VOLUNTARY COMPLIANCE UNDERTAKING OF

CELGENE CORPORATION ("Celgene")

TO THE PATENTED MEDICINE PRICES REVIEW BOARD ("PMPRB")

1. Product Summary

1.1 Thalomid® brand drug (thalidomide capsules) in combination with melphalan and prednisone (MPT) is approved in Canada for the treatment of patients with previously untreated multiple myeloma who are 65 years of age or older.

1.2 Sales of thalidomide 50 mg capsules to Canadian patients by Celgene began under the provisions of the Health Canada Special Access Programme (SAP) as early as 1993.

1.3 On August 4, 2010 Health Canada granted a Notice of Compliance (NOC) for the marketing authorization of Thalomid 50 mg capsules. At that time Health Canada also approved Thalomid 100 mg and 200 mg capsules. For purposes of this VCU, "Thalomid" refers to thalidomide capsules sold or distributed in Canada by Celgene Corporation or Celgene Inc., both pre- and post- NOC. Celgene Inc. is the Canadian subsidiary of Celgene Corporation.

1.4 The first Canadian patent (No. 2,166,315) for Thalomid was issued in 2006 but was laid open to the public January 12, 1995 (i.e., the PCT publication date of the corresponding patent application). Accordingly, the PMPRB's jurisdiction over the price Thalomid 50 mg commenced as of January 12, 1995 (the patent laid open date). Currently, the last Canadian patent (No. 2,505,964) pertaining to Thalomid (all strengths) as reported by Celgene will expire on November 13, 2023.

1.5 In accordance with the *Patented Medicines Regulations* and the 2011 decision of the Supreme Court of Canada, Celgene Corporation and Celgene Inc. filed price and sales data for the SAP sales from 1995 forward. The filing also provided information on the quantities of Thalomid provided to Canadian patients on a compassionate basis, free of charge.

2. Application of the Excessive Price Guidelines

2.1 In 1995, there were a number of major uses of Thalomid under the SAP. Where there is more than one use for a new patented medicine, the Guidelines require that the

primary use be determined. Based on the availability of randomized trials in aphthous and genital ulcers in recalcitrant patients, as well as in patients with HIV for which orogenital ulcerations represents significant morbidity, the Human Drug Advisory Panel (HDAP) recommended aphthous ulcers as the primary use of Thalomid. The HDAP did not identify any comparators. As a new medicine in 1995, the introductory price of Thalomid 50 mg was considered to be within the Board's Guidelines. At the time, it was not possible to conduct a therapeutic class comparison test (no comparators) nor were there any publicly available prices with which to conduct an international price comparison test.

2.2 For purposes of the PMPRB jurisdiction, Thalomid was provided to Canadian patients through SAP from 1995 to 2010. Over the SAP period, the majority of Thalomid capsules were distributed free of charge. However, for the 50 mg capsules that were sold to patients during the SAP period, the average transaction price exceeded the Guidelines because the average transaction price increased by more than the change in the Consumer Price Index (CPI) over the same period, triggering the PMPRB investigation criteria.

2.3 Following the issuance of the NOC in 2010, because the indication approved by Health Canada for Thalomid was different than the indication for which the price was reviewed in 1995, the HDAP reviewed Thalomid in 2010. The HDAP classified Thalomid 50 mg as a medicine offering "slight/no improvement" when compared to Velcade and identified Velcade as a comparable medicine for purposes of conducting a therapeutic class comparison (TCC) test.

2.4 The post-NOC price of $31.3500 per 50 mg capsule was reviewed with reference to the TCC test as well as the international price comparison (IPC) test and was considered to be within the Guidelines.

2.5 Thalomid 100 mg and 200 mg began to be sold in the first half of 2011; the prices of $62.7000 and $125.4000, respectively, were within the Guidelines.

3. Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Celgene that the price of Thalomid 50 mg was excessive for purposes of the *Patent Act.*

4. Terms of the Voluntary Compliance Undertaking

4.1 In order to comply with the Guidelines, Celgene Corporation undertakes as follows:

a) To make a payment of $10,000,000 to Her Majesty in right of Canada within 30 days of the acceptance of this VCU;

b) To ensure through Celgene Inc that the average transaction prices of Thalomid 50 mg, 100 mg and 200 mg in Canada are at or below the following levels effective January 1, 2012 and in each subsequent year while under the jurisdiction of the PMPRB

- 50 mg - $ 29.6100
- 100 mg - $ 59.2200
- 200 mg - $118.4400

c) To maintain through Celgene Inc compassionate programmes to provide eligible Canadian patients with access to Celgene patented drug products (Thalomid and Revlimid®

4.2 Celgene Inc. undertakes to comply fully with the provisions of paragraph 4.1 and implement any necessary measures in a timely manner to ensure full compliance no later than the end of 2017.

4.3 To ensure that the price of Thalomid is within the Guidelines in all future reporting periods in which Thalomid remains under the PMPRB's jurisdiction.

Signature:	Original singed by
Name:	Robert J. Hugin
Position:	Chairman and CEO
Company:	Celgene
Date:	12/21/2011