

Explanation Document of Reasons that the Patent Application Number 1601000296 Is Ineligible for Patent

AIDS Access Foundation found that the patent application for the innovation of “anti-tuberculosis stable pharmaceutical composition in a form of a dispersible tablet comprising granules of isoniazid and granules of rifapentine and its process of preparation”, under the Application Number 1601000296, the filing date of 22 July 2014, the application’s receipt date of 20 January 2016, the publication date of 20 December 2018; is contrary to the Patent Act B.E. 2522, as amended by the Patent Act (No.2) B.E 2535 and the Patent Act (No.3) B.E. 2542, in accordance with the following reasons:

This invention is contrary to the Patent Act (No.2) B.E. 2535, Section 5(1), Section 5(2), Section 6(5) and Section 7 as the invention is not new, does not involve an inventive step, and is obvious to a person having ordinary skill in the pharmaceutical science in regard to the supporting reasons and details described as below:

1. Claims number 1 – 4 are the claims on a pharmaceutical composition in a form of a dispersible tablet for use in the treatment of tuberculosis or a dispersible bilayer tablet comprising Isoniazid granules, rifapentine granules and extragranular excipient. The use of Rifapentine and Isoniazid in combination was already disclosed as appeared in the Patent Publication Number WO/2007/043542 (Supporting Document No. 2). The use of Rifapentine and Isoniazid in a tablet or fixed dose combination was also disclosed in a clinical research in 2006 (Supporting Document No. 3) and another clinical research in 2011 (Supporting Document No. 4). Therefore, the use of Rifapentine and Isoniazid combination in oral pharmaceutical compositions is in the absence of novelty and inventive step.

In addition, Rifapentine and Isoniazid combination in a form of a dispersible flat tablet was already disclosed in an academic document on dispersible tablets in 2004 (Supporting Document No. 5) and in 2009 (Supporting Document No. 6). Accordingly, Rifapentine and Isoniazid combination in a form of a dispersible flat tablet has lack of novelty and inventive step. It is also a dosage form that is obvious to a person ordinary skilled in the pharmaceutical science.

Therefore, it can be concluded that anti-tuberculosis stable pharmaceutical composition in a form of a dispersible tablet comprising isoniazid granules and rifapentine granules has no novelty and inventive step. It is also obvious to a person ordinary skilled in the pharmaceutical science.

2. Claims number 5 - 8 are the claims on a pharmaceutical process for the preparation of an oral composition in a specific manner by preparing the Isoniazid granules and the Rifapentine granules separately, then compressing the mixture of the Isoniazid granules and the Rifapentine granules to obtain tablets. The pharmaceutical process of such preparation and the technique that contains the drugs in separate layers in order to avoid the degradation of Rifapentine and Isoniazid composition as described is generally known, as published in Chapter 3 of Pharmaceutical Dosage Forms Pharmacopoeia: Tablets Volume 1, 1989 (Supporting Document No 7). The concept of such technique was also mentioned in the

Pharmacopoeia of the Faculty of Pharmaceutical Science of Chulalongkorn University as a case study of the research and development of solid dosage forms (Supporting Document No. 8), that provides explanation of how to solve the problem of degradation or interact between active ingredients by using granulation method to separate those active ingredients before compressing granules to obtain tablets.

It was also found that the granulation process of two active ingredients by using the method of wet granulation is a common process generally taught in the class-room of the pharmaceutical science; it appears in textbook of Pharmaceutical Technology in Bachelor of Pharmaceutical Science (Supporting Document No. 9 and 10). For that reason, the production process mentioned above is obvious to a person ordinary skilled in the pharmaceutical science.

3. Referring to Department of Intellectual Property's guideline on examination of pharmaceutical patent (Section 5, Part 2, under the topic of Consideration of Novelty and Inventive Step of Pharmaceutical invention, Page 361), it defines that, in the consideration of novelty and inventive step for pharmaceutical combinations, synergistic effects of two active ingredients should be observed (Supporting Document No. 11). However, we found that this patent application does not demonstrate results or details of synergistic effect. In addition, the application neither indicates non-obvious results in technical solution when compared to the prior-art techniques and nor have new information about anti-tuberculosis effects of this combination. Such pharmaceutical compounds are used according to the prior art, and the anti-tuberculosis effects by this combination is not demonstrated by the inventor.

4. It was also found that an evaluation document of the European Patent Office's experts shows that the same patent application is in the absence of novelty and inventive step.

In this regard, it can be concluded that patent application number 1601000296 has the lack of novelty and inventive step, and it is also obvious to a person ordinary skilled in the pharmaceutical science. Therefore, this patent application is ineligible for patent.