

Updated Feasibility Study on the Disclosure of INN in Patent Applications and Patents

Standing Committee on the Law of Patents (SCP)
Twenty-eighth session (July 9 to 12, 2018)

Presentation by the Secretariat

Feasibility study on the disclosure of INN (SCP/21/9)

INN: Unique, universal nonproprietary name to identify a pharmaceutical substance; widely used by health professionals

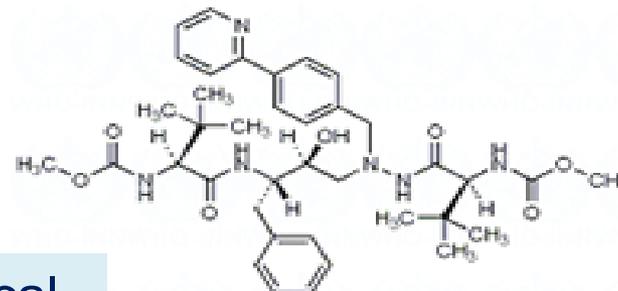
- ex. ibuprofen, paracetamol, atazanavir, sofosbuvir

Currently, an applicant may choose any indication as long as the invention is sufficiently disclosed.

atazanavir
(INN) 198904-31-3
(CAS Reg. number)

BMS-232632
(manufacturer name) C₃₈H₅₂N₆O₇
(Molecular formula)

Methyl N-[[[(1S)-1-[[[(2S,3S)-3-hydroxy-4-[2S]-2-[(methoxycarbonyl)amino]-3,3-dimethyl-N'-{[4-(pyridin-2-yl)]..... (IUPAC chemical name)

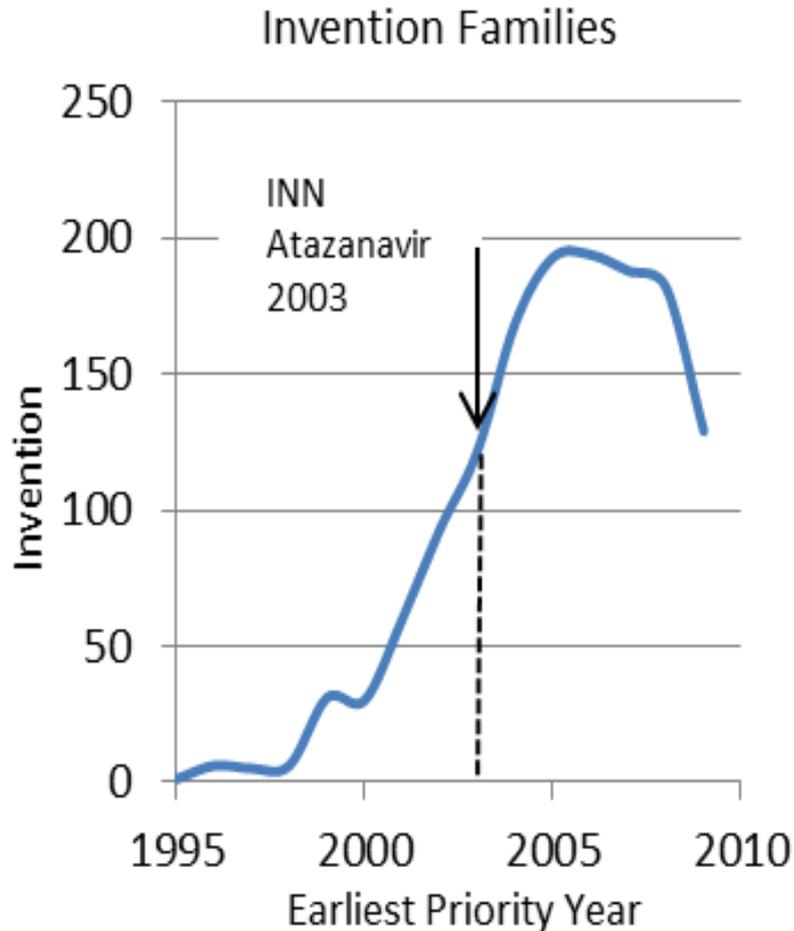


(Chemical structure)

Particular challenges in searching pharmaceutical substances disclosed in patent applications

Feasibility study on the disclosure of INN (SCP/21/9)

Patenting activities of atazanavir



- INN cannot be disclosed in patent applications before it is assigned.
 - To search a founder patent with an INN keyword, the INN must be retroactively linked to the founder patent.
- Various issues to be considered
- Alternative ways to improve patent search on pharmaceutical substances (ex. Orange Book, ICT development)?

- Feasibility Study on the Disclosure of INN (SCP/21/9)
 - Discussed at SCP/21, SCP/23 and SCP/25 between 2014 and 2016

- Updated Feasibility Study on the Disclosure of INN (SCP/28/5)
 - Maintains the same structure as SCP/21/9
 - Continues to be confined to fact finding, without engaging in evaluations and recommendations
 - Reflects the developments since 2014
 - Statistical information regarding INN
 - ex. INN on biologics (40% in 2014 → 46%)
 - Discussions at the SCP sessions

Updates in SCP/28/5 (1)

- Observation regarding **PLT Article 6(1)**: PCT Rule 10 (Terminologies and Signs) may be construed as being part of the requirements under PLT Article 6(1).
- Finalization of the **Guidelines for Examination** of Patent Applications in the Field of Pharmaceuticals published by the Office of the Controller General of Patents, Designs and Trademarks of **India**.
- **Observations** relating to **searchability of applications filed/patent granted before the publication of INN** during the SCP sessions
 - Patent offices should implement a new procedures later in the prosecution process in order to incorporate the INN information in already filed applications/ granted patents.
 - Some national laws might not provide a mechanism for reopening the prosecution of already granted patents (resource intensive).
 - SCP discussions should be confined to the disclosure of INN in a patent application if the corresponding INN is known to the applicant.
 - Applicants could voluntarily indicate INN in a patent application if it is known at the time of filing, and in practice, they usually do so.

Updates in SCP/28/5 (2)

- Further development of patent search databases using **software algorithms to match INN to a given compound**
ex. PATENTSCOPE chemical structure search, SureCHEMBL
- **Special databases** that link medicine data and patent data
ex. MedsPaL, SIGA (Mexico), Pat-INFORMED

Thank you.