

**IN THE MATTER OF THE SECURITIES ACT,
R.S.O. 1990, c. S.5, as amended**

-and-

**IN THE MATTER OF
BIOVAIL CORPORATION, EUGENE N. MELNYK,
BRIAN H. CROMBIE, JOHN R. MISZUK and KENNETH G. HOWLING**

**STATEMENT OF ALLEGATIONS
OF STAFF OF THE ONTARIO SECURITIES COMMISSION**

The Respondents

1. Biovail Corporation (“Biovail”) is a reporting issuer in the province of Ontario. The common shares of Biovail are listed and posted for trading on the Toronto Stock Exchange and the New York Stock Exchange.
2. Biovail is a fully integrated international pharmaceutical company applying advanced proprietary controlled-release, rapid dissolve, enhanced absorption and taste masking drug delivery technologies to the development of generic formulations of medications.
3. Eugene N. Melnyk (“Melnyk”) was the Chairman of the Board of Directors of Biovail until his resignation from the Board effective June 30, 2007. From December 2001 to October 2004 Melnyk was Chairman and Chief Executive Officer of Biovail. Melnyk resigned as CEO of Biovail on October 8, 2004. Melnyk first became a Director of Biovail in March of 1994. Melnyk became Executive Chairman of the Board of Biovail in November of 2004 and relinquished that title on June 27, 2006.
4. Brian H. Crombie (“Crombie”) was the Chief Financial Officer of Biovail from May 2000 to August 2004. He became the Senior Vice-President, Strategic Development in August 2004. Crombie left Biovail in 2006.

5. John R. Miszuk (“Miszuk”) is currently Vice-President, Controller and Assistant Secretary of Biovail. He has held the positions of Vice-President and Controller since November of 1997, and the position of Assistant Secretary since June of 2000.
6. Kenneth G. Howling (“Howling”) is a Senior Vice-President and he has held the position of Chief Financial Officer of Biovail since December of 2006. Howling was Biovail’s Vice-President, Finance and Corporate Affairs from October 2004 to 2006 and Vice-President, Finance from May 2000 to October 2004. During the Material Time (as defined below), Howling also served as Biovail’s head of investor relations.

Overview of Allegations

7. The conduct at issue relates to Biovail’s annual financial statements for the fiscal year ended December 31, 2001, interim financial statements for Q3 of 2001, Q1, Q2 and Q3 of 2002, and Q1, Q2 and Q3 of 2003, as well as conduct concerning Biovail’s disclosure during that time. These time periods are referred to individually as the “Relevant Fiscal Periods” and collectively as the “Material Time”.
8. As a reporting issuer in Ontario, Biovail has continuous disclosure obligations pursuant to Part XVIII of the *Securities Act*, R.S.O. 1990, c. S.5 as amended (the “Act”). Sections 77 and 78 of the Act and related provisions in the Regulations direct that all financial statements filed with the Commission must be prepared in accordance with generally accepted accounting principles (“GAAP”) recommended in the Handbook of the Canadian Institute of Chartered Accountants. Moreover, all financial statements and other material filed with the Commission must not be misleading or untrue or omit a fact which would render them misleading.

9. Because its shares trade on the New York Stock Exchange, Biovail is subject to filing requirements with the United States Securities and Exchange Commission (“SEC”). In discharging these filing requirements, Biovail filed with the SEC for each of the Relevant Fiscal Periods financial statements which represented that they had been prepared in accordance with U.S. GAAP. As required by Ontario securities law, these U.S. GAAP financial statements were also filed with the Commission.
10. Thus, for each interim and annual reporting period Biovail filed two sets of financial statements with the Commission: one set which represented that they had been prepared in accordance with Canadian GAAP, and one set which represented that they had been prepared in accordance with U.S. GAAP.
11. Biovail filed with the Commission during the Material Time financial statements that, while represented to be prepared in accordance with Canadian GAAP, were not prepared in accordance with Canadian GAAP and therefore such filings were contrary to sections 77 and 78 of the Act. Further, Biovail’s representations that the financial statements had been prepared in accordance with Canadian GAAP were misleading or untrue, contrary to Ontario securities law and the public interest.
12. Biovail made representations in its U.S. financial statements filed with the Commission for each of the Relevant Fiscal Periods that the U.S. financial statements had been prepared in accordance with U.S. GAAP. These representations were materially misleading or untrue, contrary to Ontario securities law and the public interest, because the U.S. financial statements were not prepared in accordance with U.S. GAAP.
13. The misconduct giving rise to these allegations falls into six general categories:

- (i) Biovail's failure to account properly for a special purpose entity in its annual financial statements for the year ended December 31, 2001, and interim financial statements for Q3 of 2001, and Q1, Q2, and Q3 of 2002;
- (ii) Biovail's failure to disclose in its filings with the Commission (Biovail's "Public Disclosure" as particularized in the attached Schedule "A") the establishment of and its arrangements with the special purpose entity;
- (iii) Biovail's improper recognition in its interim financial statements for Q2 of 2003 of revenue relating to a purported sale of Wellbutrin XL tablets;
- (iv) Biovail's failure to correct and disclose, on a timely basis, a known material error in its 2003 financial statements;
- (v) Biovail's materially misleading or untrue statements in certain press releases in October 2003 and March 2004, in an analyst conference call held on October 3, 2003, and in investor meetings held in October 2003 relating to a truck accident; and
- (vi) Biovail's provision of materially misleading information to OSC Staff during a continuous disclosure review conducted in 2003 and 2004.

Biovail's Failure to Account Properly for a Special Purpose Entity

14. In 2001, Biovail created a special purpose entity called Pharmaceutical Technologies Corporation ("PTC") which it controlled and from which it had the right to obtain future economic benefits while also being exposed to the related risks. The particulars of Biovail's arrangements with PTC are set out below.

(a) Establishment of PTC

15. PTC was a development-stage company created to engage in the application of Biovail's drug delivery technologies to the formulation and development of a portfolio of Biovail products.
16. The creation of PTC was intended to allow Biovail to transfer \$125 million worth of research and development expenses off of its income statement.
17. Biovail sponsored the creation of PTC which was incorporated under the laws of Barbados on June 28, 2001.
18. A Barbados law firm which had provided legal services to Biovail in the past (the "Barbados Law Firm") was involved with the incorporation of PTC. PTC did not have a physical location and it used the address of the Barbados Law Firm as a mailing address.

(b) The PTC Equity Investor

19. On June 28, 2001, an individual equity investor acquired 100% of the common shares of PTC for U.S. \$1 million, of which \$350,000 was immediately refundable to the equity investor as a fee. The equity investor had acted as a consultant to Biovail from November 1999 to November 2001.

(c) The PTC Board of Directors

20. The board of PTC comprised the equity investor, alternating members of the Barbados Law Firm (the "Barbados Law Firm Directors") and a businessman residing in Barbados (the "Barbadian Businessman").

21. One of the Barbados Law Firm Directors and the Barbadian Businessman were acquaintances of certain Biovail representatives. They were recommended by those Biovail representatives for appointment to the PTC board.

(d) The PTC Officers and Employees

22. The equity investor held the position of President and Chief Executive Officer of PTC. One of the Barbados Law Firm Directors briefly served as the Secretary of PTC and was replaced in that capacity by the wife of the equity investor. The equity investor's Assistant and the Barbadian Businessman served as vice-presidents of PTC.
23. PTC's Financial Controller was referred to PTC by a Biovail representative. All of PTC's officers and employees held other employment contemporaneous with their positions at PTC.
24. An American law firm which had done some legal work for Biovail in the past was retained to administer the business of PTC.

(e) Arrangements between Biovail and PTC

The Product Development and Royalty Agreement

25. On June 29, 2001, PTC entered into a Product Development and Royalty Agreement ("PDRA") with Biovail. Under the PDRA, PTC contracted to develop six products owned by Biovail Laboratories Inc. ("BLI"), a Biovail subsidiary, in exchange for the receipt of royalties upon the commercialization and sale of these products. PTC was also granted a license to use certain technology owned by BLI to complete the development of the products.

26. Biovail agreed to indemnify PTC against any losses arising from product liability claims and allegations of infringements of intellectual property rights in respect of products developed on its behalf under the PDRA.
27. Biovail had the discretion to change the development program or budget, as well as to set priorities for any part of the program should Biovail and PTC be unable to agree on such changes.

The Advisory Agreement

28. On June 29, 2001, PTC entered into an Advisory Agreement (“AA”) with Biovail pursuant to which Biovail would provide strategic and scientific advisory services and management and administrative services to PTC. More specifically, under the AA, Biovail would provide strategic advice on the formulation, clinical development, regulatory strategy and commercial exploitation of pharmaceutical products and scientific and technical assistance in evaluating the ability of developers to develop the products.

The Share Option Agreement

29. On June 29, 2001, the equity investor entered into a Share Option Agreement (“SOA”) pursuant to which the equity investor granted to Biovail an irrevocable option, exercisable at any time until December 31, 2006 and at Biovail’s sole discretion, to purchase all, but not less than all, of the outstanding common shares of PTC (the “Purchase Option”).
30. Several restrictive covenants concerning the operations and financing of PTC were imposed under the SOA, including a prohibition on engaging in any business activity other than research and development pursuant to the PDRA, a prohibition on increasing PTC’s indebtedness or making any loans to other entities, a

prohibition on the disposition of PTC shares by the equity investor to any person, and a prohibition on the issuance of additional PTC shares to any person.

(f) The PTC Financing

Biovail's prior relationship with Bank A

31. In December of 2000, Biovail had arranged through a major Canadian bank ("Bank A") a U.S. \$300 million revolving term credit facility which was initially fully underwritten by Bank A, and subsequently syndicated to other financial institutions. In June 2001, at the time of negotiating the financing of PTC, Bank A retained U.S. \$100 million of the Biovail credit facility which by that time had been increased to U.S. \$400 million. Bank A was and is Biovail's principal banker.
32. Bank A was also a lender to Melnyk during the Material Time, and to a holding company owned by him.

Biovail's involvement in negotiating the financing of PTC

33. In the spring of 2001, Biovail engaged Bank A in discussions regarding the provision of credit to PTC. At that time, Biovail estimated that PTC would require funding in excess of U.S. \$100 million for it to carry out its mandate.
34. Many of the negotiations were conducted between Bank A and Biovail representatives. During these negotiations, Bank A's representatives met with the equity investor only once.
35. During the negotiations, in order to secure financing for PTC, Biovail made the following representations to Bank A:
 - a) *The products were significant to Biovail:* The success of the products licensed to PTC was integral to the profitability of Biovail. These products represented Biovail's key mid-term product pipeline. In mid-2001 the expected value of the products was estimated to be \$1 billion. The products

were estimated to have a value of \$2.4 billion as at December 31, 2002. Biovail had announced in its public disclosure that four of the products were key development products and this fact had been reflected in Biovail's market capitalization.

- b) *Biovail's inherent equity in PTC:* Although the capitalization of PTC was nominal, Biovail had invested substantial value into PTC in the form of: (1) Biovail's \$245 million acquisition of a particular technology that would be used primarily by PTC; (2) R&D costs of \$31.7 million that Biovail had already incurred on the products; (3) Biovail's central R&D operation in Virginia was largely focused on the development of the products licensed to PTC; and (4) approximately 25% of Biovail's manufacturing plant in Puerto Rico, acquired for \$11 million, had been dedicated towards the manufacture of the products licensed to PTC.
- c) *Desire to retain royalties:* Biovail informed Bank A that a present value calculation would lead to a common sense decision that it would want 100% of the PTC royalties. Biovail indicated that there would be a compelling business reason for Biovail to purchase PTC at the end of 2003 since PTC's net present value at that time would eclipse the cost to acquire it. Although Biovail had not formally committed to acquiring PTC, there was a business case to do so.
- d) *Protection of technologies:* The financing was secured by an assignment of the technology license granted by Biovail to PTC. Biovail indicated to Bank A that it would not want its competitors to gain access to the trade secrets and technology assigned to PTC. Accordingly, Bank A's ability to further assign the technology licence would provide additional incentive to Biovail to exercise its Purchase Option.
- e) *Effective annual put:* Biovail indicated to Bank A that the ability to review the financing on an annual basis should be viewed as an effective put of the

loan to Biovail in that, should the financing cease, Biovail would have a commercially compelling reason to exercise the Purchase Option.

- f) *Over-collateralization of the structure:* Biovail indicated to Bank A that it would have an economic incentive to exercise its Purchase Option if there were two successful product developments from the six products licensed (that is, a 33% success rate in product development). Bank A noted that Biovail had historically achieved an 80% success rate in product development.

Bank A's Financing Commitment

36. On June 29, 2001 PTC secured a commitment from Bank A to acquire secured promissory notes issued by PTC to a maximum value of U.S. \$60,000,000 (the "PTC Credit Facility"). These notes were secured by PTC's rights under the PDRA.
37. Biovail provided Bank A with a Letter of Comfort dated June 29, 2001 which stated that Biovail would be responsible for PTC's debt if the Purchase Option were exercised.

(g) Syndication Efforts

38. In the fall of 2001, Bank A held discussions with various other financial institutions in an attempt to syndicate the PTC Credit Facility. Biovail representatives met with these financial institutions directly to attempt to secure the syndication of the PTC Credit Facility.
39. In addition, as Biovail had concerns about certain U.S. and Canadian banks' relationships with some of its competitors, Biovail played a key role in selecting syndication prospects.

40. Bank A approached another major Canadian bank (“Bank B”) to syndicate the PTC credit facility.
41. Bank B’s understanding of PTC came primarily from information provided to it by Biovail representatives. Bank B’s representatives did not meet with any PTC representatives.
42. In attempting to obtain Bank B’s participation in the syndicate, Biovail representatives repeated some of the representations previously made to Bank A. These representations included: the significance of the licensed products to Biovail, the desire to protect the technologies, the presence of an effective annual put, Biovail’s desire to retain PTC’s royalties and the overcollateralization of the PTC structure.
43. Biovail told Bank B that it would not guarantee the repurchase of PTC. However, Biovail provided comfort to Bank B regarding its need to repurchase PTC by highlighting certain facts. These representations included:
 - a) Biovail needed to establish a track record with lenders so that Biovail could fund this type of transaction again in the future;
 - b) Biovail would repurchase PTC before the U.S. Food and Drug Administration (“FDA”) approved any of the products in order to capture a positive accounting impact on Biovail’s income;
 - c) PTC was over-collateralized in that the products to be developed by PTC represented 25% of Biovail’s total product pipeline, most of its mid-term product pipeline and was composed largely of late-stage products including “blockbuster” opportunities;
 - d) Biovail had a proven track record of success in that six of its eight previously developed drug candidates were approved and taken to market;

- e) Biovail was motivated to avoid the sub-licensing of its proprietary technology to its competitors and, for this reason, Biovail would be incented to repurchase PTC even if it did not make economic sense to do so;
 - f) the annual review feature meant that Biovail was effectively providing the lenders with a put option; and
 - g) PTC was effectively a Biovail credit since the ramifications for Biovail of not repurchasing PTC were immense.
44. A Biovail representative continued to work on the syndication effort into December of 2001. In or around February of 2002, the Investment Committee of Bank B approved U.S. \$15 million worth of financing for PTC. Ultimately, however, Bank B did not advance these funds due to market concerns regarding special purpose entities that arose subsequent to its approval decision. In the end, Bank A and Biovail failed to syndicate any portion of the PTC Credit Facility.

(h) Biovail's Involvement with the Operating Activities of PTC

45. Biovail was involved in the ongoing administration of PTC. Specifically, Biovail assisted PTC with: wire payments, draw requests on the credit facility, reconciliation of financial information, the contemplated migration of PTC to either Bermuda or the British Virgin Islands, employee referrals, accounting firm referrals, the review of Board of Directors meeting minutes and resolutions before execution, the preparation of certificates appointing an alternate Director, and the assignment of developer contracts.

Research and Development

46. Pursuant to the AA, Biovail recommended to the PTC board the names of the entities that would carry out the development of the licensed products. Biovail's

own affiliates performed approximately 20-30% of PTC's research and development work.

Payment of invoices

47. Some of PTC's third party invoices were addressed to Biovail. Some third party invoices were paid by a Biovail affiliate which was subsequently reimbursed by PTC. Biovail also reviewed the appropriateness of third party invoices on PTC's behalf.

Alternative financing

48. In the summer of 2002, in response to uncertainty about whether Bank A would continue to extend credit to PTC, Biovail engaged in discussions with two prospective corporate investors in an attempt to secure alternative financing for PTC, but was unsuccessful. Ultimately, Bank A granted a six-month extension of the PTC Credit Facility.

(i) The Acquisition of PTC

49. Consistent with the "put" representations made to Bank A and Bank B, when Bank A declined to further extend the PTC Credit Facility, Biovail exercised its option to acquire 100% of the outstanding shares of PTC for U.S. \$22.6 million. On December 31, 2002, the PTC Credit Facility was repaid by PTC from the proceeds of a loan obtained by the equity investor. This loan was collateralized by funds placed in escrow by Biovail for the acquisition of PTC.

(j) Summary – Biovail's Failure to Consolidate PTC Under Canadian GAAP

50. Thus, taking into account the confluence of factors described above, from the date of PTC's incorporation, Biovail controlled PTC and had the right to obtain

economic benefits from and was exposed to the related risks of PTC. In failing to consolidate PTC in its Canadian GAAP financial statements prior to the date it acquired 100% of the equity of PTC on December 31, 2002, Biovail did not comply with Canadian GAAP, contrary to Ontario securities law and the public interest.

51. Biovail's failure to consolidate PTC in its financial statements prior to acquiring 100% of the equity of PTC resulted, among other things, in the overstatement of Biovail's net income and the understatement of debt. If Biovail had consolidated PTC in 2001 and 2002, as required under Canadian GAAP, Biovail's financial statements would have, among other things, reflected higher research and development expenses, lower net income and lower earnings per share.

Biovail's Failure to Comply With U.S. GAAP in Accounting for its Arrangements with PTC

52. Based on the factors described above, it was probable that Biovail would repay the debt of PTC to Bank A regardless of the outcome of PTC's product development activities. Therefore, in its U.S. GAAP financial statements, Biovail should have recorded the liability and charged development costs to expense as incurred. In failing to do so, Biovail did not comply with U.S. GAAP. Biovail's representations in its U.S. financial statements that the statements had been prepared in accordance with U.S. GAAP were materially misleading or untrue, contrary to Ontario securities law and the public interest.

Biovail's Failure to Disclose the Establishment of and its Arrangements with PTC

53. During the period from June 2001 to December 2002 an issuer's continuous disclosure obligations included the filing of an Annual Information Form ("AIF") and an annual and interim Management's Discussion & Analysis ("MD&A") accompanying its financial statements. OSC Rule 51-501- "AIF & MD&A" set out the filing and delivery requirements of AIF and MD&A, as well as the form and

content of these documents. The AIF was to be prepared in accordance with Form 44-101F1 and the MD&A was to be prepared in accordance with Form 44-101F2.

54. Pursuant to these disclosure requirements, Biovail was required to disclose, among other things, any event occurring during the reporting period that was reasonably expected to have a material effect on Biovail's business, financial condition or results of operations. Biovail filed AIFs and annual and interim MD&As during the Material Time.
55. In addition, Biovail was required to provide full, true and plain disclosure of material facts in its prospectuses.
56. On November 5, 2001, Biovail filed a Short Form Base Shelf Prospectus with the Canadian provincial securities commissions in relation to the potential sale of up to U.S. \$1.5 billion in any combination of common shares, debt securities and warrants. Subsequently, on November 13, 2001 and March 26, 2002, Biovail filed two Prospectus Supplements for offerings of 12.5 million common shares for U.S. \$587.5 million and U.S. \$400 million of senior subordinated notes, respectively (the "Prospectus Supplements"). The Prospectus Supplements incorporated the Q3 interim financial statements for the 2001 fiscal year. All of these filings are referred to collectively as the "Prospectuses".
57. The transfer of the development of the products and the related development expenses from Biovail to PTC was an event that was reasonably expected to have a material effect on Biovail's business, financial condition or results of operations and was a material fact.
58. Biovail first disclosed the existence of PTC in a Form 20-F filed on May 20, 2003, which contained the annual and Q4 interim financial statements for its 2002 fiscal year. This was several months after Biovail had exercised its option to acquire all

of the outstanding shares of PTC. Biovail did not disclose at this time the nature and substance of its arrangements with PTC.

59. Biovail failed to disclose in its Public Disclosure during the Material Time the existence of PTC and the nature and substance of Biovail's arrangements with PTC contrary to the requirements of Ontario securities law and the public interest. Further, Biovail failed to make full, true and plain disclosure in its Prospectuses of material facts respecting the existence of PTC and the nature and substance of Biovail's arrangements with PTC. Finally, the Prospectus Supplements incorporated by reference financial statements that were not prepared in accordance with Canadian GAAP. In so doing, Biovail violated the requirements of Ontario securities law and acted in a manner contrary to the public interest.
60. Crombie, as Biovail's CFO during the Material Time, authorized, permitted or acquiesced in Biovail's misconduct in that:
 - (a) Crombie had ultimate responsibility within Biovail for establishing, structuring, initiating and maintaining financing for PTC as well as its ongoing administration;
 - (b) Crombie made the representations detailed above to Bank A and Bank B concerning PTC;
 - (c) at no time did Crombie inform Biovail's auditors of the representations that he had made concerning PTC to Bank A and Bank B. Such information was material to the proper accounting treatment of PTC;
 - (d) Crombie certified Biovail's Public Disclosure for its fiscal year ended December 31, 2001. He also certified that its Public Disclosure for Q2 and Q3 of 2002 "fairly present[ed], in all material

respects, the financial condition and results of operations of” Biovail; and

- (e) Crombie certified that the Prospectuses contained “full, true and plain disclosure of all material facts” relating to Biovail shares and that they did not contain “any misrepresentation likely to affect the value or the market price” of Biovail shares.

Misleading Information Provided to OSC Staff during Continuous Disclosure Review

- 61. Biovail made statements to Staff during the course of Staff’s continuous disclosure review in 2003 and 2004 that, in a material respect and at the time and in the light of the circumstances under which the statements were made, were misleading or untrue or did not state a fact that was required to be stated or that was necessary to make the statements not misleading. In so doing, Biovail violated Ontario securities law and engaged in conduct contrary to the public interest.
- 62. During the continuous disclosure review, Staff requested information from Biovail in relation to several issues, including the arrangements between Biovail and PTC. Biovail provided written responses that were materially misleading or untrue. These included Biovail’s written response dated January 28, 2003 and, in particular, the statement: “[n]one of Biovail, nor any of its affiliates, directors or officers were involved in the formation of [PTC]”; and Biovail’s written response dated July 9, 2003 and, in particular, the statements: “we confirm that Biovail was not involved in the negotiation of [PTC’s] financing” , “[t]o our knowledge, [PTC] had office space in Barbados and New York” and “neither [PTC] nor its lender has any contractual, contingent or constructive right or ability to [p]ut [PTC’s] shares or its royalty interest to Biovail”.

63. Crombie signed and had ultimate responsibility for the written responses to Staff's questions detailed above. He thereby permitted, authorized or acquiesced in Biovail's misconduct.

Improper Revenue Recognition in Q2 2003 Financial Statements – the Wellbutrin XL Bill and Hold Arrangement

64. On July 29, 2003, Biovail released its financial results for the quarter ending June 30, 2003 (the "Q2 2003 Press Release"). These results were further disseminated in a conference call and webcast held on July 29, 2003 (the "Q2 2003 Analyst Call"). Biovail subsequently filed financial statements for this quarter with the Commission on August 29, 2003 (the "Q2 2003 Financial Statements").
65. The Q2 2003 Press Release, Q2 2003 Analyst Call and the Q2 2003 Financial Statements included in Biovail's revenue for the quarter approximately U.S. \$8 million relating to an arrangement involving a purported sale of Wellbutrin XL ("WXL") tablets to a large American pharmaceutical company (the "Distributor") on a "bill-and-hold" basis. Inclusion of this amount in revenue for the quarter increased Biovail's operating income by approximately U.S. \$4.4 million. This inclusion was improper.

(a) The Wellbutrin XL Agreement

66. On October 26, 2001, Biovail (through its subsidiary BLI) entered into a Development, License and Co-Promotion Agreement with the Distributor. This agreement was modified by a Memorandum of Understanding effective January 1, 2003 (together, these two documents form the "Agreement"). Under the Agreement, Biovail agreed to manufacture and supply all of the Distributor's requirements for tablets of WXL.
67. Under the Agreement, Biovail was to supply the Distributor with WXL tablets at two price points: "trade" prices for tablets which were to be sold to the public, and

“sample” prices for tablets which were to be distributed free through physicians in order to promote the tablets in the marketplace.

68. Under the Agreement, the prices were fixed for sample tablets. Prices for trade tablets were based upon a tiered percentage of the Distributor’s net sales of WXL, and were higher than the sample tablet prices. The Agreement contemplated that Biovail would package the trade tablets at its own expense.
69. At the time of entering into the Agreement, WXL had not been approved by the FDA and thus could not be sold to the public. In addition, the tablets could not be packaged until FDA approval was received.
70. The FDA approved WXL for packaging and sale on August 28, 2003.

(b) The Distributor’s Purchase Orders

71. In April 2003, the Distributor established standard terms for its purchases of WXL from Biovail, and sent out an initial order for 30,400,000 WXL tablets at the agreed sample prices (the “April Purchase Order”). These tablets were requested for June delivery.
72. On June 19, 2003 Biovail contacted the Distributor and requested that, prior to June 30, 2003, the Distributor place an order for WXL tablets at fixed trade prices. Specifically, Biovail proposed that these tablets be purchased at fixed trade prices, rather than the tiered percentage of the Distributor’s net sales specified in the Agreement, and that the Distributor pay a separate \$1.00 per bottle packaging fee. If the Distributor failed to place such an order, Biovail indicated, it would not fully commit its manufacturing facilities to producing WXL tablets in advance of the product launch.

73. In response, on June 20, 2003, the Distributor sent Biovail a purchase order requesting 27,090,000 WXL tablets at fixed trade prices per tablet and a \$1.00 per bottle packaging fee (the “June Purchase Order”). The June Purchase Order also repeated the Distributor’s request from the April Purchase Order for 30,400,000 WXL tablets at sample prices. The June Purchase Order provided that all of these tablets were required for June delivery. The June Purchase Order referenced the standard terms contained in the April Purchase Order and contained no provisions relating to Biovail’s retention and storage of any of the WXL tablets.

(c) The Recognition of Revenue

74. On June 30, 2003, Biovail invoiced the Distributor for a total of 18,020,244 WXL tablets at fixed trade prices for a total amount of \$8,073,051.24 (the “June Invoice”). Biovail recorded this latter figure as revenue for its fiscal quarter ending June 30, 2003. The inclusion of this revenue increased Biovail’s operating income for the quarter by approximately \$4.4 million, which was a material amount. Biovail did not ship any WXL tablets to the Distributor in June of 2003.

(d) The Purported Bill-And-Hold Arrangement

75. The June Invoice identified by lot number the specific WXL tablets that it encompassed (the “Specified Tablets”). Biovail represents to Staff that, subsequent to June 30, 2003, it maintained the Specified Tablets in a segregated area of its warehouse in Steinbach, Manitoba. Biovail did not, however, supply the Specified Tablets to the Distributor in accordance with the terms reflected on the June Purchase Order and the June Invoice.
76. Biovail was aware that the Specified Tablets had a limited shelf life. In July 2003 Biovail determined that it would begin to replace the Specified Tablets with new WXL tablets and sell the Specified Tablets at the sample prices, rather than the fixed trade prices set out in the June Invoice (the “Pill Switch”). When Biovail

determined that it would go forward with the Pill Switch, it had not yet manufactured a substantial portion of the new WXL tablets.

77. In July 2003, during the review of Biovail's Q2 2003 financial statements by Biovail's auditors, Biovail was questioned about the sale of the Specified Tablets at fixed trade prices. Biovail did not, at that time, inform its auditors of the purported bill-and-hold arrangement or of the Pill Switch.
78. Beginning in August 2003, Biovail shipped the Specified Tablets to the Distributor. The Specified Tablets were shipped in bulk and were never packaged by Biovail. The majority of the Specified Tablets were re-invoiced to the Distributor at the lower sample prices.
79. In September 2003, Biovail reversed the June Invoice. Biovail began to ship to the Distributor newly manufactured WXL tablets and issued another set of invoices at the fixed trade prices originally set out in the June Invoice.
80. In early 2004, as part of their 2003 year-end audit, Biovail's auditors questioned the WXL revenue recorded on June 30. In response, Biovail represented that the WXL arrangement had been conducted on a bill-and-hold basis. Biovail represented that it had reached an agreement with the Distributor prior to June 30, 2003 that the Specified Tablets would be initially segregated within its warehouse and later shipped to the Distributor after FDA approval was received.
81. There was no contemporaneous documentation reflecting such an agreement between Biovail and the Distributor. Biovail once again did not inform the auditors of the Pill Switch, and it misled them about the true reason for the reversal of the June Invoice, claiming it had been reversed for purely administrative reasons.

(e) **Premature Recognition of Revenue**

82. Biovail should not have recognized the revenue from the WXL arrangement on June 30, 2003. The primary purpose for seeking the bill-and-hold arrangement in June 2003 was Biovail's desire to recognize revenue for trade sales of WXL in Q2, rather than any requirement on the part of the Distributor to obtain supplies of WXL for sale to the public. Indeed, it was Biovail, and not the Distributor, that initiated the arrangement by threatening not to manufacture sufficient quantities of WXL tablets unless the Distributor placed a purchase order for the trade tablets prior to June 30, 2003.
83. Biovail artificially separated the task of packaging the Specified Tablets from the task of manufacturing the Specified Tablets in order to represent that it had completed all significant acts of performance associated with the arrangement.
84. There was no fixed schedule for the delivery of the Specified Tablets to the Distributor. Rather, the Specified Tablets were allegedly to be delivered at some unascertained future date following the receipt of FDA approval.
85. The Specified Tablets were not maintained in proper segregation within Biovail's Steinbach plant.
86. Finally, Biovail re-priced almost all of the Specified Tablets to the lower sample prices rather than the fixed trade prices reflected in the June Invoice.
87. The combination of all of these factors meant that, as of June 30, 2003, the arrangement between Biovail and the Distributor regarding the Specified Tablets did not meet the criteria for recognition of revenue in accordance with Canadian GAAP. Biovail should not have recognized revenue in its Q2 2003 Financial Statements from the purported bill-and-hold arrangement. The arrangement also did not meet the criteria for the recognition of revenue under U.S. GAAP.

88. As a result, Biovail made materially misleading or untrue statements in its Q2 2003 Press Release and Q2 2003 Analyst Call which disseminated the financial results incorporating this improperly recognized revenue. These materially misleading and untrue statements have not been corrected in subsequent public filings by Biovail.
89. The Q2 2003 Financial Statements, Q2 2003 Press Release and Q2 2003 Analyst Call also contained inaccurate and misleading statements by Biovail that it had “supplied” WXL tablets to the Distributor in Q2 2003. All of this conduct violated Ontario securities law and was contrary to the public interest.
90. Crombie and Miszuk authorized, permitted or acquiesced in Biovail’s misconduct in that:
 - (a) Crombie had ultimate responsibility within Biovail for conducting the negotiations with the Distributor regarding the purported bill-and-hold arrangement;
 - (b) Crombie and Miszuk had responsibility within Biovail for the accounting treatment of the purported bill-and-hold arrangement;
 - (c) Crombie initiated and Miszuk authorized the Pill Switch on behalf of Biovail;
 - (d) in July of 2003, Crombie and Miszuk failed to inform Biovail’s auditors of the purported bill-and-hold arrangement or of the Pill Switch;
 - (e) in early 2004, Crombie and Miszuk once again failed to inform Biovail’s auditors of the Pill Switch and misled them about the true reasons for the reversal of the June Invoice;

- (f) Crombie certified and Miszuk signed Biovail's Public Disclosure for Q2 2002; and
- (g) Crombie was present during the Q2 2003 Analyst Call but did not correct the misstatement made by other Biovail representatives regarding "suppl[ying]" WXL tablets to the Distributor during the quarter.

Misleading Information Provided to OSC Staff During Continuous Disclosure Review

- 91. Biovail made statements to Staff during the course of Staff's continuous disclosure review in 2003 and 2004 that, in a material respect and at the time and in the light of the circumstances under which the statements were made, were misleading or untrue or did not state a fact that was required to be stated or that was necessary to make the statements not misleading. In so doing, Biovail violated Ontario securities law and engaged in conduct contrary to the public interest.
- 92. During the continuous disclosure review, Staff requested information from Biovail in relation to several issues including the facts underlying the recognition of revenue for the purported sale of WXL tablets to the Distributor. Biovail provided responses to Staff that were materially misleading or untrue. These responses include Biovail's written response dated April 13, 2004, and, in particular, the statements: "[t]he Company stored this product belonging to [the Distributor] in a clearly marked, segregated space within its Steinbach warehouse", "[t]he Company invoiced [the Distributor] for these sales on June 30, 2003 under its normal trade terms of net 30 days. There were no unusual or modified billing or credit terms" and "[t]his product was sold to [the Distributor] at a fixed price, and was not subject to any downward reconciliation".
- 93. Crombie signed and had ultimate responsibility for the written responses to Staff's questions detailed above. He thereby permitted, authorized or acquiesced in Biovail's misconduct.

Biovail's Failure to Correct and Disclose on a Timely Basis a Known Material Financial Statement Error – The Foreign Exchange Error

94. On April 29, 2003 Biovail released its financial results for the quarter ending March 31, 2003 (the “Q1 2003 Press Release”). As set out above, Biovail released its financial results for Q2 2003 on July 29, 2003. On October 30, 2003 Biovail released its financial results for the quarter ending September 30, 2003 (the “Q3 2003 Press Release”). Biovail subsequently filed financial statements for the first quarter on May 30, 2003 (the “Q1 2003 Financial Statements”), for the second quarter on August 29, 2003 and for the third quarter on November 28, 2003 (the “Q3 2003 Financial Statements”).
95. Biovail failed to account properly for an obligation denominated in Canadian dollars in its Q1 2003 Financial Statements, its Q2 2003 Financial Statements and its Q3 2003 Financial Statements. Although Biovail’s accounting error was identified by its accounting personnel in early July 2003, prior to the release of its Q2 2003 financial results and the filing of the Q2 2003 Financial Statements, Biovail did not disclose the error until it issued on March 3, 2004 its earnings release for the fourth quarter 2003 and the full fiscal year ended December 31, 2003 (the “March 3, 2004 Press Release”).
96. In December of 2002, Biovail, through its subsidiary BLI, acquired the rights to certain drugs. In so doing, Biovail assumed an obligation denominated in Canadian dollars. Since Biovail reported its results in U.S. dollars, it was required to account for this obligation in its financial statements in U.S. dollars. Biovail properly accounted for this obligation in December 2002 when it converted the obligation from Canadian dollars to U.S. dollars using the then current U.S. \$/CAN \$ exchange rate (“FX Rate”).
97. Canadian GAAP requires that any outstanding balance of a foreign currency denominated obligation that is a monetary item be revalued using the FX Rate

current at each balance sheet date. At March 31, 2003, however, Biovail, continued to use the FX Rate from December 2002 (the "Error"). Biovail also continued to use the FX Rate from December 2002 on June 30, 2003 and September 30, 2003. The interim financial statements for Q1, Q2 and Q3 of 2003 therefore did not accurately reflect any exchange losses or gains and the outstanding balance of the obligation. Biovail thereby violated Ontario securities law and engaged in conduct contrary to the public interest.

98. In early July 2003, the Error was brought to the attention of Miszuk for resolution. Biovail took no steps to correct the Error in the Q1 2003 Financial Statements and failed to properly account for the obligation in its Q2 2003 Financial Statements and its Q3 2003 Financial Statements. As a result, Biovail overstated its net income for the quarter by approximately U.S. \$5 million in its Q1 2003 Financial Statements and approximately U.S. \$4 million in its Q2 2003 Financial Statements. It understated its net income for the quarter by approximately U.S. \$3 million in its Q3 2003 Financial Statements.
99. As described above, the Error was identified by senior Biovail accounting personnel in early July 2003, prior to the release of Biovail's Q2 2003 financial results and the filing of its Q2 2003 Financial Statements, but Biovail did not disclose the Error until it issued the March 3, 2004 Press Release. The March 3, 2004 Press Release did not state that Miszuk and Biovail had learned of the Error the previous July. The Error was not corrected until Biovail filed restated interim financial statements for Q1, Q2 and Q3 of 2003 on May 14, 2004.
100. Taken together, the improper recognition of revenue from the WXL bill-and-hold arrangement and the continuing use of the FX Rate from December 31, 2002 overstated Biovail's Q2 2003 net income by approximately U.S. \$8 million (excluding tax consequences).

101. As described above, in early July 2003, the Error was brought to Miszuk's attention for resolution. Miszuk failed to ensure that Biovail disclosed the Error prior to the release of its Q2 2003 Financial Statements. He failed to ensure that Biovail corrected the Error in the Q1 2003 Financial Statements. He also failed to ensure that Biovail properly accounted for the obligation in its Q2 2003 Financial Statements and its Q3 2003 Financial Statements. He signed Biovail's Public Disclosure for Q2 and Q3 of 2002. He thereby authorized, permitted or acquiesced in Biovail's misconduct.

Biovail Made Misleading or Untrue Statements in Press Releases – The Truck Accident

102. Biovail made statements in press releases issued on October 3, 8 and 30, 2003 and March 3, 2004 that in a material respect and at the time and in the light of the circumstances in which they were made, were misleading or untrue or did not state a fact that was required to be stated or that was necessary to make the statements not misleading.
103. The press releases concerned Biovail's disclosure that its preliminary financial results for its third quarter of 2003 would be below previously issued guidance. Particulars of the materially misleading or untrue statements are outlined below.

(a) Biovail's Revenue and Earnings Expectations

104. On February 7, 2003, Biovail publicly disclosed in a press release its revenue and earnings guidance for 2003. The revenue range projected for the third quarter of 2003 was U.S. \$260 million to U.S. \$300 million.
105. Biovail did not achieve its third quarter 2003 revenue and earnings expectations. Rather, in its October 30, 2003 press release, Biovail reported U.S. \$215.3 million in revenue for that quarter.

(b) The October 3, 2003 Press Release

106. In a press release issued on October 3, 2003 (the “October 3, 2003 Press Release”), Biovail stated that its preliminary results for its 2003 third quarter “will be below previously issued guidance...Contributing significantly to this unfavourable variance was the loss of revenue and income associated with a significant in-transit shipment loss of Wellbutrin XL as a result of a traffic accident ... Revenue associated with this shipment is in the range of [U.S.] \$10 to [U.S.] \$20 million”.
107. The statements contained in the October 3, 2003 Press Release were materially misleading or untrue. The traffic accident referred to in the press release was not a reason for Biovail’s failure to meet its previously issued revenue guidance for the third quarter of 2003. Specifically, Biovail’s statements were materially misleading or untrue in that:
- (i) a truck carrying WXL tablets, destined for the Distributor’s facility in the United States, departed from Biovail’s warehouse in Steinbach, Manitoba on September 30, 2003;
 - (ii) the contractual delivery term between Biovail and the Distributor was “f.o.b. [the Distributor]’s facilities in the USA” (or, in short, f.o.b. destination). This delivery term meant that Biovail would be entitled to recognize the revenue associated with a WXL shipment only when that shipment reached the Distributor’s facility;
 - (iii) the truck carrying the WXL shipment was scheduled to reach the Distributor’s facility after September 30, 2003. Biovail, therefore, could recognize the revenue associated with the WXL shipment only in its fourth quarter which ended on December 31, 2003; and

(iv) on October 1, 2003, the truck carrying the WXL shipment was involved in an accident. However, given the f.o.b. destination contractual term, the truck accident had no impact on Biovail's revenue for its 2003 third quarter.

108. The October 3, 2003 Press Release also stated that “[r]evenue associated with the [WXL] shipment was in the range of [U.S.] \$10 million to [U.S.] \$20 million”. This statement was misleading or untrue. Biovail could not recognize the associated revenue until its fourth quarter for the reasons outlined above. Further, Biovail's statement that the value of the WXL shipment was U.S. \$10 million to U.S. \$20 million was grossly inflated. Biovail later stated in a March 3, 2004 press release, discussed below, that the “actual revenue loss” from the shipment on the truck was U.S. \$5 million.

(c) The October 8, 2003 Press Release

109. On October 8, 2003 an employee of the Distributor contacted Biovail to correct some of the misstatements made in the October 3, 2003 Press Release, including highlighting the correct WXL delivery term.

110. Also on October 8, 2003 an American investment bank issued a research report regarding Biovail's shares (the “Research Report”) which, among other things, questioned the accuracy of Biovail's valuation of the WXL shipment involved in the accident as well as its description of the WXL delivery term. Other research analysts began to contact Biovail with questions regarding these issues.

111. In response, on the same date, Biovail issued a further press release (the “October 8, 2003 Press Release”) which stated that Biovail had recovered the WXL shipment involved in the accident and that 60% of the shipment was saleable and might be re-shipped within 30 days. The press release went on to state “Biovail re-confirms that the sales value of these goods is within previously stated guidance”.

(d) The October 30, 2003 Press Release

112. In its earnings press release for the third quarter of 2003 issued on October 30, 2003 (the “October 30, 2003 Press Release”), Biovail stated that “[a] late third quarter 2003 shipment of Wellbutrin XL involved in an accident outside of Chicago was returned to Biovail’s facility on October 8, 2003 for inspection. No revenue was recognized from this shipment in Q3 2003.”

(e) The March 3, 2004 Press Release

113. The March 3, 2004 Press Release stated that “Biovail announced [on October 3, 2003] that its estimated revenue from Wellbutrin XL for third quarter 2003 would be less than [U.S.] \$10 million partially as a result of the truck accident and that the loss in revenue due to the accident would be in the range of [U.S.] \$10.0 million to [U.S.] \$20.0 million”. The March 3, 2004 Press Release further stated that “the actual revenue loss from the accident was determined to be [U.S.] \$5.0 million”. In fact, Biovail knew that there was no revenue loss in Q3 2003 as a result of the truck accident.
114. The October 8 and October 30, 2003 Press Releases, and the March 3, 2004 Press Release contained materially misleading or untrue statements. These Press Releases continued to disseminate the prior materially misleading or untrue information provided by Biovail in its October 3, 2003 Press Release and failed to correct the incorrect information previously provided to the investing public.

(f) October 3, 2003 Analyst Call

115. Melnyk, Crombie and Howling participated in a conference call with analysts and a webcast held on October 3, 2003 following the release of the October 3, 2003 Press Release (the “October 3, 2003 Analyst Call”). During the October 3, 2003 Analyst Call, Biovail made statements that were materially misleading or untrue.

116. Specifically, during the conference call Biovail stated that the accident would have a material negative financial impact on its third quarter revenues. Biovail further stated that the negative impact of the truck accident on revenue would be in the range of U.S. \$15 million to U.S. \$20 million.
117. During the October 3, 2003 Analyst Call, an analyst questioned whether the accident would have fourth quarter rather than third quarter implications. Biovail responded that it was purely a third quarter issue.
118. For the reasons previously described, the above statements were materially misleading or untrue.

(g) October 2003 Investor Meetings

119. In October 2003, Melnyk, Crombie and Howling participated in a series of meetings with investors to, among other things, deal with questions surrounding the truck accident and the related announcements that followed (the “Investor Meetings”). The Investor Meetings took place in various cities on October 10, 13, 14 and 15 of 2003. The presentation materials contained similar materially misleading or untrue statements to those described above.
120. Specifically, the presentation materials included a slide with the heading “Revised third quarter guidance” which stated “Revenue and EPS effected (*sic*) by three items[:] 1. Wellbutrin XL shipment / traffic accident ...”. Another slide entitled “Wellbutrin XL – timing issue” stated “Impact to Q3 ... Revenue [U.S.] \$10 to [U.S.] \$20 million”.
121. In summary, in the October 3, 2003 Press Release, Biovail made the materially misleading and untrue claim that a truck accident was a reason for Biovail’s failure to meet previously issued revenue guidance for the quarter. Also, Biovail

disseminated materially misleading or untrue information in its statement that the revenue associated with the WXL shipment was in the range of U.S. \$10 million to U.S. \$20 million. Biovail repeated, or implicitly reinforced, the materially misleading and untrue claims during the October 3, 2003 Analyst Call, and in statements made in the October 8, 2003 Press Release, the October 30, 2003 Press Release, the March 3, 2004 Press Release and the Investor Meetings. Biovail thereby violated Ontario securities law and engaged in conduct contrary to the public interest.

122. Biovail knew or should have known that the information described above, which was disseminated to the public, was materially misleading or untrue.
123. Melnyk, Crombie and Howling authorized, permitted or acquiesced in Biovail's misconduct in that:
 - (a) they knew or should have known at all material times that the WXL delivery term precluded Biovail from recognizing any revenue associated with this shipment in the third quarter of 2003;
 - (b) they knew or should have known at all material times that the value of the WXL tablets that were lost in the truck accident was substantially below the U.S. \$10 to U.S. \$20 million figures that were initially provided;
 - (c) in particular, by October 2, 2003, before the first press release was made, Crombie was made aware of the WXL delivery term;
 - (d) by October 2, 2003, before the first press release was made, Melnyk and Howling should have known or taken steps to verify the WXL delivery term. In particular, on October 2, 2003 Melnyk and Howling were sent a draft press release by Crombie which contained the WXL delivery term;

- (e) on October 8, 2003, Howling received a copy of the Research Report questioning the WXL delivery term and the valuation of the WXL damaged in the accident. Howling circulated the Research Report to Melnyk and Crombie;
- (f) Howling also received information from the Distributor on October 8, 2003 highlighting the correct WXL delivery term. Howling forwarded this information to Melnyk and Crombie;
- (g) Melnyk, Crombie and Howling all participated in the drafting of the October 3, 2003 Press Release, the October 8, 2003 Press Release, the October 30, 2003 Press Release and the March 4, 2004 Press Release;
- (h) Melnyk, Crombie and Howling all participated in the October 3, 2003 Analyst Call; and
- (i) Melnyk, Crombie and Howling all participated in the Investor Meetings.

Misleading Information Provided to OSC Staff During Continuous Disclosure Review

124. Biovail made statements to Staff during the course of Staff's continuous disclosure review in 2003 and 2004 that, in a material respect and at the time and in the light of the circumstances under which the statements were made, were misleading or untrue or did not state a fact that was required to be stated or that was necessary to make the statements not misleading. In so doing, Biovail violated Ontario securities law and engaged in conduct contrary to the public interest.

125. During the continuous disclosure review, Staff requested information from Biovail in relation to several issues, including the truck accident. Biovail provided responses that were materially misleading or untrue. These responses include Biovail's written response dated April 13, 2004, and, in particular, the statement: "[i]t should be noted that the Company did not ultimately lose any revenue from sales pursuant to the WXL Agreement for fiscal 2003 as any revenue not recognized in Q3 was recognized in Q4 upon re-shipment of product in Q4." Biovail failed to forthrightly advise Staff that the truck accident was not a reason for its failure to meet its revenue guidance for Q3, 2003.
126. Crombie signed and had ultimate responsibility for the written responses to Staff's questions detailed above. He thereby permitted, authorized or acquiesced in Biovail's misconduct.

Dated at Toronto this 24th day of March, 2008

SCHEDULE A – Biovail's Public Disclosure

Document Description	Content	Filing Date
Form 20-F – For the year ended December 31, 2001	AIF, Cdn. and U.S. GAAP MD&A and financial statements	21-May-2002
Form 20-F – For the year ended December 31, 2002	AIF, Cdn. and U.S. GAAP MD&A and financial statements	20-May-2003
Form 6K – For the quarter ended September 30, 2001	U.S. GAAP MD&A and financial statements	13-Nov-2001
Third Quarter 2001 Interim Report - For Canadian Regulatory Purposes	Cdn. GAAP MD&A and financial statements	13-Nov-2001
Form 6K - For the quarter ended March 31, 2002	Cdn.. and U.S. GAAP MD&A and financial statements	30-May-2002
Form 6K - For the quarter ended June 30, 2002	Cdn. and U.S. GAAP MD&A and financial statements	29-Aug-2002
Form 6K - For the quarter ended September 30, 2002	Cdn. and U.S. GAAP MD&A and financial statements	26-Nov-2002
Shelf Prospectus	---	05-Nov-2001
Prospectus Supplement	---	13-Nov-2001
Prospectus Supplement	---	26-Mar-2002