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

AND IN THE MATTER OF Amgen
Canada Inc. and the medicine "Neulasta"

VOLUNTARY COMPLIANCE UNDERTAKING

1.0 Product Summary

1.1 Neulasta (pegfilgrastim) is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive antineoplastic drugs.

1.2 Health Canada issued a Notice of Compliance to Amgen Canada Inc. ("Amgen") for Neulasta on March 12, 2004. Amgen began selling Neulasta in Canada on April 12, 2004.

2.0 Patents and Reporting Compliance

2.1 Canadian Patent Nos. 1,297,004, 1,297,005, 1,312,569, 1,339,071, 1,341,537 and 2,178,752 pertain to Neulasta.

2.2 Amgen is, for the purposes of the Patented Medicine Prices Review Board (the "Board"), considered as the Canadian patentee.

2.3 In accordance with the *Patented Medicines Regulations* or predecessor versions, as applicable ("Regulations"), Amgen began filing its price and sales information for Neulasta on May 28, 2004 and has since continued to file its price and sales information in accordance with the Regulations.

3.0 Terms of the Undertaking

3.1 This Voluntary Compliance Undertaking ("VCU") is being made for purposes of resolving the issues relating to the pricing and sale of Neulasta and compliance with the *Patent Act* in respect thereof to date and as a result of settlement discussions with Board Staff. This VCU constitutes no admission by Amgen that the price of Neulasta in Canada is now, or was at any time since the date of the first sale of the medicine, in non-compliance with the Board's *Compendium of Guidelines, Policies and Procedures* ("Guidelines") or the *Patent Act*.

3.2 Board Staff and Amgen agree that, for purposes of the Board's Guidelines, Neulasta is properly classified as a Category 3 new medicine.

3.3 Accordingly, Board Staff and Amgen agree that the application of a domestic Therapeutic Class Comparison ("DTCC") pricing test is appropriate in the circumstances, and that the appropriate comparator is Amgen's Neupogen (filgrastim) product.

3.4 Board Staff and Amgen agree, for purposes of settlement and without admission by either Board Staff or Amgen, to a setting of the introductory maximum price of Neulasta in Canada based on a dosing of the comparator Neupogen of 5 µg/kg/day for 11 days using an average patient weight of 73.2 kg.

3.5 A dosing regimen of 5 µg/kg/day for 11 days is consistent with Neupogen's product monograph, as approved by Health Canada, and with utilization patterns of Neupogen in six head-to-head randomized controlled trials comparing Neulasta to Neupogen.

3.6 Similarly, the average patient weight of 73.2 kg was calculated based on the measured weight of all intent-to-treat patients in the six Neulasta registration trials, referenced in paragraph 3.5 above, and in one published post-registration trial. Together, these seven randomized, controlled trials provide a sample of over 1,700 patients. All of these trials concerned the approved indication for Neulasta, as set out in paragraph 1 above. Board Staff and Amgen further agree that, for the purposes of the Board's Guidelines, it is appropriate to apply the CPI-Adjustment Methodology to the price of Neulasta for all subsequent reporting periods.

3.7 Consequently, for the purposes of settlement and without admission by Amgen that the price of Neulasta in Canada is now, or was at any time since the date of the first sale of the medicine, in non-compliance with the Guidelines or the *Patent Act*,

3.7.1 Amgen agrees to the following maximum prices per syringe:

Period	Maximum Price per Syringe
April-June 2004	$2,042.7105
July-December 2004	$2,042.7105
2005	$2,087.6501
2006	$2,130.5471
2007	$2,175.4867
2008	$2,225.4350

2009	$2,269.0327

3.7.2 Amgen shall cause the maximum price at which it sells Neulasta in Canada to be reduced to the 2009 maximum price, within thirty (30) days of the acceptance of this VCU by the Board;

3.7.3 Amgen undertakes to make a payment to Her Majesty the Queen in right of Canada in the amount of $6,730,120.32 to offset any revenues above the maximum prices from date of introduction to June 30, 2009, such payment to be made no later than thirty (30) days after acceptance of this VCU by the Board;

3.7.4 to offset any revenues greater than the 2009 maximum price received by Amgen during the period commencing July 1, 2009 to the date on which the price reduction referred to in subsection 3.7.2 comes into effect, Amgen undertakes to make a payment to Her Majesty the Queen in Right of Canada equal to the amount by which the average transaction price ("ATP") of Neulasta as reported pursuant to the Regulations for the semi-annual period July 1, 2009 to December 31, 2009 is greater than the 2009 maximum price multiplied by the number of units of Neulasta sold during that period, such payment to be made within thirty (30) days of the filing of the price and sales data for Neulasta for such period.

3.8 For years following 2009, Amgen undertakes to ensure that the price of Neulasta remains within the Guidelines in all future periods in which Neulasta remains under the Board's jurisdiction.

DATED at Toronto, Canada, this 13th day of October, 2009.

AMGEN CANADA INC.

Conor D. M. McCourt
Torys LLP
Counsel to Amgen Canada Inc.
As authorized by Amgen Canada Inc.