

**Interesting Decision of Japanese Intellectual Property  
High Court on Patent Term Extension Application for  
Combination Drug**

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**Summary**

The Japanese Intellectual Property High Court (referred to as the IP High Court hereunder) rendered an interesting decision (Case No. Hei 22 (Goy ke) 10178 ) on March 28, 2011 that a patent term extension application for a combination drug of known drugs should not be rejected on the ground that each of the known drugs has been already approved for the same medical use as that of the combination drug. Also, the IP High Court rendered the same decision on even date (Case No. Hei 22 (Goy ke) 10177).

Thus, in Japan, a patent term extension for the patented combination drug of known drugs would be granted even when the approved medical use of the combination drug is the same as those of each of the known drugs , unlike in the USA where an AstraZeneca patent term extension application for a combination drug was rejected by the USPTO in June, 2008 (Patent Term Extension Application of USP No. 5,674,860).

Therefore, this decision would be extremely beneficial to new drug makers developing and marketing a combination drug of a blockbuster drug with other drugs after the expiration of the original patent term of the blockbuster drug.

## **Background**

Japanese Patent No. 2,954,357 (corresponding to WO96/30025; the filing date: March 28, 1996; the registration date: July 16, 1999) (referred to as the Instant Patent hereunder) of The Wellcome Foundation Limited (referred to as the Instant Patentee hereunder ) was patented on the basis of the synergistic effect of a combination drug on HIV infection, and claims a pharmaceutical composition containing two know drugs for HIV infection as active ingredients, as mainly claimed in claims 1, 7 and 8, as follows:

Claim 1. A pharmaceutical composition comprising (1S,4R)-cis-4-[2-amino-6-(cyclopropylamino)-9H-purin-9-yl]-2-cyclopentene-1-methanol (1592U89) or a physiologically functional derivative thereof and (2R,cis)-4-amino-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2- one (3TC) or a physiologically functional derivative thereof.

Claim 7. The pharmaceutical composition according to any one of claims 1 to 6, which is in an unit dosage form.

Claim 8. The pharmaceutical composition according to any one of claims 1 to 6 , which is for the treatment and/or prophylaxis of HIV infection.

The licensee of the Instant Patent received on December 24, 2004 from the Japanese authority a marketing approval for a tablet for the treatment of HIV infection containing abacabir sulfate and lamivudine as active ingredients (referred to the New Approval hereunder). Abacabir sulfate is the physiologically functional derivative of (1S,4R)-cis-[4-[2-amino]-6-(cyclopropylamino)-9H-purin-9-yl]-2-cyclopentene-1-methanol (1592U89) of claim 1 of the Instant Patent , and lamivudine is (2R,cis)-4-amino-(2-hydroxymethyl)1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2- one (3TC) of claim 1 of the Instant Patent. Based on the New Approval, the Patentee filed a patent term extension application of the Instant Patent on March 24, 2005 (referred

to the Instant Patent Term Extension Application hereunder)..

On the other hand, there had already been a previous approval for lamivudine wherein a tablet containing lamivudine only as an active ingredient had been approved for a combination therapy of HIV infection together with other HIV infection drug. Also, there had already been a previous approval for abacarbirsulfate wherein a tablet containing abacarbirsulfate only had been approved for HIV infection.

The Board of Appeal of the Japan Patent Office (referred to as the JPO' Board of Appeal hereunder) decided to reject the Instant Patent Term Extension Application for the reasons as follows:

The New Approval overlaps with the previous approvals in the active ingredients and their medical uses; thus, there was not necessity to obtain the New Approval for working the patented invention of the Instant Patent; and the Instant Patent Term Extension Application therefore falls under the reason for rejection of Article 67-3. (1). (i). of the Japanese Patent Law which prescribes that, when it is not deemed that the obtaining of a disposition under Cabinet Order, for which a considerable period time is required as provided in Article 67.(2), was necessary for working the patented invention, the patent term extension application should be rejected.

The Instant Patentee appealed the case to the IP High Court and requested that the decision by the JPO' Board of Appeal be overruled.

### **Judgment of IP High Court**

The IP High Court found that the JPO has erred in the interpretation and application of Article 67.(2). The IP High Court found that, although Article 67.(2) states that a patent term may be extended when the obtaining of a disposition under Cabinet Order, for which a considerable period time is required, was necessary for working the patented invention, Article 67.(2) is not provided for the purpose of prescribing reason for rejecting a patent term

extension application. But, the IP High Court found that Article 67.(2) is provided for the purpose of defining a disposition such as the Pharmaceutical Affairs Law and Agricultural Regulation Law for which a patent term should be extended.

The IP High Court judged that the eligibility requirements for a patent term extension application do not include the condition that the disposition per se requires a considerable period of time, and that this interpretation of Article 67.(2) is apparent from the fact that the lower limit of two years for the extension period was abolished from Article 67.(2) by the 2000 amendments of the Patent Law. Thus, the IP High Court found that the patent term extension should not be allowed only for an approval of a new drug in which a new active ingredient and/or a new medical use of the new drug have been examined by the Japanese authority.

Then, the IP High Court found that the purport of a patent term extension system resides in compensating a patentee who was unable to work the patented invention despite the patentee's intention and capability to work the invention because the patentee was prohibited from working the invention without obtaining an approval.

Consequently, the IP High Court found that the eligibility requirement of a patent term extension application under Article 67-3. (1). (i). stating that the obtaining of a disposition was necessary for working the patented invention should be examined on the basis of whether or not the patent term extension application satisfies two conditions, i.e., (1) the prohibition of working the invention was removed by obtaining a disposition, and (2) the working is inside the scope of the patented invention. Further, the IP High Court found that, in order for the JPO to reject a patent term extension application, the JPO should bear the burden of proving that the application does not satisfy one or two of the conditions (1) and (2).

Based on this criteria, the IP high Court judged that, in order for the JPO to reject the Instant Patent Term Extension Application, the JPO did not prove one of the two conditions that the prohibition of working the invention of the

Instant Patent was not removed by obtaining the New Approval, in spite of the facts that the clinical trial started on June 13, 2001 after the registration of the Instant Patent, and that the New Approval was received by the license of the Instant Patent on December 24, 2004. Further, the IP High Court judged that the combination drug of the New Approval is inside the scope of claim 1 of the Instant Patent, but that the JPO failed to prove one of the two conditions that the working of the combination drug is not inside the scope of claim 1 of the Instant Patent.

In conclusion, the IP High Court overruled the decision by the JPO' Board of Appeal.

## **Comments**

Noticeably, in this decision, the New Approval for the combination drug is substantially the same as or, duplicate with, the previous approval for each of the known drugs of the combination drug, in the medical use.

According to this decision, a patent term extension application of a combination drug would be allowed when the prohibition of working the combination drug was removed by obtaining an approval for the combination drug, in other word, the obtaining of the approval was necessary for working the combination drug, and when the working of the approved combination drug is inside the scope of the patented claims.

Under the Pharmaceutical Affairs Law, a combination drug containing two or more drugs which have been already approved by the Japanese authority must be approved for manufacturing and selling the combination drug even for the same medical use as those of the already approved drugs. Therefore, according to this decision, a patent term extension application of a combination drug would be allowed in Japan even when an approved medical use of the combination drug is the same as those of each of the known drugs of the combination drug in both the active ingredient and the medical use.

Nowadays, many new drug makers are facing the problem of the expiration of original patent term of new drugs including blockbuster drugs, and some of the makers are making efforts to develop and market a combination drug of the blockbuster drug together with other drugs. This decision of the IP High Court would be very favor of such new drug makers.

The JPO may further appeal this decision before the Japanese Supreme Court, but it is still unknown that the JPO filed the appeal before the Supreme Court.