ENGLISH TRANSLATION

17 April 2020

Subject: Submission of statement and evidence for the consideration of patent examiners to revoke the patent application No. 0701006189

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

Attachments:

1. Attachment No.1: WO2004011436
2. Attachment No.2: WO2006067048
3. Attachment No.3: WO2005117875
4. Attachment No.4: US6534508
5. Attachment No.5: Guidelines for Examination of Patents
6. Attachment No.6: WO2006024667
8. Attachment No.8: Opposition to the Republic of India patent application No. 1220/MUMNP/2009 filed by the Network of Maharashtra People Living With HIV

Janssen Pharmaceutica N.V. had filed a patent application for “FUMARATE SALT OF (ALPHA S, BETA R)-6-BROMO-ALPHA-[2-(DIMETHYLAMINO) ETHYL]-2-METHOXY-ALPHA-1-NAPHTHALENYL-BETA-PHENYL-3-QUINOLINEETHANOL” in the application No. 0701006189 (filing date of 8 December 2007), the publication No. 102420 (publication date of 30 June 2010).

Even though a patent application objection period of 90 days after the publication date has already expired, the AIDS Access Foundation (AAF), a non-governmental development
organization aiming to promote access to pharmaceutical treatment and healthcare, has found this 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 since this application concerns a treatment for multidrug resistant tuberculosis (MDR-TB) with the generic name of bedaquiline. 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, the estimated number of MDR-TB is 3,000 cases nationwide 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 the low treatment success rate.

Thus, AAF and TNP+ hereby submit these statement and evidence 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 application with details as described below:

1) Pertaining the subject matter of the invention, the invention concerns FUMARATE SALT OF (ALPHA S, BETA R)-6-BROMO-ALPHA-[2-(DIMETHYLAMINO) ETHYL]-2-METHOXY-ALPHA-1-NAPHTHALENYL-BETA-PHENYL-3-QUINOLINEETHANOL with antimycobacterial properties, and pharmaceutical composition consisted of a carrier and FUMARATE SALT OF (ALPHA S, BETA R)-6-BROMO-ALPHA-[2-(DIMETHYLAMINO) ETHYL]-2-METHOXY-ALPHA-1-NAPHTHALENYL-BETA-PHENYL-3-QUINOLINEETHANOL for drug administration purpose. The subject matter does not involve both novelty and inventive step because

1.1) FUMARATE SALT OF (ALPHA S, BETA R)-6-BROMO-ALPHA-[2-(DIMETHYLAMINO) ETHYL]-2-METHOXY-ALPHA-1-NAPHTHALENYL-BETA-PHENYL-3-
QUINOLINEETHANOL is not a new compound. It is a known compound which has been disclosed in WO2004011436 (Attachment 1) and WO2006067048 (Attachment 2), and

1.2) Antimycobacterial properties of the compound is already known, as disclosed in WO2005117875 (Attachment 3) and the patent No. US6534508 (Attachment 4)

2) Pertaining the patent claims, the applicant has filed the claims which lacks novelty, inventive step, and non-obviousness since it is obvious to persons having ordinary skill in the art. The details of the unpatentable claims are as follow:

2.1) Claim No. 1, FUMARATE SALT OF (ALPHA S, BETA R)-6-BROMO-ALPHA-[2-(DIMETHYLAMINO) ETHYL]-2-METHOXY-ALPHA-1-NAPHTHALENYL-BETA-PHENYL-3-QUINOLINEETHANOL is in contradiction to the Article 5(1) because of the lack of novelty. This compound has been disclosed in the conclusion in the WO2004/011436 with the publication date of 5 February 2004 (Attachment No. 1) which was filed before the filing date of the application No. EP06125443.9 filed on 5 December 2006 outside the Kingdom. Claim No. 1 has also been disclosed in the application WO2006067048 (Attachment No. 2).

2.2) Claim No. 2 and 3 are in contradiction to the Article 5(1) because of the lack of novelty. This compound has been disclosed in the WO2004/011436 with the publication date of 5 February 2004 (Attachment No. 1) which was filed before the filing date of the application No. EP06125443.9 on 5 December 2006 filed outside the Kingdom.

2.3) Claim No. 4 describes the compound, as mentioned in Claim No. 1 to No. 3, that is used as medicine. This Claim is in contradiction to the Article 5(1) because of the lack of novelty since the compound has already been disclosed in the WO2004/011436 (Attachment No. 1). Thus, the use of this compound is not new and does not involve inventive step. Furthermore, the vague claim without specific details is in contradiction to the Article 17(4).
2.4) Claim No. 5 describes the compound, as mentioned in Claim No. 1 to No. 3, that is used as medication for treatment or prevention of mycobacteria. This Claim is in contradiction to the Article 5(1) because of the lack of novelty since the compound was disclosed as a treatment for drug-resistant mycobacteria in the publication No. WO/2005/117875 (Attachment No. 3) and the patent No. US6534508 (Attachment No. 4). Furthermore, the use of the aforementioned compound as a pharmaceutical treatment or pharmaceutical prevention of mycobacteria is in contradiction to the Article 9(4).

2.5) Claim No. 6-10 describes pharmaceutical compositions composed of carriers for a variety of dosage forms are not new and do not involve inventive step. The Guidelines for Examination of Patents relating to Pharmaceutical Invention section 5, part 2 on the determination of novelty and inventive step relating to pharmaceutical inventions page 361 (Attachment No. 5) states that in determining novelty and inventive step of pharmaceutical inventions, it must be determined whether the new composition results in a non-obvious solution to a technical problem when compared to the prior art. As the patent application does not exhibit the non-obvious results nor details in comparison with the prior art, this invention is obvious to persons having ordinary skill in the pharmaceutical arts. Thus, it is in contradiction to the Article 5(2), Article 7, and Article 17(4).

2.6) Claim No. 11-14 describe the pharmaceutical composition composed of a variety of compounds as mentioned in the claims, which is not new and does not involve inventive step as the composition has been disclosed in the WO2006024667 (Attachment No. 6). The Department of Intellectual Property’s Guidelines for Examination of Patents relating to Pharmaceutical Invention section 5, part 2 on the determination of novelty and inventive step relating to pharmaceutical inventions page 361 (Attachment No. 5) states that in determining novelty and inventive step relating to pharmaceutical inventions, it must be determined whether the composition results the non-obvious technical resolution when compared to the
prior art. As the patent application does not exhibit the non-obvious results nor
details in comparison with the prior art, this invention is obvious to persons having
ordinary skill in the pharmaceutical arts. Thus, it is in contradiction to the Article
5(2), Article 7, and Article 17(4).

2.7) Claim No. 15, describing the pharmaceutical composition as mentioned in Claim
No. 12-14 with film coating, is in contradiction with the Article 5(2) for not involving
inventive step, as film coating is a known technique to persons having ordinary skill
in pharmaceutical arts and has been disclosed in the pharmaceutical textbooks
since 1990 (Attachment No. 7).

2.8) Claim No. 16-17, describing the preparation process of pharmaceutical
composition as mentioned in Claim No. 12-15, is in contradiction with the Article
5(2) for not involving inventive step, as the preparation process of pharmaceutical
composition is a general process which has been disclosed in the pharmaceutical
textbooks and is obvious to persons having ordinary skill in pharmacy.

2.9) Claim No. 18-20, describing the use of the compound mentioned in Claim No. 1-3
for manufacturing/preparation of medication for treatment or prevention of
mycobacterial infection, is in contradiction with the Article 5(2) for not involving
inventive step, as the use of this compound for treatment of mycobacteria infection
has already been disclosed in the publication No. WO/2005/117875 (Attachment
No. 3) and the patent No. US6534508 (Attachment No. 4). Furthermore, the use of
this compound as a pharmaceutical treatment also contradicts the Article 9(4).

2.10) Claim No. 21 describes the process of preparing the compound according to
Claim No.1 to 3, by the reaction between the free base form of compound with
fumaric acid in an appropriate solvent, is in contradiction to Section 5 (1). The
invention is not new as the publication No. WO2005117875 has already disclosed
that acid addition salts can be obtained by treating the base form of the compound
with appropriate acids, including fumaric acid.
Moreover, the Indian patent application No. 1220/MUMNP/2009, cited by Thai patent application No. 0701006189, was opposed and revoked on the grounds of lacking novelty and inventive step (Attachment No. 8 and 9).

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

Yours faithfully,

(Nimit Tienudom)

Director of AIDS Access Foundation