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Prospective of Foreign Prosecution History Estoppel in Korean Patent Litigation

(In Re *AstraZeneca v. Andrx Pharmaceuticals*)

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Abstract

This Article responds to an emerging view, in patent litigation, to employ foreign prosecution history estoppel as a doctrine in claim construction. In this regard, the United States Court of Appeals for the Federal Circuit has found a representation made during a patent litigation in Korea to be effective as a prosecution history estoppel in a U.S. patent infringement suit, i.e., *AstraZeneca v. Andrx Pharmaceuticals* (04-1562). This Article reviews the foundation of this decision, such as Doctrine of Equivalents and Prosecution History Estoppel. Subsequently, the present Article examines several important cases to analyze the applicability and limitation of resting on foreign prosecution history. In addition, this Article

argues that the Doctrine of Foreign Prosecution History Estoppel may be allowed under Korean Patent Practice by the Korean Supreme Court in view of the “abuse of patent rights” theory. It then explains the effects of adopting foreign estoppel in the aspects of patent holders, accused infringers and courts.

Keywords

foreign prosecution history estoppel, Korean patent litigation, doctrine of equivalents, abuse of patent rights

I. INTRODUCTION

In a recent patent infringement suit[1] between AstraZeneca and Andrx Pharmaceuticals, the U.S. Federal Circuit adopted, as an estoppel, arguments that AstraZeneca had made before Korean courts[2] for seeking Chong Kun Dan liable for patent infringement and, thereby, rendered that the patent in suit is not enforceable against the accused infringer. This decision raised a crucial question whether foreign prosecution histories may be approved as an estoppel, as if the patent's prosecution history is applied as prosecution history estoppel in the context of the doctrine of equivalents. Such issue has a profound implication: if courts rely on foreign patent histories, the current patent practice would have to pay more attention to the prosecutions of foreign counterparts.

Patents of today are apt to have a number of foreign counterparts that are filed in various countries and regional patent offices. These foreign counterparts that have a foreign prosecution history, in general, involve extensive arguments and claim amendments, because a number of searches are performed for the prior art and rejections are applied against the invention in patent prosecution. Hence, the foreign prosecution history plays an important role in patent litigation.

In the light of the growing importance of the foreign prosecution history estoppel in patent litigations, one may wonder if the foreign prosecution history estoppel should be recognized by the court without reservations. The present work indicates that the foreign prosecution history has been accepted only by some of the U.S. trial courts, while others have rejected this principle. It is also worthwhile to note that the Federal Circuit has not

1) *AstraZeneca v. Andrx Pharmaceuticals* 483 F.3d 1364 (Fed. Cir. 2007).

2) KIPT(Korean Intellectual Property Tribunal) Case No. 1993 Dang 439; KIPO Appeal Board Case No. 1994 Huh Dang 457; Korean Supreme Court Case No. 1997 Hu Dang 1108.

yet had an opportunity to fully clarify when such principle can be adopted. Therefore, it would be of great interest to examine under what circumstances a court would be inclined to allow foreign estoppels.

It appears that the Korean courts have not yet employed the doctrine of foreign prosecution history estoppel in patent litigations. In a recent case, however, the Korean Supreme Court made a remarkable decision[3] that recognized the "abuse of patent right" defense which estopped a patentee from enforcing a patent which is invalid for lacking novelty or inventiveness. This decision is worthy of note, since it may provide a foundation for the Korean courts to allow foreign prosecution history as an estoppel in the future cases. Therefore, in this Article, we will reason whether Korean courts are likely to apply the foreign prosecution history estoppel or not.

II. Background

Article 97 of the Korean Patent Act (hereinafter, referred to as KPA) stipulates that the scope of protection of a patented invention shall be defined by the matters described in the claim.

This means that the claim is the basis for determining the scope of patent protection. In this connection, a court generally interprets patent claims by looking at the ordinary meaning of words in claims, as they would have been understood by a person of ordinary skill in the art.[4] However, if a court is strictly restricted by the terminology of the claims, there will be no room for the patent claims to capture analogous inventions. Hence, it is necessary for the courts to widen the scope of the claims in some extent.

3) Korean Supreme Court Case No. 2000 Da 69194, October 28, 2004.

4) Korean Supreme Court Case No. 91 Hu 1908, October 12, 1993.

A. *Doctrine of Equivalents*

The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes.[5] The doctrine of equivalents has been developed mainly in the U.S. through court decisions. In Japan, the doctrine of equivalents was first formalized in 1998. It was held by the Japanese Supreme Court that equivalents are determined by considering (1) whether the difference relates to an important claim element, (2) the possibility for substitution without causing a failure to attain an invention's object and a change in the manner of attaining it, (3) obviousness of the substitution, (4) whether the accused item is an anticipated or obvious modification of state of the art, and (5) whether estoppel exists.[6]

In this regard, the Korean Supreme Court followed by applying the doctrine of equivalents in a scope confirmation case decided on July 28, 2000 (Case No. 97 Hu 2200). The Highest Court considered the following factors to be controlling:

> *(1) The patented process and the accused process are built on the same technical constitution of accomplishing the same inventive purpose of producing a same product, employing an identical starting material;*
> *(2) The reactant employed in the accused process is recognized to have substantially the same function and produce substantially the same result as those of the one employed in the patented process; and*

5) *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd.*, 535 U.S. 722, 733 (2002).
6) Japanese Supreme Court Case No. 1083, 1994 (o).

(3) Further, the reactant of the accused process was already known in the relevant art at the time of filing the subject patent application, and the interchangeability of the reactants to give substantially the same function could be easily conceived by an ordinary person skilled in the art.

B. *Prosecution History Estoppel*

Prosecution history estoppel is a limitation to the doctrine of equivalents that "precludes a patentee from regaining, through litigation, coverage of subject matter relinquished during prosecution of the application for the patent."[7] That is, the narrowing of a patent claim during prosecution is "presumed to be a general disclaimer of the territory between the original claim and the amended claim."[8] Further, a prosecution history may disclaim part of a claim term's ordinary meaning to distinguish the invention from the prior art, thereby limiting the scope of the patent claims.[9] Being a limitation to doctrine of equivalents, prosecution history estoppels initiated to be employed in U.S. court decisions together therewith.

On November 26, 2004, the Korean Supreme Court began to adopt prosecution history estoppels in its Case No. 2003 Da 1564, wherein the patentee argued that an alleged infringer infringed its patented invention[10]

7) *Wang Laboratories, Inc., v. Mitsubishi Electronics America, Inc.,* 103 F.3d 1571, 1577–1578, 41 U.S.P.Q.2d 1263, 1269 (Fed. Cir. 1997).

8) *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd.,* 535 U.S. 740 (2002).

9) *Rhodia Chimie v. PPG Indus. Inc.*, 402 F.3d 1371, 1377 (Fed. Cir. 2005).

10) The patented invention was directed to "a system for folding a cutting blade (500) comprising … a driving unit (410) having (i) a shaft (418) for rotating a rotary body (320a) which folds a cutting blade (500), (ii) a first toothed portion (411a) disposed on the shaft (418), (iii) a second toothed portion (413a) disposed on the rotary body (320a) so that the first and the second

under the doctrine of equivalents. It was stated that the patented invention and the accused product[11] were equivalent[12] on the ground that (i) the technical idea or principle for solving the problem is identical between the patented invention and the accused product, (ii) the elements recited in the patented invention and that of the accused product accomplish the same function and result, and (iii) the interchangeability between the recited elements and the accused product is obvious to a person skilled in the art. However, the Korean Supreme Court pointed out that the patented invention had been narrowed through a correction trial when the alleged infringer had filed an invalidation trial based on a prior art reference.[13] As a result, the Court held that, since the patentee had narrowed the claim scope to avoid the invalidation of the patent based on the prior art, the patentee was not entitled to reclaim the surrendered claim coverage under the doctrine of equivalents.

III. *AstraZeneca v. Andrx Pharmaceuticals* (04-1562) Case[14]

In this section, we would like to review the recent federal case entitled in the above, so as to circumscribe the doctrine of foreign prosecution history

toothed portions (411a and 413a) mesh with each other, and (iv) a servo motor (M) supplying a power to the shaft (418)."

11) The accused product included a driving unit comprising (i) a shaft, (ii) a first tooth portion disposed on the shaft, (iii) a second tooth portion disposed on a rotating member which bends a cutting blade, (iv) a timing belt connecting the first and the second tooth portions, and (v) a servo motor supplying a power to the shaft.

12) That is, the meshed first and the second toothed portions of the patented invention and the timing belt of the accused product were equivalent.

13) a driving unit comprising a gear and a rack connected to a hydraulic cylinder wherein the gear and the rack mesh with each other.

14) *AstraZeneca v. Andrx Pharmaceuticals* 483 F.3d 1364 (Fed. Cir. 2007).

estoppel. Specifically, in this case, arguments made during a Korean patent litigation were found to be evidence that the subject patent was inherently anticipated.

A. *Facts*

(1) AstraZeneca (hereinafter, referred to as Astra), the provider of Prilosec®, Astra's gastric acid inhibiting drug, has U.S. Patent No. 6,013,281[15] (hereinafter, referred to as `281 patent) directed to a method of making omeprazole which is the active content of Prilosec®.

(2) In 2001, Andrx et al. sought permission from the Food and Drug Administration (FDA) to market generic versions of Prilosec®, Astra's gastric acid inhibiting drug. Subsequently, Astra filed patent infringement suits with U.S. Patent No. 6,013,281 against these pharmaceutical companies before the United States District Court for the Southern District of New York. In this connection, Andrx et al. asserted that `281 patent had already been anticipated by a patent directed to a method owned by a Korean company, Chong Kun Dan Corporation (hereinafter, referred to as CKD).

(3) On May 25, 2004, Southern District Court of New York entered a final judgment[16] finding that Andrx Pharmaceuticals, Inc. (Andrx) literally infringed claims 1, 2, 3, 7, 9, 16, and 20-21 of Astra Aktiebolag's United

15) Claim 1 of 281 patent, reading:

1. A process for preparing an oral pharmaceutical formulation comprising the steps of: forming a core material comprising a proton pump inhibitor and at least one alkaline reacting compound, wherein the concentration of the alkaline reacting compound is about 0.1 mmol/g dry ingredients in the alkaline containing part of the core material, and applying an enteric coating polymer layer so as to surround the core material thereby forming in situ a separating layer as a water soluble salt product between the alkaline compound and the enteric coating polymer.

16) In re Omeprazole Patent Litig., M-21-81 (BSJ), MDL Docket No. 1291 (S.D.N.Y. July 15, 2004).

States Patent No. 6,013,281 (the `281 patent). At the same time, however, the district court also found the asserted claims of Astra's `281 patent anticipated or obvious.[17] Thereafter, such judgment was affirmed by the United States Court of Appeals for the Federal Circuit.

1. *AstraZeneca v. CKD* (KR)[18]

Prior to the subject case, Astra filed a patent infringement suit with Korean Patent No. 55426[19] (corresponding to U.S. Patent No. 4,786,505, hereinafter, referred to as `505 patent) against Chong Kun Dan (CKD) which marketed an Omeprazole (which is the generic name for Prilosec®) preparation under the name "OMP" in Korea, manufactured by a method in accordance with a CKD's patent, Korean Patent No. 115,254[20] (hereinafter, referred to as `254 patent).

In response to that, CKD initiated a proceeding on April 3, 1993 in the Korean Intellectual Property Tribunal (hereinafter, referred to as KIPT), called a "negative scope confirmation trial", KIPT Case No. 1993 Dang 439, seeking an advisory opinion that its process falls outside Astra's Korean patent claims.

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17) Final Judgment, slip op. at 2.

18) KIPT Case No. 1993 Dang 439; KIPO Appeal Board Case No. 1994 Huh Dang 457; Korean Supreme Court Case No. 1997 Hu Dang 1108.

19) Claim 1 of Astra's `505 patent, reading:
1. Process for the preparation of an oral pharmaceutical formulation containing omeprazole in which cores containing omeprazole mixed with an alkaline reacting compound or compounds or an alkaline salt of omeprazole optionally mixed with an alkaline reacting compound or compounds are coated with one or more subcoating layers whereafter the subcoated cores further coated with an enteric coating.

20) Claim 1 of CKD's `254 patent, reading:
1. An oral preparation of omeprazole, comprising omeprazole and cores containing L-arginine more than 15 to 25 times in terms of a mole ratio to omeprazole, wherein the cores are coated with an enteric coating without a separate process of coating a inner layer.

This Korean Litigation and its associated KIPT proceedings turned on whether CKD's OMP product contained a subcoating. In this regard, CKD asserted that its two-step process avoided Astra's Korean `505 patent claiming a three-step process, in that CKD's method is not involved with a separate third step that makes a sub-coating.

However, Astra conducted various experiments on CKD's product to verify CKD's denials of any third sub-coating application step. Thus, Astra's inventors continued to believe that CKD actually applied a conventional layer. During their experiments, they conceived the idea that the sub-coating layer was formed in situ. Subsequently, Astra made the following assertions during the Korean Litigation and KIPT proceedings.[21)]

(1) The CKD process (Method A) claimed in the CKD patent application resulted in the in situ formation of a separating layer in CKD's OMP tablet.

(2) Method A forms a separating layer, even though Method A does not have a separate step of applying the separating layer.

(3) Method A formed a separating layer and such formation is inherent in the process of Method A.

(4) The construction of the inner coating layer formed in Method A is exactly of the inner coating layer claimed in the `505 patent.

(5) Ultimately Method A contains the inner coating layer process.

(6) The inner coating layer of the OMP tablet is created instantly at the point of time when the substance of coating the enteric coating is sprayed.

(7) With the start of the process of the enteric coating of the OMP

21) Omeprazole III, slip op. at 29–31.

> *tablet, HPMCAS, which is an enteric coating substance, instantly reacts with the L-arginine that is in the core forms a thin membrane, i.e., an inner coating layer.*

However, in spite of Astra's assertions, KIPT held that CKD's process does not infringe Astra's Korean Patent, i.e., `505 patent.[22] Subsequently, the appeal board affirmed KIPT's decision[23] and Astra appealed to the Korean Supreme Court. On June 12, 1997, however, Astra dropped the suit[24] and the case was finalized.

2. *AstraZeneca v. Andrx Pharmaceuticals* (US)[25]

During the Astra's experiments to disprove CKD's assertion, Astra's inventors were successful in developing the process conditions for making an in situ separating layer. On January 5, 1995, the experiments finally lead to the suitable process conditions required in forming an in situ separating layer. Such work became the foundation of the `281 patent.

On October 6, 1996, Astra Aktiebolag[26] filed United States Application Number 09/413,521 (hereinafter, referred to as `521 application), later issued as the `281 patent. During the prosecution of the `521 application, the applicants disclosed five documents with descriptions of the Korean proceedings within the information disclosure statement. On September 24, 2001, however, the United States Patent and Trademark Office examiner issued a notice of allowance indicating that the claims were all patentable

22) KIPT Case No. 1993 Dang 439, September 23, 1994.

23) KIPO Appeal Board Case No. 1994 Huh Dang 457, February 28, 1997.

24) Korean Supreme Court Case No. 1997 Hu Dang 1108.

25) *AstraZeneca v. Andrx Pharmaceuticals* 483 F.3d 1364 (Fed. Cir. 2007).

26) A subsidiary of AstraZeneca.

over the Korean prior art.

Based on `281 patent, Astra brought up a suit against Andrx et al. for seeking permission from the FDA to market generic versions of Astra's Omeprazole preparation before the United States District Court for the Southern District of New York.

The district court entered a final judgment finding that Andrx literally infringed the asserted claims of `281 patent, but also found the claims anticipated or obvious.[27] During the trial, however, Andrx argued that its process was different from that described in `281 patent in that Andrx's preparation does not have a water-soluble layer, but instead a layer composed of almost 50 percent talc.

On appeal, Andrx maintained its argument disagreeing with the district court's construction of "a water soluble salt" in claim 1 of `281 patent. The Federal Circuit agreed with the district court, finding that the claim phrase "a water soluble salt" permits the inclusion of talc.[28]

Turning to the anticipation, the prior art at issue was a Korean Patent Application, i.e., Korean Laid-open Patent Publication No. 1993-0005605, published on April 20, 1993, which is two years before Astra's earliest priority date.[29] The patent issued from that application had been the basis for the AstraZeneca v. CKD case in Korea. CKD's Korean patent publications described compositions with no enteric coating processes and CKD maintained its enteric coating process – its "know how" – as a trade secret under the KPA to argue that CKD's process does not have a process of forming an in situ separating layer. However, in the Korean action, Astra argued based on their test results that the formation of a separating layer

27) In re Omeprazole Patent Litig., M-21-81 (BSJ), MDL Docket No. 1291 (S.D.N.Y. July 15, 2004) (Final Judgment).

28) *AstraZeneca v. Andrx Pharmaceuticals* 483 F.3d 1364 (Fed. Cir. 2007).

29) Sweden Patent Application No. 9500478, February 9, 1995.

results naturally from the CKD process. In this connection, the district court found that in situ formation was described inherently in CKD's Korean patent publications and relied on and set out in that opinion the following assertions Astra made during the Korean Litigation and KIPT proceedings.

(1) Dr Lövgren(an inventor of `281 patent) contended that the CKD process resulted in the formation of a separating layer.[30]
(2) C.T. Rhodes, Ph.D., opined that the CKD product contained an in situ layer in the proceedings in Korea against CKD.[31]

B. *Decision*

In a 2-1 decision, the Federal Circuit agreed with the district court, pointing to the trial record, which showed that the ingredients and protocols CKD provided in the Korean action necessarily resulted in in situ formation of a separating layer and concluded that the trial court correctly found inherent anticipation.[32]

In Judge Rader's majority decision,[33] the Federal Circuit reasoned that a prior art reference (i.e., CKD's Korean Patent No. 115,254 in the subject case) to a claim limitation may nonetheless anticipate by inherency.[34] Moreover, he cited that inherency is not necessarily coterminous with knowledge of those skilled in the art and artisans of ordinary skill may not recognize the inherent characteristics of functioning of the prior art.[35]

30) Omeprazole III, slip op. at 31.
31) *Id.*
32) *AstraZeneca v. Andrx Pharmaceuticals* 483 F.3d 1367–1368 (Fed. Cir. 2007).
33) *Id.* at 1372
34) In re Cruciferous Sprout Litig., 301 F.3d 1343, 1349 (Fed. Cir. 2002).
35) *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003).

Accordingly, though Astra's inventors may not have recognized that a characteristic of CKD's Method A ingredients, disclosed in the CKD Patent Application, resulted in an in situ formation of a separating layer, the in situ formation was inherent. Further, despite CKD's denials, Drs. Lövgren and Lundberg realized and explained that CKD's OMP tablet's formation of a separating layer was a natural result following from the combination of certain ingredients listed in Method A. Thus, the trial court correctly found inherent anticipation.

However, in the dissenting opinion,[36] Judge Newman wrote that the majority opinion applied a "novel theory" and a "flawed analysis" of inherent anticipation. She stressed that the majority failed to appreciate that claim 1 of the `281 patent is directed to a process, not a composition of matter. Moreover, she noted that it is not disputed that a sublayer does not form under the conditions in the CKD patent application. She explained that while some properties and uses of known compositions may indeed be 'inherently anticipated' in that their existence would have been known to persons in the field of the invention, even if unpublished, that is not this situation.[37] Thus, no prior art describes the Astra process, and there is no evidence that a person of ordinary skill would have known of its existence. In a stern dissent, she emphasized that what is unknown cannot 'anticipate'.[38]

36) *AstraZeneca v. Andrx Pharmaceuticals* 483 F.3d 1373 (Fed. Cir. 2007).

37) *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1345, 1355 (Fed. Cir. 2001) ("[a]nticipation by inherent disclosure is appropriate only when reference discloses prior art that must necessarily include the unstated limitation [or reference] cannot inherently anticipate the claims.")

38) *AstraZeneca v. Andrx Pharmaceuticals* 483 F.3d 1376–1377 (Fed. Cir. 2007).

C. *Foreign Prosecution History Estoppel*

The subject case above, once again, raised the issue of whether foreign prosecution histories are permitted in applying prosecution history estoppel in the context of the doctrine of equivalents. Prosecution history estoppels by amendments or arguments are typical limitations on the scope of claims under the doctrine of equivalents. This prevents an unscrupulous patentee from seeking to cover subject matter within the claim scope that it voluntarily dropped during prosecution to obtain allowable claims.[39,40)]

Whether prosecution history applies to an equivalent is a matter of law.[41)] If the patentee makes a narrowing amendment to satisfy any provision of the Patent Act, the narrowing of claim scope during prosecution is generally "presumed to be a general disclaimer of the territory between the original claim and the amended claim."[42,43)] The patentee may show that the equivalent was unforeseeable at the time of the amendment, which the reason for the amendment was only tangentially related to the equivalent in question, or that for "some other reason," the patentee could not have described the equivalent in question.[44)]

Even if a patent is issued without amendment, it may have one or more foreign counterparts that are allowed only after lengthy prosecution involving extensive arguments and claim amendments. That is to say, even if a patent is issued without any objections or rejections, the claims may still be restricted under the doctrine of equivalents by arguments and claim

39) *Wang Laboratories, Inc. v. Mitsubishi Electronics America, Inc.*, 103 F.3d 1571, 1577–1578, 41 U.S.P.Q.2d (BNA) 1263, 1269 (Fed. Cir. 1997).

40) Korean Supreme Court Case No. 2000 Hu 2712, June 14, 2002.

41) *Smithkline Beecham Corp. v. Excel Pharm., Inc.*, 356 F.3d 1357 (Fed. Cir. 2004).

42) Korean Supreme Court Case No. 2002 Hu 2105, November 26, 2004.

43) *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd.*, 535 U.S. 722, 740 (2002).

44) *Id.* at 740–741.

amendments made in foreign counterpart applications. Such legal rule has been adopted in certain jurisdictions under the name of "Doctrine of Foreign Prosecution Estoppel."

IV. Applicability Of Foreign Prosecution History Estoppel

However, unlike the prosecution history of the subject patent, the foreign prosecution history is not always welcomed by the U.S. district courts and the Federal Circuit (CAFC). Accordingly, there is a great demand for a standard for determining when foreign estoppel may be useful. In the following cases, we will try grasp a pattern thereon, regarding when the courts would adopt foreign prosecution history as evidence.

A. *Decisions in Which Evidence from a Foreign Prosecution History was Used to Limit the Scope of Equivalents*

Especially, some U.S. district courts have generally held that representations made to foreign patent offices during prosecution can be used to prevent a patentee from relying on the doctrine of equivalents in the U.S. to recapture subject matter voluntarily given up in any country, in, e.g., the following cases.

1. *Ajinomoto Co. v. Archer-Daniels-Midland Co.,* 228 F.3d 1338, 56 USPQ2d 1332 (Fed. Cir. 2000)

In the following case, CAFC affirmed the U.S. district court decisions that adopted an expert's testimony submitted to a foreign office in constructing the claims of the subject U.S. patent.

During the patent infringement suit Ajinomoto (i.e., patentee) filed against Archer-Daniels-Midland Co. (i.e., accused infringer; hereinafter, referred to as ADM), the construction of the claims and terminology in the subject patent was controversial.

In this regard, the U.S. district court examined the statements of the experts for both sides on the meaning of "DNA fragment of a donor bacterium." The usage of this term by ADM is referred to ADM's submission to the Japanese Ministry of Agriculture, Forestry and Fisheries, whereas the usage of the term by ABP is referred to the Owner's Manual for the ADM strains.

The Federal Circuit affirmed that the district court's claim construction and related conclusions are supported by the testimony of the experts and fully accord with ADM's and ABP's own usages. Accordingly, applying the district court's claim construction, the Federal Circuit conclude that the imported hybrid plasmid contains the chromosome DNA fragment of a donor bacterium; and, therefore, the finding of infringement is affirmed.

2. *Glaxo Group Ltd. v. Ranbaxy Pharms., Inc*., 262 F.3d 1333, 1335 (Fed. Cir. 2001)

The U.S. Federal Circuit held that arguments made during prosecuting a counterpart UK patent application may be applied in interpreting the term "essentially free" in the subject claims of the case mentioned below.

Glaxo Group Ltd. (i.e., pharmaceutical patentee; hereinafter, referred to as Glaxo) sought preliminary injunction barring Ranbaxy Pharms. Inc. (i.e., accused competitor; hereinafter, referred to as Ranbaxy) from selling or offering for sale antibiotic product under its Abbreviated New Drug Application (ANDA). The United States District Court for the District of New Jersey, Mary L. Cooper, J., granted injunction. However, Ranbaxy

appealed and the Court of Appeals, Randall R. Rader, Circuit Judge, held that: (1) an antibiotic "in amorphous form essentially free from crystalline material," as claimed in patent, described an antibiotic with a maximum crystalline content of less than 10%, and (2) the patentee had failed to show a likelihood of success on merits of claim of infringement by the competitor's product, which contained a higher crystalline content, or that sales of the product would cause an irreparable harm, and thus was not entitled to injunctive relief.

In Judge Rader's decision, he relied on a foreign prosecution history that bolstered the reading of "essentially free from crystalline material." It was the United Kingdom Patent Application No. 8,222,019[45] which the subject patent claimed priority to. Based on arguments submitted during the prosecution of the UK priority application, reciting that the X-ray photograph should show no rings, the Court of Appeals held that "essentially free from crystalline material" means a maximum crystalline content of less than 10%.

3. *Tanabe Seiyaku Co., Ltd. v. U.S. Intern. Trade Com'n*, 109 F.3d 726 (Fed. Cir. 1997)

As for this case, the Court of Appeals found arguments made before a foreign office by the inventor, stating that a certain compound is not interchangeable with the claimed compound, useful in determining infringement in the context of equivalents.

45) The UK application states: "The cefuroxime 1-acetoxyethyl ester in accordance with the invention is preferably essentially free from crystalline material, by which we mean that any amount of crystalline material which may be present is low as to be undetectable by X-ray crystallography, i.e., that an X-ray photograph of a sample of the compound shows no rings. The crystalline content of such a sample may be assumed to be zero for all practical purposes." *see Col. 3, ll. 25-33.*

Tanabe Seiyaku Co., Ltd. and Marion Merrell Dow, Inc. (hereinafter, referred to as Tanabe) in its complaint to the United States International Trade Commission (hereinafter, referred to as ITC) alleged that respondents by the importation, sale for importation, and sale within the United States of diltiazem hydrochloride and diltiazem preparations, produced by a process infringing claim 1 of United States Patent No. 4,438,035 (hereinafter, referred as to "`035 patent"), were in violation of 19 U.S.C. § 1337. The complaint sought an investigation by the ITC and, based on the investigation, issuance of a permanent exclusion order and permanent cease and desist orders. However, in consideration with statements made before the Finnish, Israeli, and European patent offices, the ITC determined that claim 1 was not infringed by any of the respondents, was invalid because it was obvious in view of the prior art, and was unenforceable due to inequitable conduct in its procurement.[46)]

In this regard, Tanabe had appealed from the ITC's determination that certain respondents did not infringe Tanabe's patent. Tanabe argued that the ITC erred in considering the foreign prosecution and in applying prosecution history estoppels to limit the application of the doctrine equivalents.[47)]

Relying on its earlier decision,[48)] the Federal Circuit held that in evaluating infringement under the doctrine of equivalents, representations to foreign patent offices should be considered when they offer relevant evidence. Specifically, the Federal Circuit emphasized the role of foreign prosecution in determining the knowledge of a person of ordinary skill in the art, and whether such a person would consider butanone to be

46) *Tanabe Seiyaku Co., Ltd. v. U.S. Intern. Trade Com'n*, 109 F.3d 730 (Fed. Cir. 1997).

47) *Id.* at 733.

48) *Caterpillar Tractor Corp. v. Berco S.p.A.*, 714 F.2d 1110 (Fed. Cir. 1983).

interchangeable and equivalent to the claimed solvents.[49] Accordingly, in affirming the ITC's ruling, the Federal Circuit alluded to the patentee's statements regarding unexpected results before the foreign patent offices as a basis for concluding that one of ordinary skills in the art would not consider the use of butanone to be insubstantially different from the use of the patentee's claimed acetone.

B. *Decisions in Which Evidence from a Foreign Prosecution History was not Used to Limit the Scope of Equivalents*

In other cases, for example, those discussed in the below, however, some U.S. district courts have rendered that consideration of certain types of representations made during prosecuting foreign counterparts may be inappropriate, since legal and procedural requirements for obtaining patent protection vary from country to country.

1. *Heidelberger Druckmaschinen AG v. Hantscho Commercial Products, Inc.*, 21 F.3d 1068, 1072 (Fed. Cir. 1994)

In the undermentioned case, the U.S. Federal Court did not apply foreign estoppel when the counterpart patent was simply withdrawn.

Heidelberger Druckmaschinen AG (i.e., patentee; hereinafter, referred to as Heidelberger) brought action against Hantscho Commercial Products, Inc. (i.e., accused printing press manufacturer; hereinafter, referred to as Hantscho) for infringement of patent for folding device for web-fed rotary printing presses.

49) *Tanabe Seiyaku Co., Ltd. v. U.S. Intern. Trade Com'n*, 109 F.3d 733 (Fed. Cir. 1997).

At the trial before the district court Hantscho argued that Heidelberger's patent was obvious in view of two references showing the type of drive mechanism shown in Culbertson: British Patent No. 1,427,739, and a book entitled Ingenious Mechanisms for Designers and Inventors (Franklin D. Jones ed., 1978 ed.) (1930). In this regard, the district court concluded that Ingenious Mechanisms, in combination with the Richter patent, rendered the Heidelberger's patent obvious, since Heidelberger had withdrawn the corresponding European patent application after the European examiner rejected the application based primarily on the Ingenious Mechanism reference.

However, the Court of Appeals reversed the district court's decision based on the fact that not only the examination practices but also the theories and laws of patentability are not uniformed yet.[50]

2. *Northern Telecom Ltd. v. Samsung Electronics Co*., 215 F.3d 1281, 55 USPQ2d 1065 (Fed. Cir. 2000)

CAFC has also held that statements made to distinguish different references according to different legal standards do not mandate a court to

50) "There was extensive discussion before the district court, and before us, of the significance of the withdrawal by Heidelberger of the corresponding European patent application after the European examiner rejected the application based primarily on the Ingenious Mechanisms reference. Hantscho states that this established the unpatentability of the device, and that Heidelberger so recognized. Heidelberger responds that it decided not to press prosecution of the European patent since its German, Japanese, and United States patents were meanwhile allowed, and made no concession of unpatentability. The weight that the district court appeared to place on the European examiner's rejection was not appropriate. **We take notice of the fact that the theories and laws of patentability vary from country to country, as do examination practices. Caution is required when applying the action of a foreign patent examiner to deciding whether the requirements of 35 U.S.C. § 103 are met under United States law, for international uniformity in theory and practice has not been achieved.**" *see Heidelberger Druckmaschinen AG v. Hantscho Commercial Products, Inc.*21 F.3d 1072 (Fed. Cir. 1994)

apply foreign estoppel, in the case discussed below.

Northern Telecom Ltd. (i.e., patentee; hereinafter, referred to as Northern Telecom) brought action against Samsung Electronics Co. (i.e., defendant; hereinafter, referred to as Samsung) that used the accused process, alleging infringement of patent on processes for gaseous etching of aluminum and aluminum oxide.

In this connection, the district court issued an opinion setting forth its interpretation of two disputed claim elements, "plasma etching" and "aluminum and aluminum oxide." Thus, the district court construed "plasma etching" to be a chemical process, but one that does not necessarily exclude the mechanical process of ion bombardment. Further, it construed "aluminum and aluminum oxide" to refer solely to pure aluminum and its native layer of aluminum oxide, but not to alloys such as aluminum silicon. Accordingly, the court found that, Samsung's accused reactive ion etching process[51] that employs a boron trichloride plasma falls within the literal scope of the Northern Telecom's patent, notwithstanding the additional element of ion bombardment.

However, during the appeal, Samsung pointed to statements made by the inventors in the course of prosecuting a related Japanese application, wherein the inventors distinguished plasma etching from processes using ion bombardment as an etching mechanism, arguing that references disclosing sputter etching (i.e., ion bombardment) or reactive sputter etching (i.e., reactive ion etching) were not "identical" according to Japanese patent law.

However, CAFC reasoned that "[t]o the extent that statements construing terms in different claims in a different application, made to

51) Samsung described this process as "synergistically combin[ing] energetic ion bombardment with chemically active radicals to achieve an etch rate far in excess of what would be achieved by plasma etching or sputter etching alone."

distinguish different references according to different legal standards, are relevant, we again find that they demonstrate little more than the inventors' view that plasma etching and ion bombardment are different (i.e., not "identical") etching mechanisms." Accordingly, the Federal Circuit concluded that "[w]hile we agree that the record makes clear that the patentees considered plasma etching to be different from ion bombardment, we cannot agree that this mandates a finding of noninfringement."[52] Thus, Samsung's "plasma etching" argument had demonstrated that plasma etching and ion bombardment are indeed different techniques. However, it had failed to show that the Northern Telecom's patent requires, as a part of claim 1, that no ion bombardment be present.

3. *TI Group Automotive Systems (North America), Inc. v. VDO North America, L.L.C., et al*., 375 F.3d 1126 (Fed. Cir. 2004)

The Court of Appeal rendered that statements made by TI Group during prosecution of a Japanese counterpart application to fulfill the varying legal and procedural requirements for obtaining patent protection in Japan are not always considered in a claim construction analysis of a United States counterpart, as follows.

TI Group Automotive Systems (North America), Inc. (i.e., patentee; hereinafter, referred to as, TI), an automotive supplier that owned patent

52) That is, if a patent requires A, and the accused device or process uses A and B, infringement will be avoided only if the patent's definition of A excludes the possibility of B. See, e.g., *Northern Telecom, Inc. v. Datapoint Corp.*908 F.2d 931, 945, 15 USPQ2d 1321, 1332 (Fed.Cir.1990) ("The addition of features does not avoid infringement, if all the elements of the patent claims have been adopted."); *Uniroyal, Inc. v. Rudkin-Wiley Corp.*837 F.2d 1044, 1057, 5 USPQ2d 1434, 1444 (Fed.Cir.1988) ("Adding features to an accused device will not result in noninfringement if all the limitations in the claims, or equivalents thereof, are present in the accused device."); *A.B. Dick*713 F.2d at 703, 218 USPQ at 967.

directed to fuel pump assembly technology, brought infringement claim against VDO North America, L.L.C. (i.e., an accused competitor; hereinafter, referred to as VDO).

In this regard, the district court construed "within" recited in claim 2[53] of TI's patent to mean that "the pumping means components are located inside the reservoir."

However, in its appeal brief, TI argued that because the patentee used the allegedly broader term "within," rather than "inside" or "on the interior," the full breadth should be afforded to the scope of the limitation. However, VDO argued in response that statements made by TI during prosecution of a Japanese counterpart application confirm that the patentee intended "within" to mean "inside."

With respect to VDO's argument regarding statements made during foreign prosecution, CAFC noted that "the varying legal and procedural requirements for obtaining patent protection in foreign countries might render consideration of certain types of representations inappropriate" for consideration in a claim construction analysis of a United States

53) Claim 2 of TI's patent, reading:

2. Apparatus for pumping fuel from a fuel tank to an engine comprising:

(a) a supply port for carrying fuel from the apparatus to the engine;

(b) a fuel reservoir which includes an opening for connecting the interior of the reservoir to the interior of the fuel tank;

(c) means for mounting the reservoir in the fuel tank so as to locate the opening of the reservoir in the region of the bottom of the fuel tank;

(d) pumping means for pumping fuel into the reservoir, said means being located **within** the reservoir in the region of the opening and including a nozzle and a venturi tube in alignment with the nozzle, the passage of fuel out of the nozzle and through the venture tube causing fuel to be entrained through the opening into the interior of the reservoir;

(e) a high pressure pump having an inlet connected to the interior of the reservoir and an output of high pressure fuel; and

(f) means for routing a first portion of the output of high pressure fuel to the supply port and a second portion of the output of high pressure fuel to the pumping means whereby fuel is delivered to the engine from the reservoir through the supply port and fuel is entrained into the reservoir by means of the fuel passing through the pumping means.

counterpart.[54]

C. *Sub-conclusion*

As discussed above, Foreign Prosecution History Estoppel is not always relied on by courts. It may be appropriate, and sometimes "preferable" for a court to consider foreign prosecution history in claims construction, as evidence to construe claim language or to help determine infringement under doctrine of equivalents. In view of the above cases, a wide variety of expert's testimonies, inventor's statements and arguments made during prosecution, which were submitted to the foreign office, have been considered.

However, the effect of foreign prosecution history is limited by the existing law of the subject state regarding claim construction and prosecution history estoppel. Thus, foreign patent history has never been used to contradict the ordinary meaning of a claim term during claim construction, nor used as the sole basis for limiting the scope of equivalents available to a patentee. Moreover, when it is not definite that the claims have been surrendered, such as in the case where the foreign counterpart was simply withdrawn, or when statements were made to either overcome a different reference that is irrelevant with the subject case or satisfy procedural requirements of a foreign country, a court would not be compelled to apply foreign estoppel and would rather be inclined to rule out such foreign prosecution history.

Furthermore, while representations made to foreign patent offices have been admitted and even considered by U.S. courts, claim amendments made during foreign patent prosecution have never been considered.

54) Citing *Caterpillar Tractor Co. v. Berco, S.p.A.*714 F.2d 1110, 1116 (Fed.Cir.1983).

V. Prospective In Korean Patent Litigation

Although the individual patent laws and procedures derived from the basic principles may vary from country to country, the basic principles underlying the patent laws, such as novelty and inventiveness, remain effectively the same in various countries. Due to the similarity of the basic principles, evidence from a foreign patent's prosecution history of a counterpart patent could be useful for Korean courts to determine the scope of equivalents or construe claim terminology. Therefore, it would be of great interest to investigate whether the Korean courts would introduce such evidence in patent litigation. In this section, we shall review two important recent Korean Supreme Court decisions that render the "abuse of patent rights" theory and the defense employing this theory, respectively.

An improper accusation of a patent infringement is often characterized as an abuse of patent rights.[55] A common type of abuse of patent rights is enforcing a patent which is invalid for lack of novelty. In this regard, the Korean Supreme Court rendered that:

> *If a registered IP right is substantially identical to the prior art available before the filing date thereof, such right may not be enforced regardless of the finality of the invalidation decision and without having to compare it with the accused party's technology*.[56]

It is prominently indicated in the above decision that, when the patent in suit is found to lack novelty, the defendant may move to have the

55) Korean Civil Law Article 2(2).

56) Korean Supreme Court Case No. 99 Hu 2853, April 12, 2002.

infringement action dismissed, without having to bring an invalidation trial against the patent.

In another case, the Korean Supreme Court has expanded the above exception by way of recognizing the "abuse of patent rights" theory as a defense in a patent infringement action. In this case,[57] the Supreme Court has made a marked departure from the past practice by holding that the court hearing a patent infringement action may determine whether or not the patent in suit is valid, regardless of the status of the patent nullification trial, when the patent is shown to be *prima facie* invalid: for enforcement of such patent would result in an abuse of patent right and wrongfully injure the accused party.

In view of the above decision, it is now possible for an accused infringer to successfully defend himself in a patent infringement action by demonstrating that the patent in suit is *prima facie* invalid, without having to institute a separate nullification proceeding.

Therefore, if a holder of a Korean Patent brings a patent infringement action based on a claim which has a foreign prosecution history estoppel, it is highly likely that the accused party will succeed in persuading the court to dismiss the infringement action due to the *prima facie* invalidity of the Korean patent in light of such foreign patent prosecution history. Hence, we conclude that Korean courts would adopt the foreign prosecution history estoppel.

If the doctrine of foreign prosecution history estoppel is adopted by the Korean Supreme Court, it may change the practice of prosecuting patent applications. Patent holders and their patent prosecutors will need to spend the time and money to carefully pursue foreign rights and instruct foreign patent practitioners so as not to create inconsistent problems that may later

57) Korean Supreme Court Case No. 2000 Da 69194, October 28, 2004.

be relied upon by an opinion drafter or accused infringer in litigation in the context of foreign prosecution history estoppel. In contrast, it is conceivable that the courts will be able to make decisions based on all of the available and relevant evidence in a patent infringement litigation, while accused infringers will be able to argue that the patent in suit is *prima facie* invalid.

VI. Conclusions

In patent infringement suits filed in U.S. courts, adoption of the foreign prosecution history estoppel has been customarily regarded as being rather advisory, while prosecution history estoppel has been employed in a mandatory manner, in general. As we have investigated in the present work, such as the Astra case, some U.S. courts have adopted inventor's statements, expert's testimonies and arguments made during prosecution in constructing claims, construing claim language or determining infringement under doctrine of equivalents; and, therefore, it is concluded that U.S. courts are optimistic in admitting foreign prosecution history. However, it should be pointed out that foreign prosecution history is not useful in all cases. If the foreign counterpart were simply withdrawn or arguments were submitted to overcome a rejection based on a totally irrelevant reference or a formality objection, it would be difficult for the court to adopt the foreign prosecution history estoppel as an evidence. It should be also borne in mind that it is the current attitude of the U.S. courts not to consider claim amendments made during foreign patent prosecution as the estoppel negating the patentee's infringement claims.

Motivated by significance of the similarity of the basic principles of patent law, we have examined two Korean Supreme Court cases regarding the "abuse of patent rights" theory in order to examine whether the Korean

courts would adopt foreign prosecution history in constructing claims and construing claim language. Based on our review of these cases, it is concluded that Korean courts would recognize the doctrine of foreign prosecution history estoppel in good time.

When foreign prosecution history is admitted by the Korean courts, the Korean patent practice will go through the following prominent changes. First, a patentee prosecuting foreign counterparts would have to take into consideration the contradiction arising from an unfavorable estoppel. Second, the courts would be capable of determining patent infringement with reference to foreign evidences while the accused infringer would be allowed to file a rebuttal against the patent in a suit with the foreign patent history.

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한국 특허소송에서의 외국 출원경과 금반언의 원칙에 대한 전망

이형준

국문초록

본 논문은 청구범위 해석에 있어서 외국특허출원금반언의 원칙을 적용하고자 하는 특허소송상의 새로운 관점을 다루고 있다. 이와 관련하여 미국연방순회항소법원(이하, CAFC라고 함)은 한국의 특허소송 도중에 제출한 소송자료가 미국특허소송인 AstraZeneca 대 Andrx 제약 (04-1562) 사건에 있어서 유효한 출원금반언으로써 적용된다고 보았다. 본 논문은 균등론과 출원금반언과 같은 상기 결정에 대한 기초적인 원리를 검토하고 나서, 여러 주요 판례들을 분석하여 외국출원금반원의 원칙을 적용하는 데 있어서의 적용가능성과 한계를 제시하고자 한다. 나아가서는, 본 논문은 외국출원금반언의 원칙이 한국 대법원에 의하여 한극 특허실무에도 허용될 것인지에 대하여 권리남용이론이라는 관점에서 논의한다. 마지막으로, 외국출원금반언의 적용으로 인하여, 특허권자, 경쟁업자 그리고 법원에 어떠한 영향이 있을지 살펴본다.

주제어

외국출원금반언, 청구범위, 해석, CAFC, AstraZeneca, Andrx, 권리남용