Unfair Competition	Date	October 4, 2023	Court	Intellectual Property High Court, Third Division
	Case number	2023 (Ne) 10012		
- A case in which, in a case of a claim for injunction of an act of an unfair competition and the like related to a form of a medical pharmaceutical, which is an inhalation agent for bronchial asthma, since neither of a requirement of special distinctiveness and a requirement of well-known characteristics is satisfied in the form of goods of the Appellant, it cannot be considered to fall under "indication of goods or business" under Article 2, paragraph (1), item (i) of the Unfair Competition Prevention Act, and in light of actual circumstances of transactions, it was determined that no concern of confusion was found between the Appellant's Goods and the Appellees' Goods.				

Case type: Injunction, etc.

Result: Appeal dismissed

References: Article 2, paragraph (1), item (i) of the Unfair Competition Prevention Act

Judgment of the prior instance: Tokyo District Court 2020 (Wa) 19198

Summary of the Judgment

1 This case is a case in which X, who sells a medical pharmaceutical (X Goods), which is an inhalation agent for bronchial asthma, alleged that a form of a medical pharmaceutical (Y Goods), which is an inhalation agent for bronchial asthma manufactured by Y1 company and sold by Y2 company, is similar to the form of the X Goods, and Ys' acts of manufacture and sales of the Y Goods are transfer and the like of the goods using the indication of goods or business similar to the indication of X's well-known goods or business, whereby the Appellant's business interests were infringed and the like, and claimed against Y for injunction of the transfer of the Y Goods or business, disposal of the Y Goods, payment of damages, and the like.

The X Goods and the Y Goods are both such goods with chemicals in inhalers, and X's assertion is that the form of the inhaler of the Y Goods is similar to the form of the inhaler of the X Goods. It is to be noted that the Y Goods are generic drugs (so-called generic drugs) of the X Goods.

The Judgment in prior instance dismissed all the claims by X, and X appealed.

2 The Judgment determined that the form of the X Goods is not acknowledged to fall under the "indication of goods or business" in Article 2, paragraph (1), item (i) of the Unfair Competition Prevention Act or to be likely to create confusion and dismissed the appeal as follows.

(1) Applicability of indication of goods or business of the form of the X Goods

A In order for the form itself of the goods to have the secondary meaning to

indicate a specific origin and to fall under the "indication of goods or business" in the same item, it is interpreted to require that: [i] the form of the goods objectively has a distinctive feature different from the other goods of the same type (special distinctiveness); and [ii] the form has been used by a specific business operator in a monopolistic manner for a long time or the goods having the form have become well-known (well-known characteristics) among consumers as indication of the origin of the specific business operator by extremely powerful promotional advertisements or explosive sales achievements and the like.

B The form of the X Goods is similar to the form of another specific inhalant for bronchial asthma and is not considered to objectively have a distinctive feature different from other goods of the same type.

Moreover, the inhaler of the X Goods has a shape designed to exert efficacies of a pharmaceutical of the X Goods so that patients can inhale the pharmaceutical most effectively and is considered to have an unavoidable form derived from a configuration to achieve substantial functions of the X Goods. However, to give protection to such a form as the indication of goods or business since the requirement of special distinctiveness is satisfied would result in inhibition of free competition among goods having the equal functions, which is not reasonable.

Therefore, it is not approved that the X Goods satisfy the requirement of special distinctiveness.

C X could monopolistically use the form of the X Goods because X had the design right related to the form of the inhaler and the patent right related to the pharmaceutical, and it is natural in a sense of presence of the intellectual property rights generated the monopolistic state, whereby the well-known characteristics are generated. And even if a certain well-known characteristic was generated for the form of the X Goods on the basis of the monopolistic state as above, to allow application of the Unfair Competition Prevention Act only on the basis of the well-known characteristics as above is, in the end, equal to prevention of the use by a third party even after expiration of the durations of the aforementioned intellectual property rights, which is not reasonable. However, even in the case where the well-known characteristic was generated from the monopoly based on the intellectual property rights as above, if such a circumstance is acknowledged that the form of the X Goods is well-known as the indication of the origin, after the influence of the monopolistic state based on the holding of the intellectual property right was dispelled due to passage of the duration of the intellectual property right and passage of a considerable period after competitive goods of the same type were input into the market by a third

party or the like, it should be interpreted that there is room for application of Article 2, paragraph (1), item (i) of the Unfair Competition Prevention Act, but such circumstances are not acknowledged in this case.

Therefore, it cannot be approved that the requirement of the well-known characteristics is satisfied for the form of the X Goods.

D According to the above, it is not acknowledged that the form of the X Goods falls under the "indication of goods or business" in Article 2, paragraph (1), item (i) of the Unfair Competition Prevention Act.

(2) Concern of confusion

A Major consumers of the X Goods and the Y Goods, which are medical pharmaceuticals, are doctors and pharmacists. Although patients are included in the consumers, they are positioned merely as secondary consumers.

B The doctors prescribe medication by considering disease states of the patients, efficacy, side effects, and the like of the pharmaceuticals and examine a whether or not to change to generic drugs, and there cannot be confusion of the goods because of similarities in the forms between the X Goods and the Y Goods at the prescription based on the consideration points as above.

The pharmacists prepare medication on the basis of the prescriptions by the doctors, and original drugs and generic drugs are consciously discriminated at that time. Moreover, the X Goods and the Y Goods stored in dispensing pharmacies are in a state where they are held in boxes with product names described or in a state of being capped and labeled with the product names. Thus, it cannot be acknowledged that there is a concern of confusion between the X Goods and the Y Goods due to the forms thereof by the pharmacists, either.

The patients only receive deliveries of the drugs prescribed by the doctors and prepared by the pharmacists in principle.

From such actual circumstances of transactions as above, a concern of confusion between the X Goods and the Y Goods pursuant to Article 2, paragraph (1), item (i) of the Unfair Competition Prevention Act cannot be acknowledged.

Judgment rendered on October 4, 2023
2023 (Ne) 10012 Appeal Case of Seeking Injunction Act of Unfair Competition and the like (court of prior instance / Tokyo District Court 2020 (Wa) 19198)
Date of conclusion of oral argument: July 19, 2023

Judgment

Appellant: AstraZeneca K.K.

Appellee: NIHON GENERIC Co., Ltd.

Appellee: TOA Pharmaceuticals Co., Ltd.

Main Text

1. The appeal is dismissed.
2. The Appellant shall bear the court costs.

Fact and Reason

No. 1 Object of the appeal

1. The judgment in prior instance shall be revoked.

2. The Appellee, NIHON GENERIC Co., Ltd. (hereinafter, referred to as the "Appellee, NIHON GENERIC") shall not transfer or exhibit for transfer each of the medical pharmaceuticals described in the list of Appellee's Goods in the Attachment in the judgment in prior instance.

3. The Appellee, TOA Pharmaceuticals Co., Ltd. (hereinafter, referred to as the "Appellee, TOA Pharmaceuticals") shall not manufacture, transfer, or exhibit for transfer each of the medical pharmaceuticals described in the list of Appellee's Goods in the Attachment in the judgment in prior instance.

4. The Appellees shall dispose of each of the medical pharmaceuticals described in the list of Appellee's Goods in the Attachment in the judgment in prior instance.

5. The Appellees shall pay to the Appellant jointly and severally the amount of money of 238,862,925 yen, and the money at a rate of 5% per annum from March 31, 2020 for 117,564,694 yen in the above, and the money at a rate of 3% per annum from August 26 of the same year in the case of the Appellee, NIHON GENERIC and from

the 27th day of the same month in the case of the Appellee, TOA Pharmaceuticals shall be paid for 121,298,231 yen until completion of each of the payments.

No. 2 Background (abbreviations and the like shall be as per description in the notations in the judgment in prior instance unless otherwise specified.)

1. This case is a case in which the Appellant who manufactures and sells each of goods (Appellant's Goods) described in the list of the Appellant's Goods in the Attachment of the judgment in prior instance, which are medical pharmaceuticals for bronchial asthma, alleged that a form of each of the goods (Appellees' Goods) described in the list of the Appellees' Goods in the Attachment of the judgment in prior instance manufactured by the Appellee, TOA Pharmaceuticals and sold by the Appellee, NIHON GENERIC is similar to the form of the Appellant's Goods, the Appellees' acts of manufacture and sales of the Appellees' Goods are transfer or the like of goods using the indication of goods or business that is identical or similar to the Appellant's well-known indication of goods or business, whereby the Appellant's business gains were infringed and the like, and fall under the unfair competition pursuant to Article 2, paragraph (1), item (i) of the Unfair Competition Prevention Act (Unfair Competition Prevention Act) and made claims against the Appellees for [i] on the grounds of Article 3, paragraph (1) of the same Act, injunction of transfer and the like of the Appellees' goods; [ii] on the grounds of paragraph (2) of the same Article, disposal of the Appellees' Goods; and [iii] on the grounds of Article 4, Article 5, paragraph (2) of the same Act, payment of 238,862,925 yen as compensation for damages from December in 2019 to May in 2020 and the delay damages by the rate of 5% per annum prescribed in the Civil Code (before revision by the 2017 Law No. 44) from March 31, 2020, after the act of the unfair competition committed in the aforementioned period, to completion of the payment with respect to 117,564,694 yen (the amount asserted by the Appellant to be the total amount of the amount of damages of the Appellant estimated from the amount of profits of the Appellees from December in 2019 to March in 2020 and the attorneys' fees corresponding to 10% of the same amount), and the delay damages by the predetermined rate of 3% per annum prescribed in the Civil Code from the day following the date of service of the bill (August 26, 2020 for the Appellee, NIHON GENERIC and the 27th day of the same month for the Appellee, TOA Pharmaceuticals) to the completion of the payment with respect to 121,298,231 yen (the amount asserted by the Appellant to be the total amount of the amount of damages of the Appellant estimated from the amounts of profits of the Appellees in April and May in 2020 and the attorneys' fees

corresponding to 10% of the same amount) with respect to the above.

The judgment in prior instance dismissed all the claims by the Appellant, and the Appellant made an appeal against the judgment in prior instance.

2. Regarding the basic facts, issues, and assertions by the parties against them, the supplemental assertion by the Appellant in this Court is added as in postscript 3 and also as described in "Facts and Reasons" No. 2, 1, No. 3, and No. 4 (from page 3, line 2 to page 64, line 25) in the judgment in prior instance and thus, they shall be cited.

However, in the judgment in prior instance, the wording "in light" on page 42, line 2 shall be corrected to "in light of" and "only indicate," on page 48, line 22 to "only indication".

(omitted)

No. 3 Judgment of this court

This Court also determines that none of the Appellant's claims are grounded and thus, they should be dismissed. The reasons are as follows.

1. Found facts

The found facts are as described in the "Facts and Reasons" No. 5, 1 (from page 65, line 2 to page 74, line 13) in the judgment in prior instance and thus, they shall be cited.

However, the wording "usually" on page 71, line 9 in the judgment in prior instance shall be corrected to "usual", and "medic pharmaceuticals" on the same page, line 18, page 72, line 13, page 73, lines 12, 14, and 15 to "medical pharmaceuticals".

2. Issue 1 (Applicability of the Unfair Competition Prevention Act)

This Court also determines that the assertion by the Appellees on issue 1 cannot be employed. The reasons for that are as described in "Facts and Reasons" No. 5, 2 in the judgment in prior instance (from page 74, line 15 to page 75, line 13) and thus, they shall be cited.

3. Issue 2 (Applicability of indication of goods or business of the form of the Appellant's Goods)

(1) Unlike trademarks and the like, the form of the goods does not inherently have a purpose of indicating an origin of the goods and does not naturally fall under the "indication of goods or business" in Article 2, paragraph (1), item (i) of the Unfair Competition Prevention Act, but in some cases the form itself of the goods might have a secondary meaning to indicate the specific origin. And in order for the form itself

of the goods to have the secondary meaning to indicate the specific origin and to fall under the "indication of goods or business" in the same item as above, it is interpreted to require that: [i] the form of the goods objectively has a distinctive feature which is different from the other goods of the same type (special distinctiveness); and [ii] the form has been used by a specific business operator in a monopolistic manner for a long time or the goods having the form have become well-known (well-known characteristics) among consumers as indication of the origin of the specific business operator by extremely powerful promotional advertisements or explosive sales achievements and the like.

(2) Issue 2-3 (Special distinctiveness)

Regarding the Appellant's goods, it is not found that the form of the goods objectively has a distinctive feature different from the other goods of the same type and satisfies the requirement of the special distinctiveness, which are corrected as follows and are as described in "Facts and Reasons" No. 5, 3(3)A to D (from page 81, line 5 to page 84, line 12) and thus, they shall be cited.

A. After page 82, line 14 in the judgment in prior instance, the following shall be added as a new line.

"And the sales of ASMANEX was started in 2009 (entire import of the oral argument), and the sales of the Appellant's goods was started before 2010 (Basic facts (2)A) and thus, it cannot be acknowledged that the form of ASMANEX imitated the form of the Appellant's Goods."

B. The part on page 84, lines 8 to 12 in the judgment in prior instance shall be corrected as follows.

"D. Moreover, the inhaler of the Appellant's Goods (a main-body portion and a mouthpiece portion) has a shape designed to exert performances of the medical agent of the Appellant's Goods, and patients can inhale the drug most effectively (Exhibits Ko 16, 27, the Exhibits Otsu 38-1, 3, 4, the entire import of the oral argument), and the Appellee, TOA Pharmaceuticals proceeded with development while consulting the Pharmaceuticals and Medical Devices Agency (PMDA) in the development of a generic drug of the Appellant's Goods and made the structure and shape of the inhaler similar to the inhaler of the Appellant's Goods in order to obtain determination on equivalence with the Appellant's Goods in points of therapeutic equivalence (equivalence in evaluation by clinical tests) and pharmaceutical equivalence (Exhibit Otsu 38-1, the entire import of the oral argument).

According to the aforementioned circumstances, although the forms of the inhaler and the mouthpiece portion of the Appellant's Goods are inevitable forms

derived from the configuration to achieve the substantial functions of the Appellant's Goods, it is unreasonable to give protection to the forms as above as the indication of goods or business, because satisfaction of the requirement of the special distinctiveness would incur such a result that inhibits free competition among the goods with the equivalent functions.

And a portion obtained by removing the inhaler main-body and the mouthpiece portion from the Appellant's Goods is a cap and a rotary grip portion, but the shapes of these portions can be considered to be common.

From the aforementioned points, too, it cannot be acknowledged that the Appellant's Goods satisfy the requirement of the special distinctiveness."

(3) Issue 2-4 (Well-known characteristic)

A. Regarding the Appellant's Goods, as in the Found facts (8)B, related to the form of the inhaler, it was found that the article related to the design as the "inhaler" was registered for the design right on January 28, 2000, and the duration expired on January 28, 2015. It can be considered that, during the period when the Appellant had the aforementioned design right related to the form of the inhaler of the Appellant's Goods, manufacture / sales by the others of the goods having the shape similar to the form of the Appellant's Goods were limited.

Moreover, as described in the Found facts (8)A(A), regarding combination drugs of the Appellant's Goods, the patent of the invention titled "New combination" was registered on August 23, 2002, but it is found that the duration expired on December 7, 2017. While the Appellant had the patent right related to the combination drugs of the Appellant's Goods, it is found that the others cannot receive approval for manufacture / sales of the generic drugs of the Appellant's Goods, and the generic drugs could not be manufactured or sold. And as described above, the forms of the inhaler and the mouthpiece of the Appellant's Goods have shapes designed so that the functions of the medical agent of the Appellant's Goods are exerted and patients can inhale the drug most effectively, which are in demand from the functions of the Appellant's Goods. Thus, while the Appellant had the aforementioned patent right, and the others could not manufacture or sell the generic drugs of the Appellant's Goods, it can be considered that the manufacture / sales by the others of the goods having the form similar to the form of the Appellant's Goods were substantially limited.

As described above, the Appellant could use the form of the Appellant's Goods in a monopolistic manner, since the Appellant had the aforementioned design right and patent right, and it is natural in a sense that the monopolistic state is generated by

the presence of the intellectual rights, with which the well-known characteristics are generated. And even if certain well-known characteristics were generated for the form of the Appellant's Goods on the basis of the monopolistic state as above, to allow application of the Unfair Competition Prevention Act only on the grounds of such well-known characteristics is, in the end, equal to hindrance to the use thereof by a third party even after expiration of the durations of the aforementioned intellectual property rights. Such a situation contradicts the purpose of the intellectual property right system which allows monopoly of the use thereof for a certain period of time as a consideration for provision of valuable information, while it is made open to the public and the use thereof is allowed after the period has elapsed, and this contradiction is not reasonable. However, even if the well-known characteristics are generated from the monopoly based on the intellectual property right as above, after the duration of the intellectual property right has elapsed, a reasonable period of time has passed since the competitive products of the same type by a third party were input into the market, and an influence of the monopolistic state based on the holding of the intellectual property right was dispelled, if such circumstances that the form of the Appellant's Goods is still well-known as indication of the origin are admitted, it should be considered that there is some room for application of Article 2, paragraph (1), item (i) of the Unfair Competition Prevention Act.

B. By examining this case from this point, the manufacture and sales of the Appellees' Goods were approved in February in 2019 (Basic facts (3)A), the sales started in December, 2019 (Basic facts (3)B), and from January 28, 2015, when the duration of the design right related to the form of the inhaler in the Appellant's Goods expired, only relatively short periods of time of approximately 4 years and approximately 4 years and 10 months had elapsed, respectively. And only short periods of approximately 1 year and 2 months had elapsed since December 7, 2017, when the duration of the patent right of the combination drugs of the Appellant's Goods expired, until the Appellees' Goods gained approval for manufacture and sales thereof and approximately 2 years until the sales of the Appellees' Goods, and no such circumstances are found that a third party's generic drugs other than the Appellees' Goods were sold during this period and thus, it cannot be considered that the influence of the monopolistic state based on the holding of the intellectual property right was dispelled during this period by an input of a third party's competitive goods of the same type into the market for a considerable period of time or that the form of the Appellant's Goods has been used by the Appellant monopolistically for a long period of time. Moreover, even with all the evidence of this case, it cannot be

acknowledged that the influence of the monopolistic state based on the holding by the Appellant of the intellectual property right for the Appellant's Goods during the aforementioned period was dispelled or the form of the Appellant's Goods newly obtained the well-known characteristics by extremely powerful promotional advertisements, obtainment of explosive sales achievements, and the like by the Appellant during this period.

C. With this regard, the Appellant asserts that the Judgment by the Tokyo High Court on February 25, 1993 affirmed the indication of goods or business in the case in which a period from extinction of the patent right to sales of a competitive product is approximately 3 years and a half, and in this case, since approximately 5 years have passed since expiration of the duration of the design right related to the Appellant's Goods until the sales of the Appellees' Goods was started, the influence of the monopolistic state based on the holding by the Appellant of the intellectual property right related to the Appellant's Goods was dispelled (No. 4, 5 (Assertion by Plaintiff) in Judgment in prior instance, (4)C).

However, in the first place, only short periods of approximately 1 year and 2 months to 2 years have passed since the expiry of the duration of the patent right by the aforementioned combination drugs in this case and thus, even if there is such a trial case that the indication of goods or business was affirmed by lapse of 3 years and a half, it has no influence on the determination of this case. Moreover, the Judgment by the Tokyo High Court on February 25, 1993 cited by the Appellant determined that a part of the goods of the defendant in the first instance of that case was similar to a part of the goods of the plaintiff in the first instance in shape and form, and that there was a concern of confusion of the origin. However, these goods of the plaintiff in the first instance were not registered for the patent right, the design right, or the other intellectual property rights (in this case, although it was found that the design right was registered for some of the forms in the goods of the Plaintiff in the first instance, it was determined that the goods of the Plaintiff in the first instance for which the design right was registered as above were not found to be similar to the shape and the form of the goods of the Defendant in the first instance.).

Therefore, the Appellant's assertion on the premise that the aforementioned judgment was rendered on the determination affirming the indication of the goods or business in the case where the period from extinction of the intellectual property right to the sales of the competitive goods was approximately 3 years and a half is erroneous, and it cannot be approved that the influence of the monopolistic state based on the holding of the intellectual property right of the Appellant's Goods was

dispelled until the start of sales of the Appellees' Goods on the grounds of the trial case or that the shape of the Appellant's Goods newly obtained the well-known characteristics after that.

D. According to the above, it cannot be approved that the requirement of the well-known characteristics is satisfied for the form of the Appellant's Goods.

(4) According to the aforementioned (2) and (3), the form of the Appellant's Goods satisfies neither of the requirement of special distinctiveness and the requirement of well-known characteristics required to be applicable to the "indication of goods or business" in Article 2, paragraph (1), item (i) of the Unfair Competition Prevention Act and thus, the form, of the Appellant's Goods cannot be acknowledged to be applicable to the "indication of goods or business" in the same item.

4. Issue 4 (Concern of confusion)

(1) As a premise for determination on whether or not there is found to be a concern of confusion, whether or not patients, besides doctors and pharmacists, are included in consumers of the Appellant's Goods and the Appellees' Goods will be examined.

The Appellant's Goods and the Appellees' Goods are medical pharmaceuticals, but regarding the medical pharmaceuticals, a doctor examines a patient and determines a type and an amount of a drug to be prescribed on the basis of the diagnosis in the examination. The Appellant's Goods and the Appellees' Goods are medical pharmaceuticals for the patient to inhale drugs by an inhaler and thus, in some cases the doctor shows actual pharmaceuticals in order to explain how to use the inhaler to the patient at the examination, and it is found that the patient can have a chance to state his / her opinion at that time, (Found facts (6) and (7)), but prescription of drugs are made only by the doctor by considering the disease state of the patient, efficacy, side effects, and the like of the drugs, and there cannot be such an occasion that the patient can freely select the type of drugs and the like. Moreover, the pharmacist prepares the medicine on the basis of the prescription by the doctor, but if the doctor prescribed drugs with brand names but did not determine that a change cannot be made to generic drugs, and if the doctor prescribed drugs with general names, generic drugs can be prepared. In that case, the pharmacist confirms the patient's intention on whether or not the patient prefers the generic drug and then, prepares the medicine (Found facts (7)). The patient can indicate his / her intention within the aforementioned range and select between an original drug and a generic drug at a dispensing pharmacy, but it is not found that the patient can make selection of medical pharmaceuticals more than the above.

By summing up the aforementioned circumstances, the major "consumers" referred to in Article 2, paragraph (1), item (i) of the Unfair Competition Prevention Act are doctors and pharmacists, and it is understood that, although the patients are included in the "consumers", they are only at a position of secondary consumers.

(2) A. The doctors, who are major consumers of the Appellant's Goods and the Appellees' Goods, make prescriptions with disease states of the patients, efficacy, side effects, and the like of the medical pharmaceuticals as consideration elements and examine whether or not to change to generic drugs. When making prescriptions based on the consideration elements as above, it cannot be expected that the Appellant's Goods are confused with the Appellees' Goods, since the forms of the Appellant's Goods and the Appellees' Goods are similar to each other, and that should not occur in the first place. Even if the doctor might show the Appellant's Goods or the Appellees' Goods in a state of an in-use form at the examination of the patient in order to show the shape of the inhaler to the patient, the Appellant's Goods or the Appellees' Goods at the doctor are in a boxed state or at least in a storage form, product names are printed on the box (Exhibits Ko 143-1 to 4, 144-1 to 4, Exhibits Otsu 46-1, 47-1), and labels on which the product names are printed are pasted on outer sides in the storage form (List of Appellant's Goods photos in the judgment in prior instance, Lists 1 and 2 of Appellees' Goods photos). Thus, even if the doctor pulls out the goods from the box, removes the cap to bring the goods into the in-use state, and shows it to the patient, there cannot be confusion between the Appellant's Goods and the Appellees' Goods by the form at that time.

B. The pharmacist prepares drugs on the basis of the doctor's prescription and, except the case where the doctor determines that a change to the generic drug should not be made, prepares the generic drug after confirming the patient's intention. But when the pharmacist changes the drug to the generic one, the reference on which the selection of the generic drug was based should be explained to the patient, and in an insurance pharmacy, when a prescribed drug according to the brand name prescription was changed to the generic drug or the preparation according to the general name prescription, information on the brand and the like of the dispensed drugs should in principle be provided to the insurance medical institution which issued the prescription (Found facts (7)B) and thus, it can be considered that the pharmacist consciously discriminates the original drug from the generic drug in preparation.

Moreover, the Appellant's Goods and the Appellees' Goods stored in the dispensing pharmacy are in the boxed state or in the storage form, and when they are delivered to the patient, it is considered to be in the storage form. Thus, as described

above, the goods names are described on the boxes and the appearances of the storage forms. From these circumstances, for the pharmacists, too, it cannot be found that there is a concern of confusion between the Appellant's Goods and the Appellees' Goods by the forms.

C. The patient in principle only receives the delivery of pharmaceuticals prescribed by the doctor and prepared by the pharmacist as described in the aforementioned (1).

When the doctor has not determined that the change to the generic drugs cannot be made, even if the pharmacist confirms the patient's intention on change to the generic drugs, and the patient has a chance to state the intention to change to the generic drug to the pharmacist, the pharmacist delivers the Appellant's Goods or the Appellees' Goods in the storage form. Thus, it cannot be expected that the confirmation on the intention would be made by changing the form to the in-use one, and it cannot be considered, either, that the patient would confuse the Appellant's Goods with the Appellees' Goods by the form.

Moreover, even if the doctor shows the Appellant's Goods or the Appellees' Goods in the in-use form to the patient, as described in the aforementioned A, when the doctor shows the Appellant's Goods or the Appellees' Goods in the in-use form to the patient, it cannot be acknowledged that the doctor would confuse the form, and the doctor makes prescription by considering the disease state of the patient, and efficacy and side effects of the pharmaceuticals and thus, it can be considered that the doctor discriminates the Appellant's Goods, which are original drugs, from the Appellees' Goods, which are generic drugs, and then, shows it to the patient. Then, even if the patient saw the in-use form shown by the doctor, it cannot be acknowledged that the confusion would occur between the Appellant's Goods and the Appellees' Goods by the form at that time.

(3) In light of the actual circumstances of the transactions from the aforementioned (2)A to C, it cannot be acknowledged that there is a concern of confusion under Article 2, paragraph (1), item (i) of the Unfair Competition Prevention Act between the Appellant's Goods and the Appellees' Goods.

5. Determination on assertion by the Appellant in this Court

(1) The Appellant asserts that the judgment in prior instance stated that the form of the Appellant's Goods does not fall under the indication of goods or business without direct determination on two requirements; that is, the special distinctiveness and the well-known characteristics regarding the form of the goods and that the determination was made on the unique finding that the form of the medical

pharmaceuticals does not fall under the indication of goods or business at all, which is unreasonable.

However, even if the determination that none of the forms of the medical pharmaceuticals requiring doctors' prescription as in the judgment in prior instance fall under the indication of goods or business is not reasonable, it is not acknowledged in this case that either of the requirement of the special distinctiveness and the requirement of the well-known characteristics is satisfied in relation with the form of the Appellant's Goods as taught in the aforementioned 3(2) and (3) and thus, the aforementioned assertion by the Plaintiff does not influence the determination that the indication of goods or business on the basis of the form of the Appellant's Goods is not approved.

Therefore, the Appellant's aforementioned assertion cannot be employed.

(2) The Plaintiff asserts that in the opinion by Professor A' (Exhibit Ko 110), [i] it is pointed out that doctors, pharmacists, and patients recognize and discriminate the inhalers by the form; and [ii] it is pointed out that, when the forms of the inhalers are similar to each other, such an expectation is generated that the same technology is used for the structure inside the inhaler and the drugs, and the same therapeutic effects will be gained. According to these circumstances, when the forms of the Appellant's Goods and the Appellees' Goods are similar to each other, and the features of how to use are the same, there is a concern that the doctors, pharmacists, and patients would recognize the Appellees' Goods as an AG or a new version of the Appellant's Goods, which causes confusion of origins in a narrower sense or confusion in a wider sense.

However, according to the circumstances of the transactions of the Appellant's Goods and the Appellees' Goods, any of these major consumers; that is, the doctors, pharmacists, and the patients, who are consumers at the secondary position, do not discriminate the Appellant's Goods and the Appellees' Goods by their forms, and it cannot be found that there is a concern of confusion by the form as taught in the aforementioned 4(2). Moreover, according to the entire import of the oral argument, it is found that the AG of the Appellant's Goods has not been sold at all until now and thus, such a situation that the AG of the Appellant's Goods, which does not exist in actuality, and the Appellees' Goods being erroneously recognized or confused by the consumers would not occur.

And even if the doctors, pharmacists, or patients have expectation that the Appellees' Goods, which are generic drugs, would exert the same therapeutic effects as those of the Appellant's Goods, from the circumstances of the transactions as

described in the aforementioned 4(2), the confusion based on the similarity in the forms of the Appellant's Goods and the Appellees' Goods could not occur.

Therefore, the Appellant's aforementioned assertion cannot be employed.

(3) The Appellant asserts that, in the case of prescription of drugs by a doctor, when the doctor prescribes brand-name drugs and then, leaves the column indicating that the change to the generic drug is not allowed blank, or when the doctor prescribes general-name drugs, there can be two cases; that is, the patient receives the Appellant's Goods or receives the Appellees' Goods, but in either case, there is a concern that the doctor, pharmacist, and patient misunderstand that the Appellees' Goods are the AG of the Appellant's Goods, the same device as that of the Appellant's Goods is used for the Appellees' Goods, or the Appellees' Goods use the same technology as that of the Appellant's Goods by technology transfer and the like and thus, there is a concern that confusion in a narrower sense or confusion in a wider sense could occur.

However, similarly to the aforementioned (2), from the actual circumstances of the transactions of the Appellant's Goods and the Appellees' Goods, it is not found that any one of the doctors and pharmacists as major consumers and the patients as secondary consumers discriminates the Appellant's Goods and the Appellees' Goods by their forms, and it cannot be acknowledged that there is a concern of confusion by the form.

Therefore, the Appellant's aforementioned assertion cannot be employed.

(4) The Appellant asserts that the Appellees' Goods are not identical to the Appellant's Goods as the device or formulation, or the technology of the Appellant's Goods is not used, either. But if the patient switches the Appellant's Goods to the Appellees' Goods and continuously uses it without sufficiently recognizing the circumstances, this could cause grave disadvantages to the patients.

However, the circumstances cited by the Appellant has nothing to do with the determination on presence / absence of a concern of confusion prescribed in Article 2, paragraph (1), item (i) of the Unfair Competition Prevention Act, or there is no evidence sufficient to admit that a problem would occur if the patient continuously uses the Appellees' Goods approved for manufacture and sales as generic drugs and sold.

Moreover, the Appellant asserts that, even if a generic drug of the Appellant's Goods is to be manufactured, forms of a counter (residual amount gauge) and a mouthpiece can be largely changed, but the Appellees intentionally employed the form extremely similar to that of the Appellant's Goods regardless of that, and the

Appellees paid attention to the appearance attractive to the consumers and brought the form of the Appellees' Goods closer to the Appellant's Goods.

However, as described in No. 5, 3(3)D in the judgment in prior instance (after the amendment in the aforementioned 3(2)B), the inhaler of the Appellant's Goods has such a shape designed to exert the performance of the drugs of the Appellant's Goods so that the patient can inhale the drug most effectively, while in the development of the generic drug of the Appellant's Goods, it is found that the Appellee, TOA Pharmaceuticals proceeded with the development while consulting the Pharmaceuticals and Medical Devices Agency (PMDA) and made the structure and the shape of the inhaler similar to the inhaler of the Appellant's Goods, and it is not found that the Appellees made the form of the Appellees' Goods similar to the form of the Appellant's Goods with the purpose of employing the appearance attractive to the consumers.

Therefore, the aforementioned assertion by the Appellant cannot be employed.

(5) The Appellant asserts that: [i] the AG of the Appellant's Goods has been reported in industrial papers, the doctors recognize possibility of listing of the AG of the Appellant's Goods on the market, and the AG of many pharmaceuticals are listed on the market in general and thus, even if the AG of the Appellant's Goods is not actually sold, there is a concern that the Appellees' Goods, which are GE, might be confused with the AG, and confusion of the origin would occur; [ii] as shown by the Appellant, more than 50 accidents (medical accident information or near-miss cases) caused by similarity in the appearances, outer shapes, shapes, or forms occurred from 2010 to 2021, and the fact that the doctors and pharmacists caused the medical accidents and near-miss cases indicates that the doctors and pharmacists cannot pay perfect attention in actuality and thus, the judgment in prior instance which determined that it cannot be acknowledged that there is a concern of confusion on the basis of these cases is erroneous; [iii] the judgment in prior instance determined that, regarding the questionnaire of this case presented by the Appellant in the court of prior instance, it only compares the forms of the Appellant's Goods and the Appellees' Goods in a state where labels were simply removed and thus, it does not necessarily indicate actual circumstances of identification or selection of the medical pharmaceuticals by the consumers at the time of transaction, but in the actual medical front, prescription and preparation of drugs cannot be performed with the greatest care at all times without an error, a phenomenon similar to the questionnaire of this case could occur and even if labels are different, the consumers recognize that one of them is improved goods of the other, products with different dosages, derivative goods of

the same series, and thus, the aforementioned determination of the judgment in prior instance is erroneous; [iv] a patient can select a generic-drug manufacturer by selecting a dispensing pharmacy, and particularly for the inhaler, its form is a clue to discriminate the drug, and when a patient examines an inventory of a dispensing pharmacy, if there is an inhaler whose form is similar to that of his / her desired inhaler, the patient erroneously recognizes that the inhaler is the same as his / her desired inhaler or for which the same technology is used and obtains it and thus, the patients are included in the consumers.

However, regarding the aforementioned [i], even if the possibility of sales of the AG of the Appellant's Goods is reported, the AG of the Appellant's Goods is not sold in actuality. Thus, it is difficult to consider that the doctors and pharmacists nevertheless misunderstand that the Appellees' Goods for the AG of the Appellant's Goods. Moreover, even if the aforementioned reports were posted in industrial papers related to medical practice, it is not acknowledged that general patients recognize the fact of the reporting, and together with the aforementioned absence of the erroneous recognition by the doctors and pharmacists, it cannot be acknowledged, either, that the patients misunderstand that the Appellees' Goods are the AG of the Appellant's Goods.

Regarding the aforementioned [ii], regardless of the facts of plural occurrences of medical accidents or near-miss cases caused by the similarity in the appearances, outer shapes, shapes, or forms, they are considered to be cases in which mistakes occurred due to negligence of duty of care by the medical workers, and it cannot be acknowledged that a concern of confusion prescribed in Article 2, paragraph (1), item (i) of the Unfair Competition Prevention Act was generated by the occurrences of these cases. That is, the occurrence of the aforementioned cases should be dealt with separate measures from the viewpoint of preventing occurrences of medical accidents, and the occurrences of these cases do not constitute a reason for granting injunction of the Appellees' Goods or damages to the Appellant, since a concern of confusion prescribed in the same item is generated for the form of the Appellees' Goods.

Regarding the aforementioned [iii], in light of the actual circumstances of the transactions of the Appellant's Goods and the Appellees' Goods, at the time when the doctors make prescriptions and at the time when the pharmacists prepare drugs and deliver the Appellant's Goods or the Appellees' Goods to the patients, the Appellant's Goods or the Appellees' Goods are in boxes with the product names described or in the storage form in which labels with the product names printed are pasted and thus, even if there is a person who erroneously takes the Appellees' Goods in the storage

form or in the in-use form in a state where the label with the product name printed has been removed for the Appellant's Goods, it cannot be acknowledged that there is a concern of confusion between the Appellees' Goods and the Appellant's Goods by the doctors, pharmacists, and patients at the transactions of the Appellant's Goods or the Appellees' Goods.

Regarding the aforementioned [iv], there is no evidence sufficient to acknowledge that there are such actual circumstances of transactions that general patients select the type of the generic drugs by selecting a dispensing pharmacy. Moreover, even if there is such a patient who searches a dispensing pharmacy having an inventory of the Appellees' Goods and makes a choice on the premise that the inhalers of the Appellees' Goods, which are generic drugs, are similar to the inhalers of the Appellant's Goods, it is difficult to presume that the patients who have such knowledge and search the dispensing pharmacies would confuse that business entities of the Appellees' Goods and the Appellant's goods are identical or have an organizational parent-child relation or an affiliation relation of the companies.

Therefore, none of the aforementioned assertions by the Appellant can be employed.

(6) The Appellant asserts that: [i] the Appellant's Goods belong to ICS/LABA in the inhalant for bronchial asthma treatment, while ASMANEX belongs to ICS, and since the Appellant's Goods and ASMANEX belong to different markets, and in the determination on the special distinctiveness of the Appellant's Goods, ASMANEX should not be used as a comparison target; [ii] even if the markets as ICS and ICS/LABA are assumed, the number of prescriptions of ASMANEX is only approximately 2 to 3% of the Appellant's Goods and thus, ASMANEX does not influence the special distinctiveness of the Appellant's Goods; and [iii] in the Appellant's Goods, a position of a counter is largely different, shapes of the mouthpiece and the cap are also different, and it is different from ASMANEX in either of the storage form and the in-use form.

However, the Appellant's Goods and ASMANEX are in common in a point that they are both inhalants for bronchial asthma treatment, and even though the number of prescriptions of ASMANEX is smaller than that of the Appellant's Goods, ASMANEX is sold in the market and thus, in the determination on the special distinctiveness of the form of the Appellant's Goods, it is not interpreted to be unreasonable to consider similarity with the form of ASMANEX.

And it is found that ASMANEX includes all the shapes pointed out by the Appellant to be featured in the storage form of the Appellant's Goods and also

includes most of the shapes pointed out by the Appellant to be featured in the in-use form of the Appellant's Goods, while all the common parts are ordinary as determined in No. 5, 3(3) in the judgment in prior instance (after the amendment in the aforementioned 3(2)). Therefore, the aforementioned determination is not influenced even after the examination of the assertion by the Appellant in this court.

Therefore, the aforementioned assertion by the Appellant cannot be employed.

(7) The Appellant asserts that, the Intellectual Property High Court Judgment on August 29, 2019 (Case of portable / disposable low-pressure continuous aspirator / Intellectual Property High Court 2019 (Ne) 10002) can be referred to in this case, and in that case, the form of the Goods of the medical equipment is not only acknowledged to be a consideration element when medical personnels select the goods concerned but it was also determined that, even in the case of the medical equipment, by being used by a specific business entity continuously / monopolistically, there can be such a case that the form of the goods having a unique feature that can be discriminated from the other goods of the same type obtains a function to identify its origin indicating that the form of the goods concerned is the goods of the business entity concerned and thus, the form of the Appellant's Goods should be acknowledged to be the indication of goods or business. In that case, the Defendant of the first court of the case asserted that, for purchase of the aspirator concerned, its safety and quality should be examined and predetermined procedures should be taken and thus, there is no such a case that the Goods are identified only by the form thereof. However, since the assertion was proscribed, the assertion by the Appellees that the identification by the form is not made in this case, either, on the grounds that the doctors and pharmacists prescribe or prepare drugs carefully in accordance with the predetermined procedures should also be proscribed.

However, the Goods which mattered in the case of the judgment pointed out by the Appellant are medical equipment, while the Appellant's Goods and the Appellees' Goods are medical pharmaceuticals. In the prescription of medical pharmaceuticals by doctors, even in the case of those with a shape including an inhaler as the Appellant's Goods and the Appellees' Goods, the doctors prescribe drugs by considering the disease state of the patient and drug components, and the Goods are not identified only by the form. Therefore, the case of the aforementioned judgment is different from this case, and it is not interpreted that the form of the Appellant's Goods should be acknowledged to be the indication of goods or business, because the form of the Goods was acknowledged as the goods or business in the aforementioned judgment.

Therefore, the aforementioned assertions by the Appellant cannot be employed.

6. As described above, it shall not be acknowledged that the form of the Appellant's Goods falls under the indication of goods or business or that a concern of confusion in pursuant to Article 2, paragraph (1), item (i) of the Unfair Competition Prevention Act occurred.

The aforementioned determination shall not be influenced even by examining the contents of the unceasing assertions by the Appellant.

7. Conclusion

According to the above, all the claims by the Appellant should be dismissed, and the judgment in prior instance with the same gist as this is reasonable.

Therefore, since this appeal is not grounded, it shall be dismissed, and the judgment shall be rendered as in the main text.

Intellectual Property High Court, Third Division

Presiding Judge: SHOJI Tamotsu

Judge: IMAI Hiroaki

Judge: MIZUNO Masanori