ENGLISH TRANSLATION

17 July 2020

Subject: Submission of statement and evidence for the consideration of patent examiners to revoke the patent application No. 1101001988

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

Attachments:

1. Attachment No.1: EP 1112743
2. Attachment No.2: JP 9-208468
3. Attachment No.3: JP 2007-186470
4. Attachment No.4: JP 2002-173428
5. Attachment No.5: Indian patent office's examination report on patent application No. 6955/DELNP/2011
6. Attachment No.6: Indian patent office's decision report on the revocation of patent application No. 6955/DELNP/2011

FUJIFILM Toyama Chemical Co., Ltd. filed a patent application for "Tablet and granulated powder containing 6-fluoro-3-hydroxy-2-pyrazinecarboxamide" in the application No. 1101001988 (filing date of 12 March 2010) under the PCT scheme. The patent application was accepted by Thai Department of Intellectual Property on 12 September 2011, and was published on 1 October 2012 (publication No. 116660) with 16 claims in total.

Even though the opposition 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 as it concerns a treatment for the novel coronavirus 2019 (COVID-19) with the generic name of favipiravir. Novel coronavirus 2019 (COVID-19) presents a serious threat to the wellbeing of the Thai public and public health system, while also being a global health challenge. It is true that Thailand has been able to manage and contain the spread of COVID-19 to a certain degree, and has been able the number of patients and new cases at the minimum. Still, COVID-19 continues to be a global health problem severely affected many counties around the world. As the possibility of resurgence is still high, the treatments, including favipiravir, need to be readily available. However, the Thai public health system is at risk of being unable to make the drug available and accessible in the event of a resurgence. This is due to the high cost of the original drug, and the fact that there is no generic competition to drive down costs owing due to unfair protection.

Thus, AAF hereby submits 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 said patent application pursuant to the details described below:

1. Pertaining the subject matter of the invention, the invention concerns the tablet dosage form of an antiviral containing 6-fluoro-3-hydroxy-2-pyrazinecarboxamide or salt thereof. As 6-fluoro-3-hydroxy-2-pyrazinecarboxamide or salt thereof has already been disclosed in Attachment No.1 EP1112743, the formulation of this compound into tablet form is merely a reformulation of the dosage medium. This would be obvious to any person with

ordinary skill in the pharmaceutical arts. Furthermore, the use of low substituted hydroxypropyl cellulose or croscarmellose sodium, and binders in the tablet formulation have been disclosed in Attachment No. 2, 3 and 4. Thus, the invention contains no inventive step.

2. The patent application concerns a tablet which contains high quantity of 6-fluoro-3-hydroxy-2-pyrazinecarboxamide or salt thereof; has an easily ingestible size; has superior release characteristics; and has a hardness that can withstand film coating, packaging, and transportation, with a total of 16 claims. However, all 16 claims lack inventive steps:

2.1 Attachment No.1 has already disclosed an antiviral containing 6-fluoro-3-hydroxy-2-pyrazinecarboxamide or salt thereof, and indicated its use in tablet dosage form. Although Attachment No. 1 has not specifically mentioned the use of low substituted hydroxypropyl cellulose or croscarmellose sodium and binders, these compositions are mentioned in Attachment 2, 3 and 4.

2.2 Attachment No.2 has already disclosed the granulation and tableting of the active pharmaceutical ingredient, low substituted hydroxypropyl cellulose or croscarmellose sodium, and binders mix—to increase the quantity of active pharmaceutical ingredient and achieve a smaller tablet with the same dissolution and biological properties as the bigger tablet.

2.3 Attachment No. 3 and 4 have already disclosed the mixture of low substituted hydroxypropyl cellulose or croscarmellose sodium, and binders, for a small tablet containing high quantity of active pharmaceutical ingredients.

Thus, any person with ordinary skill in the pharmaceutical arts can add low substituted hydroxypropyl cellulose or croscarmellose sodium, and the binders disclosed in Attachment No. 2, 3 and 4 to the active pharmaceutical ingredient disclosed in Attachment No. 1 to achieve a tablet formulation containing high quantity of active pharmaceutical ingredient but still small enough to be easily ingestible. The additive step and its result are neither inventive nor extraordinary. Based on the aforementioned, Claims No. 1 - 16 lack inventive steps and are in contradiction to the Article 5(2) and 7.

3. Claim No. 1 does not distinctly describe the proportion of each ingredient in the tablet formulation, making it an unclear claim. Claims No. 3 – 16, which are secondary claims with reference to many primary claims, are also unclear. The term “additionally” in Claim No. 3 and 5 continue to blur the scope of the claim even further, making them contradictory to Article 17(4).

Moreover, the patent application is the same as the one filed in the Republic of India under application No. 6955/DELNP/2011, which was rejected on the grounds detailed in Attachment 5 and 6 on 23 January 2018. The Indian patent examiner found the invention to be lacking of inventive steps and obvious to a person with ordinary skill in the pharmaceutical arts. (Attachment No. 8 and 9).

AAF hereby submits this statement and evidence as the grounds for the rejection of the patent application, as well as any not-yet-unpublished patent applications of the same drug.

Yours faithfully,

(Chalermsak Kittitrakul)
Coordinator for Access to Medicines Campaign

cc: Nimit Tienudom, Director of AIDS Access Foundation