STATUS DECISION OF CONTROLLED
AND NON-CONTROLLED SUBSTANCE(S)

Substance: I - Boceprevir
       II - Telaprevir

Based on the current information available to the Office of Controlled Substances, it appears that
the above substance is:

    Controlled    □
    Not Controlled ✔

under the schedules of the Controlled Drugs and Substances Act (CDSA) for the following
reason(s):

    • The substances are not listed in the Schedules to the CDSA and are not similar to
      any of the substances included in the CDSA.

Prepared by: _______________________________  Date: July 8, 2011
            Zack Li

Verified by: _______________________________  Date: __________
            Mark Kozlowski

Approved by: _______________________________  Date: __________
            DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: “third party information removed as per agreement with applicant”
Drug Status Report

**Drug:** I - Boceprevir  
II - Telaprevir

**Drug Name Status:** I - Boceprevir  
II - Telaprevir are proper (INN) names.

**Chemical Name:** I - 3-Azabicyclo(3.1.0)hexane-2-carboxamide, N-(3-amino-1-(cyclobutylmethyl)-2,3-dioxopropyl)-3-((2S)-2-(((1,1-dimethylethyl)carbonyl)amino)-3,3-dimethyl-1-oxobutyl)-6,6-dimethyl-, (1R,2S,5S)-  
II - Cyclopenta(c)pyrrole-1-carboxamide, (2S)-2-cyclohexyl-N-(pyrazinylcarbonyl)glycyl-3-methyl-L-valyl-N-((1S)-1-((cyclopropylamino)oxoacetyl)butyl)octahydro-, (1S,3aR,6aS)-

**Other Names:** I - (1R,2S,5S)-N-(3-Amino-1-(cyclobutylmethyl)-2,3-dioxopropyl)-3-((2S)-2-(((1,1-dimethylethyl)carbamoyl)amino)-3,3-dimethylbutanoyl)-6,6-dimethyl-3-azabicyclo(3.1.0)hexane-2-carboxamide; Victrelis; EBP 520; SCH 503034; UNII-89BT58KELH  
II - Incivek; LY 570310; MP 424; VRT 111950; VX 950

**Chemical structure:**

![Chemical structures of Boceprevir (I) and Telaprevir (II)](image)

**Molecular Formula:** I - C_{27}H_{45}N_{5}O_{5}; II - C_{36}H_{53}N_{5}O_{6}
**CAS RN:** I - 394790-60-0; II - 402957-28-2

**Pharmacological class / Application:** Antiviral

**International status:**

US: The substances are not currently listed on the schedules to the US Controlled Substances Act and is not mentioned on the DEA website.

United Nations: The substances are not listed on the Yellow List - List of Narcotic Drugs under International Control, the Green List - List of Psychotropic Substances under International Control, nor the Red List - List of Precursors and Chemicals Frequently Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances Under International Control.

Canadian Status: Boceprevir and telaprevir are Hepatitis C virus (HCV) protease inhibitors used for the treatment of hepatitis C infections\(^1\)\(^2\). The substances are not listed in the CDSA and are not structurally similar to any of the substances included in the schedules to the CDSA.

Recommendation: Boceprevir and telaprevir are not included in the schedules to the CDSA and are not controlled substances.

**Date:** July 8, 2011

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