

APPENDIX B

PRE-APPROVAL COMMERCIAL CONTEXT.

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APPENDIX B

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A. Merck's Product Pipeline and Patent Expirations.

When Merck launched Vioxx in May 1999, the Company had a number of successful drugs driving its growth as well as several potential drug candidates in its research pipeline. Five new medicines that had become key drivers of growth and were positioned to remain important to Merck's future growth were Zocor for high cholesterol, Fosamax for osteoporosis, Singulair for seasonal allergies and asthma, and Cozaar and Hyzaar for hypertension and heart failure.¹ Merck's 1999 Annual Report identified five additional drugs that also were contributing to the Company's growth: Crixivan for HIV/AIDS, Maxalt for migraines, Propecia for male pattern hair loss, Aggrastat for unstable angina, and Cosopt for glaucoma.²

Merck's research pipeline included several potential product candidates, including an injectable antibiotic; an antifungal agent; an oral compound potentially useful for treatment of chemotherapy-induced emesis (nausea and vomiting); an oral compound potentially useful for the treatment of depression and other neuropsychiatric diseases; a

¹ 3/22/00 Merck Form 10-K, MRK-AAJ0000267, at 68; 1999 Merck Annual Report, MRK-AAI0000061, at 64; 12/12/00 remarks by R. Gilmartin, MRK-ABG0000443, at 43. For chemical names of drugs, see 2000 Merck Annual Report, MRK-AAI0000125, at 27-28: Zocor (simvastatin); Fosamax (alendronate sodium); Singulair (montelukast sodium); Cozaar (losartan potassium); Hyzaar (losartan potassium and hydrochlorothiazide); Crixivan (indinavir sulfate); Maxalt (rizatriptan benzoate); Propecia (finasteride), Aggrastat (tirofiban hydrochloride); and Cosopt (dorzolamide hydrochloride and timolol maleate ophthalmic solution).

² 1999 Merck Annual Report, MRK-AAI0000061, at 64.

second-generation selective Cox-2 inhibitor, Arcoxia (etoricoxib); and certain new vaccines.³

An October 1998 assessment of Merck by market analyst Vector Securities International, however, had downgraded Merck's earnings per share from attractive to neutral.⁴ The assessment stated: "While new products such as Singulair and Maxalt are solid out of the box, we believe the base business has eroded and will ultimately affect the bottom line."⁵ The assessment also expressed concern over "lagging sales" of several Merck products, most notably Vasotec and Zocor, and noted that several of Merck's newly launched products, including Aggrastat and Propecia, had not met analysts' expectations.⁶ Finally, the assessment indicated that upcoming patent expirations of several drugs would place additional pressure on Merck's earnings per share.⁷ In October 1998, Dr. Edward Scolnick, President of Merck Research Laboratories ("MRL"), forwarded this assessment to several senior persons involved with Vioxx in the Clinical

³ 3/22/00 Merck Form 10-K, MRK-AAJ0000267, at 74.

⁴ 10/20/98 email from E. Scolnick to A. Nies *et al.*, MRK-ABS0194661, at 63 (forwarding 10/20/98 report by Vector Securities International, "MRK: Poor Composition to Q3 EPS; Downgrade to Neutral").

⁵ Vector Securities International, "MRK: Poor Composition to Q3 EPS; Downgrade to Neutral," MRK-ABS0194661, at 62.

⁶ Vector Securities International, "MRK: Poor Composition to Q3 EPS; Downgrade to Neutral," MRK-ABS0194661, at 62.

⁷ Vector Securities International, "MRK: Poor Composition to Q3 EPS; Downgrade to Neutral," MRK-ABS0194661, at 62.

and Regulatory Affairs Departments of MRL, characterizing the assessment not only as “ACCURATE,” but also as “FACT.”⁸

When Merck, in May 1999, launched Vioxx, it faced the loss of patent protection on seven of its drugs between 2000 and 2001, three of which were the largest-selling products within their respective therapeutic areas.⁹ While Merck’s 1999 Annual Report reflected strong market performance and a solid product pipeline, it described upcoming patent expirations of several major medicines as one of the “major challenges” facing the Company.¹⁰ According to Merck’s 1999 Form 10-K, domestic sales of these products represented 22% of the Company’s aggregate human health sales for 1999.¹¹ The Company expected “a significant decline” in these sales in the years 2000 through 2002 based upon the loss of patent protection,¹² and expected “a decline” in European sales

⁸ 10/20/98 email from E. Scolnick to A. Nies, B. Seidenberg et al., MRK-ABS0194661, at 63-64 (emphasis in original).

⁹ Merck’s 1999 Annual Report indicated that the Vasotec and Pepcid patents expired in 2000 and that the Prilosec (which was supplied exclusively to AstraZeneca LP), Prinivil, Prinzide, Mevacor and Vaseretic patents would expire in 2001. MRK-AAI0000061, at 94; see also 3/22/00 Merck Form 10-K, MRK-AAJ0000267, at 73. Merck’s 1999 Annual Report indicated that Prinivil and Vaseretic were the largest-selling products among Merck’s hypertension/heart failure drugs and that Pepcid was the largest-selling product among anti-ulcerants. MRK-AAI0000061, at 93.

¹⁰ 1999 Merck Annual Report, MRK-AAI0000061, at 64; see also 3/22/00 Merck Form 10-K, MRK-AAJ0000267, at 73.

¹¹ 3/22/00 Merck Form 10-K, MRK-AAJ0000267, at 73.

¹² 1999 Merck Annual Report, MRK-AAI0000061, at 94; 3/22/00 Merck Form 10-K, MRK-AAJ0000267, at 73.

upon loss of patent protection in European countries, where sales for these products represented 5% of the Company's human health sales for 1999.¹³

Although Merck identified the upcoming patent expirations as a challenge, the 1998 Annual Report made clear that the Company had long anticipated and planned for these expirations.¹⁴ The 1998 Annual Report indicated that the Company was "[m]indful of the challenges but confident in [its] ability to succeed."¹⁵ According to Mr. Raymond Gilmartin, Merck's President and Chief Executive Officer at that time, "given the success of the 14 new medicines . . . [which Merck] introduced in the past four years, and the November 1998 filing of the New Drug Application for Vioxx, [Merck was] well prepared to overcome the patent expirations."¹⁶

B. Commercial Significance of Vioxx to Merck.

In light of Merck's upcoming patent expirations and the magnitude of the arthritis and analgesia market, Vioxx held significant commercial importance for Merck.¹⁷

¹³ 1999 Merck Annual Report, MRK-AAI0000061, at 94; 3/22/00 Merck Form 10-K, MRK-AAJ0000267, at 73.

¹⁴ 1998 Merck Annual Report, MRK-AAI0000001, at 05.

¹⁵ 1998 Merck Annual Report, MRK-AAI0000001, at 05.

¹⁶ 1998 Merck Annual Report, MRK-AAI0000001, at 05.

¹⁷ See, e.g., 8/26/98 draft memorandum from W. Dixon and J. Gallivan to D. Anstice, MRK-ABI0001779, at 780 ("Given the critical importance of VIOXX to Merck . . . we recommend a revision to the Business Plan and specifically to the 1999 Profit Plan to more aggressively provide resources to successfully launch and market VIOXX in the U.S."); see also Gardiner Harris*, The Cure: With Big Drugs Dying, Merck Didn't Merge – It Found New Ones. Some Inspired Research, Aided by a Bit of Luck, Saves Company's Independence – The Path to a Novel Painkiller, Wall St. J., January 10, 2001, at A1 ("Merck's problem . . . was that patents on several of its best-selling drugs would be expiring . . . [W]ell into what was supposed to be a crunch, Merck is riding high

Merck's revenue forecast for Vioxx sales in its first seven months on the market was approximately \$120 million.¹⁸ Merck's 1999 Annual Report described Vioxx as the Company's "biggest, fastest and best launch ever,"¹⁹ and Merck's 2000 Annual Report indicated that "Vioxx [was] a blockbuster with global sales topping \$2 billion in a mere 20 months."²⁰ The 2000 Annual Report identified Vioxx, Zocor, Cozaar, Hyzaar, Fosamax and Singulair as the Company's six major drivers of growth – accounting for 57% of Merck's entire human health sales in 2000.²¹

Mr. David Anstice, President of United States Human Health at the time of the Vioxx launch, has testified that Vioxx was critical to Merck because of the size of the pain market and the advantages Vioxx provided compared to traditional non-selective NSAIDs.²² However, while Vioxx was a "blockbuster drug" with great potential, Merck had the five other key growth drivers referred to above (Zocor, Cozaar, Hyzaar, Fosamax and Singulair) as well as an active pipeline with several new potential drugs and

Merck's success demonstrates that in the drug business, as in Hollywood, one big hit can sway the fate of an entire company.").

¹⁸ 1999 Profit Plan, MRK-AAO0000001, at 06. Merck's Anti-Inflammatory and Analgesia Therapeutic Business Group's 2000 Profit Plan indicated that, since its launch in late May 1999 through mid-September 1999, Vioxx had achieved actual sales of \$156 million. MRK-AAO0000035, at 38.

¹⁹ 1999 Merck Annual Report, MRK-AAI0000061, 61 (cover page).

²⁰ 2000 Merck Annual Report, MRK-AAI0000125, at 37.

²¹ 2000 Merck Annual Report, MRK-AAI0000125, at 34.

²² 3/16/05 deposition of D. Anstice at 182-84 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.) (testifying that the size of the pain market in the United States was estimated to be "some 60 to 80 million patients").

vaccines.²³ Thus, although Vioxx was a particularly exciting product and one which Merck considered important, it was one among several products considered important to the Company's future growth.

C. Competition with Searle/Pfizer and Merck's Pre-launch Strategy.

In the mid-1990s, Merck and Searle/Pfizer²⁴ were the leading pharmaceutical companies developing selective Cox-2 inhibitors. The arthritis and analgesia market, as later described in Merck's Anti-inflammatory and Analgesia Therapeutic Business Group's 2000 Profit Plan, was "highly promotion sensitive and less science based than other markets in which Merck" had competed.²⁵

Illustrative of the mood at this time was a February 23, 1998 internal memorandum from Mr. Anstice stating: "Battle is now joined with Pfizer in another therapeutic area and one which is CRITICAL to Merck from 2000 onwards. . . . We

²³ 1999 Merck Annual Report, MRK-AAI0000061; 2000 Merck Annual Report, MRK-AAI0000125; see also 12/12/00 remarks by R. Gilmartin at the Annual Business Briefing, MRK-ABG0000443, at 45-47 (identifying six key growth drivers: Vioxx, Fosamax, Singulair, Zocor, Cozaar, and Hyzaar).

²⁴ Searle and Pfizer co-developed Celebrex in the mid-1990s. At the time, Searle was the pharmaceutical business unit of Monsanto Company. In April 2000, Pharmacia & UpJohn merged with Monsanto and Searle creating Pharmacia Corporation. Pharmacia agreed to continue Searle's agreement with Pfizer to co-promote Celebrex. In April 2003, Pharmacia and Pfizer merged and began operating as Pfizer. Pfizer – Exploring Our History, <http://www.pfizer.com/pfizer/history/2003.jsp>.

²⁵ 2000 Profit Plan, MRK-AAO0000035, at 39. Mr. Thomas Cannell, who in 2001 was Marketing Director with responsibility for physician and consumer promotion of Vioxx, stated that with regard to pain medication and the Cox-2 inhibitor class in particular, physicians would be more interested in whether the drug could alleviate pain with less risk of gastrointestinal side effects. Thus, because of the promotion-sensitive nature of the arthritis and analgesia market, Merck's ability to compete effectively was of significant importance to the commercial success of Vioxx.

simply CANNOT LOSE in any single market in The Americas.”²⁶ While Merck’s marketing strategy identified traditional non-selective NSAIDs as a key source of competition,²⁷ Celebrex was the central focus of competitive discourse within the Company.²⁸ An internal draft memorandum, prepared before either drug had been approved for sale, described the upcoming marketing battle between Vioxx and Celebrex as “extraordinary and possibly beyond anything the pharmaceutical industry has ever seen.”²⁹

1. Pre-launch Regulatory Background and Context.

Mr. Anstice has testified that beating Celebrex to the market was of significant commercial importance,³⁰ which the Marketing Department had valued at \$611 million dollars.³¹ To achieve this goal, the Company accelerated the Vioxx development

²⁶ 2/23/98 memorandum from D. Anstice to M. Carroll, W. Dixon et al., MRK-ABI0001556, at 56.

²⁷ 2/23/99 slide presentation of A&A WBST to the Merck Board of Directors, MRK-AGN00006017, at 023 (“78 million patients in the U.S. suffer from pain . . . 35 million are treated with Rx NSAIDs”).

²⁸ See, e.g., 2/23/99 slide presentation of A&A WBST to the Merck Board of Directors, MRK-AGN00006017, 036; 2/23/98 memorandum from D. Anstice to M. Carroll et al., MRK-ABI0001556; 1999 Profit Plan, MRK-AAO0000001, at 11; 6/1/98 email from E. Scolnick to E. McKinney, MRK-ABH0014114, at 14 (“If you do not beat PFIZER 2/1 MERCK should throw in the towel and just give up and hand the company over to someone else. IF YOU lose I will leave.”); 2/12/99 memorandum from D. Anstice to E. Scolnick, MRK-ABI0000751; 08/26/98 draft memorandum from W. Dixon and J. Gallivan to D. Anstice, MRK-ABI0001779.

²⁹ 8/26/98 draft memorandum from W. Dixon and J. Gallivan to D. Anstice, MRK-ABI0001779.

³⁰ Testimony of D. Anstice, 9/21/05 transcript of Humeston v. Merck & Co., No. ATL-L-2272-03MT, N.J. Super. Ct. Law Div., at 1387.

³¹ 3/99 Vioxx Product Development Plan – Stage 0 Review, MRK-NJ0220388, at 451 (“[T]he value of [Vioxx] being first to market versus second to market is \$611MM.”).

program to proceed on “an aggressive schedule.”³² Mr. Anstice has testified that, while the Company considered “ways in which [to] both compress and accelerate [the Vioxx] development program, . . . at no point did [the Company] cut corners with the program.”³³ In fact, as discussed in Appendix A, the New Drug Application for Vioxx was one of the largest applications Merck had ever submitted.³⁴

Despite Merck’s efforts, Searle/Pfizer’s Celebrex was the first selective Cox-2 inhibitor to enter the U.S. market.³⁵ It became evident in mid-1998 that Celebrex would enter the market three to six months earlier than Vioxx.³⁶ On June 29, 1998, Searle/Pfizer submitted the Celebrex New Drug Application to the FDA.³⁷ In the application, Searle/Pfizer sought FDA approval to market Celebrex in the U.S. for relief of the signs and symptoms of osteoarthritis and rheumatoid arthritis and for the

³² 3/26/96 memorandum from M. McNamara to R. Spector et al., MRK-NJ0142930 (“we can beat [Celebrex] with an aggressive development schedule”); see also 3/99 Vioxx Product Development Plan – Stage 0 Review, MRK-NJ0220388, at 412 at 412 (“To ensure that [Vioxx] is the first highly selective Cox-2 inhibitor approved, the clinical development program is based on an aggressive and highly accelerated development plan. Specifically, phase III clinical studies will be initiated while phase IIb studies are in progress.”).

³³ 9/21/05 transcript of Humeston v. Merck & Co., No. ATL-L-2272-03MT, N.J. Super. Ct. Law Div., at 1339.

³⁴ 4/1/05 deposition of A. Nies at 436 (In re Vioxx Litig., No. 619, N.J. Super. Ct. Law Div.).

³⁵ 12/31/98 Searle/Pfizer press release, “FDA Approves Celebrex™ (celecoxib) for Osteoarthritis and Rheumatoid Arthritis: A New, Important Therapy for Arthritis Patients,” MRK-ADN0010613, at 613.

³⁶ Background document for 6/12/98 HHPAC meeting, MRK-NJ0362711, at 12; see also 8/26/98 draft memorandum from W. Dixon and J. Gallivan to D. Anstice noting that “[w]e currently assume that VIOXX will launch six months behind [Celebrex].” MRK-ABI0001779.

³⁷ 7/8/98 FDA Medical Officer Review of the Celebrex NDA, MRK-AFL0009900, at 900 (stating that the “submission date” for the Celebrex NDA was June 29, 1998). The purpose and content of New Drug Applications are described in Appendix C.

management of acute pain.³⁸ The FDA granted the Celebrex New Drug Application six-month priority review,³⁹ which meant that Celebrex could be on the market as early as December 29, 1998.⁴⁰

At the time, Merck was still months from submitting its New Drug Application to the FDA and had set an internal deadline of December 1998 by which to do so.⁴¹ As a result of the June 1998 Celebrex submission, in August 1998, Merck advanced its internal application deadline by one month.⁴²

³⁸ Division of Anti-Inflammatory, Analgesic and Ophthalmologic Drug Products, FDA, Pharmacology and Toxicology Review of the 6/29/98 New Drug Application for Celebrex, MRK-ACD0049989, at 989 (stating that Searle/Pfizer's proposed indications included "acute and chronic treatment of the signs and symptoms of rheumatoid arthritis and osteoarthritis; and . . . management of acute and chronic pain").

³⁹ 12/31/98 Searle/Pfizer press release, "FDA Approves Celebrex™ (celecoxib) for Osteoarthritis and Rheumatoid Arthritis: A New, Important Therapy for Arthritis Patients," MRK-ADN0010613, at 614.

⁴⁰ The FDA assigns priority review to a New Drug Application if it appears at the time of the filing that the drug would be "a significant improvement" compared to marketed products in the treatment, diagnosis, or prevention of a disease. Center for Drug Evaluation and Research, FDA, Manual of Policies and Procedures, MAPP 6020.3, <http://www.fda.gov/cder/mapp/6020-3.pdf>; see also <http://www.accessdata.fda.gov/scripts/cder/onctools/Accel.cfm#Priority> (stating that "[a] Priority designation sets the target date for the FDA action at 6 months," as opposed to the "standard" 10 months).

In determining whether the drug meets the "significant improvement" test, the Agency can consider, among other things, whether the drug results in substantially fewer side effects than drugs that are already on the market. See Center for Drug Evaluation and Research, FDA, Manual of Policies and Procedures, MAPP 6020.3, <http://www.fda.gov/cder/mapp/6020-3.pdf> (directing the FDA to consider whether the drug would result in "elimination or substantial reduction of a treatment-limiting drug reaction").

⁴¹ Background document for 6/12/98 HHPAC meeting, MRK-NJ0362712, at 721.

⁴² Draft news release, "Vioxx on the Verge, U.S. drug agency grants priority review for our new drug for osteoarthritis and pain," MRK-ACD0072694, at 95 (attached to 1/22/99 email from S. Leavitt to "WBST, Arthritis," MRK-ACD0072636).

On December 31, 1998, the FDA approved Celebrex for relief of the symptoms of osteoarthritis and rheumatoid arthritis⁴³ and in February 1999, Celebrex was launched. The launch of Celebrex was one of the most successful new product introductions in the pharmaceutical industry.⁴⁴ Although the dramatic success of the Celebrex launch was a positive commercial indicator for the selective Cox-2 inhibitor class, and therefore Vioxx,⁴⁵ Merck would have to overcome the inherent disadvantage of being second to the market.⁴⁶

⁴³ 12/31/98 Searle/Pfizer press release, "FDA Approves Celebrex™ (celecoxib) for Osteoarthritis and Rheumatoid Arthritis: A New, Important Therapy for Arthritis Patients," MRK-ADN0010613, at 613. Although in its June 1998 New Drug Application for Celebrex, Searle/Pfizer sought to obtain an indication for management of pain, the FDA found that the Celebrex New Drug Application did not provide sufficient proof of "the analgesic properties of the proposed doses" and did not approve Celebrex for that indication. 7/8/98 FDA Medical Officer Review of the Celebrex NDA, MRK-AFL0009900, at 904; see also transcript of 12/1/98 FDA Arthritis Advisory Committee meeting, MRK-ABS0109427, at 9612 (referring to the FDA's "recommendation . . . that the usual criteria for approval for pain management was not met based on the [Celebrex] NDA"); 12/31/98 approved Celebrex product label, MRK-ADH0010624.

⁴⁴ 2/23/99 slide presentation of Arthritis WBST to the Merck Board of Directors, MRK-AGN00006017, at 6034 ("Celebrex has had a dramatic U.S. launch."); 2000 Profit Plan, MRK-AAO0000035, at 37; see also Amy Barrett & Richard A. Melcher, Why Searle Is Feeling No Pain, Business Week, Feb. 15, 1999 ("In its first two weeks, doctors wrote more than 56,000 prescriptions, making Celebrex the second-fastest starter in recent memory, ahead of cholesterol-lowering Lipitor but behind . . . Viagra").

⁴⁵ 2/23/99 slide presentation of Arthritis WBST to the Merck Board of Directors, MRK-AGN00006017, at 52 ("Exceptional launch of Celebrex is good for VIOXX.").

⁴⁶ 9/21/05 transcript of Humeston v. Merck & Co., No. ATL-L-2272-03MT, N.J. Super. Ct. Law Div. at 1387 (Mr. Anstice testifying: "We knew that there was a benefit to being first into the market . . ."; "[I]t was very competitive, and if we could we wanted to be first to market."); see also 2/23/99 slide presentation of Arthritis WBST to the Merck Board of Directors, MRK-AGN00006017, at 52 (setting lower commercial goal for Vioxx in countries where Vioxx was anticipated being second to market as compared to countries where Vioxx was anticipated to be first to market); 8/26/98 draft memorandum from W. Dixon and J. Gallivan to D. Anstice, MRK-ABI0001779, at 79.

2. Pre-launch Activities.

An August 6, 1998 draft memorandum from Dr. Wendy Dixon, Vice President, Marketing, and member of the Arthritis and Analgesia Therapeutic Business Group, to Mr. Anstice discussed the pre-launch competitive challenges and the resources that would be required to ensure a successful launch for Vioxx.⁴⁷

Dr. Dixon's memorandum noted the significant advantages Merck believed that Vioxx had over Celebrex – namely greater potency and selectivity, convenient once-daily dosing, and potentially better clinical gastrointestinal safety data – but advised Mr. Anstice about several factors that she believed placed Vioxx at a competitive disadvantage:

- Searle/Pfizer's greater capacity for sales and marketing;
- Searle/Pfizer's significant lead in filing the Celebrex New Drug Application and resulting probability for beating Vioxx to the market;
- Searle/Pfizer's lead in starting a gastrointestinal outcomes trial (CLASS); and
- Searle/Pfizer's lead in starting extensive public relations and consumer marketing programs to create market awareness about Celebrex.⁴⁸

Dr. Dixon concluded: "Given the critical importance of VIOXX to Merck and in light of . . . current analyses, competitive information and regulatory timings, we recommend a

⁴⁷ 8/26/98 draft memorandum from W. Dixon and J. Gallivan to D. Anstice, MRK-ABI0001779, at 79

⁴⁸ 8/26/98 draft memorandum from W. Dixon and J. Gallivan to D. Anstice, MRK-ABI0001779, at 79

revision to the Business Plan and specifically to the 1999 Profit Plan to more aggressively provide resources to successfully launch and market VIOXX in the U.S.”⁴⁹

Merck’s 1999 Profit Plan, revised as of September 21, 1998 to allocate additional resources for the Vioxx launch, described Searle/Pfizer as a “formidable and aggressive alliance with considerable experience in the analgesia and arthritis market, significant detailing capacity from their combines [sic] sales force, and with a tremendous desire and need to make [Celebrex] a phenomenal success.”⁵⁰ The Profit Plan listed “the battle” with Searle/Pfizer as number one among a list of issues facing the launch of Vioxx and described the combined sales force of Searle and Pfizer as “a pool of over 5,400 representatives with the capacity of delivering 4.8 million details”⁵¹ for Celebrex.⁵² The 1999 Profit Plan indicated that Searle/Pfizer had begun “extensive [public relations] and consumer marketing programs to create a large database of consumer names and [to] create awareness of COX-2’s and [Celebrex].”⁵³

Notwithstanding the competitive issues identified, the 1999 Profit Plan stated that, “[a]lthough the VIOXX and [Celebrex] clinical profiles [were] close, VIOXX possess[ed] a set of incremental product advantages that together [could] be used to tell a

⁴⁹ 8/26/98 draft memorandum from W. Dixon and J. Gallivan to D. Anstice, MRK-ABI0001779, at 80.

⁵⁰ 1999 Profit Plan, MRK-AAO0000001, at 4.

⁵¹ Detailing is one way by which pharmaceutical companies promote their product to physicians. Delivering “details” refers to face-to-face discussions regarding specific products between a pharmaceutical company representative and a physician.

⁵² 1999 Profit Plan, MRK-AAO0000001, at 11.

⁵³ 1999 Profit Plan, MRK-AAO0000001, at 04.

story about a more ‘advanced’ drug.”⁵⁴ According to the 1999 Profit Plan, the Arthritis and Analgesia Therapeutic Business Group was working to develop “a patient positioning and market approach for Vioxx” that, among other things, was “distinct and compelling with respect to both NSAIDs and [Celebrex]” and “[i]nfluenc[ed] patient behavior to create significant share growth for VIOXX.”⁵⁵

Merck’s strategy, as presented by members of Merck’s Arthritis and Analgesia Worldwide Business Strategy Team to the Merck Board of Directors on February 23, 1999, was to establish and foster an “in it to win it” attitude.⁵⁶ At the February 23, 1999 meeting of the Merck Board of Directors, three members of the Arthritis and Analgesia Worldwide Business Strategy Team – Dr. Dixon, Dr. Roger Perlmutter, Chair of the Arthritis and Analgesia Worldwide Business Strategy Team and Executive Vice President of Basic Research, and Mr. Gary Sender, Director of Investor Relations – provided the Merck Board with product profiles for Celebrex and Vioxx.⁵⁷ Their presentation reflected their belief that Vioxx was a better drug than Celebrex and outlined the Company’s performance objectives and marketing strategy for Vioxx.⁵⁸

⁵⁴ 1999 Profit Plan, MRK-AAO0000001, at 10.

⁵⁵ 1999 Profit Plan, MRK-AAO0000001, at 10.

⁵⁶ 2/23/99 slide presentation of Arthritis WBST to the Merck Board of Directors, MRK-AGN00006017, at 22; see also 7/27/99 slide presentation of W. Dixon and C. McKines to the Merck Board of Directors, MRK-AGN00006109.

⁵⁷ Minutes of 2/23/99 Merck Board of Directors meeting, MRK-AGN00007170, at 187.

⁵⁸ Minutes of 2/23/99 Merck Board of Directors meeting, MRK-AGN00007170, at 187.

They also provided the Board with sales forecasts for each drug as well as expected profits from Vioxx for 1999.⁵⁹

Notably, at this meeting the Arthritis and Analgesia Worldwide Business Strategy Team presentation indicated that the business objective for Vioxx was to exceed Celebrex in total prescriptions by 18 months post-launch in countries where Vioxx was second to the market, including the United States, and to maintain a 60% market share versus Celebrex in countries where Vioxx was first to the market.⁶⁰ According to an internal memorandum written after the Board meeting, Board members were enthusiastic about the sales objectives; however, because the Arthritis and Analgesia Worldwide Business Strategy Team presentation had indicated that Vioxx was “unambiguously superior to Celebrex,” they questioned why the strategy with regard to countries where Vioxx was first to the market was not more aggressive.⁶¹

In its presentation to the Board, the Arthritis and Analgesia Worldwide Business Strategy Team outlined three target areas to ensure the successful launch of Vioxx: (i) a “strong label allowing compelling promotional messages”; (ii) “extensive pre-launch marketing activities” and minimal time between FDA approval and product launch; and (iii) “creative and well-executed Marketing and Sales program and activities,” including

⁵⁹ Minutes of 2/23/99 Merck Board of Directors meeting, MRK-AGN00007170, at 187; see also 2/23/99 slide presentation of Arthritis WBST to the Merck Board of Directors, MRK-AGN00006017. Presentations made to the Board concerning Vioxx are discussed in Appendix T.

⁶⁰ 2/23/99 Arthritis WBST slide presentation to the Merck Board of Directors, MRK-AGN00006017, at 36.

⁶¹ 2/23/99 letter from R. Perlmutter to “WBST members,” MRK-AJK0008855, at 55.

high frequency detailing, high promotional spending, extensive programs to quickly gain physician and patient experience, and extensive physician education.⁶²

Merck's 1999 Profit Plan outlined a detailed marketing strategy that included:

- differentiating Vioxx from Celebrex, non-selective NSAIDs and acetaminophen based on Cox-2 selectivity, superior gastrointestinal safety compared to non-selective NSAIDs, efficacy equivalent to high doses of NSAIDs and once-daily dosing;
- “own[ing] advocates in key customer segments”;
- expanding clinical programs to include data that would enhance the profile of Vioxx and leverage its second to market position;
- “[I]everag[ing] key points in the consumer buying process to drive product uptake and sustain the growth of Vioxx”; and
- managing Merck's selective Cox-2 inhibitor franchise through active exploration of additional indications, formulations and follow-up compounds.⁶³

With regard to targeted initiatives specific to the field sales force (activities which are discussed in more detail in Appendix K, the 1999 Profit Plan indicated that sales representatives and Health Science Associates (“HSAs”)⁶⁴ would be needed to:

⁶² 2/23/99 slide presentation of Arthritis WBST to the Merck Board of Directors, MRK-AGN00006017, at 40-41, 43.

⁶³ 1999 Profit Plan, MRK-AAO0000001, at 12 (emphasis omitted).

⁶⁴ Health Science Associates report to the Sales Department and are a group of highly trained representatives tasked with supporting “opinion leaders.” Opinion leaders are scientists and doctors who the medical and scientific community consider to be experts in their respective fields.

(i) combat Searle/Pfizer's attempts to "pre-position Vioxx"; (ii) effectively differentiate Vioxx as the preferred selective Cox-2 inhibitor based on superior specificity,⁶⁵ efficacy comparable to high doses of traditional non-selective NSAIDs, convenient once-daily dosing, and superior gastrointestinal safety profile compared to non-selective NSAIDs; (iii) develop advocacy among key opinion leaders; (iv) prepare high potential prescribers to prescribe Vioxx once launched; and (v) protect access to hospital and managed care formularies.⁶⁶

The 1999 Profit Plan provided that, to execute the pre-launch strategy, approximately \$70 million had been reserved for 1999 promotional spending for Vioxx.⁶⁷ An estimated 1,500 sales representatives were assigned to target approximately 95,000 high-NSAID-prescribing physicians,⁶⁸ and an estimated 69 Health Science Associates were assigned to target a total of approximately 4,824 regional opinion leaders in rheumatology, gastroenterology and orthopedic surgery,⁶⁹ with 25 additional Health Science Associates assigned to target 1,625 national opinion leaders.⁷⁰ Finally, six Regional Medical Directors with responsibility for the analgesia and arthritis therapeutic

⁶⁵ "Superior specificity" refers to the ratio of Cox-2/Cox-1 inhibition.

⁶⁶ 1999 Profit Plan, MRK-AAO0000001, at 13, 25.

⁶⁷ 1999 Profit Plan, MRK-AAO0000001, at 25.

⁶⁸ 1999 Profit Plan, MRK-AAO0000001, at 28.

⁶⁹ 1999 Profit Plan, MRK-AAO0000001, at 29.

⁷⁰ 1999 Profit Plan, MRK-AAO0000001, at 30.

area targeted physician opinion leaders, decision makers in academia, and managed care and organized medical groups.⁷¹

3. Post-launch Market Evaluation.

In July 1999, approximately two months after Vioxx entered the market, a post-launch sales and marketing presentation to Merck's Board of Directors indicated that Merck's pre-launch strategy for Vioxx had been successful.⁷² According to the presentation, within eight weeks of market entry, Vioxx had achieved a new prescription share of 6% within the arthritis and analgesia market and 29% within the selective Cox-2 inhibitor class.⁷³ The presentation further stated that Vioxx was "outperforming the market" and "driving the overall market growth."⁷⁴ Vioxx also surpassed all traditional non-selective NSAIDs and was gaining on Ultram in number of prescriptions.⁷⁵

The July 1999 presentation to the Board characterized the Vioxx launch as the "Biggest, Fastest, Best Launch in the History of Merck."⁷⁶ Indeed, by December 1999,

⁷¹ 1999 Profit Plan, MRK-AAO0000001, at 31.

⁷² 7/27/99 slide presentation of W. Dixon and C. McKines to the Merck Board of Directors, MRK-AGN00006094, at 95.

⁷³ 7/27/99 slide presentation of W. Dixon and C. McKines to the Merck Board of Directors, MRK-AGN00006094, at 95.

⁷⁴ 7/27/99 slide presentation of W. Dixon and C. McKines to the Merck Board of Directors, MRK-AGN00006094, at 95.

⁷⁵ 7/27/99 slide presentation of W. Dixon and C. McKines to the Merck Board of Directors, MRK-AGN00006094, at 95.

⁷⁶ 7/27/99 slide presentation of W. Dixon and C. McKines to Merck Board of Directors, MRK-AGN00006094, at 100.

approximately seven months after entering the market, Vioxx had achieved more than
“40% of new U.S. prescriptions in its class.”⁷⁷

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⁷⁷ 12/9/99 Merck press release, “Innovative Medicines Drive Revenue and Earnings Growth, Merck Tells Analysts; Merck Growth Strategy Is on Track,” MRK-ABG0000204.