PATENTED MEDICINE PRICES REVIEW BOARD

IN THE MATTER OF the *Patent Act*,
R.S.C., 1985, c. P-4, as amended

AND IN THE MATTER OF
Alexion Pharmaceuticals Inc. ("Respondent")
and the medicine "Soliris"

ALEXION'S SUPPLEMENTARY RESPONSE TO BOARD STAFF'S AMENDED STATEMENT OF ALLEGATIONS

1. The Amended Statement of Allegations ("Amended Allegations") fundamentally change the liability theory of the case against Alexion. The proceeding as originally framed sought about $5 million in excess revenues based on alleged violation of the Highest International Price Comparison test (HIPC Test) found in the Guidelines, even though: the price of Soliris never increased after introduction; any perceived price increases were based on fluctuations in foreign currency exchange rates over which Alexion had no control; and Board Staff had previously represented to Alexion that the price of Soliris was "within Guidelines". Now, *after* Board Staff have had the opportunity to review Alexion's expert reports and witness statements, a new case is alleged seeking confiscation of up to $ million of Alexion's assets based on retroactive application of new tests, rules, and price sources not found in the Guidelines or any other law. Neither Alexion nor any other patentee could have anticipated, let alone complied with, unpublished rules in setting or maintaining prices in Canada.

Confiscation Contrary to Rule of Law, Fairness, and Reasonable Expectations

2. Several years after the Board's repeated statements that the introductory price of Soliris was *below* the National-Non-Excessive Price and "Within Guidelines", Board Staff now assert that the Board's earlier determinations were incorrect. Instead, Board Staff allege that both the "Introductory Maximum Non-Excessive Price" and the "National-Non-Excessive Average Price" calculations used to determine excess revenues should be based on the application of tests, and use of data sources, not found in the: *Patent Act* ("*Act*"); *Patented Medicines Regulations* ("*Regulations*"); Compendium of Policies, Guidelines and Procedures ("Guidelines"); or jurisprudence of the Board. The new liability theory is an outrageous attempt by the Board to retroactively confiscate Alexion's assets based on the application of previously unknown tests. This new liability theory is contrary to the rule of law and violates bedrock principles of fairness and due process.

3. The new allegations in paragraph 31 of the Amended Allegations run contrary to the Board's publications (including the Guidelines), established administrative practices at the time Soliris was introduced on the Canadian market in 2009, and explicit representations by the Board to Alexion after Soliris was introduced on the Canadian market. Alexion reasonably relied on these publications, practices, and representations in setting and maintaining the price of Soliris in Canada. The new theory of liability in the Amended Allegations, seeking retroactive application of unprecedented tests, belies representations by the Board to Alexion, the industry, and the public at large and undermines the Board's stated commitment to predictability, fairness, openness, and transparency.

4. The new allegations in paragraph 31 constitute unilateral changes to the Guidelines. The changes are contrary to the *Patent Act* and violate the Board's obligations to provide advance notice to, and consult with, patentees and the industry before instituting material changes to patentee liability. The retroactive liability theory advanced in the Amended Allegations has not been the subject of any previous notice or consultation and therefore contravenes section 96(5) of the *Patent Act*, the rules of natural justice, fairness, and the rule of law.

"Scenario "B", Option 2"

5. The left-hand column under Scenario "B" in the chart reproduced under paragraph 31 a) of the Amended Allegations (referred to as "Scenario "B" Option 2") purports to apply the Median International Price Comparison Test ("MIPC Test") retroactively between 2010 and 2015 to arrive at alleged excess revenues of $ based on prices reported to the Board under the *Regulations*.

6. There is no basis in law or the Guidelines for re-determining an introductory price based on the MIPC if, as in the case of Soliris, the product was sold in more than 5 other countries at the time of introduction. Furthermore, there is no basis in law or the Guidelines for retroactive adjustment of the MIPC Test to impose retroactive confiscatory liability on a patentee.

7. Before the Amended Allegations were allowed in early June 2016, there had been no notice to, or consultation with, the industry and other stakeholders about the possibility of retroactive liability under the MIPC Test, as expressly required by section 96(5) of the *Patent Act*.

8. Up until amendment of the Statement of Allegations in June 2016, neither Alexion, nor any other patentee, could have known that there was possible exposure to excess revenue allegations based on recalculation of prices using the MIPC Test, retroactive or otherwise.

"Scenario "B", Option 3"

9. The right-hand column under Scenario "B" in the chart reproduced under paragraph 31 a) of the Amended Allegations (referred to as "Scenario "B" Option 3") purports to apply a so-called Lowest International Price Comparison test ("LIPC Test") retroactively between 2010 and 2015 to arrive at an alleged excess revenue amount of $ based on prices reported to the Board under the *Regulations*.

10. There is no LIPC Test mentioned in the *Act*, the *Regulations*, or the Guidelines. No LIPC Test was mentioned at all in any publication of the Board at the time Soliris was introduced on the Canadian market in 2009. Before the Amended Allegations were permitted in early June 2016, there had been no notice to, or consultation with, the industry and other stakeholders about the possible application of an LIPC Test as expressly required by section 96(5) of the *Patent Act*.

11. There is no basis in law or the Guidelines for application of an LIPC Test to impose financial liability on a patentee. Retroactive imposition of confiscatory liability without notice offends the most basic principles of law.

12. In late June 2016, *after* the Panel's decision to permit the amendments was issued, the Board released a "Discussion Paper" soliciting comment on possible changes to the Guidelines, including whether the Board "should...set its excessive price

ceilings at the low end" of the seven comparator countries mentioned in the *Regulations*. This recent development is a signal admission of the Board's obligation to provide notice to, and seek consultation with, the industry and other stakeholders before instituting any rule changes and demonstrates that notice and consultation concerning even the possibility of an LIPC Test are only in the formative stages. The timing of release of the Discussion Paper also demonstrates that an LIPC test is being imposed on Alexion selectively, and retroactively, in a naked attempt to confiscate Alexion's assets contrary to the rule of law and in complete disregard of the principles of predictability, transparency, openness, and fairness that the Board purports to follow, and upon which Alexion and the industry rely.

"Scenario "C", Options "2" and "3" – IMS Data

13. The right-hand column under Scenario "C" of the chart reproduced under paragraph 31 a) of the Amended Allegations (referred to as "Scenario "B" Option 3") purports to apply the MIPC retroactively to arrive at alleged excess revenues of $ based on data obtained by Board Staff from IMS Health Incorporated ("IMS Data"), a private company that sells drug pricing information.

14. The left-hand column under Scenario "C" of the chart purports to apply an LIPC test retroactively based on IMS Data to arrive at alleged excess revenues of $.

15. Retroactive application of either the MIPC Test or an LIPC Test in Scenario "C" is improper for the reasons stated in paragraphs 4-11 above.

16. The *Regulations* prescribe, the practice and procedures of the Board follow, and Alexion and the industry rely upon, well-known and accepted price sources to apply the international price comparison tests found in the Guidelines. The price sources used to establish and maintain prices are "publicly available ex-factory prices" that must be reported twice yearly to the Board under the *Regulations*.

17. The IMS Data are privately collected prices that must be purchased from IMS and not "publicly available" information prescribed by the *Regulations*. Nothing in the *Act*, Guidelines, administrative practice, Board jurisprudence, or other law permits a departure from the "publicly available" price sources used to conduct international price comparisons.

18. The use of IMS Data in the Amended Allegations to inflate the calculation of allegedly excess revenues subject to confiscation by between $ and $ is as deeply flawed and outrageous an attempt at illegal confiscation as retroactive application of the MIPC or LIPC Tests. Alexion could not have known when it first introduced Soliris on the Canadian market that a different set of prices, other than what it was legally obligated to report under the *Act* and *Regulations*, would be used as a basis for alleging excessive prices and seeking retroactive confiscation of Alexion's assets. The Board has never notified or consulted with industry, even in the recent Discussion Paper, about changing the Guidelines to allow use of "IMS prices" as a substitute for publicly available prices prescribed by the *Regulations*.

19. The purported use of IMS Data in Board Staff's selective prosecution of Alexion to seek confiscation of Alexion's lawfully earned revenues is discriminatory, unfair, and contrary to the rule of law.

Price Reductions

20. Paragraph 31(c) of the Amended Allegations requests price reductions within 30 days of the Board's Order based upon an LIPC or, alternatively, the MIPC. Price reductions on either basis are unsupportable for the same reasons stated in paragraphs 4-19 above in relation to calculation of alleged excess revenues between 2009 and 2015. Price reductions based upon liability under *ad hoc* rules that have not been the subject of notice to, or consultation with, the industry and other stakeholders are inconsistent with: the Guidelines; the Board's previous practices and publications; fairness, natural justice, and due process; and the statutory requirements of section 96 (5) of the *Patent Act*.

Rules Against Retroactive Confiscation of Assets

21. For centuries, the common law has prohibited governmental confiscation of assets, particularly confiscation based on retroactive application of previously unpublished rules. There can be no taking of property without an express statement by Parliament and, in the case of federal Canadian law, a taking of property by the government invariably calls for payment of fair and reasonable compensation to the person whose property has been taken. The power of the government to retroactively confiscate property requires nothing short of absolute clarity of Parliament's authorization and intention to do so.

22. In this case, there are no rules in place permitting confiscation of Alexion's assets based on a modified MIPC Test, a new LIPC Test, or data sources not prescribed in the *Regulations*. The absence of any liability for confiscation in the first place makes retroactive application of such grounds devoid of principle and abhorrent to the rule of law.

23. The *Canadian Bill Of Rights* S.C. 1960. C. 44 prohibits the Board from interpreting or applying any statute to interfere with Alexion's property rights "except by due process of law." Confiscation of property based on *ad hoc* application of rules, or retroactive application of *ad hoc* rules, cannot be understood as "due process of law." Resort to such measures is inconsistent with the democratic rule of law in Canada.

24. International law also forbids confiscation of assets from foreign investors like Alexion, the patentee of Soliris. No asset can be expropriated from a foreign investor without notice and fair compensation: confiscation based upon unpublished or *ad hoc* rules violates international norms completely. One source of international law, the *North American Free Trade Agreement* (or *NAFTA*), requires in Article 1110 that expropriations be "non-discriminatory", in accordance with "due process of law", and comport with international minimum standards of treatment. The confiscation of assets contemplated by the Amended Allegations violates international law because: (a) the confiscation is discriminatory—no other patentee has ever been subject to application of such rules; (b) the foundation for the requested taking consists of retroactive application unpublished rules, tests, and sources that were not, and could not have been, known to Alexion, thus violating basic due process of law; and (c) international standards require publication, in plain terms, of all rules that may subject an investor to expropriation

and/or confiscation of assets which are indisputably violated in this case given the absence of any publication.

25. In summary, the Amended Allegations assert an entirely new (and novel) theory of liability, not merely a change in the quantum of penalties sought. The new case seeks retroactive application of rules contrary to: the common law (including principles of fairness, due process, and natural justice); principles of statutory interpretation (including the Canadian *Bill of Rights*), the regulatory context (including the *Patent Act*, Regulations and Guidelines), and even international law prohibiting confiscation of investor assets. The new allegations should be dismissed.

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Original signature redacted

Malcolm Ruby
GOWLING WLG (CANADA) LLP
1 First Canadian Place
100 King Street West, Suite 1600
Toronto ON M5X 1G5

Malcolm N. Ruby
Tel: 416-862-4314
Fax: 416-862-7661
malcolm.ruby@gowlingswlg.com

Alan West
Tel: 416-862-4308
Fax: 416-862-7661
alan.west@gowlingwlg.com

Lawyers for the Respondent

TO: **PATENTED MEDICINE PRICES REVIEW BOARD**
Legal Services Branch
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa ON K1P 1C1
Tel: (613) 952-7623
Fax: (613) 952-7626

Guillaume Couillard *(Secretary of the Board)*
guillaume.couillard@pmprb-cepmb.gc.ca

Delia Lewis *(Legal Counsel PMPRB)*
parul.shah@pmprb-cepmb.gc.ca

AND TO: **PERLEY-ROBERTSON HILL & MCDOUGAL LLP**
340 Albert Street, Suite 1400
Ottawa, ON K1R 7Y6
Tel: (613) 566-2833
Fax: (613) 238-8775

David Migicovsky
dmigicovsky@perlaw.ca

Christopher Morris
cmorris@perlaw.ca

Lawyers for Board Staff

AND TO: **MINISTRY OF JUSTICE**
Legal Services Branch
PO Box 9280 STN PROV GOVT
1001 Douglas Street
Victoria, BC V8W 9J7
Tel: (250) 356-893
Fax: (250) 356-8992

Ms. Sharna Kraitberg
Sharna.Kraitberg@gov.bc.ca

Lawyer for Her Majesty the Queen in Right of the Province of British Columbia, as represented by the Minister of Health
Representative for the Interveners, the Provinces of Manitoba, Ontario, and Newfoundland and Labrador

AND TO: **CANADIAN LIFE AND HEALTH INSURANCE ASSOCIATION**
79 Wellington St. West, Suite 2300
P.O. Box 99, TD South Tower
Toronto, ON M5K 1G8
Tel: (416) 777-2221
Fax: (416) 777-1895

Craig Anderson
CAnderson@clhia.ca
Lawyer for Canadian Life and Health Insurance Association