

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	Group Art Unit: 1629
Inventors: Joseph J. Buggy, <i>et al.</i>	Confirmation No.: 7251
Serial No.: 13/340,522	Examiner: RAMACHANDRAN, U.
Filed: December 29, 2011	Customer No.: 21971
Title: THE USE OF BRUTON'S TYROSINE KINASE (BTK)	<hr/> <p style="text-align: center;"><u>Certificate of Electronic Filing</u></p> <p>I hereby certify that the attached Response and all marked attachments are being deposited by Electronic Filing on February 4, 2013 by using the EFS – Web patent filing system and addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</p> <p>By: <u>/Kelley Brown/</u> Kelley Brown</p>

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir/Madam:

Responsive to the Requirement for Restriction and Election of Species, mailed on January 3, 2013, Applicants hereby elect **Group II with traverse** and provide an election of species. This Response is being filed within the shortened one-month statutory period for reply. Therefore, this response is timely filed and no fee should be due. The Commissioner is authorized to charge any fees which may be due in connection with the application to Deposit Account No. 23-2415, referencing Docket No. 25922-819.301. Consideration of the above-referenced application is respectfully requested in view of the following remarks.

Amendments to the Claims begin on page 3.

Remarks begin on page 4.

Conclusion is on page 6.

AMENDMENTS TO THE CLAIMS

Please amend claims 131, 132, and 134-144. Please cancel claims 130 and 133. Please add new claims 145-149. This listing of claims replaces all prior versions and listings of claims in the above-referenced patent application. The following amendments do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed.

Applicants reserve the right to pursue the subject matter of the canceled claims in this or any other appropriate patent application. Deletions are denoted by ~~striketrough~~ and additions are denoted by underline.

Listing of Claims

1. -129. (Cancelled)

130. (Canceled).

131. (Currently Amended) A method for treating a relapsed or refractory hematological malignancy in an individual comprising administering to the individual an inhibitor of Bruton's tyrosine kinase (Btk).

132. (Currently Amended) ~~[[A]] The method for treating a~~ of claim 131, wherein the relapsed or refractory hematological malignancy is a relapsed or refractory non-Hodgkin's lymphoma in an individual comprising administering to the individual an inhibitor of Bruton's tyrosine kinase (Btk).

133. (Canceled).

134. (Currently Amended) The method of ~~any of claims 130-133~~ claim 131, wherein the inhibitor of Btk is administered orally.

135. (Currently Amended) The method of ~~any of claims 130-133~~ claim 131, wherein the inhibitor of Btk is administered once per day, twice per day, or three times per day.

136. (Currently Amended) The method of ~~any of claims 130-133~~ claim 131, wherein the inhibitor of Btk is administered daily or every other day.

137. (Currently Amended) The method of ~~any of claims 130-133~~ claim 131, further comprising administering a second cancer treatment regimen.

138. (Currently Amended) The method of claim ~~[[138]]~~ 137, wherein the second cancer treatment regimen comprises bendamustine, bortezomib, CAL-101, chlorambucil, cyclophosphamide,

dexamethasone, docetaxel, doxorubicin, endostatin, everolimus, etoposide, fludarabine, fostamatinib, hydroxydaunorubicin, ibritumomab, ifosfamide, lenalidomide, mesalazine, ofatumumab, paclitaxel, pentostatin, prednisone, rituximab, temsirolimus, thalidomide, tositumomab, vincristine, or a combination thereof.

139. (Currently Amended) The method of ~~any of claims 130-133~~ claim 131, wherein the amount of the inhibitor of Btk is between 1.25 -17.5 mg/kg/day.

140. (Currently Amended) The method of claim ~~[[133]]~~ 131, wherein >95% of the Btk is occupied by the inhibitor of Btk at 4 hours post dose.

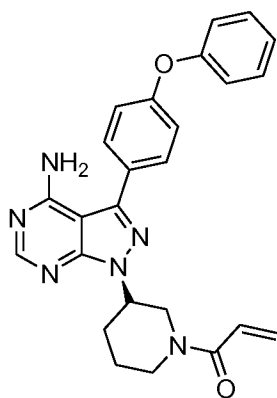
141. (Currently Amended) The method of ~~any of claims 130-133~~ claim 131, wherein the inhibitor of Btk is an irreversible inhibitor of Btk.

142. (Currently Amended) The method of ~~any of claims 130-133~~ claim 131, wherein the inhibitor of Btk forms a covalent bond to a Btk.

143. (Currently Amended) The method of ~~any of claims 130-133~~ claim 131, wherein the inhibitor of Btk forms a covalent bond to a cysteine sidechain of a Bruton's tyrosine kinase (Btk).

144. (Currently Amended) The method of ~~Claim~~ claim 143, wherein the cysteine sidechain of the Btk is cysteine 481.

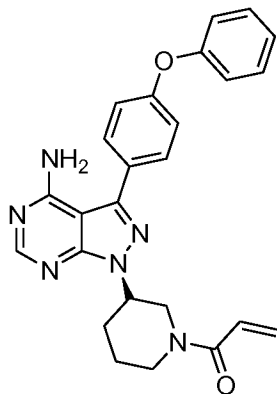
145. (New) The method of claim 131, wherein the inhibitor of Btk is a compound having the structure



146. The method of claim 132, wherein the relapsed or refractory non-Hodgkin's lymphoma is a relapsed or refractory diffuse large B-cell lymphoma (DLBCL), relapsed or refractory mantle cell lymphoma (MCL), relapsed or refractory follicular lymphoma (FL), relapsed or refractory chronic

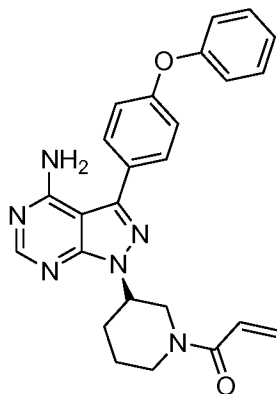
lymphocytic leukemia (CLL), relapsed or refractory small lymphocytic leukemia (SLL), or relapsed or refractory multiple myeloma (MM).

147. (New) A method for treating a relapsed or refractory non-Hodgkin's lymphoma in an individual comprising administering to the individual an inhibitor of Bruton's tyrosine kinase (Btk), having the structure



148. (New) The method of claim 147, wherein the relapsed or refractory non-Hodgkin's lymphoma is a relapsed or refractory diffuse large B-cell lymphoma (DLBCL), relapsed or refractory mantle cell lymphoma (MCL), or relapsed or refractory follicular lymphoma (FL), relapsed or refractory chronic lymphocytic leukemia (CLL), relapsed or refractory small lymphocytic leukemia (SLL), or relapsed or refractory multiple myeloma (MM).

149. (New) A method for treating a relapsed or refractory mantle cell lymphoma in an individual comprising administering to the individual an inhibitor of Bruton's tyrosine kinase (Btk), having the structure



REMARKS

Any fees that may be due in connection with the filing of this paper or with this application may be charged to Deposit Account No. 23-2415. If a Petition for Extension of time is needed, this paper is to be considered such Petition.

Claims 131, 132, and 134-149 are pending. Claims 131, 132, and 134-144 are amended. Claims 130 and 133 are canceled. New claims 145-149 are added. Claim 131 is amended to provided proper antecedent basis for now dependent claim 132. Basis for the amendment can be found, for example, in paragraphs [0004], [0047], and [0171], in the specification as filed. Claim 132 is amended to depend from claim 131. Claims 134-143 are amended to correct claim dependency. Claim 144 is amended to correct a typographical error. Basis for new claims 144-149 can be found in the application and claims as originally filed. No new matter is added.

Restriction Requirement

The Examiner has required restriction among the following groups.

Group I: Claims 130, 133-146 directed towards a method for treating a lymphoma in an individual comprising administering to the individual an inhibitor of Bruton's tyrosine kinase (Btk), wherein the lymphoma is a Cutaneous B-Cell Lymphoma, Cutaneous Marginal Zone Lymphoma (MZL), Diffuse Mixed Small and Large Cell Lymphoma, Diffuse Small Cleaved Cell, Diffuse Small Lymphocytic Lymphoma, Endemic Burkitt's lymphoma, Follicular Large Cell (Grade 3), Follicular Mixed Small Cleaved and Large Cell (Grade 2), Follicular Small Cleaved Cell (Grade 1), immunoblastic large cell lymphoma, indolent lymphoma, intravascular large B cell lymphoma, Intravascular Lymphomatosis, Large Cell Immunoblastic Lymphoma, Large Cell Lymphoma (LCL), low-grade small B-cell lymphoma Lymphoblastic Lymphoma, lymphoplasmocytic lymphoma, Mediastinal Large B-Cell Lymphoma, precursor B-Lymphoblastic lymphoma, primary central nervous system (CNS) lymphoma, primary mediastinal B-cell lymphoma, or Sporadic Burkitt's Lymphoma, further comprising a second cancer treatment (claim 138) and dosage regimen..

Group II: Claims 131, 133-144, 147, and 148 directed towards a method for treating a refractory hematological malignancy in an individual comprising administering to the individual an inhibitor of Bruton's tyrosine kinase (Btk).

Group III: Claims 131, 133-144, 149, and 150 directed towards a method for treating a relapsed or refractory non-Hodgkin's lymphoma in an individual comprising administering to the individual an inhibitor of Bruton's tyrosine kinase (Btk).

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