees**."[354] Similarly, in this case, Pfizer has caused significant and unwarranted delays and forced BYU to incur substantial attorneys' fees in order to obtain basic discovery and compliance with the Court's 26 March 2008 Order.

Before filing its Motion to Compel on 10 January 2008, BYU spent almost a year working with Pfizer to obtain basic discovery. As described above, Pfizer required BYU to identify potentially responsive documents before it would search for and produce them. Pfizer's

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[352] "Willful" discovery misconduct is "[d]isobedient conduct not outside the control of the litigant" and such a showing "is all that is required to demonstrate willfulness, bad faith or fault." *Construction Laborers Trust Funds for Southern California Administrative Co. v. Rosal*, 2008 WL 4500757 (C.D. Cal.) citing *Henry v. Gill Industries, Inc.*, 983 F.2d 943, 948-949 (9th Cir. 1993).

[353] Fed. R. Civ. P. 37(b)(2)(C) (emphasis added); *see also* Fed. R. Civ. P. 37(a)(5) (requiring payment of attorneys' fees related to successful motion to compel).

[354] *Ehrenhaus*, 965 F.2d at 921.

actions greatly prejudiced BYU's ability to prosecute the case, and to date have required it to spend two years and over $1 million to obtain the most relevant and discoverable information.

B. Pfizer Has Significantly Interfered With The Judicial Process.

In *Ehrenhaus*, the Tenth Circuit approved the District Court's dismissal of the party's pleading where the party "**willfully failed to comply with a direct court order** [and] flouted the court's authority."[355] The Tenth Circuit also approved the District Court's reasoning that if the party "could ignore court orders here without suffering the consequences, **then the district court cannot administer orderly justice, and the result would be chaos**."[356]

As in *Ehrenhaus*, Pfizer's ongoing pattern of discovery misconduct significantly disrupts the legal process. Pfizer ignores the Court's Order and requires ongoing Court supervision.

In its Order, the Court required Pfizer to provide a "complete production" within "60 days of the date of this order," 26 May 2008. Rather than comply, on 27 May 2008, Pfizer filed a "Motion for an Extension of Time." By filing its Motion without requesting BYU's consent, or even informing BYU of its intent to file the motion, Pfizer just took what resulted in a 10-week (70-day) extension of time to respond to the Court's Order, thereby doubling the Court-allotted time to comply with the discovery order. Then, as BYU has demonstrated, Pfizer did not even comply with the Court's Order. Pfizer's actions flout the Court's authority and significantly disrupt the judicial process.

C. Pfizer Is Culpable For Its Misconduct.

In *Ehrenhaus*, the Tenth Circuit upheld a finding of culpability where the District Court determined that the party "simply and intentionally refused to appear [at a deposition], which the

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[355] *Id*. (emphasis added).

[356] *Id*. (emphasis added).

Court finds to be in **bad faith and willful and intentional disobedience** to two court orders."[357] Here, Pfizer is similarly culpable because its ongoing pattern of discovery abuses demonstrates a willingness to disregard discovery obligations and this Court's orders in an effort to prejudice and prevent BYU's prosecution of its claims.

As noted in the Court's Order, one of the categories of documents which Pfizer has been compelled to produce include "prior litigation documents"—which includes depositions and related deposition exhibits.[358] In fact, deposition exhibits should be among the easiest of documents to produce, as such documents are often found in attorneys' offices. Notwithstanding, Pfizer continues to fail to produce deposition exhibits from relevant depositions.

Pfizer's refusal to produce easily accessible deposition exhibits continues. Despite this Court's clear order requiring Pfizer's production of depositions and exhibits, Pfizer has not yet produced the $10M/day Needleman exhibit or the IREF documents despite BYU's direct requests.

D. Pfizer Ignored This Court's Warnings.

In *Ehrenhaus*, the Tenth Circuit addressed the factor of notice and determined that the District Court put the party

> on notice that failure to comply with the court's order would subject Ehrenhaus' claims to dismissal **when he invited defense counsel to file a motion to dismiss** if Ehrenhaus failed to attend the ordered continuation of his deposition.[359]

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[357] *Id.* (emphasis added).

[358] *See* Order Granting BYU's Motion to Compel Immediate Production of Documents, 26 Mar 08, Dkt. No. 106 at 2.

[359] *Ehrenhaus*, 965 F.2d at 921 (emphasis added).

Similarly, this Court warned Pfizer that no more discovery abuses would be tolerated. In its Order, this Court noted that Pfizer was to

> **provide a complete production, after a full search for all documents** in defendant's possession, custody or control **responsive to BYU's first request for production of documents**.[360]

The Court then stated that it was

> **concerned because Pfizer appears to be primarily relying on its production of documents in prior litigation** that may involve issues which differ from those in instant case.[361]

Further, the Court warned Pfizer that the production of information from those prior litigation matters

> **does not absolve Pfizer of its duties in this litigation to provide responsive discovery** and the appropriate certifications regarding its efforts to provide such discovery.[362]

However, in spite of this Court's Order, Pfizer continues to withhold documents. This Court's warnings to properly participate in discovery, similar to this Court's warnings discussed in *Salinas v. Select Portfolio Servicing, Inc.*,[363] are sufficient warning to Pfizer that it faced serious sanctions if it did not comply with the Court's Order, which it has not.

E. <u>Lesser Sanctions Are Ineffective.</u>

Pfizer has almost unlimited resources. BYU understands that Pfizer has generated over $30 billion in profits from Celebrex alone. Indeed, as the $10M/day Needleman exhibit notes,

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[360] Order Granting BYU's Motion to Compel Immediate Production of Documents, 26 Mar 08, Dkt. No. 106 at 1 (emphasis added).

[361] *Id*.

[362] *Id*.

[363] No. 2:05-CV-00975 PGC, 2007 WL 2956329, at *2 (D. Utah 2007).

the damages in this case exceed $3.65 billion dollars. As a consequence, the mere payment of attorneys' fees will never entice Pfizer to comply with its discovery obligations.

Moreover, Pfizer's conduct in this and other cases related to Celebrex demonstrate that lesser sanctions, even a threat of a spoliation instruction as in IREF, are ineffective.

Because Pfizer's pattern in this case and in other cases is to hide the facts and flout its discovery obligations, lesser sanctions will not be effective in changing Pfizer's behavior.

As set forth above, consideration of the *Ehrenhaus* factors demonstrates that Pfizer's Answer should be stricken.[364] BYU respectfully moves the Court for an Order striking Pfizer's Answer.

III. OTHER NECESSARY SANCTIONS.

BYU seeks to recover all of its expenses, including attorneys' fees, incurred in connection with this motion and its original motion to compel that led to the Court's 26 March 2008 Order. Under the plain language of Rule 37, BYU must recover these expenses absent a contrary showing from Pfizer, which Pfizer cannot make here. Given the egregious nature of Pfizer's actions, BYU seeks all of the fees and costs associated with discovering Pfizer's misconduct, the fees and costs associated with bringing and arguing the motion, and the fees and costs associated with monitoring Pfizer's production. Those expenses, as of early November 2008, amount to approximately $1,178,478.34. When appropriate, BYU will submit to the Court the supporting documents.

A. Spoliation Instruction.

According to the Tenth Circuit,

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[364] *See Creative Gifts, Inc. v. UFO*, 235 F.3d 540, 549 (10th Cir. 2000) (affirming dismissal of counterclaims afater considering *Ehrenhaus* factors); *Danjanovich v. Robbins*, No. 2:04-CV-623, 2006 U.S. Dist. LEXIS 31175, at *7 (D. Utah May 15, 2006) (striking answer and entering default judgment afater considering *Ehrenhaus* factors); *Salinas*, at *2 (granting a motion to dismiss a case after considering *Ehrenhaus* factors).

> the bad faith destruction of evidence relevant to proof of an issue at trial **gives rise to an inference that production of the document would have been unfavorable to the party responsible for its destruction**.[365]

Spoliation sanctions are

> proper where (1) **a party has a duty to preserve evidence because it knew, or should have known, that litigation was imminent**, and (2) the adverse party was prejudiced by the destruction of the evidence.[366]

"**A litigant has a duty to preserve evidence** that he knows or should know is relevant to imminent or ongoing litigation."[367] Pfizer's duty to preserve documents arose when BYU sent Monsanto a letter on 9 December 1999 explaining its account of the events and establishing that it had been in contact with its counsel regarding this matter.[368] Additionally, the Tolling Agreement between Monsanto and BYU, effective 8 May 2001, further evidences Monsanto's notice of potential litigation.[369] The letter and the Tolling Agreement put Pfizer on notice and created a duty in Pfizer to preserve all relevant documents. Pfizer has failed to produce these documents, even in the face of this Court's Order, and, as a result, has breached its duty to preserve evidence.

Because the documents Pfizer is withholding, including IREF depositions, MDL and IREF exhibits, scientific notebooks, and board meeting minutes, are relevant to BYU's claims, BYU is prejudiced by not having access to these documents. A spoliation instruction for the jury is appropriate.

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[365] *Aramburu v. The Boeing Co.*, 112 F.3d 1398, 1407 (10th Cir. 1997) (emphasis added).

[366] *Burlington N. & Santa Fe Ry. Co. v. Grant*, 505 F.3d 1013, 1032 (10th Cir. 2007) (quoting *103 Investors I, L.P. v. Square D. Co*., 470 F.3d 985, 989 (10th Cir. 2006)) (emphasis added).

[367] *Jordan F. Miller Corp. v. Mid-Continental Aircraft Service, Inc.*, 1998 WL 68879 *3 (10th Cir. (Okla.)), 139 F.3d 912 (Table), (paraphrasing *Dillon v. Nissan Motor Co.*, 986 F.2d 263, 267 (8th Cir. 1993) (emphasis added)).

[368] Ltr. from E. Bramhall (BYU) to W. Ide (Monsanto), 9 Dec 99, BYU-01-1419-23, Ex. 130.

[369] Standstill and Tolling Agreement, 8 May 01, Ex. 131.

B. Contempt Of Court.

This Court, in *S.E.C. v. Novus Technologies*,[370] recently set forth the standards for civil contempt. It is well-settled that "'a district court has broad discretion in using its contempt power to require adherence to court orders.'"[371] Civil contempt has a remedial objective and seeks to compel compliance with a Court's Order.[372] To hold a party in civil contempt, the Court must find, by clear and convincing evidence, that: (1) a valid court order exists; (2) the contemnor had knowledge of the order; and (3) the contemnor has disobeyed the order.[373] Once the moving party establishes a *prima facie* case, the alleged contemnor must produce evidence explaining his or her noncompliance.

This standard is easily satisfied here. The Court's 26 March 2008 Order is a valid and existing Order. Pfizer clearly had knowledge of the Order as its counsel received a copy of it through the Court's electronic filing system on 26 March 2008. As set forth above, Pfizer has repeatedly violated the Order by failing to produce documents directly commanded by the Order. As a coercive sanction, BYU requests that Pfizer be fined $10,000 per day from the day of Pfizer's last certification, 15 October 2008, until it is in full compliance with the 26 March 2008 Order.

C. Depositions Regarding Discovery Compliance.

In order to test Pfizer's claim that it has made a complete production, BYU asks that the Court order Pfizer to produce the following individuals for depositions regarding the location of documents, searches conducted, representations made during discovery, compliance with the

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[370] No. 2:07-CV-00235, 2008 WL 623765 (D. Utah, March 4, 2008).

[371] *Consumers Gas & Oil, Inc. v. Farmland Indus. Inc.*, 84 F.3d 367, 370 (10th Cir. 1989) (quoting *United States v. Riewe*, 676 F.2d 418, 20 (10th Cir. 1982)).

[372] *International Union, United Mine Workers of America v. Bagwell*, 512 U.S. 821, 827-28 (1994).

[373] *Federal Trade Comm. v. Kuykendall*, 371 F.3d 745, 756-57 (10th Cir. 2004).

Court's Order Granting BYU'S Motion to Compel Immediate Production of Documents, and other document production issues: Dr. Philip Needleman; Dr. Karen Seibert; Dr. Jaime Masferrer; Lisa Schneider; Dr. Beverly Reitz; Richard O'Malley; Shaukat Rangwala, Janet Johnson—Pfizer's Records Compliance Manager from 1987–2006 and Pharmacia's Records Management Analyst from 1998–2005; and Lynne Palmer—BYU believes Palmer was Pharmacia's Facilities and Purchasing Manager during the relevant time period and will have information regarding the storage and maintenance of scientific notebooks and other archives.

Pfizer has already offered to allow BYU to tour its Kalamazoo document storage facility and depose the individual in charge, and BYU requests that the Court so order. Additionally, Pfizer has agreed to make Kathy Owen and Scott Hauser, its 30(b)(6) deponents, available for continuations of their depositions, and BYU requests that the Court so order.

None of these depositions should be counted against BYU's total number of depositions allowed in this litigation.

D. Damages Jury Instruction.

Given Pfizer's intentional withholding of the $10M/day Needleman presentation and all supporting material relating to the monetary value of Celebrex's head start advantage, the Court should enter a jury instruction that, in the event BYU proves at trial that Dr. Simmons's contribution to Pfizer's development of Celebrex provided Pfizer with a head start and/or first to market advantage, BYU's damages for the head start Dr. Simmons's biological materials and other trade secrets provided Pfizer should be calculated at, at least, $10 million per day.

E. The Court Should Make An In Camera Inspection.

BYU further requests that the Court remedy Pfizer's improper redaction of documents, especially scientific notebooks. As described above, Pfizer first told BYU that the hundreds of pages it produced containing unexplained redactions were irrelevant. Subsequently, Pfizer

produced unredacted copies of a few of the same documents. The unredacted copies demonstrated that the redacted portions of the documents contained relevant information. At the 29 July 2008 hearing, Pfizer claimed that the redactions were based on the attorney-client privilege.

Then, rather than comply with the Court's Order to produce unredacted versions of the non-privileged documents and to place the redacted privileged documents on a privilege log, Pfizer simply placed all of the redacted documents on its privilege log with vague descriptions of the redacted information.

This blanket effort to cloak all of these redactions in a privilege claim entirely disregards the Court's Order. Moreover, it is typical of Pfizer's misconduct in the case. Pfizer first claimed that the redactions were irrelevant. When BYU demonstrated that the redactions were relevant, Pfizer changed its story to claim that the redactions were privileged and now seeks to hide all of the redacted information from BYU.

Accordingly, BYU requests that the Court review unredacted copies of the documents in camera to determine whether they are, in fact, privileged.

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PRAYER

Based on the foregoing, BYU respectfully requests that the Court enter an order (1) striking Pfizer's Answer; (2) ordering that Pfizer pay BYU's costs and fees incurred in discovering Pfizer's discovery abuses; (3) entering a spoliation instruction that all the documents Pfizer has destroyed or otherwise withheld support BYU's contention that Dr. Simmons's COX-2 clones worked; (4) holding Pfizer in contempt of Court; (5) allowing depositions of witnesses, including, among others, its attorneys, Mr. O'Malley and Ms. Schneider, to explain its discovery abuses; and (6) entering a jury instruction that, in the event BYU proves at trial that Dr. Simmons's contribution to Pfizer's development of Celebrex provided Pfizer with a head start and/or first to market advantage, that BYU's damages for the head start Dr. Simmons's biological materials and other trade secrets provided Pfizer should be calculated at, at least, $10 million per day. As set forth in detail above, these sanctions are both just and related to the particular claims at issue in the Order to provide discovery.

RESPECTFULLY SUBMITTED this 14th day of January 2009.

BEUS GILBERT PLLC

By *s/ Leo R. Beus*
Leo R. Beus
L. Richard Williams
Adam C. Anderson
Keith C. Ricker

By *s/ Mark M. Bettilyon*
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CERTIFICATE OF SERVICE

I hereby certify that on the 14th day of January, 2009, I electronically filed the foregoing Response To Pfizer's Third Supplemental Certification Regarding Discovery Efforts And Memorandum In Support Of Motion For Discovery Sanctions with the Clerk of the United States District, District of Utah Central Division, using the CM/ECF system which sent notification of such filing to the following:

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And the following non-CM/ECF participant was served by email to cdouglas@sidley.com.

s/ Adam C. Anderson

INDEX TO EXHIBITS

EXHIBIT #	DESCRIPTION
1.	Motions Hearing Transcript, 29 Jul 08, Ex. 1, 5:11-15
2.	Depo. of Dr. Philip Needleman, 4 Mar 08, Celebrex Marketing Sales Practices Product Liability Litigation, BYU-PFE 211315 at 347-48, 33:18-34:21 **(FILED UNDER SEAL)**
3.	"From a twinkle in the eye to a blockbuster drug: the story of Celebrex® holds lessons for R&D leaders everywhere," authored by Philip Needleman, published in Research-Technology Management, Volume 44, Number 6, 1 Nov 2001, pp. 38-41
4.	Law.com: Pfizer Hit With $38 Million Jury Verdict in IP Case, 12/29/2008, at http://www.law.com/jsp/law/ LawArticleFriendly.jsp?id=1202426997770
5.	Motions Hearing Transcript, 29 Jul 08, 50:5-12
6.	Message points on history of Needleman/Searle and COX-2 science, 20 Jul 00, BYU-PFE 553590 **(FILED UNDER SEAL)**
7.	Ltr. from D. Hoscheit to E. Bramhall, 17 Mar 00, BYU-PFE 002960 **(FILED UNDER SEAL)**
8.	Ltr. from D. Simmons to K. Seibert and J. Masferrer, 29 Apr 91, BYU-PFE 087023 **(FILED UNDER SEAL)**
9.	Langreth, Richard. "Merck's Health Hinges on Sales of Arthritis Pill." The Wall Street Journal 14 Apr 1999, nat'l. ed.: B1
10.	Motion to Compel Hearing Transcript, 19 Mar 08, 58:14-16
11.	Ltr. from L. Schneider to L.R. Williams, 9 Oct 07
12.	Ltr. from L. Schneider to L.R. Williams, 7 Jan 08
13.	Motion To Compel Hearing Transcript, 19 Mar 08, 55:1-2
14.	Scott Hauser 30(b)(6) Deposition, 10 Jun 08
15.	Ltr. from L. Schneider to L.R. Williams, 16 Jan 08
16.	Ltr. from L. Schneider to L.R. Williams, 22 Oct 07

INDEX TO EXHIBITS

EXHIBIT #	DESCRIPTION
17.	Dr. Needleman's 1991 letters to Dr. Amiram Raz, S00664940 and S00664738 **(FILED UNDER SEAL)**
18.	Dr. Seibert's 1992 email to Dr. Needleman, S00663784-85 **(FILED UNDER SEAL)**
19.	Slide prepared by Pfizer referred to as the "blue slide", S00504065.367 **(FILED UNDER SEAL)**
20.	Plaintiffs' First Request for Production of Documents, 12 Jan 07, at 10, 12, 15, 18, 20, 21
21.	Pfizer Response to Plaintiffs' First Request for Production of Documents, 14 Feb 07, at 3-4, 14-15, 25, 38
22.	Ltr. from L. Beus to R. O'Malley, 28 Feb 07
23.	Ltr. from L.R. Williams to L. Schneider and R. O'Malley, 16 Aug 07
24.	Ltr. from L.R. Williams to L. Schneider, 24 Aug 07
25.	Ltr. from L. Schneider to L.R. Williams, 3 Oct 07
26.	Ltr. from L.R. Williams to L. Schneider, 9 Oct 07
27.	Ltr. from L. Schneider to L.R. Williams, 29 Oct 07
28.	Ltr. from L.R. Williams to L. Schneider, 9 Nov 07
29.	Ltr. from L. Schneider to L.R. Williams, 15 Nov 07
30.	Ltr. from L. Schneider to L.R. Williams, 20 Nov 07
31.	Ltr. from L.R. Williams to L. Schneider, 21 Dec 07
32.	Motion to Compel Hearing Transcript, 19 Mar 08, 42:6-22; 46:10
33.	Motion To Compel Hearing Transcript, 19 Mar 08, 48:16-49:1; 49:21-25; 50:24-51:1; 70:3-4
34.	Ltr. From L. Schneider to L. Beus, 29 Dec 08

INDEX TO EXHIBITS

EXHIBIT #	DESCRIPTION
35.	BYU-PFE-ARC 1002590338; S00675830; BYU-PFE 650301; BYU-PFE 653110; Needle-P 10000008149; Needle-P 10000007350 **(FILED UNDER SEAL)**
36.	Plaintiffs' First Set of Interrogatories to Defendant Pfizer, Inc., 4 May 07, at 2, 6
37.	Defendant Pfizer, Inc.'s Response to Plaintiffs' First Set of Interrogatories, 5 Jun 07, at 5, 6
38.	Ltr. to M. Bettilyon from L. Schneider, 18 Apr 08
39.	Ltr. to L. Schneider from M. Bettilyon, 18 Apr 08
40.	Ltr. to L. Schneider from M. Bettilyon, 30 May 08
41.	Ltr. to L. Schneider from M. Bettilyon, 26 Jun 08
42.	Ltr. to M. Bettilyon from L. Schneider, 29 Jul 08
43.	Plaintiffs Trial Brief, Case No. 1-04-CV-026653, *Ischemia Research and Education Foundation v. Pfizer, Inc.*, 19 Oct 07
44.	Ltr. from L. Schneider to L.R. Williams, 20 Aug 07
45.	Ltr. from J. Spanbauer to K. Ricker, 21 May 08
46.	Ltr. from L.R. Williams to L. Schneider, 28 Nov 07
47.	Ltr. from L. Schneider to M. Bettilyon, 13 May 08
48. MON001768	**(FILED UNDER SEAL)**
49. MON001767	**(FILED UNDER SEAL)**
50. MON001787	**(FILED UNDER SEAL)**
51. PFC01212081	**(FILED UNDER SEAL)**
52.	Ltr. to K. Ricker from J. Spanbauer, 17 Jul 08

INDEX TO EXHIBITS

EXHIBIT #	DESCRIPTION
53.	Ltr. from L.R. Williams to L. Schneider, 25 Oct 07
54.	Ltr. from L. Schneider to L.R. Williams, 8 Nov 07
55.	Ltr. from L.R. Williams to L. Schneider, 30 Jan 08
56.	Ltr. from L. Schneider to L.R. Williams, 4 Feb 08
57.	Motion to Compel Transcript, 19 Mar 08, 51:24-52:2
58.	Motion to Compel Transcript Ruling, 19 Mar 08, 4:23-5:1, 9:25-10:1
59.	Monsanto's Records Management Manual, April 1994, MON001557-633 at 620 **(FILED UNDER SEAL)**
60.	Aff. of Dr. Karen Seibert, G.D. Searle & Co. v. Novopharm Ltd., 3 Oct 05, PFC01579754-774 at 760 **(FILED UNDER SEAL)**
61.	Searle Laboratory Notebook Instructions, BYU-PFE-LNB-K 1000012909 **(FILED UNDER SEAL)**
62.	Pfizer Laboratory Lab Book Instructions, BYU-PFE-LNB-E 1000391706 **(FILED UNDER SEAL)**
63.	Motion to Compel Transcript, 19 Mar 08, 51:4-8
64.	Kathy Owen 30(b)(6) deposition, 10 Jun 2008, 77:11-16; 81:2-7; 83:14-24
65.	Ltr. from L. Schneider to M. Bettilyon, 14 Apr 08
66.	http://www.tab.com /about.aspx
67.	http://www.tab.com /ecms.aspx/resources/Pharmacia.pdf
68.	Ltr. from L. Schneider to M. Bettilyon, 9 Sep 08
69.	Pfizer List of Specific Notebooks Searched For Or Produced In Response to March 26, 2008 Court Order. (BYU-PFE 268135-75) **(FILED UNDER SEAL)**

INDEX TO EXHIBITS

EXHIBIT #	DESCRIPTION
70.	Transcript of Motions Hearing, *Merck Frosst Canada & Co. v. G.D. Searle & Company, et al.,* 12 Feb 02, 25:1-8; 26:14-21 (BYU-PFE 008193 at 217-218) **(FILED UNDER SEAL)**
71.	Beverly Reitz Notebook No. 5296801 at 822, MON001941 **(FILED UNDER SEAL)**
72.	Karen Siebert Notebook No. 4956601 at 623-624, 650, 660, PFC01549702-704, 766, 790 **(FILED UNDER SEAL)**
73.	Ltr. from D. Bart Dewey to L. Schneider, 12 Oct 07
74.	Beverly Reitz Notebook No. 5296801 at 840, MON001952 **(FILED UNDER SEAL)**
75.	Beverly Reitz Notebook No. GDS-3592, PFC01577755-56 **(FILED UNDER SEAL)**
76.	Ltr to D. Thomas (BYU) from D. Hoscheit (Pfizer counsel), 17 May 00, BYU-12-0088-89
77.	BYU-PFE 042354 - 60 **(FILED UNDER SEAL)**
78.	BYU-PFE 355255 **(FILED UNDER SEAL)**
79.	BYU-PFE 348554-56 **(FILED UNDER SEAL)**
80.	BYU-PFE 141355-479 at 423 **(FILED UNDER SEAL)**
81.	Dep. Of Gwen Krivi, *University of Rochester v. G.D. Searle & Co., et al.,* 30 Apr 02, 153:15-154:19 (BYU-PFE 118302 at 340-41) **(FILED UNDER SEAL)**
82.	T.E. Eling, et. al, Prostaglandin H-Synthase Xenobiotic Oxidation, Annual Reviews of Pharmacology and Toxicology, 1990, at 5
83. PFC00646762	**(FILED UNDER SEAL)**

INDEX TO EXHIBITS

EXHIBIT #	DESCRIPTION
84. PFC01512483	**(FILED UNDER SEAL)**
85. PFC01512491	**(FILED UNDER SEAL)**
86.	Monsanto's Guidelines for Research Records, PFC01582628-42, PFC01582633 **(FILED UNDER SEAL)**
87.	Karen Seibert Personal Notebook No. 13, Aug 03, PFC00678414 **(FILED UNDER SEAL)**
88. BYU-PFE-	ARC 1001476975-81
89.	Karen Seibert Notebook No. 4,956,601, 20 Jul 92, PFC91548749 **(FILED UNDER SEAL)**
90.	Motion to Compel Hearing Transcript, 19 Mar 08, 46:13
91.	Karen Seibert Notebook No. 4956601 at 690, 24 Aug 92, PFC01549856 **(FILED UNDER SEAL)**
92.	August 1993 Draft Article, PFC00652108, 110 **(FILED UNDER SEAL)**
93.	Monsanto Draft Article, PFC00652146-152 **(FILED UNDER SEAL)**
94.	Pharmacological and biochemical demonstration of the role of cyclooxygenase 2 in inflammation and pain, Proc.Natl.Acad.Sci. USA, Vol. 91, pp. 12013-12017, December 1994, PFC00388780-784 at 781 **(FILED UNDER SEAL)**
95.	Motion to Compel Hearing Transcript, 44:21-45:10
96.	Ltr. to L. Schneider from L.R. Williams, 6 Sep 07
97.	Ltr. from L.R. Williams to L. Schneider, 18 Jan 08
98.	Ltr. from L.R. Williams to N. Wyland, 9 Apr 08
99.	Ltr. from N. Wyland to L.R. Williams, 23 Apr 08

INDEX TO EXHIBITS

EXHIBIT #	DESCRIPTION
100.	Monsanto 1994 Annual Report, p. 38, BYU-PFE 167982-049 **(FILED UNDER SEAL)**
101. BYU-PFE 544495-96	**(FILED UNDER SEAL)**
102.	Research Agreement § 3.5, 1 Aug 91, BYU-18-3243
103.	Ltr. to L. Schneider from A. Anderson, 16 Jul 07
104.	Ltr. to L. Schneider from L. Beus, 30 Aug 07
105.	Ltr. to L.R. Williams from L. Schneider, 21 Sep 07
106.	Ltr. to A. Anderson from L. Schneider, 3 Oct 07
107.	Decision and Order, 28 Mar 02, BYU-PFE077427 at 453 **(FILED UNDER SEAL)**
108. SM264805-806	**(FILED UNDER SEAL)**
109.	Ltr. to L. Schneider from L.R. Williams, 12 Feb 08
110. PFC00678613-615	**(FILED UNDER SEAL)**
111. PFC01589046-9047	**(FILED UNDER SEAL)**
112.	Ltr. to L.R. Williams from N. Kopinski (with attached Privilege Log), 24 Jul 08
113.	Motions Hearing Transcript, 29 Jul 08, 65:10-25
114.	Ltr. to D. Parkinson from L.R. Williams, 5 Aug 08
115.	Ltr. to L.R. Williams from N. Kopinski, 7 Aug 08
116.	Motions Hearing Transcript, 29 Jul 08, at 69:14-24
117.	BYU-PFE 209124; BYU-PFE 209127; and BYU-PFE-BM_002780 **(FILED UNDER SEAL)**

INDEX TO EXHIBITS

EXHIBIT #	DESCRIPTION
118. BYU-PFE-	BM_001551 **(FILED UNDER SEAL)**
119. BYU-PFE	209139 **(FILED UNDER SEAL)**
120.	Dep. of Kathy Owens, 10 Jun 08, 125:13-18
121. BYU-PFE-	BM_002277, BYU-PFE-BM_001538 **(FILED UNDER SEAL)**
122.	Ltr. from L. Schneider to L.R. Williams, 15 Oct 08
123.	Ltr. from L. Schneider to M. Bettilyon, 16 Oct 08
124.	Ltr. from L. Beus to L. Schneider, 31 Oct 08
125.	Ltr. from L. Schneider to L. Beus, 25 Nov 08
126.	Ltr. from L. Beus to L. Schneider, 8 Dec 08
127.	Ltr. from L. Schneider to L. R. Beus, 16 Dec 08
128.	Ltr. from L.R. Beus to R. O'Malley and L. Schneider, 24 Dec 08
129.	Motions Hearing Transcript, 29 Jul 08, 11:10-12
130.	Ltr. from E. Bramhall (BYU) to W. Ide (Monsanto), 9 Dec 99, BYU-01-1410-23
131.	Standstill and Tolling Agreement, 8 May 01