Public Competition Assessment

31 August 2010

Novartis AG - proposed acquisition of Alcon Laboratories Inc

Introduction

1. On 29 July 2010, the Australian Competition and Consumer Commission (**ACCC**) announced its decision not to oppose the proposed acquisition of Alcon Laboratories Inc (**Alcon**) by Novartis AG (**Novartis**) (the **proposed acquisition**), subject to section 87B undertakings accepted by the ACCC on 29 July 2010 (the **Undertakings**). The ACCC decided that the proposed acquisition, when considered in light of the undertakings, would be unlikely to have the effect of substantially lessening competition in any relevant market in Australia in contravention of section 50 of the *Trade Practices Act 1974* (the **Act**).

2. The ACCC made its decision on the basis of the information provided by the merger parties and information arising from its market inquiries. This Public Competition Assessment outlines the basis on which the ACCC has reached its decision on the proposed acquisition, subject to confidentiality considerations.

Public Competition Assessment

3. To provide an enhanced level of transparency and procedural fairness in its decision making process, the ACCC issues a Public Competition Assessment for all transaction proposals where:

   - a merger is opposed;
   - a merger is subject to enforceable undertakings;
   - the merger parties seek such disclosure; or
   - a merger is not opposed but raises important issues that the ACCC considers should be made public.

4. This Public Competition Assessment has been issued because Novartis' proposed acquisition of Alcon is subject to court enforceable undertakings.

5. By issuing Public Competition Assessments, the ACCC aims to provide the public with a better understanding of the ACCC's analysis of various markets and the associated merger and competition issues. It also alerts the public to the

circumstances where the ACCC's assessment of the competition conditions in particular markets is changing, or likely to change.

6. Each Public Competition Assessment is specific to the particular transaction under review by the ACCC. While some transaction proposals may involve the same or related markets, it should not be assumed that the analysis and decision outlined in one Public Competition Assessment will be conclusive of the ACCC's view in respect of other transaction proposals, as each matter will be considered on its own merits.

7. Public Competition Assessments are intended to outline to the general public the ACCC's principal reasons for reaching a decision on a proposed acquisition. As such they may not definitively explain all issues and the ACCC's analysis of such issues. Further, the ACCC's decisions generally involve consideration of both non-confidential and confidential information provided by the merger parties and market participants. In order to maintain the confidentiality of particular information, Public Competition Assessments do not contain any confidential information or its sources.

The parties

The acquirer: Novartis AG

8. Novartis is a global pharmaceutical company that specialises in the development, production, distribution and marketing of medical products.

9. In Australia, Novartis offers a wide range of healthcare products including branded and generic prescription medicines, over-the-counter medicines and animal health products.

10. In relation to eye care products, Novartis supplies contact lenses and lens care products, artificial tears and ocular lubricants, injectable miotics, allergic conjunctivitis and other ocular allergy treatment products and anti-glaucoma preparations.

The target: Alcon Laboratories Inc

11. Alcon is a global pharmaceutical company focused on eye care. Alcon develops, manufactures and markets pharmaceuticals, surgical equipment devices and consumer eye care products to treat diseases and disorders of the eye in more than 180 countries worldwide.

12. Alcon is a majority owned subsidiary of Nestle S.A. (**Nestle**) and is based in Switzerland. In Australia, Alcon is active in the areas of ophthalmic and miotic pharmaceuticals, ophthalmic surgical products, including surgical and diagnostic equipment, injectable miotic products, as well as contact lens care products.

Other market participants

Allergan Inc

13. Allergan Inc (**Allergan**) is a multi-specialty healthcare company that has a portfolio of eye care pharmaceuticals. Allergan supplies a range of eye care pharmaceuticals, including artificial tears and ocular lubricants, preparations for use with contact lenses, treatments for allergic conjunctivitis and other ocular allergies and anti-glaucoma preparations.

Bausch & Lomb Inc

14. Bausch & Lomb Inc (**Bausch & Lomb**) is a privately owned eye health company. Its core products include soft and rigid gas permeable contact lenses and lens care products, and ophthalmic surgical and pharmaceutical products, including a topical miotics product. Bausch & Lomb is headquartered in Rochester, New York. Its products are available in more than 100 countries, including Australia.

Johnson & Johnson Pacific Pty Ltd

15. Johnson & Johnson Pacific Pty Ltd (**Johnson & Johnson**) is a global pharmaceutical company which supplies consumer healthcare, pharmaceutical and surgical devices and diagnostic products and services. In relation to eye care products, Johnson & Johnson supplies a range of eye care products, notably treatments for ocular allergies, artificial tears and ocular lubricants.

The proposed transaction

16. On 4 January 2010, Novartis exercised a call option to purchase shares held by Nestle in Alcon. Novartis will become the majority shareholder in Alcon as a result of the proposed acquisition. The transaction will be effected worldwide, as Novartis and Alcon are each the ultimate holding companies of the respective Novartis and Alcon groups.

17. The proposed acquisition was considered by other national competition agencies and the ACCC consulted with these agencies regarding the proposed acquisition and divestiture occurring at the international level.

Timing

18. The following table outlines the timeline of key events in this matter.

Date	Event
8th April 2010	ACCC commenced review under the Merger Review Process Guidelines.
29th April 2010	Closing date for submissions from interested parties.
25th May 2010	ACCC timeline suspended to allow the ACCC to conduct further inquiries. Former proposed date for announcement of ACCC's findings of 27 May 2010 deferred.
16th July 2010	Divestiture proposal proffered by Novartis. ACCC commenced market inquiries on divestiture proposal. ACCC timeline recommenced.
29th July 2010	ACCC announced it would not oppose the proposed acquisition subject to undertakings. 87B undertakings accepted by the ACCC.

Market inquiries

19. The ACCC conducted market inquiries with a range of industry participants, including competitors, potential competitors, customers, industry bodies, other regulatory agencies and other interested parties. Submissions were sought in relation to the substantive competition issues and proposed undertakings.

The relevant markets

20. In Australia, Novartis and Alcon compete in a number of pharmaceutical product markets relating to eye care, including injectable miotics, preparations for use in contact lenses, artificial tears and ocular lubricants, anti-glaucoma preparations and allergic conjunctivitis treatments. The ACCC considered the effect of the proposed acquisition on markets relating to these eye care products.

21. The ACCC formed the view that there were separate national markets for the wholesale supply of:

- injectable miotics;
- artificial tears and ocular lubricants;
- preparations for use with contact lenses;
- allergic conjunctivitis and other ocular allergy treatments; and
- anti-glaucoma preparations.

22. In coming to the conclusion that each of these products constituted a distinct market, the ACCC considered the views of market participants regarding the clinical use and treatment profile, the mechanisms of action, the mode of administration and design, the active ingredient and the side effect profile of the products.

23. In relation to miotics, the ACCC considered a separate product market for injectable miotics, as other miotic products were unlikely to be considered as suitable substitutes. Miotics are designed for use in cataract surgery and cause the constriction (miosis) of the eye's pupil after delivery of the lens. The most common miotics are acetylcholine hydroxide, but other miotics include carbachol and pilocarpine. Miotics are typically administered via intraocular injection (**injectable miotics**), although they can be administered via eye drops (**topical miotics**).

24. The ACCC did not consider that topical miotics were substitutable for injectable miotics, and did not include them in the relevant product market. Injectable miotics induce rapid miosis of the pupil during ocular surgery. Topical miotics also induce miosis, but much more slowly, and are generally used in the treatment of glaucoma rather than for the purposes of surgery.

25. The ACCC considered that there was limited substitutability on the supply side between injectable miotics and topical miotics. The ACCC concluded that the appropriate product market was the market for injectable miotics.

26. In relation to the geographic scope of the relevant markets, the ACCC considered that, given that pharmaceutical manufacturers compete to market and supply products nationally, the appropriate basis on which to consider each of the product markets was national.

Competition analysis

Injectable miotics

27. The merger parties are the only suppliers of injectable miotics in Australia. Alcon supplies Isopto Carpine and Miostat, while Novartis supplies Miochol-E. The ACCC considered that barriers to entry in this market are high, particularly given the existence of patents in this market. The proposed acquisition would remove the only significant competitor to Novartis in the supply of injectable miotic products in Australia, and therefore lead to there being a single supplier of injectable miotics in Australia post acquisition.

28. Consequently, the ACCC considered that, by virtue of the proposed acquisition, the merged firm would have the ability and incentive to increase the price of its injectable miotics. The ACCC considered that the proposed acquisition was likely to result in a substantial lessening of competition in the national market for the wholesale supply of injectable miotics.

29. Novartis offered the ACCC court enforceable undertakings to address these competition concerns. The impact of the undertakings is discussed at paragraphs 39 - 48 below.

Artificial tears and ocular lubricants

30. Artificial tears and ocular lubricants are used for the relief of dry eyes and ocular irritations and come in the form of liquid drops, gels and ointments. Both Novartis and Alcon supply multiple brands in the market for the supply of artificial tears and ocular lubricants.[1] Allergan is a major supplier of artificial tears and ocular lubricants in Australia, and other smaller suppliers include Contact Lens Cent, Aspen, Johnson & Johnson, Biorevive and Sigma.

31. The proposed acquisition is likely to leave two large suppliers of artificial tears and ocular lubricants, being Allergan and the merged firm, and a number of smaller suppliers. The ACCC considered that the proposed acquisition was unlikely to result in a substantial lessening of competition as the merged firm would continue to face competition from Allergan as well as other smaller suppliers. The majority of products supplied in this market are not protected by patent which lowers the barriers to entry.

Preparations for use with contact lenses

32. In the market for the supply of preparations for use with contact lenses Novartis supplies AoSept and Aquify. Alcon supplies Opti-Free Express and Opti-Free Replenish. Other suppliers of contact lens care products are Bausch & Lomb, Abbott, Allergan and Aaxis Pacific.

33. The ACCC considered that the proposed acquisition would not lead to a substantial lessening of competition in this relevant market, as the merged firm would continue to face competition from other suppliers, particularly from Bausch & Lomb and Abbott.

Allergic conjunctivitis and other ocular allergy treatments

34. In the market for the supply of allergic conjunctivitis and other ocular allergy treatments, Novartis supplies Zaditen and Antistine-Privine. Alcon supplies Lomide, Naphcon-A, Naphcon Forte, Zinfrin and Patanol. Other suppliers of allergic conjunctivitis and other ocular allergy treatments include Johnson & Johnson, Aspen and Allergan.

35. The ACCC considered that the proposed acquisition was unlikely to bring about a substantial lessening of competition in this relevant market, as the merged firm's pricing decision would be constrained by the presence of at least three established competitors.

[1] Novartis supplies PAA, Genteal, Viscotears, HPMC PAA and *In A Wink*. Alcon supplies Duratears, Poly Tears, Poly Visc, Poly Gel, Tears Naturale, Systane, Systane Ultra and Bion Tears.

Anti-glaucoma preparations

36. Anti-glaucoma products are used to lower intraocular pressure which can damage the optic nerve. Novartis and Alcon each supply anti-glaucoma products. Other suppliers of these products include Pfizer, Allergan, Merck & Co and Sigma. The ACCC noted that the proposed acquistion would result in a very small aggregation in this product area. The ACCC considered that the proposed acquisition was unlikely to result in substantial lessening of competition in this market as the merged firm would be constrained by a number of competitors post acquisition.

Conclusion

37. On the basis of market inquiries and the information before it, the ACCC formed the view that the proposed acquisition would be likely to result in a substantial lessening of competition in the market for the wholesale supply of injectable miotics.

38. The ACCC did not identify competition concerns with respect to the wholesale supply of:

- artificial tears and ocular lubricants;
- preparations for use with contact lenses;
- allergic conjunctivitis and other ocular allergy treatments; and
- anti-glaucoma preparations.

Undertakings

39. On 29 July 2010 the ACCC accepted court enforceable undertakings offered by Novartis pursuant to section 87B of the Act. The undertakings were offered by Novartis to address the ACCC's competition concerns in the market for the wholesale supply of injectable miotics in Australia.

40. To address competition concerns identified by the United States Federal Trade Commission (**the FTC**), Novartis also put forward a remedy proposal to divest certain assets related to injectable miotic products in the United States. The undertakings offered to the ACCC were consistent with the remedy proposal offered to the FTC.

41. On 16 August 2010, the FTC announced its decision not to oppose the proposed acquistion, subject to the agreement given by Novartis to divest certain assets related to injectable miotics products to Bausch & Lomb.

42. The manufacturing of Novartis' injectable miotics products involves production steps in Germany, Switzerland and Belgium. The products are imported into Australia in a finished form with no manufacturing occurring in Australia. Novartis' Australian injectable miotics assets are largely used to supply and market the products in Australia.

43. Given that the manufacturing process occurs outside of Australia, the ACCC considered it necessary that Novartis' Australian injectable miotics assets were divested to the same purchaser as Novartis' global injectable miotics assets, provided this purchaser did not raise competition concerns in Australia.

44. The ACCC concluded that the divestment of the injectable miotics business in Australia by Novartis to Bausch & Lomb, would create a viable, effective, independent and long term competitor to the merged firm and thereby address the ACCC's competition concerns in the market for the supply of injectable miotics.

45. The undertakings require Novartis to divest to Bausch & Lomb necessary trademarks and other intellectual property rights relating to the marketing and/or sale in Australia of the divested products. Bausch & Lomb will acquire Novartis' injectable miotics business globally (including relevant manufacturing contracts), and will have the ability to manufacture the divested products under those contracts.

Conclusion on undertakings

46. The ACCC considered that the undertakings offered by Novartis satisfactorily addressed the competition concerns identified in the market for the wholesale supply of injectable miotics.

47. Accordingly, the ACCC considered that, in light of the undertakings offered by Novartis, a substantial lessening of competition in the national market for the wholesale supply of injectable miotics was unlikely.

48. A copy of the undertakings is available on the Undertakings Register (s.87B) at http://www.accc.gov.au. A copy is also included at Attachment A to this Public Competition Assessment.

Conclusion

49. On the basis of the above, including taking into account the enforceable undertakings, the ACCC formed the view that the proposed acquisition of Alcon by Novartis would not be likely to result in a substantial lessening of competition in any relevant market in contravention of section 50 of the Act.

Undertaking to the Australian Competition and Consumer Commission

Given under section 87B of the Trade Practices Act by Novartis AG

Clayton Utz
Lawyers
Levels 19-35 No. 1 O'Connell Street Sydney NSW 2000 Australia
PO Box H3 Australia Square Sydney NSW 1215
T +61 2 9353 4000 F +61 2 8220 6700

www.claytonutz.com

Our reference /15244

Contents

1. Person giving the Undertaking 3

2. Background 3

3. Defined terms and interpretation 5

3.1 Definitions in the Dictionary 5
3.2 Interpretation 5

4. Commencement and termination of Undertaking 5

4.1 Commencement 5
4.2 Termination 5

5. Sale of Injectable Miotics Australian Assets 6

6. Licences, permits, regulatory approvals and Third Party Consents 7

7. Preservation of the Injectable Miotics Australian Assets 8

7.1 Maintenance of the Injectable Miotics Australian Assets 8
7.2 Direction to personnel 8
7.3 Confidential Information 8
7.4 Novartis's obligations in relation to the Injectable Miotics Australian Assets 9

8. [Confidential - not for public register] 9

9. Independent audit 14

9.1 Proposed Auditor 14
9.2 Appointment of Approved Independent Auditor 15
9.3 Obligations relating to the Approved Independent Auditor 15
9.4 Compliance Audit 17
9.5 Resignation or termination of the Approved Independent Auditor 18

10. Information 18

11. Disclosure of Undertaking 19

12. Related Bodies Corporate 20

13. No Derogation 20

14. Costs 20

15. Notices 20

15.1 Giving Notices 20
15.2 Change of address or fax number 21

Schedule 1 - Injectable Miotics Australian Assets 23

Schedule 2 - Dictionary 24

1. Dictionary 24

2. Interpretation 26

Schedule 3 [Confidential - not for public register] **28**

Annexure 1 [Confidential - not for public register] **29**

1. Person giving the Undertaking

This Undertaking is given to the Australian Competition and Consumer Commission (**ACCC**) by Novartis AG together with its subsidiaries, including Novartis Pharmaceuticals Australia Pty Limited ACN 004 244 160 (**Novartis**), on behalf of itself and its subsidiaries.

Novartis AG is the ultimate holding company of the multinational group of pharmaceutical companies that comprise the Novartis Group, including six wholly owned subsidiaries in Australia.

2. Background

(a) On 4 January 2010, Novartis exercised a call option to purchase the shares held by Nestlé SA (**Nestlé**) in Alcon, Inc (**Alcon**) (the **Proposed Acquisition**). Novartis would become the majority shareholder in Alcon as a result of the Proposed Acquisition.

(b) In Australia, Novartis offers a wide range of healthcare products including branded and generic prescription medicines, over-the-counter medicines, contact lenses and lens care products, injectable miotic products and animal health products.

(c) Alcon focuses primarily on the vision sector, and is active in Australia in the areas of ophthalmic and miotic pharmaceuticals; ophthalmic surgical products, including surgical and diagnostic equipment, injectable miotic products, as well as contact lens care products.

The ACCC's review

(d) On 8 April 2010, the ACCC commenced its informal review of the Proposed Acquisition.

(e) The ACCC undertook market inquiries and considered information provided by the parties, industry participants and others. The ACCC's inquiries were aimed at assessing whether or not the Proposed Acquisition would have the effect or be likely to have the effect of substantially lessening competition in a market in contravention of section 50 of the *Trade Practices Act 1974* (the **Act**).

The ACCC's competition concerns

(f) Novartis and Alcon are the only suppliers of injectable miotic products in Australia. The ACCC is concerned that, in the absence of this Undertaking, the Proposed Acquisition would remove the only significant competitor to Novartis in Australia in the supply of injectable miotic products. The Proposed Acquisition would result in Novartis being the sole supplier of injectable miotics products in Australia.

(g) The ACCC considered that in the absence of this Undertaking, the Proposed Acquisition would have the effect or be likely to have the effect of substantially lessening competition in relation to the market for the supply of injectable miotics products.

The Federal Trade Commission

(h) The Federal Trade Commission (**FTC**) in the United States of America (US) initiated an investigation of the Proposed Acquisition.

(i) In order to avoid delay in securing clearance from the FTC, Novartis has committed to divest certain assets related to the Injectable Miotics Product, and pursuant to this commitment, Novartis has entered into the Miotics Divestiture Agreement to sell its Injectable Miotics Assets to Bausch & Lomb. This global divestment is evidenced by its inclusion as an Exhibit to a Consent Decree that will be issued by the FTC.

(j) The Consent Decree will manage the process of the sale of the Injectable Miotics Assets, including handling of confidential information and regulatory approvals for those assets.

(k) The Consent Decree contains provisions including: an Interim Monitor Provision (Order III), which provides for the appointment of an Interim Monitor to ensure Novartis expeditiously complies with all of its obligations and perform all of its responsibilities under the Consent Decree; a preservation of the business associated with the Injectable Miotics Product provision (Order II, J); and a Divestiture Trustee provision (Order IV), which provides for the appointment of a Divestiture Trustee in the event that Novartis has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Injectable Miotics Assets as required by the Consent Decree.

Proposed divestiture of Injectable Miotics Australian Assets

(l) Novartis does not consider that the Proposed Acquisition would be likely to substantially lessen competition in relation to the supply of injectable miotics products. However, in order to avoid delay and to address the ACCC's competition concerns, Novartis has, without admission, provided this Undertaking pursuant to section 87B of the Act.

(m) The objective of this Undertaking is to address the ACCC's competition concerns which would otherwise arise as a consequence of the Proposed Acquisition.

(n) The manufacturing of the Injectable Miotics Product involves steps of production in Germany, Switzerland and Belgium, with the Injectable Miotics Product being imported into Australia. The Injectable Miotics Product is then supplied in Australia using the Injectable Miotics Australian Assets.

(o) As part of the global divestments, the Injectable Miotics Assets, which includes the Intellectual Property used to manufacture Injectable Miotics Product, are being divested to a single global purchaser: Novartis is seeking approval to divest the Injectable Miotics Assets to Bausch & Lomb.

(p) Consistent with the global divestments, the ACCC requires the Injectable Miotics Australian Assets to be divested to the same purchaser as the Injectable Miotics Assets are being divested to globally, provided this purchaser does not raise competition concerns in Australia.

(q) Given that the manufacturing of the Injectable Miotics Product occurs globally, the Injectable Miotic Australian Assets that are to be divested consist of the Intellectual Property and inventory detailed in Schedule 1. These assets are used only to supply the Injectable Miotics Product in Australia.

(r) This Undertaking addresses the ACCC's competition concerns by:

(i) ensuring that the Injectable Miotics Australian Assets are sold to an ACCC Approved Purchaser who will supply the Injectable Miotics Product in Australia effectively;

(ii) creating or strengthening a viable, effective, stand-alone, independent and long term competitor for the supply of injectable miotics products in Australia;

(iii) ensuring that the purchaser of the Injectable Miotics Australian Assets has the necessary assets (including Intellectual Property and Product Approvals) to compete effectively with Novartis in the supply of injectable miotics products in Australia; and

(iv) enabling the purchaser of the Injectable Miotics Australian Assets to constrain Novartis in the supply of injectable miotics products including by increasing the price of products, or decreasing the quality of its service.

3. Defined terms and interpretation

3.1 Definitions in the Dictionary

A term or expression starting with a capital letter:

(a) which is defined in the Dictionary in Schedule 2 (**Dictionary**), has the meaning given to it in the Dictionary; and

(b) which is defined in the Corporations Act, but is not defined in the Dictionary, has the meaning given to it in the Corporations Act,

3.2 Interpretation

The interpretation clause in Schedule 2 sets out rules of interpretation for this Undertaking.

4. Commencement and termination of Undertaking

4.1 Commencement

This Undertaking comes into effect when:

(a) the Undertaking is executed by Novartis; and

(b) the Undertaking so executed is accepted by the ACCC.

4.2 Termination

(a) Subject to clause 4.2(b) this Undertaking terminates on the Final Date.

(b) Notwithstanding clause 4.2(a), this Undertaking terminates on the date the ACCC consents in writing to the withdrawal of this Undertaking in accordance with section 87B of the Act.

5. Sale of Injectable Miotics Australian Assets

(a) Subject to clause 6(c) below, Novartis will comply with the Consent Decree in relation to the Injectable Miotics Assets.

(b) No later than the Initial Divestiture Date, Novartis must, in accordance with this Undertaking, divest, or cause the divestiture of, the Injectable Miotics Australian Assets to the Approved Purchaser in accordance with the Miotics Divestiture Agreement.

(c) Nothing in the Miotics Divestiture Agreement will be taken to limit or contradict the terms of this Undertaking.

(d) The ACCC has approved, as a condition precedent to accepting this Undertaking, Bausch & Lomb as an Approved Purchaser of the Injectable Miotics Australian Assets on the basis of the following:

(i) Bausch & Lomb will complete the transaction contemplated by the Miotics Divestiture Agreement with Novartis (as amended and restated) by which Bausch & Lomb will acquire the Injectable Miotics Assets;

(ii) Bausch & Lomb is and will remain independent of, and has no direct or indirect interest in, Novartis;

(iii) Bausch & Lomb is of good financial standing and has an intention to maintain and use the Injectable Miotics Australian Assets and sell the Injectable Miotics Product in Australia;

(iv) Bausch & Lomb is able to supply the Injectable Miotics Product in Australia effectively; and

(v) the sale of the Injectable Miotics Australian Assets to Bausch & Lomb will address any competition concerns of the ACCC, including the likely long-term viability and competitiveness of the Injectable Miotics Australian Assets under the ownership of Bausch & Lomb.

(e) The ACCC may revoke its:

(i) acceptance of an Approved Purchaser; and/or

(ii) acceptance of this Undertaking,

if the ACCC becomes aware that the information provided to it was incorrect, inaccurate or misleading.

(f) Novartis must:

(i) enforce the terms of the Miotics Divestiture Agreement and any contract, arrangement or understanding with an Approved Purchaser under which an Approved Purchaser is obliged to acquire the Injectable Miotics Australian Assets; and

(ii) ensure that the Injectable Miotics Australian Assets are sold to an Approved Purchaser simultaneously with an Approved Purchaser's acquisition of the Injectable Miotics Assets.

6. Licences, permits, regulatory approvals and Third Party Consents

(a) Novartis must effect or obtain the transfer, subject to law, of all licences, permits and/or other regulatory approvals to an Approved Purchaser that are required by the Approved Purchaser in order to:

(i) maintain and use the Injectable Miotics Australian Assets; and

(ii) import into Australia, and supply in Australia, the Injectable Miotics Product.

(b) Novartis must:

(i) obtain or assist an Approved Purchaser to obtain all Third Party Consents before, or as soon as practicable after the Initial Divestiture Date;

(ii) comply with all requirements necessary to obtain any Third Party Consents, including by promptly providing information to the third party; and

(iii) act in good faith in its negotiations with an Approved Purchaser in relation to gaining any Third Party Consents.

(c) If, before the Initial Divestiture Date:

(i) the Approved Purchaser fails to obtain or is unable to obtain any licence, permit or other regulatory approval referred to in clause 6(a) above, then Novartis must continue to do everything in its power to satisfy clause 6(a) above as soon as possible after the Initial Divestiture Date (and until such time as clause 6(a) is satisfied); or

(ii) Novartis fails to obtain or is unable to obtain any Third Party Consents, then Novartis must provide the ACCC, at least 7 Business Days prior to the Initial Divestiture Date, with details of those licences, permits, approvals or third Party Consents (including reasons why approval, consent or transfer could not be given prior to that date, and what is required to obtain the approval, consent or transfer).

(d) Subject to clause 6(e), notwithstanding that Novartis has complied with clauses 6(b) and 6(c) of this Undertaking it remains a breach of this Undertaking if Novartis is unable to effect the divestiture of the Injectable Miotics Australian Assets by reason of a failure to obtain any Third Party Consents.

(e) Nothing in this Undertaking shall be construed as an attempt or agreement to assign any Injectable Miotics Australian Asset, including any Product Approvals, or other right, which by its terms or by law is non-assignable without the consent, authorisation, qualification or similar approval of a third party or a governmental authority or is cancellable by a third party in the event of an assignment unless and until such consents, authorisations, qualifications or approvals have been obtained.

7. Preservation of the Injectable Miotics Australian Assets

7.1 Maintenance of the Injectable Miotics Australian Assets

(a) From the Control Date, Novartis must not sell or transfer its interest, or any assets comprising part of, or used in, the business associated with the Injectable Miotics Australian Assets or make any Material Change, except in accordance with this Undertaking.

(b) Until the Divestiture Date, Novartis must take such actions as are necessary to:

(i) maintain the full economic viability, marketability and competitiveness of the business associated with the Injectable Miotics Product;

(ii) minimize any risk of loss of competitive potential for the business associated with the Injectable Miotics Product; and

(iii) prevent the destruction, removal, wasting, deterioration, or impairment of any of the Injectable Miotics Product except for ordinary wear and tear.

7.2 Direction to personnel

As soon as practicable after the Control Date, Novartis must in writing direct its personnel in Australia, including directors, contractors, managers, officers, employees and agents, not to do anything inconsistent with Novartis's obligations under this Undertaking.

7.3 Confidential Information

(a) Subject to clauses 7.3(b), 7.3(c) and 7.3(d), Novartis must not, at any time from the Control Date and for a period of 12 months after the end of the term of this Undertaking, use or disclose any confidential information about the Injectable Miotics Australian Assets gained through:

(i) the ownership and/or management of the Injectable Miotics Australian Assets; or

(ii) the provision of any services or Technical Assistance to, or through any interim supply or toll manufacturing arrangement with, the Approved Buyer of the Injectable Miotics Australian Assets.

(b) Clause 7.3(a) does not apply to information that Novartis requires to comply with legal and regulatory obligations, including obligations relating to:

(i) taxation;

(ii) accounting;

(iii) ASIC, Securities & Exchange Commission and stock exchange disclosure obligations; and

(iv) pharmacovigilance.

(c) Clause 7.3(a) does not apply to information that Novartis requires to carry out its obligations under this Undertaking, including its obligations to sell the Injectable Miotics Australian Assets, or to comply with legal and regulatory obligations, provided such information:

(i) is only made available to those officers, employees, contractors and advisers of Novartis who need to know the information for the purpose of ensuring compliance with the Undertaking or with legal and regulatory obligations; and

(ii) is not used for any other purpose.

(d) Clause 7.3(a) does not apply to information that relates to both the Injectable Miotics Australian Assets and to products or businesses retained by Novartis which cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Injectable Miotics Australian Assets. To the extent that this information exists, Novartis is permitted to use such information in connection with its retained products and businesses only.

7.4 Novartis's obligations in relation to the Injectable Miotics Australian Assets

Without limiting this clause 7.4 Novartis must, from the Control Date until the Divestiture Date (or other period specified) take all steps having regard to the nature of the Injectable Miotics Australian Assets to ensure that:

(a) existing arrangements, agreements, or contracts with customers, suppliers or other third parties that were in place at the Control Date relating to the Injectable Miotics Australian Assets continue, subject to any Material Changes made by Novartis to improve the operational efficiency of the Injectable Miotics Australian Assets and which are notified to the ACCC;

(b) Novartis does not directly or indirectly procure, promote or encourage the redeployment of personnel necessary for the operation of the Injectable Miotics Australian Assets as at the Control Date to any other business operated by Novartis;

8. Confidential clause 8

The details of clause 8 are confidential.

9. Independent audit

9.1 Proposed Auditor

(a) By no later than 10 Business Days before the Control Date, Novartis must identify a prospective independent auditor (**Proposed Auditor**) and provide the ACCC with written notice of the identity of the Proposed Auditor, together with such information and documents as the ACCC requires to assess whether to object to the appointment of the Proposed Auditor, including a copy of the proposed terms of appointment.

(b) The Proposed Auditor must be a person who has the qualifications and experience necessary to carry out the functions of the Approved Independent Auditor and is independent of Novartis and Alcon. The criteria by which the independence of the Proposed Auditor will be determined include whether the person is:

(i) a current employee or officer of Novartis or Alcon;

(ii) a person who has been an employee or officer of Novartis or Alcon in the past 3 years;

(iii) a person who, in the opinion of the ACCC, holds a material interest in Novartis or Alcon;

(iv) a professional adviser of Novartis or Alcon, whether current or in the past 3 years;

(v) a person who has a contractual relationship, or is an employee or contractor of a firm or company that has a contractual relationship with Novartis or Alcon, but for the terms of any Approved Independent Auditor agreement with Novartis;

(vi) a supplier, or a person who is an employee or contractor of a firm or company that is a supplier of Novartis or Alcon; or

(vii) a material customer of, or a person who is an employee or contractor of a firm or company that is a material customer of Novartis or Alcon.

9.2 Appointment of Approved Independent Auditor

If:

(a) within 5 Business Days of receipt by the ACCC of the written notice referred to in clause 9.1(a); or

(b) such further period as is required by the ACCC and notified to Novartis in writing prior to the expiration of the 5 Business Day period,

the ACCC informs Novartis that it:

(c) does not object to the Proposed Auditor, Novartis will:

(i) appoint the Proposed Auditor as the Approved Independent Auditor as soon as practicable, and by no later than the Control Date, on terms approved by the ACCC and consistent with the performance by the Approved Independent Auditor of his or her functions under this Undertaking, and

(ii) forward to the ACCC a copy of the executed terms of appointment; or

(d) does object to the Proposed Auditor, Novartis will:

(i) appoint a person identified by the ACCC at its absolute discretion as the Approved Independent Auditor on terms approved by the ACCC and consistent with the performance by the Approved Independent Auditor of his or her functions under this Undertaking; and

(ii) forward to the ACCC a copy of the executed terms of appointment.

9.3 Obligations relating to the Approved Independent Auditor

(a) Novartis must procure that the terms of appointment of the Approved Independent Auditor include obligations on the Approved Independent Auditor to:

(i) continue to satisfy the independence criteria in clause 9.1(b) for the period of his or her appointment;

(ii) provide any information or documents requested by the ACCC about Novartis's compliance with this Undertaking directly to the ACCC;

(iii) report or otherwise inform the ACCC directly of any issues that arise in the performance of his or her functions as Approved Independent Auditor or in relation to any matter that may arise in connection with this Undertaking; and

(iv) follow any direction given to him or her by the ACCC in relation to the performance of his or her functions as Approved Independent Auditor under this Undertaking.

(b) Without limiting the obligations in this Undertaking, Novartis must:

(i) provide a copy of the executed terms of appointment for the Approved Independent Auditor to the ACCC within 1 Business Day of their execution;

(ii) comply with and enforce the terms of appointment for the Approved Independent Auditor;

(iii) maintain and fund the Approved Independent Auditor to carry out his or her functions;

(iv) indemnify the Approved Independent Auditor for any expenses, loss, claim or damage arising directly or indirectly from the performance by the Approved Independent Auditor of his or her functions as the Approved Independent Auditor except where such expenses, loss, claim or damage arises out of the gross negligence, fraud, misconduct or breach of duty by the Approved Independent Auditor;

(v) not interfere with, or otherwise hinder, the Approved Independent Auditor's ability to carry out his or her functions as the Approved Independent Auditor;

(vi) provide and pay for any external expertise, assistance or advice required by the Approved Independent Auditor to perform his or her functions as the Approved Independent Auditor;

(vii) provide to the Approved Independent Auditor any information or documents requested by the Approved Independent Auditor that he or she considers necessary for carrying his or her functions as the Approved Independent Auditor or for reporting to or otherwise advising the ACCC;

(viii) not request any information relating to the compliance audit from the Approved Independent Auditor without such a request having been approved by the ACCC;

(ix) ensure that the Approved Independent Auditor will provide information or documents requested by the ACCC directly to the ACCC;

(x) ensure that the Approved Independent Auditor reports or otherwise informs the ACCC directly of any issues that arise in the performance of his or her functions as Approved Independent Auditor or in relation to any matter that may arise in connection with this Undertaking;

(xi) direct its personnel, including directors, contractors, managers, officers, employees and agents, to act in accordance with this clause 9.3;

(xii) from the Control Date, ensure that all relevant personnel are aware of the Approved Independent Auditor and the obligations in clause 9.3; and

(xiii) not appoint the Approved Independent Auditor, or have any agreements, understandings or arrangements with the Approved Independent Auditor, to utilise the Approved Independent Auditor's services for anything other than compliance with this Undertaking.

9.4 Compliance Audit

(a) Novartis will procure that the Approved Independent Auditor prepares the audit report set out in clause 9.4(b) below. The first audit report is to be provided within 30 Business Days after the Initial Divestiture Date and thereafter every 12 months until the termination of this Undertaking.

(b) The Approved Independent Auditor is to prepare a detailed report (**Auditor's Report**) on:

(i) Novartis's compliance with this Undertaking;

(ii) full reasons for the conclusions reached in the audit;

(iii) any qualifications made by the Approved Independent Auditor in forming his or her views; and

(iv) any recommendations by the Approved Independent Auditor to improve the integrity of the auditing process and any reasonable recommendations to improve Novartis's processes or reporting systems in relation to compliance with this Undertaking.

(c) Novartis must provide the ACCC with copies of the Auditor's Report within two Business Days of the Auditor's Report being received by Novartis.

(d) Novartis must require the Approved Independent Auditor to provide to the ACCC details of any possible failure to comply by Novartis with the obligations in this Undertaking immediately upon such a possible failure to comply coming to the attention of the Approved Independent Auditor.

(e) Novartis must implement any recommendations of the Approved Independent Auditor made pursuant to clause 9.4(b)(iv), and notify the ACCC of the implementation of the recommendations, within 10 Business Days of receiving the Auditor's Report or after a period agreed with the ACCC.

(f) Novartis must comply with any direction of the ACCC in relation to matters arising from the Approved Independent Auditor's report within 10 Business Days of being so directed (or such longer period as agreed with the ACCC).

(g) Notwithstanding this clause 9.4, the Approved Independent Auditor may report or otherwise inform the ACCC directly and immediately of any issues that arise in the performance of his or her engagement and functions as Approved Independent Auditor or in relation to compliance by Novartis with this Undertaking.

9.5 Resignation or termination of the Approved Independent Auditor

(a) Novartis must immediately notify the ACCC in the event that an Approved Independent Auditor resigns or otherwise stops acting as an Approved Independent Auditor before the termination of this Undertaking.

(b) The ACCC may approve any proposal by, or alternatively may direct, Novartis to terminate an Approved Independent Auditor if in the ACCC's view the Approved Independent Auditor acts inconsistently with the provisions of this Undertaking or the terms of his or her appointment.

(c) If either clauses 9.5(a) or 9.5(b) applies, the ACCC may nominate alternative auditor to be the Approved Independent Auditor.

(d) Novartis must, within 5 Business Days of the ACCC nominating an alternative Approved Independent Auditor:

(i) appoint an Approved Independent Auditor nominated by the ACCC on terms approved by the ACCC and consistent with the performance by the Approved Independent Auditor of his or her functions under this Undertaking; and

(ii) forward to the ACCC a copy of the executed terms of appointment.

10. Information

(a) Novartis must notify the ACCC in writing of the date of the proposed Control Date at least one week before the proposed Control Date.

(b) Novartis must notify the ACCC in writing of the occurrence of:

(i) the completion of the Proposed Acquisition within one Business Day of the Control Date; and

(ii) the divestiture of the Injectable Miotics Australian Assets within one Business Day of the Injectable Miotics Divestiture Date.

(c) Novartis must provide the ACCC with a copy of the executed Asset Purchase Agreement, and any other agreements between Novartis and the Approved Purchaser relating to the sale of the Injectable Miotics Australian Assets within one Business Day of any such agreement being executed.

(d) In respect of Novartis' compliance with this Undertaking, the ACCC may request the Interim Monitor and/or Divestiture Trustee to produce information, documents and materials to the ACCC that may be within the Interim Monitor's and/or Divestiture Trustee's (as the case may be) custody, power or control in the time and in the form requested by the ACCC.

(e) Novartis must respond in a timely manner to any queries or requests for information or documents made by the ACCC (including by a person authorised by the ACCC under Schedule 2, paragraph 2(o)) about this Undertaking.

(f) The ACCC may direct Novartis in respect of its compliance with this Undertaking to, and Novartis must:

(i) furnish information, documents and materials to the ACCC in the time and in the form requested by the ACCC;

(ii) produce information, documents and materials to the ACCC within Novartis's custody, power or control in the time and in the form requested by the ACCC; and/or

(iii) direct its personnel, including its directors, contractors, managers, officers, employees and agents, to attend the ACCC at a reasonable time and place appointed by the ACCC to answer any questions the ACCC (including its Commissioners, its staff or its agents) may have.

(g) In respect to Novartis's compliance with this Undertaking, the ACCC may request the Approved Independent Auditor or Divestiture Agent to:

(i) furnish information, documents and materials to the ACCC in the time and in the form requested by the ACCC;

(ii) produce information, documents and materials to the ACCC within the Approved Independent Auditor's or Divestiture Agent's custody, power or control in the time and in the form requested by the ACCC; and/or

(iii) attend the ACCC at a time and place appointed by the ACCC to answer any questions the ACCC (including its Commissioners, its staff or its agents) may have.

(h) Novartis will use its best endeavours to ensure that the Approved Independent Auditor or Divestiture Agent complies with any request from the ACCC in accordance with clause 10(g).

(i) Information furnished, documents and material produced or information given in response to any request or direction from the ACCC under this clause 10 may be used by the ACCC for any purpose consistent with the exercise of its statutory duties.

(j) Any direction made by the ACCC under clause 10(e) will be notified to Novartis, in accordance with clause 15.1.

(k) The ACCC may, in its discretion, to be exercised in good faith:

(i) advise the Approved Independent Auditor or Divestiture Agent of any request made by it under this clause 10; and/or

(ii) provide copies to the Approved Independent Auditor or Divestiture Agent of any information furnished, documents and material produced or information given to it under this clause 10.

(l) Nothing in this clause 10 requires the provision of information or documents in respect of which Novartis has a claim of legal professional or other privilege.

11. Disclosure of Undertaking

(a) Novartis and the ACCC agree that:

(i) Confidential Annexure 1 will remain confidential at all times;

(ii) Clause 8 will remain confidential until after the Initial Divestiture Date; and

(iii) Schedule 3 will remain confidential until after the Divestiture Date.

(b) Novartis acknowledges that the ACCC may, subject to clause 11(a):

(i) make this Undertaking publicly available;

(ii) publish this Undertaking on its Public Section 87B Undertakings Register; and

(iii) from time to time publicly refer to this Undertaking.

(c) Nothing in the confidential parts of this Undertaking referred to in clause 11(a) prevents the ACCC from disclosing such information as:

(i) is required by law;

(ii) is permitted by s 155AAA of the Act;

(iii) is necessary for the purpose of enforcement action under section 87B of the Act; or

(iv) is necessary for the purpose of making such market inquiries as the ACCC thinks fit to assess the impact on competition arising in connection with this Undertaking.

(d) Nothing in the confidential parts of this Undertaking prevents the ACCC from using the information contained in this Undertaking for any purpose consistent with its statutory functions and powers.

12. Related Bodies Corporate

Where the performance of an obligation under this Undertaking requires a Related Body Corporate of Novartis to take or refrain from taking some action, Novartis will procure that Related Body Corporate to take or refrain from taking that action, as the case may be.

13. No Derogation

(a) This Undertaking does not prevent the ACCC from taking enforcement action at any time whether during or after the period of this Undertaking in respect of any breach by Novartis of any term of the Undertaking.

(b) Nothing in this Undertaking is intended to restrict the right of the ACCC to take action under the Act for penalties or other remedies in the event that Novartis does not fully implement and/or perform its obligations under this Undertaking or in any other event where the ACCC decides to take action under the Act for penalties or other remedies.

14. Costs

Novartis must pay all of its own costs incurred in relation to this Undertaking.

15. Notices

15.1 Giving Notices

(a) Any notice or communication to the ACCC pursuant to this Undertaking must be sent to:

Name:	Australian Competition and Consumer Commission
Address:	23 Marcus Clarke Street CANBERRA ACT 2601
Fax number:	(02) 6243 1212
Attention:	Executive General Manager - Mergers and Acquisitions Group

(b) Any notice or communication to Novartis pursuant to this Undertaking must be sent to;

Name:	Novartis International AG
Address:	Novartis Campus, Lichtstrasse 35, CH-4056 Basel, Switzerland
Fax no:	+41 61 324 4300
Attention:	Susan Jones, Head Corporate Legal Antitrust
With a copy to:	
Name:	Novartis Pharmaceuticals Australia Pty Limited
Address:	54 Waterloo Road, North Ryde, NSW 2113
Fax number:	(02) 9805 3751
Attention:	Ray Steinwall, General Counsel

15.2 Change of address or fax number

If Novartis or the ACCC gives the other 3 Business Days' notice of a change to its address or fax number, any notice or communication is only given to the relevant entity if it is delivered, posted or faxed to the most recently advised address or fax number.

Signed by **Novartis AG** by its authorised signatory:

Signature of officer

Felix Senn
Authorized Signature

Full name of officer and office held

26.07.10

Date: July 2010

Signature of officer

Dr. Martin Henrich
Authorized Signatory

Full name of officer and office held

26.07.10

Date: July 2010

Accepted by **The Australian Competition and Consumer Commission** pursuant to section 87B of the Trade Practices Act 1974 (Cth):

Signature of officer

GRAEME SAMUEL

Full name of officer and office held

29th July 2010.

Date:

Signature of officer

Full name of officer and office held

Date:

Schedule 1 - Injectable Miotics Australian Assets

The Injectable Miotics Australian Assets in Australia includes:

(a) the following trade mark registrations in Australia

Trade Mark	Country	Registration No.	Owner
Miochol	Australia	429211(Australian registration)	Novartis AG
Miochol	Australia	890162 (Australian registration) 690308 (International registration)	Novartis AG

(b) Australia Patent No. 745124 - Methods and compositions for stabilizing acetylcholine compositions

(c) domain registration:

Domain name	Country	Owner	Expiry date
miochol.com.au	Australia	Novartis Pharmaceuticals Australia Pty Ltd	17 July 2012

(d) the Australian Register of Therapeutic Goods certification being Registration No. 118510 issued by the TGA to Novartis for the approval to supply the Injectable Miotics Product in Australia;

(e) the inventory of the Injectable Miotics Product as at the date of the transfer of the Australian Register of Therapeutic Goods certificate to Bausch & Lomb; and

(f) the product specification and associated artwork relating solely to the Injectable Miochol Product.