PATENT COURT OF KOREA

ELEVENTH DIVISION

DECISION

Case No.	2016Heo21 Revocation (Patent) Invalidation of term extension 2016Heo45 (consolidated) Cancellation (Patent) Invalidation of term extension
Plaintiff	1. A CEO B 2. C CEO D Counsel for Plaintiffs ILP Patent & Law Firm Patent Attorney in Charge Gyeongeop BAEK, Eunhee KIM, Yeongsoo LEE
Defendant	E Germany Counsel for Defendant Attorney Deoksoon JANG, Changsoo PARK, Patent Attorney Jinil JEONG Subagent Counsel for Defendant: Patent Attorney Taemin KIM
Date of Closing Argument	October 17, 2016
Decision Date	March 16, 2017

ORDER

1. The Plaintiffs' claims are all dismissed.

2. The cost arising from this litigation shall be borne by the Plaintiffs.

PLAINTIFFS' DEMAND

Plaintiff A Co., Ltd.: The IPTAB Decision 2015Dang1389, December 7, 2015 shall be revoked.

Plaintiff C Co., Ltd.: The IPTAB Decision 2015Dang1390, December 7, 2015 shall be revoked.

OPINION

1. Background

A. Patented Invention Whose Patent Term Shall Be Extended and Registered (hereinafter, "Subject Invention")

1) Title of invention: Substituted oxazolidinones and their use in the field of blood coagulation

2) International filing date/ date of claimed priority/ application number/ date of registration/ registration number: December 11, 2000/ December 24, 1999/ No. 10-2002-7008172/ February 12, 2008/ No. 804932

B. Registration of Extension of Patent Term (hereinafter, "Extension Registration at Issue")

1) Procedural History

a) Application for registration of extension (hereinafter, "Extension Registration Application at Issue")/ Application number: July 13, 2009/ No. 10-2009-63509

b) Applicant for extension registration: F (Company name prior to amendment: G)

c) Extended term for which application is filed (corrected by written opinion and amendment dated February 11, 2010): September 22[1] (term of examination of drug specifications and test methods method[2] and Drug Master

1) Paragraph (1)(vi) of Article 6 (How to Prepare Application for Extension Registration) of the old Provisions for Operation of Extension of Patent Terms (prior to being amended by KIPO Announcement No. 2012-34, October 22, 2012), as internal rules of KIPO, provides that "the term of extension application shall specify a term calculated under Article 4 as YYYY MM DD."

File[3] (3 months and 14 days from March 13, 2008 to June 27, 2008) + term of examination of 1st supplementary materials (7 days from July 24, 2008 to July 31, 2008) + term of examination of 2nd supplementary materials (1 day from August 11, 2008 to August 12, 2008) + term of examination of drug marketing approval and term of evaluation of standards for Good Manufacturing Practice[4] (4 months and 5 days from August 27, 2008 to January 2, 2009)[5] + term of examination of supplementary materials for safety and efficacy[6] (1 month and 25 days from February 18, 2009 to April 13, 2009[7]))

d) Date of decision to extend registration (hereinafter, "Decision of Registration Extension"): June 21, 2010

2) Details of Extension Registration

a) Claims to be extended: Claims 1, 7, 8, 10, 12, and 13 (hereinafter, "Extended Invention at Issue")

b) Expiration date prior to registration of extension: December 11, 2020

c) Extended term: September 22

d) Contents of approval or registration: Drug import marketing approval No. 85

C. History and Contents of Drug Import Marketing Approval (hereinafter,

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2) The examination of drug specifications and test methods examines the following: standards for manufacturing and quality control of drugs (for example, description, purity, content, dose, special tests (digestion, microbial test), etc.) and detailed test methods to confirm the same, etc. Hereinafter "specifications and test methods examination."

3) The Drug Master File (DMF) means the information of raw material drugs, i.e. facility details of the relevant raw material drug plant, impurity, residual organic solvents, process control, packing materials, stability test data, etc. The drug master file examination evaluates the matters stated above. Hereinafter, the drug master file examination shall be referred to as the "DMF examination."

4) Good Manufacturing Practice refers to the standards for structure and facilities of the plant and the entire production process including purchase of raw materials, manufacturing, packaging, and shipment to manufacture drugs with excellent quality. Good Manufacturing Practice evaluates whether these standards are met. This shall be referred to as the "GMP evaluation."

5) Under the principle of term calculation, the term shall be written as April 6 or as stated in the written opinion and amendment.

6) The examination of safety and efficacy examines the safety and efficacy of drugs to be approved, such as the results of clinical trials, toxicity, pharmacological action, etc. This shall be referred to as the "safety and efficacy examination."

7) Under the principle of term calculation, the term shall be written as January 26, but is stated as is in the above written opinion and amendment.

"Approval at Issue")

1) History of Approval at Issue

E Korea Co., Ltd. (hereinafter, "E Korea") filed an application for the Approval at Issue with regard to "Xarelto Tab", which is a drug. Its approval history is as follows:

	Date	Details			
		Patent establishment	**Approval (safety and efficacy examination / specifications and test methods examination)**	**GMP evaluation**	**DMF examination**
1	February 12, 2008	Patent establishment registration			
2	March 13, 2008		Submission of standards / test request		Submission of DMF declaration
3	June 24, 2008		Request for standards / test supplementary materials (1st)		
4	June 27, 2008				Notification of DMF acceptance
5	July 24, 2008		Submission of standards / test supplementary materials (1st)		
6	July 31, 2008		Request for standards / test supplementary materials (2nd)		
7	August 11, 2008		Submission of standards / test supplementary		

			materials (2nd)		
8	August 12, 2008		Approval of result of standards / test examination		
9	August 27, 2008		Submission of application for import marketing approval	Application of GMP evaluation	
10	November 26, 2008		Request for safety / validity supplementary materials		
11	January 2, 2009			Notification of GMP result	
12	February 5, 2009		Application for postponement of submission of supplementary materials		
13	February 18, 2009		Submission of safety / validity supplementary materials		
14	April 13, 2009		Drug import marketing approval		
15	April 13, 2009		Issuance of import marketing approval certificate		

2) Details, etc. of Approval at Issue

a) Decision date of import marketing approval: April 13, 2009

b) Date on which import marketing approval reached applicant (date on which import marketing approval certificate was issued): April 13, 2009

c) Details of approval: Drug import marketing approval under Article 42(1) of Pharmaceutical Affairs Act

d) Article to be approved: Rivaroxaban (product name: Xarelto Tab.)

e) Use of article to be approved: Prevent phlebemphraxis in adult patients having undergone major orthopedic operation in lower extremities (total knee or hip arthroplasty)

D. IPTAB Decisions

1) On March 24, 2015, the Plaintiffs filed a petition for trial on invalidation of the Extension Registration at Issue (hereinafter, "Each Trial Petition at Issue") with the IPTAB against the Defendant, arguing the following: "① Since an extended term of the Extension Registration at Issue exceeds the period during which the Extended Invention at Issue could be practiced, the Extension Registration at Issue shall be invalidated under Article 134(1)(iii) of the old Patent Act (prior to being amended by Act No. 11117, December 2, 2011; hereinafter, the same shall apply). ② Since the Extension Registration at Issue is rendered to an application not approved under the Pharmaceutical Affairs Act but filed by a patentee or a person having an exclusive license or a registered non-exclusive license on the patent right, the Extension Registration at Issue shall be invalidated under Article 134(1)(ii) of the old Patent Act."

2) The IPTAB heard the petition for trial filed by the Plaintiff A Co., Ltd. as 2015Dang1389 and the petition for trial filed by the Plaintiff C Co., Ltd. as 2015Dang1390. Further, on December 7, 2015, the IPTAB rendered its decision to dismiss Each Trial Petition at Issue (hereinafter, "Each IPTAB Decision") on the following grounds:

① The period taken for import marketing approval of Xarelto Tab., the drug subject to the Approval at Issue, is a total of 380 days, which is a sum of 152 days from March 13, 2008, when the request for examination of specifications and test methodss was submitted, to August 12, 2008, when the result of examination of specifications and test methodss was approved, and 228

days from August 27, 2008, when an application for import marketing approval was filed, to April 13, 2009, which is the Approval Date at Issue.

② The period taken for causes attributable to the patentee shall be excluded from the 380 days stated above to calculate the extended term of the Extension Registration at Issue. Where the request for safety and efficacy examination, request for specifications and test methods examination, application for GMP evaluation, DMF declaration, etc., which are required in order to receive drug marketing approval, are filed and accepted with the Korea Food & Drug Administration,[8] each department in charge of the Korea Food & Drug Administration conducts examination independently and separately demands materials to be supplemented (if any). Thus, if a department demands submission of supplementary materials and, in the meantime, the examination is suspended in the department but another department continues to conduct the examination, it may not be deemed that approval is delayed for such period due to a cause attributable to the patentee.

Accordingly, since the Extended Invention at Issue could not be practiced for 297 days as calculated above, the extended term of the Extension Registration at Issue does not exceed the period for which the Extended Invention at Issue could not be practiced. Thus, there is no cause of invalidation stipulated by Article 134(1)(iii) of the old Patent Act in the Extension Registration at Issue.

1) Period taken for import marketing approval of Xarelto Tab., drug subject to Approval at Issue
① From date on which request for specifications and test methods examination was filed

8) On March 23, 2013, the Korea Food & Drug Administration was abolished and the Ministry of Food and Drug Safety was established under Article 2 of the "Organization of the Ministry of Food and Drug Safety and its Affiliated Organizations" Supplementary Provisions enacted by Presidential Decree No. 24456, March 23, 2013. Hereinafter, this shall be referred to as the Korea Food & Drug Administration under the name of organization as of the Approval at Issue.

(March 13, 2008) to date on which result of examination was approved (August 12, 2008) = 152 days

② From date on which application for marketing approval was filed (August 27, 2008) to date on which import marketing was approved (April 13, 2009) = 228 days

→ Total: ① + ② = 380 days

2) Period taken due to causes attributable to patentee

① From date on which supplementary materials for 1st specifications and test methods examination were requested (June 24, 2008) to date on which supplementary materials were submitted (July 24, 2008)

② From date on which supplementary materials for 2nd specifications and test methods examination were requested (July 31, 2008) to date on which supplementary materials were submitted (August 11, 2008)

③ From date on which submission of marketing supplementary materials was requested (November 26, 2008) to date on which supplementary materials were submitted (February 18, 2009)

→ Total: ① + ② + ③ - DMF examination date (from June 24, 2008 to June 27, 2008) - GMP evaluation date (November 26, 2008 to January 2, 2009) = 83 days

3) Sub-conclusion

Period taken for Approval at Issue (380 days) - period taken due to causes attributable to patentee (83 days) = 297 days

③ Where establishment and registration of a non-exclusive license are completed while registering the extension of patent term, such facts are not a cause for invalidation stipulated by Article 134(1)(ii) of the old Patent Act, provided that a person who receives drug marketing approval, etc. is closely related to the patentee. E Korea, which received the Approval at Issue to practice the Subject Invention, is a Korean subsidiary of the patentee of the Subject Invention and is closely related to the patentee. Also, on July 22, 2009, which is before the Extension Registration at Issue, a non-exclusive license was registered for the Subject Invention. Thus, there is no cause for invalidation

prescribed by Article 134(1)(ii) of the old Patent Act in the Extension Registration at Issue.

[Factual basis] Undisputed facts, statements in Plaintiff's Exhibits 1 through 4, Defendant's Exhibits 1 through 5 (including hyphenated numbers, if any), purport of the overall argument

2. Summary of Parties' Arguments

A. Summary of Plaintiffs' Arguments

1) Arguments on Article 134(1)(iii) of old Patent Act

The IPTAB erred in adopting a method to calculate the extended term in light of the following: ⓐ Where a patentee makes a certain department proceed with the examination, notwithstanding the fact that materials are not prepared for some items, and then makes a different department continue to examine with complete materials, the period taken to submit the incomplete materials would not be excluded from the period taken due to causes attributable to the patentee, which would bring about an unreasonable result. ⓑ A method which deems that there is no "delay" in the approval procedures in light of the progress of examination by another department in the Korea Food & Drug Administration and calculates an extended term accordingly has no legal ground and is contrary to laws that stipulate the exclusion, from the period during which it is impossible to practice the patented invention, of the period taken, and not the period "delayed," due to causes attributable to the patentee. ⓒ In comparison with a case in which a patentee receives marketing approval in the best mode without receiving a supplementation request from the Korea Food & Drug Administration, it would be counter to the laws in light of the fact that it would extend the term of the patent further.

Thus, it would be reasonable to calculate an extended term of the Patent Right at Issue by way of one of Calculation Methods 1 through 3 stated below.

However, since the Extension Registration at Issue calculated its extended term using an incorrect method other than Calculation Methods 1 through 3, the extended term was registered in excess of the period during which the Extended Invention at Issue could not be practiced. Thus, since the Extension Registration at Issue corresponds to a "case where the registered extension exceeds the period during which the patented invention was not practicable," its registration shall be invalidated. The IPTAB decision is inconsistent with the above analysis and shall not be upheld.

a) Calculation Method 1 Argued by Plaintiffs

Extended term = Period during which patented invention was not practicable for safety and efficacy examination (① in the table shown below) - Period required due to cause attributable to patentee for safety and efficacy examination (② in the table shown below) = **145 days** (The Plaintiffs argue that since the specifications and test methodss were examined before the filing of the drug import marketing approval and the safety and efficacy examination, the period required for the specifications and test methods examination shall not be included in the period during which the patented invention was not practicable.)

	일자	내역				연장 기간	특허 권자 책임 기간
		특허설정	품목허가 (안·유/기·시 심사)	GMP 평가	DMF 심사		
1	2008. 2. 12.	특허권 설정등록					
2	2008. 3. 13.		기·시 심사의뢰서 제출		DMF 신고서제출		
3	2008. 6. 24.		기·시 보완자료 요청(1차)				
4	2008. 6. 27.				DMF 수리통보		
5	2008. 7. 24.		기·시 보완자료 제출(1차)				
6	2008. 7. 31.		기·시 보완자료 요청(2차)				
7	2008. 8. 11.		기·시 보완자료 제출(2차)				
8	2008. 8. 12.		기·시 심사결과 승인				
9	2008. 8. 27.		수입품목허가 신청서 제출	GMP 평가 신청		① 229일	
10	2008. 11. 26.		안·유 보완자료 요청				② 84일
11	2009. 1. 2.			GMP 결과 통보			
12	2009. 2. 5.		보완자료 제출 연기신청				
13	2009. 2. 18.		안·유 보완자료 제출				
14	2009. 4. 13.		의약품 수입품목허가				
15	2009. 4. 13.		수입품목허가증 교부				
허가 연장기간		145일 = [229일 - 84일]					

일자	Date	내역	Details
연장 기간	Extended term	특허권자 책임 기간	Period during which patentee is responsible
특허설정	Patent establishment	품목허가(안유/기시 심사)	Marketing approval (safety and efficacy / specifications and test methods examination)
GMP 평가	GMP evaluation	DMF 심사	DMF examination
특허권 설정등록	Patent right establishment registration	기시 심사의뢰서 제출	Filing of request for specifications and test methods
DMF 신고서 제출	Submission of DMF declaration	기시 보완자료 요청(1차)	Request for specifications and test methods supplementary materials (1st)
DMF 수리 통보	Notification of receipt of DMF	기시 보완자료 제출(1차)	Submission of specifications and test methods supplementary materials (1st)

기시 보완자료 요청(2차)	Request for specifications and test methods supplementary materials (2nd)	기시 보완자료 제출(2차)	Submission of specifications and test methods supplementary materials (2nd)
기시 심사결과 승인	Approval of result of specifications and test methods examination	수 입 품 목 허 가 신청서 제출	Submission of application for import marketing approval
GMP 평가 신청	Application for GMP evaluation	안유 보완자료 요청	Request for safety and efficacy supplementary materials
보안자료 제출 연기신청	Application for postponement of submission of supplementary materials	안유 보완자료 제출	Submission of safety and efficacy supplementary materials
의약품 수입품목 허가	Approval of drug marketing approval	수입품목 허가 증 교부	Issuance of import marketing approval certificate
허가 연장 기간	Extended term of approval	일	Days

b) Calculation Method 2 argued by Plaintiffs

Extended term = Period during which patented invention was not practicable for safety and efficacy examination (①+② in the table shown below) - Period required due to cause attributable to patentee for safety and efficacy examination (③+④+⑤ in the table shown below) = **256 days** (The Plaintiffs argue that the period during which any item was examined shall be included in the period during which the patented invention was not practicable, but any supplementation period shall be deemed to be "required" for a cause attributable to the patentee and thus excluded from the period during which the patented invention was not practicable, irrespective of whether any department continued its examination while the supplementation was rendered in the examination procedures in another department.)

	일자	내역				연장 기간	특허 권자 책임 기간
		특허설정	품목허가 (안·유/기·시 심사)	GMP 평가	DMF 심사		
1	2008. 2. 12.	특허권 설정등록					
2	2008. 3. 13.		기·시 심사의뢰서 제출		DMF 신고서제출	① 152일	
3	2008. 6. 24.		기·시 보완자료 요청(1차)				③ 30일
4	2008. 6. 27.				DMF 수리통보		
5	2008. 7. 24.		기·시 보완자료 제출(1차)				
6	2008. 7. 31.		기·시 보완자료 요청(2차)				④ 11일
7	2008. 8. 11.		기·시 보완자료 제출(2차)				
8	2008. 8. 12.		기·시 심사결과 승인				
9	2008. 8. 27.		수입품목허가 신청서 제출	GMP 평가 신청		② 229일	
10	2008. 11. 26.		안·유 보완자료 요청				⑤ 84일
11	2009. 1. 2.			GMP 결과 통보			
12	2009. 2. 5.		보완자료 제출 연기신청				
13	2009. 2. 18.		안·유 보완자료 제출				
14	2009. 4. 13.		의약품 수입품목허가				
15	2009. 4. 13.		수입품목허가증 교부				
허가 연장기간		256일 = [152일 + 229일 – 125일(30일 + 11일 + 84일)]					

c) Calculation Method 3 Argued by Plaintiffs

Extended term = Longest examination period among actual examination periods by examination item - Period for submission of supplementary materials in longest examination procedures = **145 days** (the longest among ①, ② or ③ in the table shown below) (The Plaintiffs argue that the longest period among actual examination periods is sufficient to complete each examination and receive marketing approval.)

① = Specifications and test methods examination – Period for submission of supplementary materials = 111 days

② = Safety and efficacy examination – Period for submission of supplementary

materials = 145 days

③ = GMP evaluation period = 128 days

	일자	내역					
		가시 심사	기간 계산 ①	안유 심사	기간 계산 ②	GMP 평가	기간 계산 ③
1	2008. 2. 12.	특허권 설정등록					
2	2008. 3. 13.	가시 심사의뢰서 제출	152일				
3	2008. 6. 24.	가시 보완자료 요청(1차)	30일				
4	2008. 6. 27.						
5	2008. 7. 24.	가시 보완자료 제출(1차)					
6	2008. 7. 31.	가시 보완자료 요청(2차)	11일				
7	2008. 8. 11.	가시 보완자료 제출(2차)					
8	2008. 8. 12.	가시 심사결과 승인					
9	2008. 8. 27.			수입품목허가 신청서 제출	229일	GMP 평가 신청	128일
10	2008. 11. 26.			안유 보완자료 요청	84일		
11	2009. 1. 2.					GMP 결과 통보	
12	2009. 2. 5.			보완자료 제출 연기신청			
13	2009. 2. 18.			안유 보완자료 제출			
14	2009. 4. 13.			의약품 수입품목허가			
15	2009. 4. 13.			수입품목허가증 교부			
허가 연장기간		①, ②, ③ 중 최장일인 145일 = [229일 - 84일]					

[*See previous chart for translation*]

2) Argument on Article 134(1)(ii) of old Patent Act

A legislative intent of Article 134(1)(ii) of the old Patent Act is to protect a third party's interest by publicly announcing the existence of non-exclusive licenses. Thus, any non-exclusive license should have been registered before filing the application of the Approval at Issue, etc. or at the time of the Approval at Issue.

However, E Korea, a non-exclusive licensee of the Subject Invention, completed the registration of its non-exclusive license not when applying for the Approval at Issue, but on July 22, 2009, which was after the Approval at Issue. In other words, the Extension Registration at Issue was rendered for an application filed by the patentee, an exclusive licensee of the patented right, or a registered non-exclusive licensee not in accordance with provisions of the Pharmaceutical Affairs Act. Thus, the Extension Registration at Issue includes a cause of invalidation under Article 134(1)(ii) of the old Patent Act, and the IPTAB Decisions are not consistent with the above analysis and shall not be upheld.

B. Summary of Defendant's Arguments

1) Arguments on Article 134(1)(iii) of old Patent Act

① In relation to Calculation Method 1 argued by the Plaintiffs, the Pharmaceutical Affairs Act contains no provision that stipulates requesting the specifications and test methods examination at the same time as filing an application for the Approval at Issue or requesting the safety and efficacy examination. Thus, the Plaintiffs' arguments are based on a different premise and are not reasonable.

② In relation to Calculation Method 2 argued by the Plaintiffs, this court found the following: ⓐ Primarily, where a supplementation period was required by a supplementation request made by one department of the Korea Food & Drug Administration, and, in the meantime, another department separately examined an application, etc. for the Approval at Issue, the supplementation period may not be viewed as a period delayed due to a cause attributable to the patentee, and its causal relationship with the delay in approval is denied. Thus, the supplementation period cannot be excluded from the "period during which the Extended Invention at Issue was not practicable" without the need to determine whether the request for supplementation was made due to a

cause attributable to the patentee. ⓑ Secondarily, if a different determination is made on the causal relationship with the delay in approval and the extended term of the Extension Registration at Issue is calculated to be shorter than September 22, it is fundamentally wrong to assume that there would be a cause attributable to the patentee based only on the fact that a request for supplementation was made. Thus, it shall be deemed that the supplementation period was not required due to a cause attributable to the patentee, and the extended term shall be re-calculated accordingly. Even if an applicant for approval has submitted all required materials, the Korea Food & Drug Administration may demand that the applicant supplement his/her application in the following cases: each examining department requires additional materials; even if the applicant submitted the relevant materials, the relevant examining department failed to perceive such fact; or even if the materials were submitted without any incompleteness or omission, additional materials are required to secure the safety of the public or implement the best public health administration. It is difficult to deem that the applicant is at fault in the cases stated above. Thus, it would be unreasonable to assume that the applicant was at fault only from the fact that the Korea Food & Drug Administration demanded that the applicant supplement his/her application.

③ In relation to Calculation Method 3 argued by the Plaintiffs, if all examining departments demand that the applicant supplement his/her application not at the same time but separately, it cannot be deemed that the approval period is prolonged due to a cause attributable to the patentee. Thus, the Plaintiffs' arguments based on a different premise are not reasonable.

2) Arguments on Article 134(1)(ii) of old Patent Act

Article 134(1)(ii) of the old Patent Act does not restrict when to register any non-exclusive license, but prescribes who shall register any extension. A

non-exclusive license shall be registered to oppose the same to an assignee of patent right or an exclusive licensee. The registration of non-exclusive license is not related to the protection of a third party through public announcement thereof. Thus, even if E Korea, which filed an application for the Approval at Issue as a non-exclusive licensee of the Subject Invention, registered its non-exclusive license while filing an application for extension registration by the patentee after the Approval at Issue, such facts do not correspond to a cause of invalidation prescribed by Article 134(1)(ii) of the old Patent Act.

3. Discussion

A. Discussion on Arguments on Article 134(1)(iii) of old Patent Act

1) Relevant Laws

a) Article 89 of the old Patent Act provides that “notwithstanding Article 88(1), the term of a patent on an invention may be extended only once by up to five years to compensate for the period during which the invention could not be practiced, if the invention is specified by Presidential Decree and requires permission, registration, etc. under any other statute (hereinafter referred to as "permission, etc.") to practice the patented invention, but it takes a long time to undergo necessary tests for validity, safety, etc. for such permission, registration, etc.” On the other hand, Article 91(1) of the old Patent Act enumerates cases under which an examiner shall determine to reject an application for registration of an extended patent term. Subparagraph 3 thereof stipulates “where the length of extension requested exceeds the period during which the relevant patented invention could not be practiced.” Also, paragraph (2) provides that “the period required due to a cause attributable to the patentee shall not be included in the period during which the relevant patented invention could not be practiced in paragraph (1)(iii).”

The system that extends the term of patent right in the old Patent Act

extends, as long as a period during which a patented invention could not be practiced, but within 5 years, the term of the patented invention for which the approval, etc. prescribed by the relevant laws shall be obtained, and for which it would take a long period of time to obtain the approval, etc. due to required tests, etc. In the case of drugs, agricultural chemicals, etc., it is required to obtain approval, registration, etc. under the Pharmaceutical Affairs Act, the Pesticide Control Act, etc. (hereinafter, the "Approval, etc. under the Pharmaceutical Affairs Act, etc.") which aim to secure the safety and efficacy, and it would take a long period of time to perform required tests, examination, etc., therefor. In this case, even if a patent right continues to exist, the patentee could not practice the patented invention for the period stated above, enjoy benefits by monopolizing such right, and recoup expenses required for R&D. Thus, it would be unfair compared to patent rights in other industrial fields. Therefore, Article 89 of the old Patent Act permits extension of the term of a patent for a period not exceeding 5 years, as long as the patented invention could not be practiced due to receiving approval, etc. under the Pharmaceutical Affairs Act, to promote technical progress in the field of drugs by resolving irrationality and protecting and encouraging the invention of drugs, etc. However, a third party who could practice the patented invention freely after the term of a patent originally set expires would not be able to practice the patented invention until the extended term expires. Thus, Article 91(2) of the old Patent Act stipulates the exclusion of a period delayed due to a cause attributable to the patentee from the period during which the patented invention could not be practiced in order to adjust the interests between the patentee and a third party and to cause the patentee to follow the procedures, such as approval, etc., sincerely and quickly.

b) On the other hand, it is generally and abstractly prohibited to

manufacture or sell drugs without approval, etc. under the Pharmaceutical Affairs Act, etc. Also, since it is allowed to manufacture and sell drugs only after undergoing individual and concrete administrative measures under the administrative laws, such as the Pharmaceutical Affairs Act, etc., it shall continue to be prohibited to manufacture or sell drugs without approval, etc. under the Pharmaceutical Affairs Act, etc. However, the old Patent Act does not calculate the extended term based on all periods during which it is impossible to practice a patented invention, including where a patentee or exclusive licensee or non-exclusive licensee who could practice the patented invention on a lawful basis (hereinafter, collectively the "Patentee, etc.") does not endeavor to receive approval, etc. under the Pharmaceutical Affairs Act. Rather, the old Patent Act extends the term of a patent based only on a period during which the Patentee, etc. could not practice the patented invention notwithstanding their intent and capability to practice the patented invention, such as a period required to receive approval, etc. under the Pharmaceutical Affairs Act, etc. Thus, the "period during which the patented invention cannot be practiced" in Article 89 of the old Patent Act is the latter of the date on which the patentee, etc. commences performance of a test of activity, safety, etc. required to receive approval, etc. under the Pharmaceutical Affairs Act and the date on which the patent right is registered. The period ends on the date on which the disposition of approval, etc. under the Pharmaceutical Affairs Act, etc. reaches its applicant and thus comes into effect. Furthermore, Article 91(2) of the old Patent Act excludes a period required due to causes attributable to the patentee from the period during which the patented invention cannot be practiced. Here, the "period required due to causes attributable to the patentee" means a period during which approval, etc. under the Pharmaceutical Affairs Act, etc. are actually delayed due to causes attributable to the patentee. In other words, the phrase refers to a period for

which a significant causal relationship is recognized between causes attributable to the patentee and the approval, etc. under the Pharmaceutical Affairs Act, etc.

2) Discussion on Error of IPTAB Decision Argued by Plaintiffs

a) In light of the history of the Approval at Issue stated above, a period during which the Extended Invention at Issue cannot be practiced shall be calculated based on the following: a period from the date on which a request for specifications and test methods examination was submitted (March 13, 2008) to the date on which a result of specifications and test methods examination was approved (August 12, 2008); and a period from the date on which an applicant for the Approval at Issue was submitted (August 27, 2008) to the date on which the determination of the Approval at Issue reached the applicant (April 13, 2009). Based on this, this court discusses whether the IPTAB erred, as the Plaintiffs argue, for the "period required due to causes attributable to the patentee" which shall be excluded from each period stated above.

b) First, the Plaintiffs argue the following: It is unfair for the patentee to extend a period required for the Approval at Issue by strategically "requesting the specifications and test methods examination" before filing an application for the Approval at Issue and by separating the "request for the safety and efficacy examination" and the application for the Approval at Issue by filing them at the same time; and thus only a period related to the safety and efficacy examination shall be viewed as a period during which the Extended Invention at Issue could not be practiced, as in Calculation Method 1 argued by the Plaintiffs; and Each IPTAB Decision is inconsistent with the above analysis and shall not be upheld.

To obtain import marketing approval, a drug shall pass ① safety and efficacy examination, ② specifications and test methods examination, ③ GMP evaluation, and ④ DMF examination under Articles 31(2) and 42(1) of the old Pharmaceutical Affairs Act (prior to being amended by Act No. 9932, January

18, 2010; hereinafter, the same shall apply) and Article 24(1) of the Enforcement Rules of the Pharmaceutical Affairs Act (prior to being amended by Ordinance of the Ministry of Health and Welfare, May 6, 2011; hereinafter, the same shall apply). A period during which the patented invention could not be practiced may be calculated based on all periods required, in the procedures for the Approval at Issue for the safety and efficacy examination, the specifications and test methods examination, GMP evaluation, DMF examination, etc. Moreover, under the laws and regulations related to the old Pharmaceutical Affairs Act at the time of the application of the Approval at Issue, etc., a request for the safety and efficacy examination and a request for the specifications and test methods examination may be made at the same time with an application of the drug import marketing approval. Also, a preliminary examination may be requested independently before filing an application for drug import marketing approval, and then the results of such examination may be filed when applying for the drug import marketing approval (see, e.g., Article 24(1)(i) and (ii) of the Enforcement Rules of the old Pharmaceutical Affairs Act). In particular, the latter would help drugs to be approved more quickly through the preliminary examination. In light of the facts stated above, it may not be deemed that an applicant for approval is under an obligation to exercise the duty of care so that an application for import marketing approval and a request for examination would be filed together only when all materials are completed and thus all examination procedures proceed at the same time. Also, it may not be viewed that the patentee separated requests for examination in order to delay the approval procedures. Thus, it is difficult to view that the procedures were delayed due to causes attributable to the patentee only because the patentee requested the specifications and test methods examination before filing the application for drug import marketing approval and then filed the application for

drug import marketing approval and the request for safety and efficacy examination at the same time.

Thus, it may not be deemed, as the Plaintiffs argue, that the IPTAB decision shall not be upheld because it calculated a period during which the Extended Invention at Issue could not be practiced based on not only a period for the safety and efficacy examination, but also a period for the specifications and test methods examination.

c) Next, the Plaintiffs present a premise that a period to be excluded from a period during which the patented invention could not be practiced shall only be "required" irrespective of whether the period was "delayed" due to causes attributable to the patentee. Further, the Plaintiffs argue the following: where a supplementation proceeds according to a request made by one examination department as in Calculation Method 2 argued by the Plaintiffs, the entire supplementation period shall be excluded from the period during which the Extended Invention at Issue could not be practiced irrespective of whether another department conducted examination during the supplementation period; and the IPTAB decision is inconsistent with the above analysis and thus shall not be upheld.

However, in light of the legal principles stated above, only a period for which the substantial causal relationship is recognized between causes attributable to the patentee and the delay in approval, etc. can be excluded from a period during which the Extended Invention at Issue could not be practiced. However, each department in charge in the Korea Food & Drug Administration examines the submitted materials on an independent basis. Thus, it is common that even if any department demands that an applicant supplement his/her application and suspend its examination accordingly, another department would continue to perform its own examination, unless there are special circumstances. Even if a

supplementation period is required due to any department's demand for supplementation but another department continues to perform its own examination, it may not be deemed that approval is delayed due to causes attributable the patentee, etc., provided that the delayed period overlaps with a period during which another department continues to proceed with its own examination. Thus, the overlapping period may not be excluded from the period during which the Extended Invention at Issue cannot be practiced.

Thus, it may not be deemed, as the Plaintiffs argue, that Each IPTAB Decision, which viewed that a period overlapping with a period during which another examining department proceeded with its own examination does not correspond to a period delayed due to causes attributable to the patentee and accordingly calculated a period during which the Extended Invention at Issue could not be practiced, shall not be upheld.

d) Lastly, the Plaintiffs argue the following: It is unfair to calculate, depending on the overlapping of supplementation period, a period required due to causes attributable to the patentee; a period during which the patented invention cannot be practiced shall be calculated, as in Calculation Method 3 argued by the Plaintiffs, by selecting the longest examination period from actual examination periods of examining departments without checking whether the supplementation period overlaps with the periods and then excluding the supplementation period required due to a supplementation demand of the relevant examining department; and each IPTAB decision inconsistent with the above analysis shall not be upheld.

As stated above, Calculation Method 3 calculates the period during which the patented invention could not be practiced by assuming that all examination procedures, such as specifications and test methods examination, safety and efficacy examination, etc., proceeded with the filing of the application

of the approval for drug import marketing. However, the Approval, etc. at Issue have never proceeded as stated above. Also, there is no duty of care imposed on an applicant for approval to file an application for import marketing approval and request various examinations all at once only when all materials are fully prepared. Thus, it may not be deemed, only in light of the fact that the patentee fails to take measures stated above in a responsible manner, that the procedures were delayed. Ultimately, Calculation Method 3 is based on a flawed premise, and thus, it may not be deemed that Calculation Method 3 is reasonable.

Next, it shall be determined, in calculating the "period required due to causes attributable to the patentee" under Article 91(2) of the old Patent Act, how long the approval was delayed as the patentee, etc. neglected the duty of care generally required under social norms in light of procedures and structure for examination, approval, etc. of the Korea Food & Drug Administration. However, Calculation Method 3 stated above takes no account of the actual structural and procedural problems in the examination and approval process of the Korea Food & Drug Administration, and calculates a period during which approval is delayed due to causes attributable to the patentee by replacing the actual examination and approval procedures with a virtual ideal examination and approval process. In other words, as stated above, each examining department in the Korea Food & Drug Administration examines applications for approval and demands supplementation thereof in an independent manner. Thus, it shall be deemed that a period required for approval is prolonged due to the fact that each department in the Korea Food & Drug Administration makes its own demand for supplementation at different times, and accordingly, supplementary materials, etc. are submitted at different times. The supplementation demands were not made at the same time, and thus the time required to obtain approval was prolonged due to causes attributable not to the patentee but to the Korea

Food & Drug Administration. Thus, the patentee shall not be held accountable therefor.

Thus, it may not be deemed, as the Plaintiffs argue, that each IPTAB decision shall not be upheld in that it calculated a period during which the Extended Invention at Issue could not be practiced by being based on a period for examination of the specifications and test methods, a period for examination of the safety and efficacy, etc., which were conducted separately, and determining how long the approval, etc. were delayed due to causes attributable to the patentee in light of the actual procedures, structure, etc. for examination, approval, etc. of the Korea Food & Drug Administration.

3) Summary of Decision

It may not be deemed that each IPTAB decision, to the effect that the Extension Registration at Issue does not fall under Article 134(1)(iii) of the old Patent Act, shall not be upheld, as the Plaintiffs argue.

B. Argument on Article 134(1)(ii) of old Patent Act

1) Relevant Laws

Article 134(1) of the old Patent Act stipulates that "in any of the following cases, an interested party or examiner may file a petition for trial to invalidate the registration of an extension of a patent." Also, subparagraph (2) of the same Article provides that "where the extension has been registered with respect to an application for which the patentee, exclusive licensee, or registered non-exclusive licensee on the patent has not obtained permission, etc. under Article 89." On the other hand, Article 90(1) of the old Patent Act enumerates matters that an applicant for extension registration shall specify in his/her application for extension registration of the extended term of a patent. Among these, subparagraph 6 stipulates "the ground for extension, specified by Ordinance of the Ministry of Knowledge Economy (accompanied by materials

substantiating the ground)", and Article 90(6) provides that "an applicant for registration of an extension may amend any matter specified in paragraph (1)(iii) through 6, which are declared in the application for registration of an extension (excluding the patent number allocated to the patent, the term of which is to be extended under subparagraph 3), before an examiner serves a certified copy of a decision on registration of rejection of the extension on the applicant." Article 53 of the Enforcement Rules of the old Patent Act (prior to being amended by the Ordinance of the Department of Knowledge Economy, December 2, 2011; hereinafter, the same shall apply) enumerates materials that fall under Article 90(1)6 of the old Patent Act, and of which subparagraph 3 stipulates that "materials that prove that a person who obtained approval or registration under subparagraph 1 is the patentee, exclusive licensee, or registered non-exclusive licensee of the patent right."

As examined above, the old Patent Act extends the term of a patent only for a period during which the patentee, etc. could not practice a patented invention, notwithstanding their intent and capability to practice the patented invention. A patentee, exclusive licensee, or non-exclusive licensee who may practice a patented invention in a legal manner in place of the patentee shall file an application for approval, etc. so that a period after filing an application for approval, etc. under the Pharmaceutical Affairs Act posterior to the date of establishment registration shall be included in the "period during which a patented invention could not be practiced" under Article 89 of the old Patent Act. However, unlike an exclusive license, a non-exclusive license may be created only with explicit and implicit agreement between a patentee and a licensee, and does not require any specific form of agreement. The registration of non-exclusive license is required only as a requirement for a claim or defense against a third party (see Articles 102(1) and 118(3) of the old Patent Act).

Thus, to become a non-exclusive licensee, only an agreement is required at the time when an application for approval, etc. is filed under the Pharmaceutical Affairs Act, but it is not required to complete the registration of a non-exclusive license. However, a non-exclusive licensee shall satisfy requirements, etc. of application for extension registration stipulated by Article 90(1)(vi) of the old Patent Act to file an application for approval, etc. under the Pharmaceutical Affairs Act and obtain approval, etc. accordingly. Also, a non-exclusive licensee shall register his/her non-exclusive license and submit evidentiary materials therefor before an examiner of KIPO serves a certified copy of decision of extension registration.

Thus, it would be reasonable to construe that Article 134(1)(ii) of the old Patent Act stipulates “where the extension has been registered with respect to an application for which the patentee, exclusive licensee, or registered non-exclusive licensee on the patent has not obtained permission, etc. under Article 89” as one of the causes of invalidation of extension registration to invalidate the registration of non-exclusive license where the extension registration is made without specifying matters required in an application for extension registration or evidentiary materials therefor and thus fails to satisfy the requirements for extension registration, notwithstanding the fact that not only a patentee or an exclusive licensee, but also a non-exclusive licensee can file an application for approval, etc. necessary to obtain the extension registration of the term of a patent right. It may not be deemed that Article 134(1)(ii) of the old Patent Act provides that a non-exclusive licensee shall complete the registration of non-exclusive license before applying for approval, etc.

2) Discussion

In light of statements in Plaintiff’s Exhibits 2 and 3, Defendant’s Exhibits 1, 5, and 11, and the purport of the overall argument, the following facts are

recognized and no contrary evidence thereto was produced: ① On February 12, 2008, E Healthcare AG completed the patent registration of the Subject Invention and entered into a non-exclusive license establishment agreement for the Subject Invention with E Korea to the effect that the term of non-exclusive license shall be “from February 12, 2008 to December 11, 2020”, its territory shall be “throughout the Republic of Korea”, and its scope shall be “production, use, assignment, rental, importation, subscription of assignment, and subscription of rental.” ② On March 13, 2008, E Korea, as a non-exclusive licensee of the Subject Invention, filed a request for examination of specifications and test methods and proceeded with the procedures for drug import marketing approval with respect to drugs subject to the Approval, etc. at Issue. ③ On the other hand, on July 8, 2009, after merging with E Healthcare AG, F completed the registration of transfer of the Patent Right at Issue to himself/herself and, on July 13, 2009, filed the application for the Extension Registration at Issue. ④ On July 22, 2009, E Korea completed the registration of the non-exclusive license and, around that time, filed evidentiary materials therefor with an examiner of KIPO. ⑤ On June 21, 2010, an examiner of KIPO rendered his/her decision on the Extension Registration at Issue and, around that time, served F with a registered copy thereof.

In light of the established facts stated above, E Korea was a non-exclusive licensee that could practice the Subject Invention in a lawful manner when filing a request for examination of specifications and test methods for drugs subject to the Approval at Issue or filing an application for the Approval at Issue. Also, E Korea completed the registration of non-exclusive license and the submission of evidentiary materials therefor before an examiner of KIPO served a registered copy of decision on the Extension Registration at Issue. Thus, it may not be deemed that the Extension Registration at Issue falls

under Article 134(1)(ii) of the old Patent Act.

3) Summary of Discussion

It may not be deemed that Each IPTAB Decision, which determined that the Extension Registration at Issue does not fall under Article 134(1)(ii) of the old Patent Act, shall not be upheld as the Plaintiffs argue.

4. Conclusion

The Plaintiffs' claim to revoke each IPTAB decision is without merit and therefore dismissed in its entirety. It is decided as ordered.

Presiding Judge	Daekyeong LEE
Judge	Chungsuk LEE
Judge	Youngjoon OH