

Date	October 8, 2009	Court	Tokyo District Court
Case number	2007 (Wa) 3493		47th Civil Division
<p>– A case in which the plaintiff, who holds a patent right for absorbents for oral administration, remedies or preventives for kidney diseases, and remedies or preventives for liver diseases, sought an injunction against the manufacture and sale, etc. of the defendant's products as well as the disposal thereof and compensation for damages based on an allegation that the defendant's act of selling and manufacturing the defendant's products constitutes infringement of the patent right, and the court affirmed the application of Article 102, paragraph (2) of the Patent Act based on a finding that, if the right holder can be found to have potential profits which it could have earned if not for the act of infringement, the provision to presume the amount of damages under said paragraph is applicable even if the right holder has not worked the invention covered by the relevant patent.</p>			

References: Article 102, paragraph (2) and Article 184-10, paragraph (1) of the Patent Act

Number of related rights, etc.: Patent No. 3835698

Summary of the Judgment

The plaintiff, who holds a patent right ("Patent Right"; Patent No. 3835698) for absorbents for oral administration, remedies or preventives for kidney diseases, and remedies or preventives for liver diseases, claimed against the defendant an injunction against the manufacture and sale, etc. of the defendant's products (the "Defendant's Products") as well as the disposal thereof and compensation for damages based on an allegation that the defendant's act of selling and manufacturing the Defendant's Products constitutes infringement of the Patent Right.

In this judgment, the court first found that the Defendant's Products before the change of the specification fall within the technical scope of the inventions covered by the Patent Right and that no grounds for invalidation can be found with respect to the patent in question and then made the following determinations with respect to the defendant's allegation that Article 102, paragraph (2) of the Patent Act is not applicable since the plaintiff has not worked the inventions in question.

i. Article 102, paragraph (2) of the Patent Act presumes the amount of damages but not the occurrence of damage. Thus, unless it is proved that lost profits have been caused by the act of infringement, said paragraph shall not apply. Yet, there are no reasons to find that lost profits will be caused by the act of infringement only in the case where the right holder is working the invention covered by the relevant patent. Rather, it

should be construed that said paragraph shall apply if the right holder can be found to have potential profits which it could have earned if not for the act of infringement for various reasons.

ii. In this case, the following facts can be found: [a] the Defendant's Products have been sold after receiving approval for manufacture as a generic drug of the plaintiff's product, which is a therapeutic agent for kidney diseases; [b] the manufacture and sale of the Defendant's Products do not generate new demands; [c] the Defendant's Products compete with the plaintiff's product in the market for therapeutic drugs for kidney diseases; the defendant and the plaintiff compete for market share; [d] the plaintiff's product has a high share in the field of therapeutic agents for kidney diseases that are spherical activated carbons; and [e] there is no evidence to support the possibility that other generic drugs, rather than the plaintiff's product, would have sold well if the Defendant's Products did not exist. In this case where the abovementioned facts can be found, the plaintiff is found to have potential profits which it could have earned if not for the act of infringement by the defendants and thus, Article 102, paragraph (2) of the Patent Act apply to this case.

Judgment rendered on October 8, 2009, the original of the judgment was received by the court clerk on the same day

2007 (Wa) 3493, Case of Seeking Injunction Against Patent Right Infringement, etc.

Date of conclusion of oral argument: July 28, 2009

Judgment

Plaintiff: KUREHA CORPORATION

Defendant: Nichi-Iko Pharmaceutical Co., Ltd., successor of action of
Teikoku Medix Co., Ltd.

Main text

1. The defendant shall pay to the plaintiff 53,014,217 yen and money accrued at the rate of 5% per annum on 567,450 yen among the first-mentioned amount for the period from February 21, 2007 until the date of completion of the payment and on 52,446,767 yen among the first-mentioned amount for the period from December 5, 2008 until the date of completion of the payment.
2. The other claims made by the plaintiff shall be dismissed.
3. The court costs shall be divided into two portions, half of which shall be borne by the plaintiff while the other half shall be borne by the defendant.
4. This judgment may be provisionally executed as far as paragraph 1 of the main text is concerned.

Facts and reasons

No. 1 Judicial decisions sought by the parties

1. Object of claims

(1) (Principal claims)

A. The defendant shall not manufacture, sell or display for sale the products stated in the attached list of the defendant's products (Exhibit Ko).

B. The defendant shall dispose of the products stated in the attached list of the defendant's products (Exhibit Ko) it possesses.

(Alternative claims)

A. The defendant shall not manufacture, sell or display for sale the products stated in the attached list of the defendant's products (Exhibit Otsu).

B. The defendant shall dispose of the products stated in the attached list of the defendant's products (Exhibit Otsu) it possesses.

(2) The defendant shall pay to the plaintiff 3,285,098 yen and money accrued thereon at the rate of 5% per annum for the period from February 21, 2007 until the date of completion of the payment.

(3) The defendant shall pay to the plaintiff 127,142,816 yen and money accrued thereon at the

rate of 5% per annum for the period from December 5, 2008 until the date of completion of the payment.

(4) The court costs shall be borne by the defendant.

(5) A declaration of provisional execution

2. Answer to the object of claims

(1) All of the plaintiff's claims shall be dismissed.

(2) The court costs shall be borne by the plaintiff.

(3) A declaration of avoidance of provisional execution

No. 2 Outline of the case

In this case, the plaintiff, who holds a patent right for an invention titled "absorbents for oral administration, remedies or preventives for kidney diseases and remedies or preventives for liver diseases," alleged that the defendant's act of selling and manufacturing the products stated in the attached list of the defendant's products (Exhibit Ko) (hereinafter referred to as the "Defendant's Products") infringes the abovementioned patent right. Based on this allegation, the plaintiff sought an injunction against the manufacture and sale, etc. of the Defendant's Products based on Article 100, paragraph (1) of the Patent Act and the disposal thereof based on paragraph (2) of said Article, as well as the payment of a total of 130,427,914 yen, the breakdown of which is 1,397,914 yen as compensation based on Article 184-10, paragraph (1) of the Patent Act and 129,030,000 yen as compensation for damages based on Article 709 of the Civil Code, and money accrued on the amount of 3,285,098 yen among the total amount of payment claimed (which is the total of the amount of the first-mentioned compensation and 1,887,184 yen, the amount of damages for the period from August 4, 2006, until October 31 of the same year, among the amount of damages mentioned above) at the rate of 5% per annum provided by the Civil Code for the period from February 21, 2007, which is the date after the claim or tort (date immediately following the day of service of complaint) until the date of completion of the payment, and money accrued on the amount of 127,142,816 yen among the total amount of payment claimed at the rate of 5% annum provided by the Civil Code for the period from December 5, 2008 (the date immediately following the day of service of written petition for amendment of claim), until the date of completion of the payment.

While this action was pending, the specification of the Defendant's Products was changed. The plaintiff, principally, sought an injunction against the manufacture and sale of the Defendant's Products specified by the product name (attached list of the defendant's products (Exhibit Ko)) and also the disposal thereof without distinguishing the Defendant's Products before and after the change of the specification based on the allegation that the Defendant's Products after the specification change still infringe the plaintiff's patent right. In addition, the plaintiff, alternatively, sought an injunction against the sale of the Defendant's Products

specified by the lot number of the stocks of the Defendant's Products having the specification prior to the change (stated in 1(1) and 2(1) in the list of the defendant's products (Exhibit Otsu)) as well as the disposal thereof, and an injunction against the manufacture and sale of the Defendant's Products having the specification prior to the change (stated in 1(2) and 2(2) in said list) as well as the disposal thereof.

No. 3 Undisputed facts, etc. (there are no disputes between the parties with respect to the facts for which no evidence is presented)

1. Parties

(1) The plaintiff is a stock company engaged in the manufacture and sale, etc. of industrial chemicals, industrial chemical products, agricultural chemicals, medicinal products, and quasi-drugs, etc. in the course of trade (Exhibit Ko 1).

(2) Teikoku Medics Kabushiki Kaisha (hereinafter referred to as "Teikoku") was a stock company engaged in the manufacture and sale as well as sale by import, etc. of medicinal products, quasi-drugs, drugs for animals, and medical machinery and appliances, etc. in the course of trade (Exhibit Ko 2). The defendant merged Teikoku Medics Kabushiki Kaisha on June 1, 2009 (the entire import of the oral argument; hereinafter Teikoku and the defendant will be collectively referred to as the "defendant" without distinguishing them).

2. Patent right held by the plaintiff

(1) The plaintiff holds the following patent right (hereinafter referred to as the "Patent Right" and the invention described in Claim 6 that cites Claim 1 shall be referred to as "Invention 1" while the invention described in Claim 6 that cites Claim 2 shall be referred to as "Invention 2" and these inventions shall be collectively referred to as the "Inventions"; the patent granted for the Inventions shall be referred to as the "Patent" and the description for the Patent (see the attached patent gazette) shall be referred to as the "Description").

Patent No. 3835698

Title of the invention: absorbents for oral administration, remedies or preventives for kidney diseases and remedies or preventives for liver diseases

Application date: October 31, 2003

Priority date: November 1, 2002

International publication date: May 13, 2004

Registration date: August 4, 2006

(omitted)

3. The plaintiff sent to the defendant a written notice stating the contents of the scope of claims contained in the application of the Patent (International publication No. WO2004/039381)

(Exhibit Ko 11-1; hereinafter referred to as the "Written Notice") on June 14, 2004, and the Written Notice reached the defendant on the 15th of the same month (Exhibit Ko 11-2).

4. The defendant's acts

The defendant started the manufacture and sale of "Kyūkaru Fine Granules 2g" stated in item 1 of the attached list of the defendant's products (Exhibit Ko) (hereinafter referred to as "Defendant's Product 1") and "Kyūkaru Capsule 286mg" stated in item 2 of said list (hereinafter referred to as the "Defendant's Product 2") in the course of trade and is still continuing the manufacture and sale.

(The defendant alleges that the specification of the Defendant's Products was changed in March 2008 to one which does not fulfill Constituent Feature D. Thus, hereinafter, Defendant's Products 1 and 2 prior to such specification change shall be referred to as the "Defendant's Product 1-1" and "Defendant's Product 2-1," respectively, while Defendant's Products 1 and 2 after the specification change shall be referred to as the "Defendant's Product 1-2" and "Defendant's Product 2-2," respectively. In addition, Defendant's Products 1-1 and 2-1 shall be collectively referred to as the "Defendant's Products Prior to the Specification Change" while the Defendant's Products 1-2 and 2-2 shall be collectively referred to as the "Defendant's Products After the Specification Change.")

5. Structure of the Defendant's Products

Both Defendant's Products 1 and 2 are therapeutic agents for chronic renal failure, which is a renal disease, that use as active ingredients absorbents for oral administration using phenolic resin as a carbon source and thus fulfill Constituent Features A, G and H. In addition, the sieve passing percentage that corresponds to the scope of 0.01 to 1mm opening of the sieve is 90% or more in both of Defendant's Products 1 and 2 and thus, they fulfill Constituent Feature B. When the specific surface is calculated by the Langmuir adsorption model, the specific surface of Defendant's Product 1 is $1,390\text{m}^2/\text{g}$ while that of Defendant's Product 2 is $1,330\text{m}^2/\text{g}$. Thus, both Defendant's Products 1 and 2 fulfill Constituent Feature C. Furthermore, the total basic group of Defendant's Products 1 and 2 is 0.67meq/g and thus they fulfill Constituent Feature I.

With respect to the Defendant's Products Prior to the Specification Change, when the pore volume of their fine pore diameter of 7.5 to 15000nm is measured by using the mercury intrusion technique, Defendant's Product 1-1 has a pore volume of 0.14mL/g , while Defendant's Product 2-1 has a pore volume of 0.11mL/g , and thus they both fulfill Constituent Feature D.

No. 4 Issues

1. Whether or not the Defendant's Products fulfill Constituent Features E and F
2. Whether or not the Defendant's Products After the Specification Change fulfill Constituent Feature D
3. Whether or not the Patent should be invalidated

4. Whether or not the Defendant's Products that fulfill Constituent Feature D are highly likely to be manufactured and sold (whether or not there are any risks of infringement of the Patent Right)
5. Whether or not it is necessary to notify the contents of the amended invention (in relation to the claim for compensation)
6. Amount of compensation
7. Amount of damages based on tort

(omitted)

6. Issue 6 (Amount of compensation)

- (1) Sales volume of the Defendant's Products (for the period from September 2004 to August 3, 2006)

There is no dispute between the parties regarding the fact that the sales volume of the Defendant's Products for the period from September 2004 to August 3, 2006, was at least 18,915,000 yen. Moreover, there is not enough evidence to find that the sales volume exceeds such amount.

- (2) Royalty rate for the Patent

The invention covered by the Patent has an excellent selective absorbability by using phenol resin or ion-exchange resin as a carbon source instead of using petroleum pitch, a conventional art (paragraphs [0004] and [0005] of the Description). However, the plaintiff has not worked the Inventions and has manufactured and sold the plaintiff's product which is a spherical activated carbon using petroleum pitch, a conventional art, as a carbon source. Taking these circumstances into consideration, it is appropriate to determine that, in this case, the royalty rate for the Patent is 3%.

- (3) As described above, the sales volume of the Defendant's Products for the period from September 2004 to August 3, 2006, is 18,915,000 yen and the royalty rate for the Patent is 3%. Thus, the amount of compensation for this period is found to be 567,450 yen.

7. Issue 7 (Amount of damages based on tort)

- (1) The defendant alleges that Article 102, paragraph (2) of the Patent Act shall not apply since the plaintiff has not worked the Inventions.

It is true that said paragraph presumes the amount of damages but not the occurrence of damage. Thus, it is construed that unless it is proved that lost profits have been caused by the act of infringement, said paragraph shall not apply. Yet, there are no reasons to find that lost profits will be caused by the act of infringement only in the case where the right holder is working the relevant patent. Rather, it should be construed that said paragraph shall apply if the

right holder can be found to have potential profits which it could have earned if not for the act of infringement for various reasons.

Moreover, according to the entire import of the oral argument, the following facts can be found: [i] the Defendant's Products have been sold after receiving approval for manufacture as a generic drug of the plaintiff's product, which is a therapeutic agent for renal diseases (encapsulated formulation and subtle granules); [ii] the manufacture and sale of the Defendant's Products do not generate new demands; [iii] the Defendant's Products compete with the plaintiff's product in the market for therapeutic drugs for renal diseases; the defendant and the plaintiff compete for market share; [iv] the plaintiff's product has a high share in the field of therapeutic agents for renal diseases that are spherical activated carbons; and [v] there is no evidence to support the possibility that other generic drugs, rather than the plaintiff's product, would have sold well if the Defendant's Products did not exist. In this case where the abovementioned facts can be found, the plaintiff is found to have potential profits which it could have earned if not for the act of infringement by the defendants and thus, it is appropriate to construe that Article 102, paragraph (2) of the Patent Act apply to this case.

(2) Calculation of damages based on Article 102, paragraph (2) of the Patent Act

A. Sales volume of the Defendant's Products Prior to the Specification Change (after August 4, 2006)

The defendant alleges that the sales volume per one box of the Defendant's Products Prior to the Specification Change is 14,273 yen (84 packs per box) for Defendants Product 1-1 and 14,347 yen (588 capsules per box) for Defendant's Product 2-1, while the number of shipments after August 4, 2006, is 9,896 boxes for Defendant's Product 1-1 and 1,411 boxes for Defendant's Product 2-1. Based on the following facts, the sales volume of the Defendant's Products Prior to the Specification Change for the period from August 4, 2006, to March 2008 is found to be a total of 161,489,225 yen as shown in the calculation formula below: [i] the sales volume per box is calculated based on the drug prices; and [ii] there is not enough evidence to find that shipment was made beyond the number of shipments mentioned above.

According to the defendant's allegation, the manufacture and sale of the Defendant's Products Prior to the Specification Change have completely terminated in March 2008 and there is not sufficient evidence to find that the Defendant's Products Prior to the Specification Change have been manufactured or sold thereafter.

(Calculation formula)

$$14,273 \text{ yen} \times 9,896 \text{ boxes} + 14,437 \text{ yen} \times 1,411 \text{ boxes} = 161,489,225 \text{ yen}$$

B. Profit rate of the Defendant's Products Prior to the Specification Change

According to the evidence (Exhibit Ko 61) and the entire import of the oral argument, it is found that the ratio of net profits to the sales volume in the consolidated accounting period

starting from December 1, 2006, and ending on October 30, 2007, of Nichi-Iko Pharmaceutical Co., Ltd., the parent company of the defendant, was 48.3% while the ratio of operating profits to said sales volume was 35.4%. In light of these facts, it is appropriate to find that the profit rate of the Defendant's Products is 30% as alleged by the plaintiff.

The defendant alleges that the raw material expenses, processing expenses, testing expenses as well as sales administrative expenses and development expenses should be deducted from the sales volume. However, no proof has been shown with respect to these expenses alleged by the defendant and it remains unclear as to whether or not these expenses were additional costs required for the act of infringement. In light of these facts, it is difficult to calculate the amount of profits by deducting these expenses from the sales volume.

C. Amount of damages

As found above, the sales volume of the Defendant's Products Prior to the Specification Change after August 4, 2006, is 161,489,225 yen and the profit rate thereof is 30%. Thus, the amount of damages sustained by the plaintiff is found to be 48,446,767 yen.

(3) Fee for attorneys, etc.

Taking into consideration the contents of this action, the amount upheld and other various circumstances, it is found that 4,000,000 yen is appropriate as the fee for attorneys, etc.

(4) The defendant alleges that the degree of contribution should be reduced for the following reasons: [i] the status as a generic drug attained by obtaining approval for manufacture without any relation to the Patent has contributed to the sales of the Defendant's Products; [ii] the Defendant's Products have been able to be continuously sold even if their specifications have been changed in order to avoid any infringement of the Patent; [iii] the plaintiff is not working the Patent; and [iv] the inventive step of the Patent is extremely small and there are other alternative technologies.

However, in light of the following facts, it cannot be found appropriate to reduce the degree of contribution based on the circumstances alleged by the defendant: [i] the Inventions are worked in the Defendant's Products Prior to the Specification Change as a whole; and [ii] a high selective absorbability has been realized by working the Inventions and the Defendant's Products Prior to the Specification Change have been manufactured and sold by obtaining approval for manufacture as a generic drug of the plaintiff's product.

(5) Based on the abovementioned findings, the amount of damages sustained by the plaintiff as a result of the sales of the Defendant's Products Prior to the Specification Change during the period from August 4, 2006, to March 2008 is 52,446,767 yen, which is obtained by adding the fee for attorneys, etc. of 4,000,000 yen to 48,446,767 yen.

(6) In the object of claim (2) mentioned above, the plaintiff has claimed payment of 1,887,184 yen separately from the claims stated in the object of claims (3) as the damages sustained during

the period from August 4, 2006, to October 31 of the same year, which is a period that partly overlaps with the period claimed in the object of claim (3), in addition to the claim for compensation of 1,397,914 yen. However, as stated above, in the proceedings of this case, only the total amount of damages sustained during the period from August 4, 2006, to March 2008 has become clear and not the breakdown for each period. Thus, the amount of damages sustained in the period claimed in the object of claim (2) remains unclear and therefore, such additional claim is groundless.

Yet, the plaintiff has claimed the damages sustained during the period from August 4, 2006, to October 31, 2008, and the fee for attorneys, etc. in the object of claim (3) stated above, and thus, such claim is found to be well-grounded with respect to the total amount of damages mentioned above (52,446,767 yen).

8. Conclusion

Based on the abovementioned findings, among the plaintiff's claims, all of the claims seeking an injunction against the manufacture and sale of the Defendant's Products stated in the object of claim (1) (object of claim (1)), including the alternative claims thereof, are groundless, and thus will be dismissed.

The claims stated in the object of claim (2) (claims stated in the complaint) are well grounded to the extent of seeking payment of compensation in an amount of 567,450 yen based on Article 184-10 of the Patent Act and delay damages accrued thereon at the rate of 5% per annum provided by the Civil Code for the period from February 21, 2007, which is the day immediately following the date of service of complaint, until the date of completion of the payment, and thus will be upheld while the other claims are groundless and thus will be dismissed.

The claims stated in the object of claim (3) (the claims stated in the written petition for amendment of claim dated December 1, 2008) are well-grounded to the extent of seeking payment of damages in an amount of 52,446,767 yen based on tort and delay damages accrued thereon at the rate of 5% per annum for the period from December 5, 2007, which is the day immediately following the date of service of the written petition, until the date of completion of the payment and thus will be upheld while the other claims are groundless and thus will be dismissed.

A declaration of provisional execution shall be granted with respect to paragraph 1 of the main text while the declaration of avoidance of provisional execution shall not be granted for being inappropriate and the judgment shall be rendered in the form of the main text.

Tokyo District Court, 47th Civil Division

Presiding judge: ABE Masayuki

Judge: MASEKI Sumiko

Judge: FUNABASHI Nobuyuki