ENGLISH TRANSLATION

5 May 2020

Subject: Submission of statement and evidence for the consideration of patent examiners to revoke the patent application No. 0501005795

Attention to: Director-General of the Department of Intellectual Property

Attachments:

1. Attachment No.1: WO/2004/011436
2. Attachment No.2: Examination Guidelines for Patent / Petty Patent Applications revised edition B.E. 2555 (A.D. 2012)
3. Attachment No.3: Republic of India patent rejection decision no. 5213/DELNP/2007

Janssen Pharmaceutica N.V. filed a patent application for “treatment of latent tuberculosis” in application No. 0501005795 (filing date of 8 December 2005), publication No. 80291 (publication date of 12 October 2006) with total of 28 claims.

Even though a patent application opposition period of 90 days after the publication date has already expired, AIDS Access Foundation (AAF), a non-governmental development organization aiming to promote access to pharmaceutical treatment and healthcare, found the patent application to be in contradiction 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.

This particular patent application is important and will have a considerable impact on the public health system of Thailand. The application concerns bedaquiline, a treatment for multidrug resistant tuberculosis (MDR-TB), which is also effective against latent tuberculosis. Tuberculosis (TB) is a serious and growing threat to the wellbeing of the public and the public health system of the country. It is also a global health challenge. According to the Ministry of Public Health data, more than 100,000 TB patients were treated annually while the number of MDR-TB is estimated at 3,000 cases per year and rising. If the country cannot afford to include bedaquiline in the

Universal Health Coverage Scheme—owing to the exorbitant cost of the drug and the lack of generic equivalents resulting from the unjustified patent protection granted—Thai patients will not be able to access the treatment. This will result in diminishing quality of life and even death, due to the serious side effects and low treatment success rate.

The AAF hereby submits these statements and evidences proving that the patent application is in contradiction 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 for the consideration of the examiners to revoke the said patent with details as described below:

1. The name of the invention in this patent application is "Treatment of Latent Tuberculosis," which obviously aims to treat or cure human and animal diseases. Therefore, the subject matter of this invention is relating to the treatment or cure of human and animal diseases which is in contradiction to the Article 9(4). Thus, this invention is not protected by the Patent Act.

2. The subject matter of this invention relates to the use of the compound according to Formula (Ia) or (Ib) in manufacturing of medication for the latent tuberculosis treatment. This subject matter lacks both novelty and inventive step, since according to Formula (Ia) or (Ib) is not a new compound but a known compound which has been disclosed in the WO/2004/011436 (Attachment No.1). Furthermore, this subject matter is also in contradiction with the Article 9(4) of the Patent Act.

3. Claim No. 1-28 describe the use of the compound according to Formula (Ia) or (Ib) for the manufacturing of drug for the treatment of latent tuberculosis in the form of Swiss-type claim, but the subject matter of these claims is the use of the compound according to Formula (Ia) or (Ib) for the treatment of latent tuberculosis. Thus, this invention is unpatentable, as it is in contradiction to the Article 9(4) of the Patent Act. The form of claim also matches with an example of the unpatentable form of claims given in the Article (16) of the Examination Guidelines for Patent/Petty Patent Applications revised edition B.E. 2555 (Attachment No.2) on the page 353, such as "the use of compound… for the manufacturing of drug for the prevention (treatment, cure, suspension) of the ….. disease in the dosage of ….. per day (per application)." Moreover, these

claims are unclear and fail to provide the details of the usage and dosage of the compound. The vagueness of the claims makes them to be in contradiction to the Article 17(4).

4. Claim No. 1-28 describe the use of the compound according to Formula (Ia) or (Ib) in the manufacturing of drugs for the treatment of latent tuberculosis. These claims lack both novelty and inventive step as it is merely an act of adding a compound previously disclosed in the WO/2004/011436 (Attachment No.1) published on 5 February 2004 which had been filed in Europe and outside the Kingdom on 5 December 2004 with the filing No. 05815876.3 to manufacture drugs for the treatment of latent tuberculosis without describing the manufacturing process clearly. These claims fail to show results and other details supporting the non-obviousness of the use in comparison with the prior art. That is to say, the said compound has been used in drug manufacturing in the prior art and is obvious to the persons having ordinary skill in pharmaceutical arts. Thus, these claims are in contradiction to the Article 5 and 7.

Moreover, the invention being claimed in the patent application No. 0501005795 was also claimed in Indian patent application No. 5213/DELNP/2007 and was opposed. Consequently, the said Indian patent application was revoked on 29 October 2016 (Attachment No.3). The main subject matters of the revocation decision are as follow:

- The compound according to the Formula (Ia) or (Ib) has been previously disclosed in the WO/2004/011436 (Attachment No.1). Thus, the said compound is not new and the discovery of indication for latent tuberculosis is not in accordance with the Article 2(1)(j) of the Patent Act 1970.
- The subject matter of the invention is not enough to support the claims indicated in the application.
- The entire claims fall under the (d) in the Section 3 of the Patent Act 1970: the mere discovery of new use of a known substance. Thus, the compound mentioned in the claims are not new and lacks inventive step.

- As it is not the claim of novelty, there is no need to determine whether the act of using the compound involves an inventive step or not. Moreover, the argument that the compound involves an inventive step is based on the assumption that “Commonly known treatments for active TB do not always have efficacy against latent TB. On the other hand, latent TB infection are resistant to most antimycobacterials. This supports the concept that the macromolecular synthesis pathway, targeted by currently available antimycobacterial, is of no importance to M. tuberculosis in non-replicating (dormant) state, as the general principle dictates that antimicrobials are only active against bacteria in the replicating stage. Thus, latent tuberculosis in non-replicating state is resistant to antimicrobial treatment; and it can be assumed that current antituberculosis drugs do not have efficacy against latent TB.” The application has been filed on the basis that current antituberculosis drugs do not have efficacy against latent TB. As the subject matter disclosed cannot be proved, it is impossible to accept such claim of inventive step.
- The entire claims fall under the (e) of the Section 3 of the Patent Act 1970 as the active pharmaceutical ingredient mentioned in the claims has previously been disclosed in the WO/2004/011436 (Attachment No.1) thereby lacking both novelty and inventive step. The excipients in this particular pharmaceutical compositions are commonly used and not specifically described. Thus, it is difficult to prove the synergistic effect of the said composition. As the synergistic effect of the composition in the subject matter of the invention cannot be proven, this is a mere act admixture. Also, the subject matter of the invention does not describe any anti-latent tuberculosis properties of the composition by providing examples or other details.

Based on these reasons, invention examiners of the Republic of India decided that the claims in the said patent application were not new and did not involve inventive step as it is merely a new use for the disclosed compound. Consequently, the patent application was revoked on 29 October 2016.

The AAF hereby submitted these statement and evidence as the grounds for the rejection of the patent granted, as well as any not-yet-unpublished patent applications of the same drug.

Yours faithfully,

(Chalermsak Kittitrakul)

Coordinator for Access Campaign

Copy to Mr. Nimit Tienudom, Director of AIDS Access Foundation