## 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 SETTLEMENT AGREEMENT OF BRIAN H. CROMBIE

# I. INTRODUCTION

 By Notice of Hearing and related Statement of Allegations dated March 24, 2008 (the "Notice of Hearing"), the Ontario Securities Commission (the "Commission") announced that it proposed to hold a hearing to consider whether, pursuant to sections 127 and 127.1 of the Securities Act, R.S.O. 1990, c. S.5, as amended (the "Act"), it is in the public interest for the Commission to make certain orders against Biovail Corporation ("Biovail"), Eugene N. Melnyk ("Melnyk"), Brian H. Crombie ("Crombie"), John R. Miszuk ("Miszuk") and Kenneth G. Howling ("Howling").

## II. JOINT SETTLEMENT RECOMMENDATION

2. Staff of the Commission ("Staff") agree to recommend settlement of the proceeding initiated in respect of Crombie by the Notice of Hearing in accordance with the terms and conditions set out below. Crombie agrees to the settlement on the basis of the facts set out in Part IV and consents to the making of an Order in the form attached as Schedule "A".

## **III. ACKNOWLEDGEMENT**

3. Crombie admits the facts set out in Part IV of this Settlement Agreement solely for the purposes of this Settlement Agreement. This Settlement Agreement and the facts and admissions as set out herein are without prejudice to Crombie in any other proceeding including, without limitation, any civil, administrative, quasi-criminal or criminal actions or proceedings currently pending or that may be brought by any person or agency, whether or not this Settlement Agreement is approved by the Commission. No other person or agency may raise or rely upon the terms of this Settlement Agreement or any agreement or the facts stated herein whether or not this Settlement Agreement is approved by the Commission. Without limiting the generality of the foregoing, Crombie expressly denies that this Settlement Agreement is intended to be an admission of civil or criminal liability and expressly denies any such admission of civil or criminal liability.

## IV. FACTS

## Background

- 4. 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. Biovail is a fully-integrated pharmaceutical company.
- During the period May 2000 to August 2004, Crombie was Biovail's Chief Financial Officer. From August 2004 to May 2007, Crombie was Vice-President, Strategic Development. Crombie is no longer employed by Biovail.
- 6. As Chief Financial Officer, Crombie had overall responsibility for Biovail's finance and accounting function. He reported to Melnyk, Biovail's Chief Executive Officer. Crombie is not a Chartered Accountant or a Certified Public Accountant and has no other accounting licences or designations. He was assisted in the overseeing of the accounting

function of the company by experienced accounting staff. Crombie would have input into financial press releases and participate in their drafting from time to time but did not have final authority to issue press releases on Biovail's behalf.

#### The Wellbutrin XL Bill and Hold Arrangement

- 7. 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").
- 8. 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 a sale of Wellbutrin XL ("WXL") tablets to GlaxoSmithKline PLC ("GSK") that Biovail has represented was carried out 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.

### (a) The Wellbutrin XL Agreement

9. On October 26, 2001, Biovail (through its subsidiary Biovail Laboratories Inc. ("BLI")) entered into a Development, License and Co-Promotion Agreement with GSK. 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 GSK's requirements for tablets of WXL.

- 10. Under the Agreement, Biovail was to supply GSK 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.
- 11. Under the Agreement, the prices were fixed for sample tablets. Prices for trade tablets were based upon a tiered percentage of GSK'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.
- 12. At the time of entering into the Agreement, WXL had not been approved by the U.S. Food and Drug Administration ("FDA"), and thus could not be sold to the public.
- 13. The FDA approved WXL on August 28, 2003. This included approving the form of packaging and labeling for WXL.

## (b) **GSK's Purchase Orders**

- 14. The Agreement did not impose an obligation on Biovail to manufacture WXL prior to FDA approval. The Agreement did not make specific provision, whether through milestone payments or otherwise, for the expenses of pre-launch manufacture of WXL. It also did not specifically contemplate a price at which pills manufactured prior to launch would be sold.
- 15. During 2002, Biovail and GSK representatives met to discuss the pre-launch manufacture of WXL.
- 16. In April 2003, GSK sent out an initial order for 30,400,000 WXL tablets, for which it proposed to pay the sample prices provided in the Agreement (the "April Purchase Order"). These tablets were requested for June delivery.

- 17. Throughout April, May and June 2003, GSK and Biovail representatives continued to discuss the pre-launch manufacture of WXL. The parties agreed that, in addition to the April Purchase Order, GSK would place an order for WXL for which it would pay a fixed price.
- 18. On June 20, 2003, GSK sent Biovail a purchase order requesting 27,090,000 WXL tablets at a fixed price per tablet and a \$1.00 per bottle packaging fee (the "June Purchase Order"). The June Purchase Order replaced the April Purchase Order and therefore also contained an order for 30,400,000 WXL tablets at sample prices.

# (c) Recognition of Revenue

19. On June 30, 2003, Biovail invoiced GSK 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.

## (d) The Bill-and-Hold Arrangement

- 20. The June Invoices identified by lot number the specific WXL tablets that it encompassed (the "Specified Tablets"). Crombie was advised by Biovail staff and understood that, subsequent to June 30, 2003, Biovail maintained the Specified Tablets in a segregated area of its warehouse in Steinbach, Manitoba and in a designated "site" in its inventory system. Biovail did not, however, supply all of the Specified Tablets to GSK in accordance with the terms reflected on the June Purchase Order and the June Invoice.
- 21. On August 1, 2003 and August 22, 2003, Biovail shipped some of the Specified Tablets to GSK as sample product. By August 31, 2003, Biovail had replaced most if not all, of those Specified Tablets with new WXL tablets (the "Pill Switch").

- 22. Biovail ultimately issued credit memos for the June Invoice and re-issued a different invoice, with different lot numbers, reflecting the sale of the new WXL tablets at the fixed prices agreed in the June Purchase Order.
- 23. Canadian GAAP provides that in most cases, revenue is not recognized until the passing of possession of goods. In other words, in most cases, revenue should not be recognized until delivery has occurred. Delivery generally is not considered to have occurred unless the product has been delivered to the customer's place of business or to another site specified by the customer.
- 24. "Bill and hold" transactions, in which delivery of the goods does not immediately take place, provide an exception to general revenue recognition principles. Such transactions, however, must meet very specific accounting requirements.
- 25. Biovail has admitted in a Settlement Agreement entered into with Staff dated January 7, 2009 (the "Biovail Settlement Agreement") that Biovail represented that it recognized the revenue with respect to the sale of the Specified Tablets on June 30, 2003 on a "bill and hold" basis. However, Biovail acknowledged in the Biovail Settlement Agreement that the revenue recognition requirements under Canadian GAAP for "bill and hold" arrangements were not met with respect to the Specified Tablets and that, accordingly Biovail should not have recognized revenue in its Q2 2003 Financial Statements from the sale of the Specified Tablets. Biovail admitted that it thereby violated Ontario securities law and acted in a manner that was contrary to the public interest.
- 26. As the senior financial officer of Biovail, Crombie had principal responsibility for ensuring that the Q2 2003 Financial Statements complied with Canadian GAAP. He certified the public disclosure of these Financial Statements on behalf of Biovail and thereby acquiesced in their release to the public. Crombie acknowledges that he ought to have been more careful in considering the recognition of revenue for the sale of the Specified Tablets. Specifically, he ought to have made further inquiries or ensured that Biovail sought further guidance from a qualified accounting professional concerning this

arrangement prior to the completion and release to the public of Biovail's Q2 2003 Financial Statements. He therefore now acknowledges that he acquiesced in conduct by Biovail that was a violation of Ontario securities law and, by his conduct, acted contrary to the public interest.

## **Biovail's Statements in Press Releases – the Truck Accident**

- 27. Biovail has admitted in the Biovail Settlement Agreement that Biovail made statements in press releases issued on October 3, 8 and 30, 2003 and March 3, 2004 that, in a material respect, inaccurately disclosed the implications, for Biovail, of a truck accident that occurred on October 1, 2003.
- 28. The press releases concerned Biovail's disclosure that its preliminary financial results for its third quarter of 2003 would be below previously issued guidance. Full particulars are contained in the Biovail Settlement Agreement. A description of the statements is outlined below.

## (a) **Biovail's Revenue and Earnings Expectations**

- 29. 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.
- 30. 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

31. 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".

- 32. A truck carrying WXL tablets, destined for GSK's facility in the United States, departed from Biovail's warehouse in Steinbach, Manitoba on September 30, 2003.
- 33. The contractual delivery term between Biovail and GSK was "F.O.B., GSK's facilities in the U.S.A. (freight collect)." This meant that the contractual delivery term only entitled Biovail to recognize the revenue associated with the shipment once it reached GSK's facilities.
- 34. The truck carrying the WXL shipment was scheduled to reach GSK's facility after September 30, 2003.
- 35. On October 1, 2003, the truck carrying the WXL shipment was involved in an accident.
- 36. 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". Biovail later stated in a March 3, 2004 press release (the "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

37. On October 8, 2003, 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 percent 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

38. 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

39. 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".

## (f) October 3, 2003 Analyst Call

- 40. Biovail held a conference call with analysts and a webcast 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 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.
- 41. 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.

#### (g) October 2003 Investor Meetings

42. In October 2003, Biovail held 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.

- 43. 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".
- 44. In the Biovail Settlement Agreement, Biovail admitted that it had disseminated incorrect statements in the Press Releases of October 3, 8 and 30, 2003 and March 3, 2004, in the Analyst Call held on October 3, 2003, and in Investor Meetings held in October 2003 relating to the truck accident. In particular, Biovail admitted, that regardless of the truck accident, it would not have been able to recognize the revenue associated with the shipment until its fourth quarter. It also admitted that the value attributed to the WXL shipment (U.S. \$10 to U.S. \$20 million) was materially in error. Biovail admitted that it should have taken greater care, from the outset, to accurately assess the revenue associated with the product on the truck, and to accurately assess whether, but for the accident, it would have been able to recognize revenue from the sale of the product on the truck in Q3 2003. Finally, Biovail admitted that it should have clearly disclosed, at the earliest opportunity, that previous statements suggesting that the truck accident was one of the reasons for the Q3 earnings miss, and that the revenue associated with the product on the truck was between U.S. \$10 million and U.S. \$20 million were incorrect. Biovail admitted that in so doing it violated Ontario securities law and engaged in conduct contrary to the public interest.

### (h) Crombie's Role in Relation to Press Releases and Statements in Issue

45. As Chief Financial Officer of Biovail, Crombie played a leading role in the preparation and drafting of the press releases in issue, including being the person to provide the estimate as to the range of revenue loss in the October 3, 2003 Press Release. Final approval of the press releases was, however, made by the Chief Executive Officer. Crombie was also a participant in the October 3, 2003 Analyst Call and provided the estimate as to the range of revenue loss in the call. He also attended the October 2003 Investor Meetings as a member of Biovail's senior management.

46. Crombie should have taken greater care to ensure that the correct information was disseminated to the investing public and that this was done in a timely fashion. Therefore, he now acknowledges that he acquiesced in conduct by Biovail that was a violation of Ontario securities law and, by his conduct, acted contrary to the public interest.

# (i) Misleading Information Provided to OSC Staff during Continuous Disclosure Review

- 47. During a continuous disclosure review of Biovail conducted by OSC Staff in 2003 and 2004, Staff requested information from Biovail in relation to several issues, including arrangements between Biovail and Pharmaceutical Technologies Corporation ("PTC").
- 48. A letter to Staff from Biovail dated January 28, 2003 (the "January 28<sup>th</sup> Letter") contained the following statement: "[n]one of Biovail, nor any of its affiliates, directors or officers were involved in the formation of [PTC]". In the Biovail Settlement Agreement, Biovail admitted that this statement was materially inaccurate. Biovail further admitted that, by making this statement, it violated Ontario securities law and engaged in conduct contrary to the public interest.
- 49. Crombie participated in the drafting of the January 28<sup>th</sup> Letter and signed it on behalf of Biovail. He should have taken greater care to ensure that the letter did not contain an inaccurate statement. Therefore, he now acknowledges that, by his conduct, he acted contrary to the public interest.

## (j) Mitigating Factors

- 50. Crombie states that he acted in good faith.
- 51. Crombie further states that at all times, his intention was to ensure that news of Biovail's unfavourable earnings variance be communicated to the public in a timely fashion.

## V. TERMS OF SETTLEMENT

- 52. Crombie agrees to the terms of settlement listed below. The Commission will make an order pursuant to section 127(1) and section 127.1 of the Act that:
  - (a) the Settlement Agreement be approved;
  - (b) Crombie be reprimanded;
  - (c) Crombie be prohibited from becoming or acting as an officer or director of a reporting issuer for a period of eight (8) years from the date of approval of the Settlement Agreement;
  - (d) Crombie will cooperate with the Commission and Staff in this matter and will appear and testify at the hearing in this matter if requested by Staff;
  - (e) Crombie shall pay an administrative penalty of CAN\$250,000, to be paid for the benefit of third parties designated by the Commission pursuant to section 3.4(2) of the Act; and
  - (f) Crombie shall pay the sum of CAN\$50,000 in respect of a portion of the costs of the investigation and hearing in relation to this matter.

## **PART VI - STAFF COMMITMENT**

- 53. If the Commission approves this Settlement Agreement, Staff will not commence any proceedings against Crombie under Ontario securities law in relation to the facts alleged in the Notice of Hearing.
- 54. If the Commission approves this Settlement Agreement and Crombie fails to comply with any of the terms of the Settlement Agreement, Staff may bring proceedings under Ontario securities law against Crombie. These proceedings may be based on, but are not limited to, the facts alleged in the Notice of Hearing as well as the breach of the Settlement Agreement.

## PART VII - PROCEDURE FOR APPROVAL OF SETTLEMENT

- 55. The parties will seek approval of this Settlement Agreement at a public hearing before the Commission according to the procedures set out in this Settlement Agreement and the Commission's Rules of Practice.
- 56. Staff and Crombie agree that this Settlement Agreement will form all of the agreed facts that will be submitted at the settlement hearing, unless the parties agree that additional facts should be submitted at the settlement hearing.
- 57. If the Commission approves this Settlement Agreement, Crombie agrees to waive all rights to a full hearing, judicial review or appeal of this matter under the Act.
- 58. If the Commission approves this Settlement Agreement, Crombie will not make any public statement that is inconsistent with this Settlement Agreement or with any additional agreed facts submitted at the settlement hearing provided however, that Crombie shall not be prohibited from making any statement or argument in the proceeding issued by the United States Securities and Exchange Commission involving

similar issues to those raised in this proceeding.

59. Whether or not the Commission approves this Settlement Agreement, Crombie will not use, in any proceeding, this Settlement Agreement or the negotiation or process of approval of this agreement as the basis for any attack on the Commission's jurisdiction, alleged bias, alleged unfairness, or any other remedies or challenges that may otherwise be available.

## PART VIII - DISCLOSURE OF SETTLEMENT AGREEMENT

- 60. If the Commission does not approve this Settlement Agreement or does not make the order attached as Schedule "A" to this Settlement Agreement:
  - this Settlement Agreement and all discussions and negotiations between Staff and Crombie before the settlement hearing takes place will be without prejudice to Staff and Crombie; and
  - (ii) Staff and Crombie will each be entitled to all available proceedings, remedies and challenges, including proceeding to a hearing of the allegations contained in the Statement of Allegations. Any proceedings, remedies and challenges will not be affected by this Settlement Agreement, or by any discussions or negotiations relating to this agreement.
- 61. Both parties will keep the terms of the Settlement Agreement confidential until the Commission approves the Settlement Agreement. At that time, the parties will no longer have to maintain confidentiality. If the Commission does not approve the Settlement Agreement, both parties must continue to keep the terms of the Settlement Agreement confidential, unless they agree in writing not to do so or if required by law.

# PART IX - EXECUTION OF SETTLEMENT AGREEMENT

- 62. The parties may sign separate copies of this agreement. Together, these signed copies will form a binding agreement.
- 63. A fax copy of any signature will be treated as an original signature.

Dated this 9th day of February, 2009

"Paul Le Vay"

Witness

"Brian H. Crombie"

Brian H. Crombie

Dated this 10th day of February, 2009

"Peggy Dowdall-Logie"

Staff of the Ontario Securities Commission Per: Peggy Dowdall-Logie Executive Director

# SCHEDULE "A" - DRAFT ORDER

# 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

ORDER (Sections 127 and 127.1)

WHEREAS on March 24, 2008 the Ontario Securities Commission (the "Commission") issued a Notice of Hearing and related Statement of Allegations (the "Notice of Hearing") against Biovail Corporation, Eugene N. Melnyk, Brian H. Crombie, John R. Miszuk and Kenneth G. Howling ("Howling");

**AND WHEREAS** Crombie has entered a settlement agreement with Staff of the Commission dated February \_\_\_\_\_, 2009 (the "Settlement Agreement") in relation to the matters set out in the Notice of Hearing;

**UPON** reviewing the Notice of Hearing and Settlement Agreement, and upon hearing submissions from counsel for Crombie and for Staff of the Commission;

**AND WHEREAS** the Commission is of the opinion that it is in the public interest to make this Order;

# **IT IS HEREBY ORDERED** that:

1. The Settlement Agreement is approved.

2. Crombie is reprimanded.

3. Crombie is prohibited from becoming or acting as a director or officer of a reporting issuer for a period of eight (8) years from the date of this Order.

4. Crombie shall cooperate with the Commission and Staff in this matter and shall appear and testify at the hearing in this matter if requested by Staff;

5. Crombie shall pay an administrative penalty of CAN \$250,000, to be paid to or for the benefit of third parties designated by the Commission, pursuant to section 3.4(2) of the Act.

6. Crombie shall pay CAN\$50,000 in respect of a portion of the costs of the investigation and hearing in relation to this matter.

Dated at Toronto this da

day of February, 2009