Gamification Code:

COACH

Restrictive vs. Permissive Approaches to Pharmaceutical Patentability

THIS SESSION IS SPONSORED BY

IP for Innovation

Clarissa Regler

Winter, Brandl – Partnerschaft mbB

Session introduction

- The issue is politically and socially sensitive, especially with regard to medicines and vaccines.
- COVID-19 has highlighted the tensions between patent rights and public health.
- Pharmaceutical patents are not only held by large pharmaceutical companies. Universities, research institutes and hospitals also develop medical inventions.
- Patent protection can support the development of therapies from research.
- Many disputes arise around the new medical uses of compounds that are already known. How much evidence of therapeutic effect is required in a patent application?
- Different jurisdictions can lead to different outcomes for the same pharmaceutical invention.

Introduction

Moderator

Clarissa Regler

Winter, Brandl – Partnerschaft mbB

Germany

Speaker

Dr. Takeshi Akatsu

Open Frontier IP

Japan

Speaker

Dr. Daisy Machytka-Frank

Gödölle, Kékes, Mészáros, & Szabó

Hungary

Speaker

Dr. Emilio Berkenwald

Berken IP

Argentina

Speaker

Dr. Serge Shahinian

Lavery

Canada

Common reference point: Cabazitaxel

- Cabazitaxel as a common example for comparison.
- Look at how the same, or closely related, pharmaceutial invention is treated.
- The comparison covers Europe, Japan, North America and South America.

Dr. Emilio Berkenwald

Berken IP

Restrictive practices in pharma patents

- Non-uniform practice across LatAm
- Statutory provisions:
  - TRIPS: patents shall be available in all fields of technology
  - national exclusions of methods of treatment applied to human or animal body
  - can extend to claims seen as related to methods of treatment
  - “Use” can be a non-recognized claim category
- Chemical-invention (Markush structures, selection, “clarity umbrella”, etc.)
- Greater emphasis on experimental evidence
- Guidelines for pharmaceutical inventions

Restrictive practices in pharma patents

- For pharma inventions (small molecules):
  - Primary (or 1st Gen): new active compounds, production processes
  - Secondary (2nd Gen): alternative forms (crystal, solvates, hydrates, etc.), formulations, dosages, combinations, medical uses, groups of patients, etc.
- Primary patents can block product across all uses
- Secondary add protection for specific forms of the product, formulations, compositions, uses, etc.
- Primary patent expires first

Restrictive practices in pharma patents

- Argentina: 2012 Joint Ministerial Resolution (Health, Industry, AR PTO)
- Guidelines for Examination of Chemical-Pharmaceutical Inventions
- Category-specific negative presumptions (“how to reject”):
  - Compositions, formulations
  - Salts
  - Enantiomers
  - Crystal forms, solvates, hydrates, etc.
  - Metabolites, combinations, dosage regimes, etc.
- Repealed on 18 March 2026

Second medical uses

- "Product X for treating Y": useful when active product X is not novel

- Rejections in some LatAm jurisdictions based on:
  - exclusion of methods of treatment, considered "equivalent"
  - use claims not recognized as a category
  - no novelty conferred by new use
  - Irrespective of drafting format

- More permissive jurisdictions: EP "product-for-use" and/or Swiss claims

- Some jurisdictions require narrowly defined Y (e.g. "severe chronic migraine")

Second medical uses

- Restrictive practice can extend to combinations, regimens, etc.
- Higher threshold for inventive step / sufficiency
- Experimental support for therapeutic effect
- In AR, only accepted if dependent from a novel product claim (☹)
- Effect of repeal of 2012 Guidelines still unclear, in AR118495A1:
  - “the use feature relates to a non-patentable method of treatment”
  - “the use feature does not confer novelty”
  - “a disclosure of product X anticipates the claim”

Second medical uses

- Jurisdictional strategy

- For new medical indications:

Format	AR	CL	BR	CO	MX	PY
Swiss-type	✗	✓	✓	✗	✓	✗
EP “product-for-use”	?	✗	✗	✗	✓	✗

- More restrictions for other types of claims (dosage, patient, etc.)

- Guidelines specifically targeting new uses of known products

Impacts on patent landscape

- Guidelines can set negative presumptions for secondary inventions
- Fewer or narrower pharma grants
- Can reduce predictability in examination and enforcement
- Can spillover into e.g. veterinary and agrochemical inventions
- Different claims for different jurisdictions

Impacts on patent landscape

Example – Same family, narrower scope

US 8420656 B2

Claim 1: **compound** formula where R^1 is **H or C1–C4 alkyl, optionally fluorinated/trifluoromethyl-substituted, N-oxides** and **salts**

- Claim 4: **process** for preparing compound
- Claim 5: pharmaceutical **formulation**
- Claim 6: **combination** with other active agents

AR 081628 B1

- Claim 1: **compound** formula where R^1 is **H or C1–C2 alkyl** and **salts**

Impacts on patent landscape

- Case-by-case examination in AR after Repeal of Guidelines
- Transitional “safe harbor”
- Applications could be granted for previously restricted inventions
- Pre-existing local commercialization by third-parties carved out
- PCT accession pending before Congress

Context

- Strong local pharma industry in the region
- Most pharma patents held by foreign entities
- Public debate: access to medicines / public health / sovereignty
- Secondary patents as extension of market exclusivity / “evergreening”
- Local regulation and practice can be influenced by political climate

Key takeaways

- Second medical uses unavailable in some LatAm jurisdictions
- Increased patentability threshold for secondary inventions
- Drafting strategy and relevance of experimental data
- Impact of political context
- Argentina: repeal of Guidelines and return to case-by-case

Common example

AR 078824 A1 - NOVEL ANTITUMORAL USE OF CABAZITAXEL

Claims a second medical use (combination):

"a compound corresponding to **cabazitaxel**, (…) in combination with prednisone or prednisolone, **for use in treating prostate cancer.**"

Examined in 2018-2019 under Pharma Guidelines

Several objections linked to restrictive practice:

- Lack of clarity: "combination" is not a clear claim category
- The compound is characterized by a method of treatment, etc.

No reply to Substantive Examination Report

Also not granted in UY, BR, PE,…

Granted in MX

Dr. Serge Shahinian

Lavery Lawyers

Restrictive vs. Permissive Approaches to Pharmaceutical Patentability: The Canadian perspective

FICPI Open Forum
September 18, 2026

Serge Shahinian

Patent Agent, Partner
Lavery

Montreal, Canada
sshahinian@lavery.ca

Virtually all types of pharmaceutical/medical inventions are patent-eligible in Canada

- Chemical or biological molecules/products - small molecules, biologics (antibodies); engineered cells/vectors
- Therapeutics
- Diagnostics
- Personalized medicine
- New uses of known compounds
- Formulations/dosage forms
- New crystal forms, salts, isomers
- New dosing regimens of known drugs

invention *means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter* (Patent Act, S. 2)

… As always – the devil is in the details!

Therapeutics – acceptable formats

While claims in "method" format are not permitted, it is typically, simply a matter of recasting claims into an acceptable "product for use" or "use" format:

- X for use in treating Y (similar to EPO)
- Use of X for treating Y
- Use of X for the preparation of a medicament for treating Y (Swiss-type)

Note: Avoid "active" language:

Bad: Use of X for treating Y, comprising administering X subcutaneously.

Good: Use of X for treating Y, wherein X is for subcutaneous administration.

US-style "method" steps typically become "wherein" clauses.

Therapeutics – general principles

Prohibition of "method" claims only applies to medical treatment

- e.g., can claim a method of contraception in "method" format (because pregnancy is not a disease)
- e.g., can claim a method of administering a therapeutically-inert agent to a subject, e.g., for imaging/diagnostics (as long as the agent does not also have a therapeutic benefit)

Regardless of claim format, claim cannot require professional skill

- Ranges of values may provoke an objection:
  - Dosage ranges
  - Ranges in frequency/timing of administration

Such issues, if raised can often be overcome by argument/amendment, and various supporting precedents now exist, including a positive July 2026 decision of the Supreme Court relating to dosing regimen-type inventions.

An aside: Professional Skill

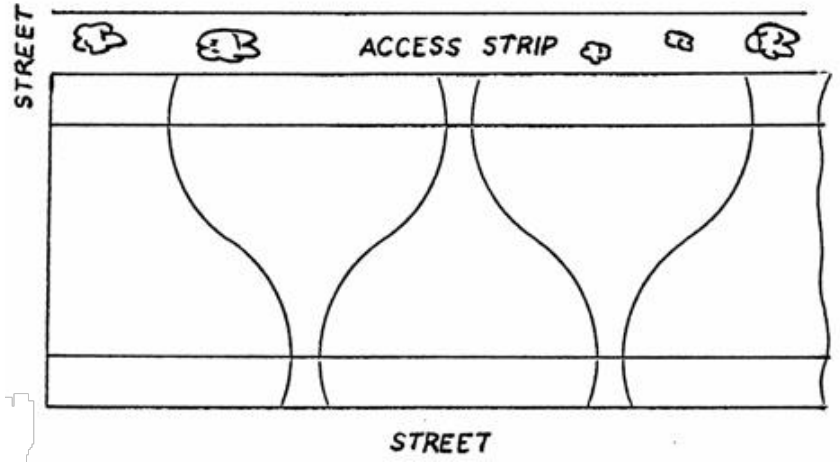
- Notably discussed in *Shell Oil Co. v. Commissioner of Patents (SCC 1982)*, with reference to:

Tennessee Eastman Co. v. Commissioner of Patents (Ex. Ct. 1970; aff'd SCC 1974)

- Method of closing incisions following surgery using an adhesive substance.
- Essentially non-economic and unrelated to trade, industry or commerce; rather, relates to professional skill.

Lawson v. Commissioner of Patents (1970)

- New method for subdividing land.



- "It seems to me that a method of describing and laying out parcels of land in a plan of subdivision of a greater tract of land in the skill of a solicitor and conveyancer and that of a planning consultant and surveyor. It is an art which belongs to the professional field and is not a manual art or skill."

Dosage regimens: *Pharmascience Inc. v. Janssen Inc.*

- Litigation stemming from CA's pharmaceutical patent linkage regime
- Decision of the Supreme Court of Canada (SCC), July 17, 2026
- Issue: Is the patent directed to an unpatentable method of medical treatment?
- Later-gen pharma inventions often relate to how the drug is used, e.g., dosage and schedule/timing of administration.
- Historically, fixed values are generally considered to be patentable, whereas variable values (appearing in claims as ranges) are sometimes considered to require professional skill and are thus unpatentable – each case turns on its facts.
- SCC found that Janssen's patented dosing regimen **did not require professional skill** and therefore **related to patentable subject matter** – validity of patent was upheld.

Claimed invention: *Pharmascience Inc. v. Janssen Inc.*

Use of a depot formulation of paliperidone palmitate for the treatment of Schizophrenia, under the following regimen:

- **Day 1:** A first dose via deltoid injection;
- **Day 8 ± 2 days:** A second dose via deltoid injection;
- **Monthly ± 7 days thereafter:** Maintenance doses via deltoid or gluteal injection;
- **Two regimens** are defined depending on renal impairment status, with specified mg-eq doses.

Claim example: *Pharmascience Inc. v. Janssen Inc.*

Use of a dosage form of paliperidone as paliperidone palmitate formulated as a depot formulation of an aqueous nanoparticle suspension for administration by intramuscular injection for treating a psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder, wherein the dosage form comprises:

a) a first loading dose comprising about 150 mg-eq. of the depot formulation of paliperidone as paliperidone palmitate adapted for intramuscular administration into a deltoid muscle of the psychiatric patient on a first day of treatment;

b) a second loading dose comprising about 100 mg-eq. of the depot formulation of paliperidone as paliperidone palmitate in a dosage form adapted for intramuscular administration into a deltoid muscle of the psychiatric patient one week ± 2 days after the first loading dose; and

c) a maintenance dose comprising about 75 mg-eq. of the depot formulation of paliperidone as paliperidone palmitate adapted for intramuscular administration into a deltoid or a gluteal muscle of the psychiatric patient according to a continuous schedule having a monthly ± 7 days dosing interval after the second loading dose.

(Parallel claims with lower doses for a renally impaired psychiatric patient)

The decision: *Pharmascience Inc. v. Janssen Inc.*

The SCC established that the patented dosing regimen does not require professional skill because:

- Once the regimen is selected, **no professional skill/judgment is required to implement it** as claimed.
- The renal-impairment split reflects an **objective distinction** and does not meaningfully constrain professional judgment.
- The ± dosing windows and alternate injection sites were supported by evidence as **clinically interchangeable / operational flexibility** without clinical implications.

Key takeaways: *Pharmascience Inc. v. Janssen Inc.*

- Even though Janssen's dosing regimen was found to be patentable, the SCC maintained that a doctrine still exists in CA under which methods of medical treatment are unpatentable **if they involve professional skill**, based on the broader principle that "professional skills" are not patentable.
- **Dosing regimen patents remain viable**: Assessment of evidentiary record and claim substance; focus on the claimed subject matter, not on the fact that doctors exercise judgment in choosing whether to use it for a particular patient. Clinical judgment in selecting/monitoring treatment generally does not make the invention unpatentable.
- **No bright-line "fixed vs. range" rule**: Rather, the actual role of medical skill/judgment in practicing the claimed regimen is key.
- **Case-by-case assessment:** Factors such as individualization or ordinary-course professional development may be indicative of professional skill.
- **Important decision** for pharma innovators in view of the development of such next-generation inventions relating to how a drug is used.

Dr. Daisy Machytka-Frank

Gödölle, Kékes, Mészáros, & Szabó

Second Medical Use Claims – European Perspective

LEGAL BACKGROUND

- Art. 53(c) EPC: exclusion of medical treatment methods: "*European patents shall not be granted in respect of …. methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions,* for use *in any of these methods.*"
- Article 54(5) EPC provides the legal basis for purpose-limited product claims directed to second and further medical uses: *The provisions defining the state of the art (i.e. Art, 54(2) and (3)) shall not exclude the patentability of any substance or composition already comprised in the state of the art for any specific use in a method referred to in Article 53(c), provided that such specific use is not comprised in the state of the art*.

NEW MEDICAL USE

- Art. 54(5) ➔ a new specific use can establish novelty, i.e. novelty is not derived from the claimed substance or composition as such.
- G 2/08 ➔ "specific use" under Article 54(5) EPC is not limited to the treatment of a different illness: "*Where it is already known to use a medicament to treat an illness, Article 54(5) EPC does not exclude that this medicament be patented for use in a different treatment by therapy of the same illness*."
- If it is already known to use a substance or composition to treat an illness, a new medical use may consist in the use of that substance or composition for the treatment of a different illness, or in a different treatment of the same illness, for example in a novel patient subgroup or according to a novel dosage regimen → EPO is permissive as to what can constitute a new medical use.

BASIC CLAIM STRUCTURE

Follows from the legal background: Purpose-limited product claim:

„Product X for use in the treatment of disease Y”.

SUFFICIENCY

- Established case law: where a therapeutic use is claimed, attaining the claimed therapeutic effect is a functional technical feature of the claim and the requirements of sufficiency are only met if the patent discloses the suitability of the substance for the claimed therapeutic use, i.e. renders it credible that the therapeutic agent is suitable for the claimed therapeutic use, unless this was already known to the POSA at the priority date.
- What is required to establish sufficiency depends on the nature of the claimed therapeutic use and may range from a credible technical explanation or in vitro data to human clinical evidence.

PRIORITY

- The priority document must also provide an enabling disclosure of the claimed therapeutic use, i.e. render it credible that the therapeutic agent is suitable for the claimed use; otherwise, it does not disclose the "same invention".
- Example: T 0411/19 – Kallikrein inhibitors EP 1 854 477 B1
  - Claim 1 covered kallikrein-inhibiting peptides for treating macular oedema or retinal vein occlusion. Priority document P1 literally disclosed the peptides and the indications but provided no supporting evidence for their suitability for such treatment.
  - The BoA held this was a mere allegation, so P1 did not disclose the "same invention" under Art. 87(1) EPC and priority was invalid.

NOVELTY

- EPO Guidelines: A document is prejudicial to the novelty of a claim directed to a specific further medical use if it (i) clearly identifies the essential conceptual features of the therapeutic treatment, i.e. the substance/composition used for treating the medical indication and any essential features of the treatment; and (ii) plausibly establishes the underlying therapeutic effect. Plausibility may be established by way of data or scientific reasoning.
- Disclosure of clinical trials without positive results does not automatically destroy novelty.

NOVELTY cont.

Example: „Cabazitaxel patent” (2 493 466 B1) T0136/24

- *1. Compound of formula…, in combination with prednisone or prednisolone, for use in treating prostate cancer, in patients with castration resistant metastatic prostate cancer [mCRPC] who have been* previously treated *with docetaxel…and have prostate cancer that progressed during or after said treatment.*
- CPA discloses the set up for the ongoing „TROPIC” phase III clinical study of cabazitaxel and prednisone in mCRPC; primary and secondary objectives; inclusion criteria met the claimed patient subgroup.
- CPA: „Cabazitaxel has shown a promising safety profile and activity in patients progressing after docetaxel therapy”. No experimental data are disclosed.
- No phase II data existed for mCRPC, only for breast cancer, „sparse” phase I results.

NOVELTY cont.

BoA: functional feature of the treatment attaining the therapeutic effect was not disclosed in the CPA, novelty is met.

Why?

- No explicit disclosure: „Promising safety profile and activity" cited by the Opponents from the CPA is not disclosed specifically for mCRPC; it cannot be inferred from the remark that it relates to unpublished preliminary results of TROPIC.
- No implicit disclosure: For the skilled person, the TROPIC CPA, even together with the available clinical data, did not establish the therapeutic effect as a clear and unambiguous consequence of its disclosure.

INVENTIVE STEP

- **Cabazitaxel: BoA: INVENTIVE - UPC LD Munich : OBVIOUS**
- In medical-use cases, both the EPO and the UPC generally assess whether the skilled person would have pursued the therapeutic approach suggested by the prior art with a reasonable expectation of successfully solving the technical problem.
- BoA and UPC LD formulated the problem differently and defined 'success' differently (BoA: improved overall survival; UPC LD: therapeutic benefit, including survival and palliation), but the divergence in outcome is not due to these differences, as confirmed by the UPC LD.
- **Both** BoA and UPC LD: rejected the presumption that in lack of contrary evidence Phase III trial announcement creates a reasonable expectation of success. The assessment depends on the positive and negative pointers in the prior art for and against success and the circumstances of the case.

INVENTIVE STEP cont.

- **Invoked positive pointers for success**: e.g. phase I/II data, approval of phase III without phase II, the long, costly phase III trial was nearing completion without early termination.
- BoA and UPC LD attached different weights to said positive pointers.
- **BoA:** Rejected the positive pointers by stressing limitations and uncertainties: earlier data are „sparse and incomplete", survival effects are cancer-specific, interim results were unknown, most phase III trials fail.
- **UPC LD**: Focused on the extent to which earlier data nevertheless supported an expectation of efficacy, even from other cancer types → earlier data are encouraging. Emphasis is on the absence of evidence against cabazitaxel efficacy in mCRPC, incident-free progress and near completion.

POST-FILED DATA

G2/21:

- *„…the scope of reliance on post published evidence is much narrower under sufficiency of disclosure… compared to the situation under inventive step”.*
- *„….A patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention.”*

POST-FILED DATA cont.

- T 2046/21 (16 Jan 2024): example of an effect that could not be relied on under G 2/21.
- The claim covered a preservative-free bimatoprost/timolol composition for lowering intraocular pressure (IOP); CPA disclosed the same composition and use with a preservative.
- After the alleged benefit of maintained efficacy despite preservative removal was found obvious, patentee wanted to rely on a post-hoc subgroup effect: greater IOP reduction in treatment-naive patients.
- BoA: this effect is not derivable from the original application ➔ cannot support inventive step under G 2/21.

ENFORCEMENT

- Fair balance: generics should be free to market a drug for off-patent uses, while patent protection must be effective for the still-patented use.
- In Europe, indications approved by the authorities are listed e.g. in the public official document SmPC (Summary of Product Characteristics), section 4.1 (“Therapeutic indications”), other SmPC information may encourage use outside the approved terms („off-label”).
- UPC CFI 505/2024, Düsseldorf Local Division, Sanofi vs Amgen, 13 May 2025, EP 3 536 712 B1
  - The patent claimed PCSK9 inhibitors for use in reducing lipoprotein(a) (Lp(a)) levels in a certain patient group. Lowering LDL-C with PCSK9 inhibitors was known, lowering Lp(a) was the new therapeutic use.
  - Claimants alleged infringement by the PCSK9 inhibitor product Repatha.

ENFORCEMENT – cont.

UPC LD:

- For finding infringement of a purpose-limited product claim, Claimant must prove that the allegedly infringing product fulfils also the „use" feature of the claim.
- For finding infringement of a second medical use claim, the alleged infringer must offer or place the medical product on the market in such way that it leads or may lead to the claimed use. In addition, as a subjective element the infringer must know or reasonably should have known that said offering or placing on the market leads or may lead to the claimed use.
- No marketing aimed at the claimed use; the dispute focused on whether the information in the SmPC could influence prescribing so that placing Repatha on the market leads or may lead to the claimed use.

ENFORCEMENT – cont.

- Lp(a) reduction: not approved, not listed in Repatha SmPC 4.1., only mentioned under pharmacodynamic effects → the claimed use would be off-label.
- No evidence of actual off-label prescriptions for the claimed use → no evidence that marketing Repatha leads to the claimed therapeutic use.
- Experts disagreed whether physicians were likely to prescribe Repatha off-label for Lp(a) reduction → no evidence that marketing Repatha may lead to the claimed therapeutic use.
- UPC LD rejected that marketing Repatha leads or may lead to the off-label use → no need to assess subjective element (knowledge of the alleged infringer), nevertheless listed factors relevant thereto (e.g. significance of the infringing use; market practice; measures by the alleged infringer encouraging or preventing the patented use).

Dr. Takeshi Akatsu

Open Frontier IP

Claim Drafting, Regulatory Context, and Enforcement

Claim-form driven. Disclosure-sensitive. Label-centered.

Patent Attorney (Benrishi), certified in infringement litigation

Founder & Managing Partner, Open Frontier IP

FICPI 23rd Open Forum · Budapest · 18 September 2026

The starting point

The Universal Policy Tension

- Reward the discovery that a known drug treats a new disease
- Keep patent rights away from the doctor at the bedside

US	EP	JP
Allow the method claim. Control who can be sued.	Convert the method into a purpose-limited product.	Exclude the method. Rebuild it as a product.

Same policy. Three claim architectures.

Japan is permissive about claim form, and strict about evidence.

Article 29(1), Main Paragraph

What Is Japan-Specific

- An invention must be **industrially applicable**
- Methods of surgery, therapy or diagnosis on humans are held **NOT industrially applicable**
- A **category** exclusion, not a morality exclusion. Japan never needed a Swiss-type claim

✕ Method of treatment	✓ **Product, use-limited**

A real file wrapper. In the JP application for the cabazitaxel patent, the examiner objected that four claims covered a **method of treating a human being** and so could not be an industrially applicable invention. Those claims were deleted. Only the product claims were granted.

Notification of reasons for refusal, 27 September 2013, application 2012-535996 (summarised, not an official translation)

PANEL CONNECTION POINT

Comparative Claim Forms

US	"A method of treating disease X by administering compound Y"	Method
EP	"Compound Y for use in the treatment of disease X"	Purpose-limited product
JP	"A pharmaceutical composition for treating disease X, comprising compound Y as an active ingredient"	**Use-limited product**

EP → JP light

category already compatible

US → JP heavy

category change is unavoidable

SIX FORMATS. ONE CATEGORY.

Japanese Claim Examples

STEM

> "A therapeutic agent for disease X, comprising compound Y as an active ingredient …"

1	**Basic use**	*(no further limitation)*
2	**Agent / composition**	agent · composition · **for use in** treating disease X
3	**Dosage regimen**	**is used so as to be administered** at 10 mg once daily
4	**Patient subgroup**	**used for treating** a patient who failed prior agent Z
5	**Biomarker-defined**	**used for treating** a patient positive for biomarker Z
6	**Combination**	**used in combination with** compound W

All six are product claims. None recites a step performed on a patient.

用いられる "is used so as to be …" — what keeps a dosage regimen in a product claim

THE SAME PATENT YOU HAVE JUST SEEN

Cabazitaxel · EP 2 493 466

JP 5,566,466 — a pharmaceutical composition for treating advanced metastatic prostate cancer, **in combination with prednisone**, for patients **previously treated with docetaxel**.

Formats **2**, **4** and **6**. In one real claim.

JP 6,182,510, the divisional, **removed** the subgroup — a broader claim. Refused for novelty **and** inventive step. Granted on appeal, 2017.

Jevtana has **one** approved indication. The divisional covers the whole label.
No carve-out. The only route is invalidation.

THE SAME INVENTION

EPO Board of Appeal
2025
upheld

UPC Munich LD
Dec 2025
revoked — on appeal

Japan
granted 2014 / 2017
invalidation trials filed 24 Feb 2026

The Japanese answer is not in yet.

Invalidation trials 2026-800022 and 2026-800023, filed 24 February 2026, pending · Japanese family: these two patents only, expiring 27 October and 2 November 2030

FOREIGN-ORIGINATING CASES

“Japanization”

US
method claim → Art. 17bis(3) added matter
Art. 36(6)(i) support → **JP**
product claim

It is not translation. It is **re-characterisation**.

The claim changes category. The specification does not change at all.

Added matter, Article 17bis(3), is applied strictly. Three failures seen repeatedly:

- Narrowing “cancer” to a specific cancer that was never named
- Adding a subgroup that is visible in the data but was never described **as a subgroup**
- Adding a dosage taken from an example table, not from the disclosure

PATENTABILITY FILTERS

Novelty Is the Easy Part

Novelty — usually available

- A new medical use of a known compound is novel
- Since **2009**, a specific dosage or route can also confer novelty

Inventive step — where cases are won and lost

- **Supreme Court, 2019**: unexpected effect is judged against what the skilled person could predict from the claim
- Every office action in the file repeats one line — **no remarkable effect that could not be predicted**

In Japan you win on **unexpected effect**, not on claim wording.

Novelty

Inventive step

Support

Supreme Court, 3rd Petty Bench, 27 Aug 2019, Case No. 2018 (Gyo-Hi) 69 · office actions in application 2012-535996 (summarised)

THE BINDING CONSTRAINT

Data at the Filing Date

Japanese practice expects pharmacological support making the claimed use **credible** at the filing date. In vitro, in vivo or clinical — **the format is flexible, the timing is not**.

POST-FILED DATA CAN

- Supplement what was disclosed
- Rebut a specific objection

POST-FILED DATA CANNOT

- Create a use that was not disclosed
- Rescue an over-broad claim
- Supply missing credibility

Priority is examined on the substance. In the cabazitaxel file the examiner held that the US provisionals did **not** support the prednisone-combination claim — which would have left the applicant's own trial publication, 25 days before filing, as prior art.

Second notification of reasons for refusal, 14 January 2014, application 2012-535996. The patent was ultimately granted.

BEYOND THE PATENT ACT

The Non-Patent Framework

PATENT LAYER

Claim scope, novelty, inventive step, support.

Decided at the JPO and in court.

REGULATORY LAYER · PMD ACT

Indication and **dosage and administration**.

Package insert, interview form, promotional materials.

Decided at MHLW and PMDA — and published.

Japan has no data exclusivity statute.

The **re-examination period** under the PMD Act operates as a de facto exclusivity — four to ten years; **eight years** for a new active ingredient, **ten** for orphan drugs.

NO STATUTE — MINISTERIAL NOTIFICATIONS ONLY

Patent Linkage and Skinny Labeling

Application
Generic or biosimilar files

Gate 1 /review
Not approved for a patented indication or dosage

Approval
Indication fixed

Gate 2 /listing
Prior adjustment between the parties

Market entry
NHI price listing

2025

first revision in sixteen years

- **8 October 2025** — biosimilars brought expressly within patent linkage
- **14 November 2025** — a separate notification adds a trial expert-committee mechanism

Japan produces skinny labels **administratively**, before any court is involved.

CASE STUDY

Aflibercept · carve-out first, courts after

The asserted patents claimed **subgroup-defined medical uses** — patients defined by prior treatment history and genotype.

1	Biosimilar applied for approval **including wet AMD**
2	Patentee told MHLW: wet AMD would infringe
3	wet AMD **withdrawn** — before any approval
Jun 2024	Approved: **RVO, pathologic myopia, DME**. Not wet AMD
Oct/Dec 2024	Tokyo District Court dismissed both applications
13 Aug 2025	IP High Court dismissed the appeal

The carve-out happened at the **agency**. The courts came **afterwards**.

Caveat. Preliminary injunctions under unfair competition law. Infringement was a **preliminary question**, not a final judgment.

Tokyo District Court, 28 Oct and 16 Dec 2024 · IP High Court, 13 Aug 2025 · the label was later amended in December 2025

ENFORCEMENT

A Label-Based Analysis

Who is the defendant

- Manufacturer, importer, seller, marketing entity
- **Not physicians. Not patients.**
- Art. 69(3): no effect against compounded medicines

× *Can the drug be used for the patented use?*

✓ Is it **objectively supplied, approved, labelled or promoted** for that use?

The asymmetry. On patentability, an examiner will say that what a label or package insert states does not distinguish one product from another. On infringement, the package insert decides the case.

Japan will not let the label create patentability — but lets the label decide infringement.

Ménière's disease drug, IP High Court, 28 July 2016, Case No. 2016 (Ne) 10023 — infringement denied because the dosage in the accused product's package insert differed from the claim

WHAT THE AFLIBERCEPT DISPUTE EXPOSED

The Validity / Enforcement Tension

The patentee argues:
incidental use in the subgroup is enough

→ then the claim is not novel

You cannot have both

The patentee argues:
the claim is narrow

→ then the product must be objectively directed to it

And there is a third end to this. In another cabazitaxel application a claim limited to patients **without a risk of gastrointestinal disorder** was allowed — then abandoned.
A limitation you can obtain, but that never appears on a label, cannot be enforced.

What to Take Home

- Japan protects second medical use — **as a product, never as a method**
- Claim form sets your added-matter risk, your scope and your enforcement theory
- **Disclosure at the filing date is the binding constraint.** Post-filed data will not rescue you
- Enforcement is decided on the **label**, not on clinical reality
- **Count the indications.** With one, a use patent blocks like a compound patent
- Design the claim, the specification, the label and the infringement theory **together**

Japan's approach is claim-form driven, disclosure-sensitive, and label-centered.

Thank you! - Questions?

Topic	EP	Canada	Argentina	Japan
Legal Background	Art. 53(c) EPC: exclusion of medical treatment methods. Protection through purpose-limited product claims under Art. 54(5) EPC.	Medical treatment cannot be claimed in "method" format. Focus on acceptable claim formats and avoiding protection of professional medical judgment.	Treatment methods are excluded. The restrictive 2012 Guidelines were repealed in March 2026. Examination is now case-by-case.	Art. 29(1): methods of surgery, therapy or diagnosis practised on humans are not "industrially applicable" and are excluded. No equivalent of Art. 54(5) EPC.
Basic claim structure	Purpose-limited product claim: „Product X for use in the treatment of disease Y".	Product-for-use claims, use claims, Swiss-type claims. Passive vs. active language is relevant.	Prefer product or process claims. Avoid direct method of treatment wording. Swiss-type claims are excluded. Product-for-use claims accepted if dependent from novel product.	Use-limited product claim: "A pharmaceutical composition for treating disease X, comprising compound Y." The EPC 2000 "for use in" wording is also accepted.
New medical use	A new medical use can establish novelty.	Medical use claims must avoid directly claiming active treatment steps.	Historically non-patentable. Former categorical restriction was repealed.	A new medical use of a known compound confers novelty. The Swiss-type claim never developed here.
Dosage regimes	New dosage regimes can be relevant for second medical use protection. Main issue is inventive step.	Dosage regimes raise questions of professional skill/judgment. Relevant factors: evidence of clinical decision-making; personalization	Previously expressly excluded. Method of treatment exclusions remain likely.	Available since the 2009 revision of the Examination Guidelines. Drafted as "used so as to be administered", which keeps the regimen inside a product claim.
Patient subgroups	New patient groups can form part of a second medical use claim if supported.	New patient subgroup can form part of a new medical use claim if supported; potential inherency issues may need to be addressed.	No specific current prohibition. Method of treatment exclusions remain likely.	Permitted, including prior treatment history and genotype. Risks: added matter on amendment, and a claim too narrow to read onto the accused product.
Sufficiency	Therapeutic effect is a functional feature of the claim.	Support and sufficiency are central issues for medical use claims; *in vitro*/animal data is often sufficient; extrapolation permitted on a "sound prediction" basis.	Importance of examples, and qualitative/quantitative definitions. Can overlap with clarity and inventive step.	Pharmacological support making the claimed use credible is expected at the filing dat.

Topic	EP	Canada	Argentina	Japan
Novelty	Disclosure of clinical trials without positive results does not automatically destroy novelty.	Depends on disclosure of the claimed use and parameters.	Ordinary novelty test. A new use does not confer novelty to a known product.	Generally available for a new use. Inverse trap: a genus claim ("anticancer agent") can lack novelty over a known species use ("anti-lung-cancer agent").
Inventive step	Often the main issue. Requires technical effect and reasonable expectation of success analysis.	No pharma-specific heightened test. A non-obvious technical effect should be shown.	No pharma-specific heightened test after repeal. A non-obvious technical effect should be shown, preferably with comparative data.	The main issue. Optimising dosage is "ordinary creative ability" (JPO Handbook). Supreme Court, 27 Aug 2019, on unexpected effect.
Post-filed data	G 2/21: Post-published evidence has limits even for inventive step. Original disclosure must support the claimed effect.	Cannot really be used to address support/sufficiency issues – support and sufficiency are based on content of application as filed	May corroborate the filed disclosure and technical effect, cannot supply missing support or add new matter.	May supplement what was disclosed. Cannot create an undisclosed use, or cure an over-broad claim (Grand Panel, 11 Nov 2005).
Priority	Same invention requirement. Priority document must support the claimed invention.	Support of claimed subject-matter is important; literal support not required	Support of claimed subject-matter is important. Added scope may lose priority.	Same-invention requirement: the priority document must itself make the claimed use credible. Domestic priority (Art. 41) is often used to add data.
Enforcement	Focus on scope of claims and relationship with actual or possible use.	Relevant issues: product information and practical use.	Court-based. 2026 transitional provision targets certain products already marketed by third parties.	Objective test: is the product supplied, approved, labelled or promoted for the claimed use — not whether it could be. No subjective knowledge element.
Regulatory interaction	Patent system interacts with regulatory approval and clinical use.	Regulatory aspects linked with product information and use; pharma patent linkage system linking regulatory approval with patent grant.	No linkage between patents and regulatory approval. No regulatory data exclusivity.	PMD Act approval fixes indication and dosage. Patent linkage runs on notifications, revised 8 October 2025 to cover biosimilars. No data exclusivity statute; the re-examination period substitutes.

Topic	EP	Canada	Argentina	Japan
Comparison with other jurisdictions	European approach focuses on the claimed product for a medical purpose.	Method-style claims and any active languagewill need to be reformulated.	Historically restrictive, currently transitioning to case-by-case examination.	US: method of treatment. EP: purpose-limited product. JP: use-limited product; the method category is excluded outright. Cabazitaxel (EP 2 493 466): upheld at the EPO, revoked at the UPC, in force in Japan with invalidation trials pending.

Gamification Code:

COACH

STRENGTHENING THE PRACTICE OF THE INDEPENDENT IP ATTORNEY

THIS SESSION IS SPONSORED BY

IP for Innovation

APPENDIX · NOT PRESENTED

Sources

CABAZITAXEL

- JP 5,566,466 (application 2012-535996, granted 2014) and JP 6,182,510 (divisional, refused for lack of novelty and inventive step, granted on appeal 20 June 2017). Japanese family: these two patents only, expiring 27 October and 2 November 2030

- Invalidation trials 2026-800022 and 2026-800023, filed 24 February 2026, pending
- EP 2 493 466: EPO Board of Appeal T 0136/24 (2025, upheld); UPC Munich Local Division (December 2025, revoked, on appeal)
- Notification of reasons for refusal, 27 September 2013, and second notification, 14 January 2014, application 2012-535996

GUIDELINES, NOTIFICATIONS, STATUTES

- JPO Examination Handbook, Annex B, Chapter 3 (Medicinal Inventions); Examination Guidelines revised 2009, applied to examinations from 1 November 2009
- MHLW notifications of 8 October 2025 (patent linkage extended expressly to biosimilars) and 14 November 2025 (trial expert-committee mechanism)
- Patent Act, Arts. 29(1), 17bis(3), 36(4)(i), 36(6)(i), 41 (domestic priority), 69(3); PMD Act re-examination system

Sources (cont.)

COURT DECISIONS

- Supreme Court, 3rd Petty Bench, 27 Aug 2019, Case No. 2018 (Gyo-Hi) 69 — unpredictable remarkable effect in a medical use invention; on remand IP High Court, 17 June 2020, patent maintained
- IP High Court, 28 July 2016, Case No. 2016 (Ne) 10023; below, Tokyo District Court, 28 Jan 2016, Case No. 2014 (Wa) 25013 — Ménière's disease drug, dosage-regimen claim
- Tokyo District Court, 28 Oct and 16 Dec 2024; IP High Court, 13 Aug 2025 — aflibercept, patient-subgroup medical use
- IP High Court Grand Panel, 11 Nov 2005, Case No. 2005 (Gyo-Ke) 10042 — support requirement and post-filed data