

Call for Public Comments on Medical Use Inventions and the Scope of Effect of Patent Term Extended Patents

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Summary

The Osaka District Court Decision of March 3, 2026, Reiwa 7 (Wa) Nos. 10786 and 10790, an action seeking an injunction for infringement, concerned two medical use inventions relating to the originator drug AMITIZA Capsules 24 µg/12 µg, containing lubiprostone as the active ingredient. The plaintiffs sought an injunction against the generic drug SAWAI Lubiprostone Capsules 24 µg. Although the court found that the defendant's product itself fell within the technical scope of the inventions, it held that the effect of the patent term extensions concerning the 12 µg formulation (Extensions 1-2 and 2-2) did not reach the 24 µg formulation and dismissed the plaintiffs' claims. Third-party public comments were solicited in the appeal, IP High Court Reiwa 8 (Ne) No. 10041, concerning how to determine the technical scope of medical use inventions and the scope of effect of patent term extended patents. This article outlines the Osaka District Court decision, the public-comment topics, and issues concerning medical use inventions and the patent term extension system.

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1. Related Cases and Information

(1) Supreme Court Decision of October 22, 1999, Heisei 10 (Gyo-Hi) No. 43

This decision set out the standard for calculating the period of patent term extension for pharmaceutical patents. The Supreme Court held that the start of the period during which “the patented invention could not be worked” is the later of the date on which the tests necessary for the marketing approval application commenced and the date on which the patent was registered. It further held that the end of the period is the day before the approval became effective upon reaching the applicant. Thus, the decision made clear that the extension covers only the period during which the patented invention could not actually be worked because of pharmaceutical regulations, rather than a period determined by formal dates.

(2) IP High Court Decision of January 20, 2017, Heisei 28 (Ne) No. 10046 (Oxaliplatin Case)

This decision addressed the extent to which a patent term extended patent has effect against a generic product that is not completely identical to the approved drug product. The court held that the effect of the patent extends to the working of the patented invention with respect to a drug product identified by the approved “ingredient, amount, dosage and administration, and indications and effects”. It also held that the effect extends where differences from the generic product are slight or merely formal when viewed as a whole and the products are “substantially identical” as pharmaceuticals. The court gave four categories as examples.

Category 4 applies where the “amount” of the active ingredient differs between the approved drug product and a generic product, but the products are substantially identical when the difference is considered together with the “dosage and administration”. For example, although the amount of active ingredient per tablet is half, the amount per administration and the method of administration may be the same because two tablets are taken at one time. This appeal may be viewed as raising whether it falls within such a case.

(3) Supreme Court Decision of November 17, 2015, Heisei 26 (Gyo-Hi) No. 356 (Bevacizumab Case)

This case concerned whether a patent term extension based on a later approval may be granted where an earlier approval exists. The earlier approval was for administration of bevacizumab at 5 or 10 mg/kg every two weeks, and the later approval added administration at 7.5 mg/kg every three weeks. The Supreme Court held that the issue should be decided by comparing matters directly related to the pharmaceutical product’s substantial identity, i.e., ingredient, amount, dosage and administration, and indications and effects, and determining whether the earlier approval encompassed the manufacture and sale approved by the later approval. Because the new dosage and administration were not encompassed by the earlier approval, the Court allowed the extension based on the later approval.

(4) The “Label Theory” and the “Exclusive-Use Theory”

The “label theory” determines the use of an accused product, when assessing infringement of a medical use invention, primarily from the “indications and effects” and “dosage and administration” stated in the package insert, interview form, package labeling, and similar materials. An infringement finding is more likely where the patented use is stated; conversely, a skinny label excluding the patented use generally weighs against infringement. However, even if the use is excluded on the label, inducement of use for the patented indication through promotional activities or actual prescribing practices may raise issues such as indirect infringement. The “exclusive-use theory” limits working of a use invention to manufacture or sale “exclusively for use in the patented use” of a known product. Under this approach, a product that is a general-purpose product also used for non-patented uses does not infringe merely because it can be used for the patented use. The former focuses on approval and labeling, whereas the latter focuses on actual market use and the availability of other uses.

(5) “Skinny Label” Approval

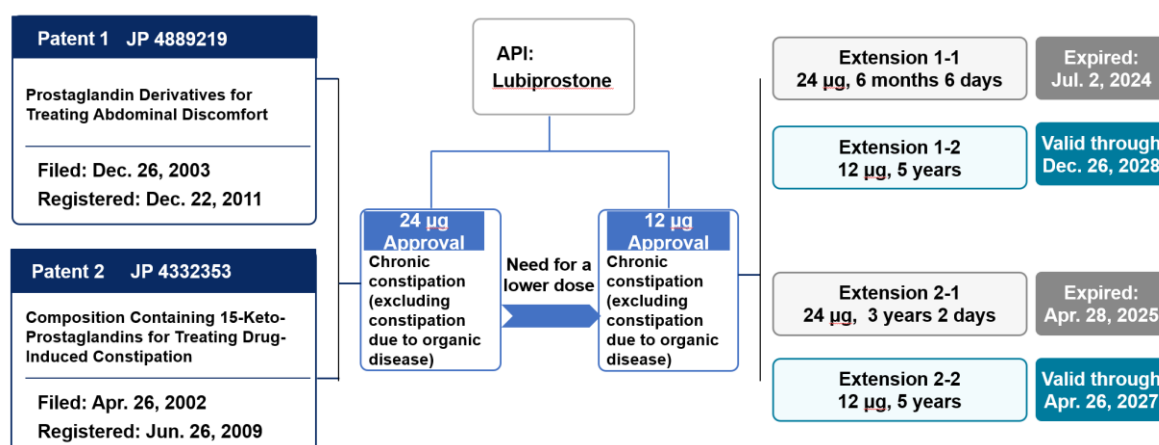
Where an approved indication of an originator drug is protected by a use patent, a generic drug may obtain approval for indications other than the patented use by excluding the patented indication from the approved matters. In Japan, this is called “mushikui shonin” (skinny-label approval).

2. Overview of the First-Instance Decision (Osaka District Court Decision of March 3, 2026, Reiwa 7 (Wa) Nos. 10786 and 10790)

Position	Party	Description
Plaintiff	Viatrix Pharmaceuticals Japan Inc.	Manufacturer and seller of AMITIZA Capsules 24 µg and 12 µg (the “Plaintiffs’ 24 µg and 12 µg Products”). Exclusive licensee of Patents 1 and 2. Seeks an injunction against the production, etc. of the defendant’s product, its disposal, and an application for NHI price listing.
Intervenor for Plaintiff	Sucampo GmbH	Patent owner. Granted an exclusive license to the plaintiff. Obtained Extensions 1-2 and 2-2.
Defendant	Sawai Pharmaceutical Co., Ltd.	Generic-drug manufacturer that applied for marketing approval for Lubiprostone Capsules 24 µg “SAWAI” (the “Defendant’s Product”). It applied for approval on February 24, 2023 and obtained approval on February 16, 2026.

(1) The Patents, Marketing Approval Applications, and Patent Term Extensions

As shown in the figure below, the matter involves two patents, two marketing approval applications for the plaintiffs’ 24 µg and 12 µg products, and four patent term extensions. The extensions based on the 24 µg product have expired, whereas the extensions concerning the 12 µg product remain in force.



Claim 1 of Patent 1 (the “Invention 1-1”)

A pharmaceutical composition for treating abdominal discomfort caused by a functional gastrointestinal disorder in a mammalian subject, comprising a compound represented by general formula (II)

Claim 14 of Patent 1 (the “Invention 1-14”)

A pharmaceutical composition for treating a functional gastrointestinal disorder, comprising a compound represented by general formula (II)

Claim 4 of Patent 2 (as corrected; the “Invention 2”)

A composition for treating drug-induced constipation caused by an opioid compound or an anticholinergic agent, comprising, as an active ingredient, a 13,14-dihydro-15-keto-16-mono- or dihalo-prostaglandin E compound represented by general formula (II), wherein the 13,14-dihydro-15-keto-16-mono- or dihalo-prostaglandin E compound is 13,14-dihydro-15-keto-16,16-difluoro-prostaglandin E1

(2) Features of the Plaintiffs' and Defendant's Products

Plaintiffs' Products

Brand name: AMITIZA Capsules 24 µg and 12 µg

Active ingredient: Lubiprostone

Indication: Chronic constipation (excluding constipation due to organic disease)

Dosage form: Capsules (24 µg or 12 µg per capsule)

Defendant's Product

Brand name: SAWAI Lubiprostone Capsules 24 µg

Active ingredient: Lubiprostone

Indication: Chronic constipation (excluding constipation due to organic disease)

Dosage form: Capsules (24 µg per capsule)

(3) Issues

The parties do not dispute that the active ingredient of the defendant's product falls within the active ingredient of Patent 1, "a compound represented by general formula (II)", and the active ingredient of Patent 2, "13,14-dihydro-15-keto-16,16-difluoro-prostaglandin E1". The principal issues are satisfaction of the use requirement (Issue 1) and whether the effect of the extended patents reaches the defendant's product (Issue 2).

Issue 1: Does the defendant's product fall within the technical scope of Inventions 1 and 2 (satisfaction of the use requirement)?

Issue 2: Does the effect of Patents 1 and 2, whose terms were extended by Extensions 1-2 and 2-2, extend to the production, assignment, etc. of the defendant's product?

Issue 3: Are there grounds for invalidity of Extensions 1-2 and 2-2 (calculation of the extension period and estoppel during the prosecution history)?

Issue 4: Is an injunction, etc. necessary (including an injunction against an application for NHI price listing)?

(4) Summary of the Parties' Arguments

The plaintiffs' arguments were as follows.

Issue 1: "Functional gastrointestinal disorder" in Patent 1 includes the defendant product's indication, "chronic constipation (excluding constipation due to organic disease)". "Drug-induced constipation" in Patent 2 is a type of medication-induced constipation and is classified as chronic constipation. Although the defendant invokes the label theory and the exclusive-use theory, patients with functional gastrointestinal disorders and drug-induced constipation are necessarily included among patients for whom the product is prescribed for chronic constipation. In response to the defendant's assertion that the applicant intentionally excluded "treatment of constipation" during prosecution of Patent 1, the plaintiffs argue that the applicant's statement merely distinguished the prior art, which disclosed constipation generally without specifying a classification, by explaining that the medical use of Invention 1-1 is treatment of abdominal discomfort specifically caused by a functional gastrointestinal disorder.

Issue 2: The plaintiffs' 12 µg product and the defendant's product have the same ingredient, dosage and administration, and indications and effects; only the amount differs. Their technical characteristics and effects as pharmaceuticals are the same. They therefore fall within Category 4 of the Oxaliplatin IP High Court decision and are substantially identical. The Bevacizumab case also contemplates and permits the effect of an extension based on a later disposition to reach a formulation of a different amount.

Issue 3: In light of the Supreme Court decision of October 22, 1999, it is clear that the approval of the plaintiffs' 12 µg product required the clinical trial results for the plaintiffs' 24 µg product.

The defendant's arguments were as follows.

Issue 1: Regarding technical scope, the defendant invokes the exclusive-use theory and the label theory. Inventions 1 and 2 are use inventions for “treatment of abdominal discomfort caused by a functional gastrointestinal disorder”, “treatment of a functional gastrointestinal disorder”, and “treatment of drug-induced constipation caused by an opioid compound or anticholinergic agent”. On the other hand, the proposed package insert for the defendant's product states the indication to “chronic constipation (excluding constipation due to organic disease)” and does not provide a label for exclusive use for a “functional gastrointestinal disorder” or “drug-induced constipation”. Further, during prosecution of Patent 1, the applicant argued that “treatment of constipation” and “treatment of abdominal discomfort caused by a functional gastrointestinal disorder” are different medical uses and emphasized that difference from the cited documents to obtain allowance. Thus, “treatment of constipation” was intentionally excluded from the scope of the claims.

Issue 2: The requirements for extension registration and the scope of effect of an extended patent should be understood as linked. Extensions 1-2 and 2-2 based on the plaintiffs' 12 µg product correspond to the scope of working of a low-dose formulation, for which the prohibition was lifted by the administrative disposition specific to the 12 µg formulation. Working of the 24 µg formulation was already protected by Extensions 1-1 and 2-1 based on the 24 µg disposition. If the extensions based on 12 µg formulation can also be applied to the 24 µg formulation, it would constitute a substantial re-extension of the term of the earlier extensions.

Issue 3: As to grounds for invalidity of the extensions, the tests necessary for approval of the plaintiffs' 12 µg product were primarily bioequivalence and stability tests. It is improper to include in the “period during which the invention could not be worked” the clinical trial period for the earlier 24 µg formulation.

(5) The Decision

The Osaka District Court held as follows and dismissed all of the plaintiffs' claims.

Issue 1: In light of common general knowledge in clinical medicine, the defendant product's indication, “chronic constipation (excluding constipation due to organic disease)”, includes functional constipation, which falls within functional gastrointestinal disorders, and medication-induced constipation caused by opioids, anticholinergic agents, etc. The court could not find that the use of treatment of constipation had been intentionally excluded during prosecution.

Issue 2: The scope of effect of an extended patent should be delineated in a segmented manner based on the ingredient, amount, dosage and administration, and indications and effects of the drug product in the marketing approval under the Pharmaceuticals and Medical Devices Act. Extending effect from a later disposition to a product that is the same, in ingredient, amount, dosage and administration, and indications and effects, as the subject matter of an extension based on an earlier disposition would effectively re-extend the earlier extension and would be improper. In the present case, the defendant's product is the same, in ingredient, amount, dosage and administration, and indications and effects, as the subject matter of the 24 µg disposition (the plaintiffs' 24 µg product) that formed the basis for earlier Extensions 1-1 and 2-1, whose extension periods have already expired. Although it differs only in amount from the subject matter of the 12 µg disposition (the plaintiffs' 12 µg product) that formed the basis for later Extensions 1-2 and 2-2, treating the defendant's product, completely identical to the plaintiffs' 24 µg product, as “substantially identical” to the plaintiffs' 12 µg product and extending the effect of the later extensions to it would be inconsistent with the earlier extensions and contrary to the purpose of the patent term extension system.

Issues 3 and 4: The court did not decide these issues because the plaintiffs' claims were to be dismissed in any event.

3. Call for Public Comments on the Second-Instance Appeal (Reiwa 8 (Ne) No. 10041)

(1) Overview of the Appeal

In this action, the Plaintiff, as appellant, appealed the above first-instance decision.

Appellant: Viatris Pharmaceuticals Japan Inc.

Intervenor for Appellant: Sucampo Pharma Americas, LLC

Appellee: Sawai Pharmaceutical Co., Ltd.

Intervenor for Appellee: Towa Pharmaceutical Co., Ltd.

(2) Questions asked by the Court in the Call for Public Comments

Under its third-party public comment system, the IP High Court invites opinions from the public in this appeal (comment period: June 29 to September 30, 2026). The outline of the requested topics is set out below. They concern issues in the PTE system, including how to determine infringement of medical use inventions and patent term extensions where multiple formulations exist, such as formulations with different amounts.

Question 1. Medical Use Inventions

(1) Where a medical use invention that discovers a new use for a known substance has been patented, what factors should be considered in determining whether an accused generic drug falls within the technical scope of the patented invention or whether manufacture, sale, etc. of the drug constitutes working of the patented invention?

(2) Where an accused product covered by a medical use patent may also be used for purposes other than the patented use, and an injunction against working is granted, how should the operative part of the judgment be framed?

Question 2. Scope of Effect of a Patent Term Extended Patent

(1) Where the patent term has been extended and the basis for extension registration is approval under the Pharmaceuticals and Medical Devices Act, how should the scope of “product” to which the extended patent has effect be interpreted? How should its relationship with the requirements for extension registration be understood?

(2) Does the effect of a patent whose term was extended based on approval of an originator drug product containing 12 µg of active ingredient extend to a generic product, containing 24 µg of the active ingredient and differing in excipients, where the dosage and administration and the indications and effects are the same as the originator product?

(3) In considering item (2), how should the following circumstances be assessed?

a. A separate extension registration has been granted based on approval of an originator drug product containing 24 µg of the active ingredient.

b. The extension period for the extension registration in (a) has already expired.

c. An approval exists for an originator drug product containing 24 µg of the active ingredient, but no extension registration has been granted based on that approval.

4. Issues Concerning Medical Use Inventions and the Scope of Effect of Patent Term Extended Patents

(1) Medical Use Inventions

Many medical use inventions confer a new medical use on a known compound, and their claims state use requirements such as “for treating XX” or “for treatment of disease YY”. In the first-instance proceedings, the label theory and the exclusive-use theory were debated in determining technical scope. The Osaka District Court, however, held on the basis of clinical-medical classification and the description of the specification that the “chronic constipation” use falls within “treatment of abdominal discomfort caused by a functional gastrointestinal disorder” and “treatment of a functional gastrointestinal disorder” in Patent 1, and “treatment of drug-induced constipation” in Patent 2, to reject an excessive limitation under the label

theory and the exclusive-use theory. The court further held that the use of treatment of constipation could not be found to have been intentionally excluded during prosecution and did not accept the defendant's prosecution-history-estoppel argument.

On the other hand, in prosecution of Patent 1, the applicant amended the claimed use from “*abdominal discomfort*” to “*abdominal discomfort caused by a functional gastrointestinal disorder*” in the amendment dated July 26, 2010, in response to novelty and inventive-step rejections based on references disclosing an intestinal-transit-promoting effect, a laxative effect, treatment of constipation, etc. The applicant argued in a written opinion dated July 26, 2010, that “*constipation and abdominal discomfort are different concepts, and it is unknown whether effectiveness for constipation also results in effectiveness for improvement of abdominal discomfort*” and that “*abdominal discomfort caused by a functional gastrointestinal disorder and constipation are clinically clearly distinguished*”.

In prosecution of Patent 2, the applicant responded to references disclosing laxatives and the like by arguing that “*a substance useful as a laxative is not necessarily effective for treatment of drug-induced constipation*” in a written opinion dated March 18, 2010. Under this background, the issue is whether the use of the plaintiffs' and defendant's products, “*chronic constipation (excluding constipation due to organic disease)*”, should be considered within the technical scope of the patented inventions.

Patent	Use	Prosecution History
Patent 1	Invention 1-1 Treatment of abdominal discomfort <u>caused by a functional gastrointestinal disorder</u>	Amended from “ <i>abdominal discomfort</i> ” to “ <i>abdominal discomfort caused by a functional gastrointestinal disorder</i> ” Argued that “ <i>constipation and abdominal discomfort are different concepts, and it is unknown whether effectiveness for constipation results in effectiveness for improvement of abdominal discomfort.</i> ”
	Invention 1-14 Treatment of a functional gastrointestinal disorder	
Patent 2	Invention 2 Treatment of drug-induced constipation caused by an opioid compound or an anticholinergic agent	Argued that “ <i>a substance useful as a laxative is not necessarily effective for treatment of drug-induced constipation.</i> ”
Plaintiffs' & Defendant's Products	Chronic constipation (excluding constipation due to organic disease)	

Public-comment Question 1(1) asks what factors, such as the package insert, actual clinical use, and medical classifications, should be considered and weighed in determining medical use inventions. Disease concepts may have a hierarchical structure in medical classifications. Even though the disease name in the patent and the disease name on the product label are not identical, they may overlap clinically to a material degree. The question also asks how to take account of a prosecution history involving limitations and arguments such as those described above.

Public-comment Question 1(2) asks how to frame the operative part of a judgment where an accused product may be used for purposes other than the patented use and an injunction against working is granted. A conventional operative part would state: “The defendant shall not produce, assign ... the XX product”. Such wording may mean an injunction against all uses of that product. Where an injunction is granted based on a medical use invention, however, the practical issue is what wording is appropriate if there are non-infringing uses other than the patented use. Even where disease names differ, there may be clinical overlap in disease concepts as described above. The court appears to be seeking concrete proposals concerning the availability and wording of an injunction in such circumstances.

(2) Scope of Effect of Patent Term Extended Patents

The patent term extension registration system is to restore the period lost because working of a patented invention is restricted for a certain period by an administrative disposition. Regarding the requirements for extension, the Supreme Court's Bevacizumab decision set out a framework that defines the scope and unit of a "product" by the drug product's ingredient, amount, dosage and administration, and indications and effects, to examine the relationship between the earlier and later dispositions. The IP High Court's Oxaliplatin decision identified four categories of cases in which the accused product should be deemed as substantially identical to the subject of the administrative disposition. The court held that the effect of an extended patent may reach products that are substantially identical, i.e., have the same technical characteristics and effects, even if one or more of ingredient, amount, dosage and administration, and indications and effects differs. The issue in this case is how to reconcile this framework with the scope of effect where multiple extensions based on different amounts coexist for the same patent.

A feature of this case is the temporal relationship: for the same patents, extensions based on the 24 µg formulation (24 µg disposition) (Extensions 1-1 and 2-1) coexist with extensions based on the 12 µg formulation (12 µg disposition) (Extensions 1-2 and 2-2), and the later extensions remain valid after the earlier extension periods have expired. Emphasizing consistency with the overall purpose of the patent term extension system, restoration of the period during which the invention could not be worked and fairness to third parties, the Osaka District Court held that the scope of effect of a patent extended on the basis of a later disposition does not reach a product having the same ingredient, amount, dosage and administration, and indications and effects as the product subject to the administrative disposition that formed the basis for the earlier extension. It further held that assessment of substantial identity should be constrained in light of the quantitative and qualitative differences from the earlier extension. Through Question 2 of the call for public comments, the IP High Court seeks third-party views on whether this interpretation is appropriate or whether another framework is needed, for example to maintain consistency with cases where no earlier extension exists.

Regarding Public-comment Question 2(1), a requirement for extension registration is that "it was necessary to obtain the administrative disposition for working the patented invention". In this case, after approval of the 24 µg formulation was obtained, an application for approval of the 12 µg formulation was filed on the ground that the low-dose formulation had been developed for dose-reduction prescribing. The court appears to request opinions on which factors should be considered or weighed, including whether such an administrative disposition was necessary for working the 12 µg formulation, and on how far the effect of the extended patent should reach where the disposition is found necessary.

Public-comment Questions 2(2) and 2(3) appear to request views on concrete scenarios in which the effect of an extension based on the 12 µg formulation reaches a generic version of the 24 µg formulation. Generally, where the ingredient, dosage and administration, and indications and effects are the same, a difference in amount often falls within Category 4 of the Oxaliplatin decision and should be deemed substantially identical. In this case, however, the first-instance court held that the effect of an extension based on a later disposition with a different amount does not extend to the later product. This reflects the existence of an earlier disposition for the same amount as the generic product and the need for consistency with it. The issue is how far substantial identity should be considered in conjunction with the relationship between earlier and later dispositions. Careful consideration is needed of how to connect regulatory practice and clinical realities, such as how approval is managed for each amount, how dose reductions and drug holidays are implemented, and how prescribing, dispensing, and switching to generic products are handled in practice. The Osaka District Court also held that extending the effect of the later extension would improperly re-extend the earlier extension. Question 2(3) asks whether the conclusion should differ depending on the particular circumstances, i.e., whether a separate extension exists for the 24 µg originator product, whether it has expired, or whether no extension has been registered at all, and, if so, how it should differ.

As outlined above, this appeal includes controversial issues for pharmaceutical patent practice: determination of the technical scope of increasingly complex medical use inventions; the scope of effect where extensions based on multiple administrative dispositions coexist; and interpretation of “substantial identity” for products having different amounts. In particular, as requirements concerning use, dose, amount, and the like become more finely differentiated in defining the scope of patented inventions and allowable extensions, the scope of approvals becomes increasingly complex when multiple approvals exist at different times. The public opinions from third-party submitted from various perspectives and the IP High Court’s decision in light of them, will merit close attention.

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