LIFE SCIENCES IP EVENT 2026

Case Law in Europe

- NL – Floris Patijn
- UK – Callum Beamish-Lacey
- FR – Thomas Bouvet
- DE –Kai Rüting
- FR – Frédéric Portal

Case Law in Europe

- Jurisdiction: recent developments
- Preliminary Injunctions
- Claim construction EPO & UPC: the emerging methodology
- Enforcement of Second Medical Use patents
- Equivalence

JURISDICTION: RECENT DEVELOPMENTS

FLORIS PATIJN – HOGAN LOVELLS

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Cross-border jurisdiction at the UPC and national courts

- Since the decision by the CJEU in *BSH v Electrolux* (25 February 2025), it is clear that courts (including the UPC) in Europe applying the Brussels I bis Regulation have
  i. The power to adjudicate patent matters on the merits in relation to European patents granted for other countries
  ii. At least against defendants that are domiciled in their jurisdiction (art. 4 BR)
  iii. Inside and outside the EU
  iv. And while they cannot adjudicate validity:
    — They can make preliminary assessment of validity in response to a challenge of the respective national part of an EU/Lugano member state and stay or proceed with the case
    — Rule *inter partes* on validity as a defence to infringement for non-EU/Lugano member states

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Application by national courts and the UPC

National courts:

- Long-standing practice by the Dutch courts in particular in PI cases
- Application also by other national courts in the EU, e.g. Munich District Court in *Regeneron v Formycon* against German-based defendants (Art. 4 BR), assessment of foreign patent under German law unless evidence to the contrary

UPC (1/2):

- Open to cross-border requests, see for example the LD The Hague in HL Display v BSRP (October 2025)
  - Dutch defendant (Art. 4 BR)
  - Relief requested for UPC countries, non-UPC EU countries (Spain and Poland), Lugano countries (Switzerland) and non-EU/Lugano countries (UK)
  - Validity raised as defence for the non-UPC countries
  - Court found UPC designations of patent valid. Based thereon:
    i. For the non-UPC EU countries and Lugano countries the Court found that there is no serious, non-negligible chance the patent will be revoked by the competent national court
    ii. For non- EU/Lugano countries the Court held *inter partes* that the patent is valid

Cross-border jurisdiction at the UPC and national courts

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UPC (2/2):

- But:
  - Recently, the LD Hamburg in *Horl v Magna* (May 2026) required the claimant to also prove that there is infringement under the laws of all non-UPC countries for which relief was requested
    - With respect to Switzerland and Liechtenstein, the defendant did not establish that offering on the internet amounts to an infringing act under the laws of Switzerland and Liechtenstein
  - Also, the LD Mannheim in *Fujiflim v Kodak* (January 2026) held in an *obiter dictum* that a decision is only enforceable as far as it concerns the UPC territory while a decision for countries outside the UPC territory can only be enforced after it has been recognized by the country for which enforcement is sought
    - ➢ Defendant can continue infringement outside UPC territory until recognition proceedings are final?

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Court of Appeal in *Fujifilm v Kodak* (1)

- BSH v Electrolux principles confirmed: where the patentee has requested relief based on a non-UPC EP and where the defendant has – as a defence – asserted that the EP relied on is invalid, then:
  - For non-UPC EU and Lugano designations, the Court shall not consider the validity but does not lose jurisdiction to decide the infringement action based on such patents
  - For non-EU/Lugano designations, the Court can consider the validity of such patents in *inter partes* proceedings and the Court may on that basis decide the infringement action based on such patents
- The CoA also touches on the comity

  "A court which has jurisdiction to hear an alleged infringement of a patent validated outside of its own territory, is not only required to apply the law applicable to that patent, but must also apply international law principles such as comity"
- In addition, the CoA also gives specific guidance as it sets out which approach it considers in line with BSH v Electrolux and comity in three situations regarding actions based on non-UPC EU, Lugano and non-EU/Lugano designations (see next slide)

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Court of Appeal in *Fujifilm v Kodak* (2)

- Situation I: revocation action is lodged with the Court with respect to a non-UPC EU, Lugano and non-EU/Lugano designation
  - UPC approach: no jurisdiction to decide the action
- This is not surprising in view of art. 24(4) Brussels I Bis Regulation
  - While situation I relates to a revocation 'action', this includes counterclaims

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Court of Appeal in *Fujifilm v Kodak* (3)

- Situation II: in an infringement action which is also based on non-UPC EU, Lugano and non-EU/Lugano designation and the **patent in force in the UPC territory is considered invalid**, but the **attacked embodiment or process would infringe if it were valid**
  - UPC approach:
    - — Appropriate to first offer patentee opportunity to withdraw the infringement action based on non-UPC EU, Lugano and non-EU/Lugano designation with specified time

    Then, in case of non-UPC EU or Lugano patent:

    i. If the patentee does not wish to withdraw, offer defendant opportunity to file revocation action before relevant competent national court (if not already pending) within specified time

    ii. If a revocation action is pending, it is appropriate for the Court to stay the infringement action insofar as based on non-UPC EU, Lugano designation until a decision on validity is reached

    iii. If the defendant does not lodge a revocation action within the specified time period, the Court "**must assume that the patent(s) is/are valid and shall decide the infringement action on that basis**"

    Or otherwise, in case of non-EU/Lugano patent:

    i. If the patentee does not wish to withdraw, the infringement action shall be dismissed (unless specific circumstances such as when the non-UPC patent is different and valid, see also situation III on next slide)

➢ Swiss approach? Signal that the Court should first issue a decision on infringement in these cases? What happens if there is no UPC patent involved?

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Court of Appeal in *Fujifilm v Kodak* (4)

- Situation III: in an infringement action which is also based non-UPC EU, Lugano and non-EU/Lugano designation, and the **patent in force in the UPC territory is considered valid and infringed** in the UPC territory
- *UPC approach for non-UPC EU, Lugano (in view of Art. 24(4) BR) and non-EU/Lugano designations (in view of comity):*
    i. The Court may consider there to be a reasonable, non-negligible possibility that the patent is held valid by competent national court and issue decision under the condition that the patent is not held wholly or partially invalid to the extent infringement is based thereon by the competent court
    ii. If upheld by final decision of competent national court, the injunction becomes permanent
    iii. If the patent is deemed invalid in first instance or appeal by competent national court, the condition falls away and the patentee may request the UPC for consequential orders including a request to stay the proceedings until a final decision on validity

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What will the impact of CoA decision in Fujifilm v Kodak be?

- In case of a successful validity defence for non-UPC EU/Lugano patents:
  - Reason for claimant to withdraw action for these patents in view of invalidation and cost risks?
- UPC approach may also lead to more national revocation actions in case of an injunction for non-UPC patents in view of conditionality of injunction
  - Defendant may try to invalidate/cause the patentee to amend the patent by initiating national revocation
    - Conditional counterclaims for infringement expected?
- Higher bar for substantiation for claimant for cross-border relief?
  - In line with the recent ruling by the LD Hamburg, CoA ruled that whether the UK designation of the patent is infringed is a matter of substantive law of the jurisdiction of its registration to which UK law applies (Art. 8 Rome II jo. Art. 24(2)(a) UPCA)

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Cross border relief based on Art. 7(2) BR?

- CoA 13 March 2026, *Adobe v KeeeX* (jurisdiction based on where harm occurred)
  - All defendants were domiciled outside the EU, or in Ireland (not yet a UPC CMS)
  - Jurisdiction for UPC territory based on harm occurring in the UPC territory (Art. 7(2) Brussels Regulation)
  - CoA held that UPC jurisdiction is strictly limited to damage occurring within the UPC territory – no cross-border jurisdiction possible
- Confirmation of long-standing understanding of CJEU Shevill
- Cross-border jurisdiction based on Art. 7(2) BR still possible when relying on the place of the event giving rise to the damage?
  - CJEU Shevill leaves the door open to this
  - LD Mannheim in *Hurom v NUC* (October 2025) refers to CJEU Wintersteiger and finds cross-border jurisdiction based on acts of German subsidiary attributable to Korean parent defendant (multiple events giving rise to damage?)

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Intermediaries and Art. 8(1) BR?

- Cross-border competence based on Art. 8(1) BR if one of the two defendants is an intermediary?
- CoA referred questions to CJEU in *Dyson v Dreame* (March 2026)
  - Must Art 8(1) jo Art 71b(2) BR be interpreted as meaning that a situation where, in proceedings before a common court within the meaning of Article 71a(2) BR, a first company that is established in a Third State [Hong Kong] is alleged to have committed an infringement of a national part of a European patent which is in force in an EU Member State that is not party to the instrument establishing the common court [Spain], and a second company that is established in an EU Member State that is party to the instrument establishing the common court [Germany] is alleged to be an intermediary whose services are used by the first company to infringe in the EU Member State that is not party to the instrument establishing the common court, is capable of leading to "irreconcilable judgments" resulting from separate proceedings as referred to in Article 8(1) BR?
  - *"(...) it is not sufficient that there be a divergence in the outcome of the dispute, but that divergence must also arise in the same situation of fact and law (CJEU, judgment of 12 July 2012, Solvay v Honeywell, C-616/10, ECLI:EU:C:2012:445, para. 24). It may be argued that the position of an alleged infringer is not the same as that of an intermediary who allegedly offers services which a third party uses to infringe."*

PRELIMINARY INJUNCTIONS

CALLUM BEAMISH-LACEY – POWELL GILBERT

UK – Preliminary Injunctions – Overview

American Cyanamid v Ethicon

1. Arguable case / serious issue to be tried (validity and infringement) - Not a mini trial.
2. Damages an adequate remedy?
   - Patentee to suffer irreparable harm?
   - Defendant to suffer irreparable harm?
3. Balance of convenience / risk of injustice?
   - *Status quo*, urgency, "clearing the way"

- Damages often considered adequate remedy for patentee: exception is pharmaceuticals.
- Patentee cross-undertaking in damages

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UK – Preliminary Injunctions – Recent Developments in Pharmaceuticals

Gx don't cause irreparable harm / price spiral?

- Neurim v Generics [2020] EWCA Civ 793 – upheld no PI
- Neurim v Teva [2022] EWHC 954 (Pat) and [2022] EWHC 1641(Pat), and Novartis v Teva [2022] EWHC 959 (Ch) – no PI
- Specific fact patterns
  - Short periods of potential loss
  - Lack of urgency
  - *Status quo* in favour of Gx
  - No price spiral (secondary care only product)

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UK – Preliminary Injunctions – Recent Developments in Pharmaceuticals

Recent Court of Appeal decision – acutally, business as usual

- AstraZeneca v Glenmark (dapagaflozin)
- [2025] EWHC 748 (Pat) - 28 March 2025 no PI post trial / pre-judgment – no price spiral, multiple Gx
- [2025] EWCA Civ 480 - PI granted by CoA – price spiral, maintain status quo, no clearing the way
- [2025] EWHC 1339 (Pat) – patent invalid (previous FI judgment) but PI granted pending appeal
- [2025] EWCA Civ 903 / [2025] EWCA Civ 924 – patent invalid – short PI to "hold the ring" pending UKSC permission to appeal
- UKSC granted indefinite PI pending permission to appeal – refused on 31 July 2025

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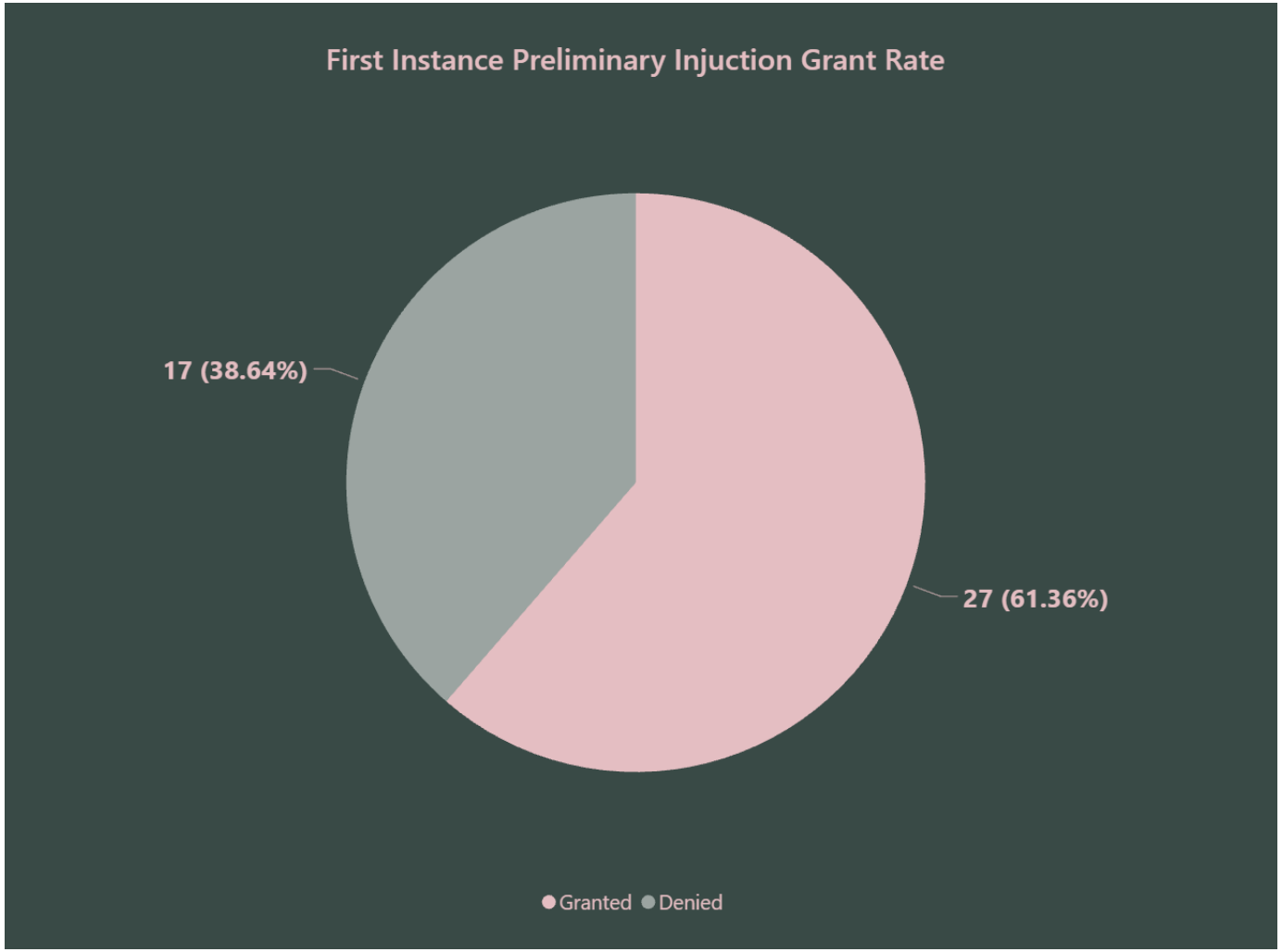
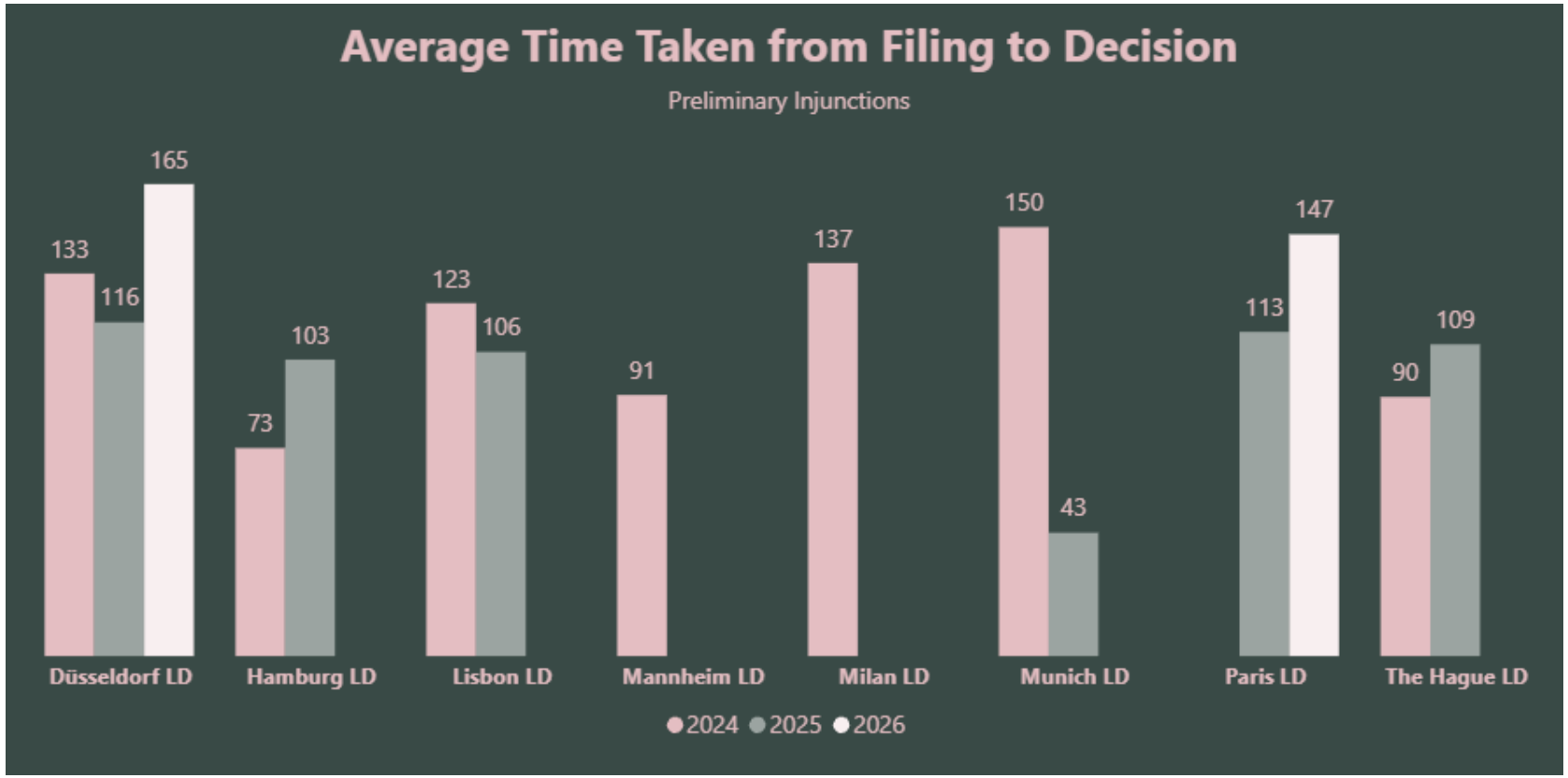
UPC – Preliminary Injunctions – Grant Rate 2024 to May 2026



UPC – Preliminary Injunctions – Days from Filing to Decision 2024 to May 2026



UPC – Preliminary Injunctions – Overview

Basis

- R211(2) - reasonable evidence to satisfy Court with a sufficient degree of certainty (more likely than not) that patent is valid and infringed, or infringement is imminent
- R211(3) - Weigh interests of parties
  - Necessity, Urgency / Unreasonable delay, Damage

Scope

- Cover territory of CMS in which patent has effect (unless circumstances for restriction)
- Can be generally worded (*Abbott v Sibio – Feb '25 – [158]*)
- Claim amendments permissible (?) (*Onward v Niche – Mar '26 – [39] et seq.*)

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UPC – Preliminary Injunctions – Imminent Infringement

Boehringer Ingelheim v Zentiva – CoA – Aug '25 – idiopathic pulmonary fibrosis ([53] et seq.)

- Potential infringer has "**set the stage**" for infringement to occur – only a matter of starting the action because preparations fully complete

- Application or grant of MA is **not** imminent infringement
- Completion of national procedures for health technology assessment, pricing and reimbursement **can** amount to an imminent infringement
- Completion of Portuguese Prior Evaluation Procedure **is** sufficient

Merz v Viatris – CoA – Apr '26 – FAMPYRA / multiple sclerosis ([49] et seq.)

- Publication of price and reimbursement rate in France **not** sufficient certainty that Gx would launch – imminent infringement and urgency

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UPC – Preliminary Injunctions – Weighing Interests – Urgency

Mammut v Ortovox – CoA – Sep ’24 – search device for avalanche victims

- the day on which the Applicant became aware (or should have become aware) of the infringement that would enable him to file an application for provisional measures with a reasonable prospect of success. [HN5, 228]
- Circumstances of each case [HN6, 232] – here 28 Nov 2023 – 1 Dec 2023

Barco v Yealink – CoA – Nov ’25 - meeting room audiovisual equipment

- Waited too long – could have purchased 12 June 2024 and initiated 15 July 2024 (rather than 4 September 2024 to 2 October 2024)

Abbot v Sinocare – CoA – Apr ‘26 – glucose monitoring device

- Patentee cannot act in negligent and hesitant manner in the pursuit of its claims that, from an objective perspective, it must be concluded that the infringed party is not interested in promptly enforcing its rights.
- “*Although a delay of eight weeks to start PI-proceedings is relatively long, the requirements of urgency have been fulfilled under the circumstances of this case*”

UPC – Preliminary Injunctions – Weighing Interests – Necessity

Biolitec v Light Guide Optics - CoA - Feb '25 - single use laser radiation devices

- Not possible to await outcome of main proceedings (if possible to wait, interim measures not necessary) [HN1, 18]
- Damage – not only damage to one party, but time factor [HN2, 19]
- Direct competition – indication of necessity, but not absolute [26]
- Maintain *status quo* – in this case, marketed many years before patent grant (2021 vs 2024) [HN3, 27]

UPC – Preliminary Injunctions – Weighing Interests – Necessity

Abbot v Sinocare – CoA – Apr '26 – glucose monitoring device

- [177] - Necessity
  - Irreparable harm – not a necessity (*Mammut v Ortovox*)
  - Direct competition (*Biolitec v Light Guide*)
  - Maintain *status quo* (*Mammut, Biolitec, Insulet v EOFlow*)
  - Move from one to multiple competing products – price pressure and **permanent** price erosion – important factor (*Sumi v Syngenta*)

- Interests of patients can be considered (*Insulet*, *Merz v Viatris*)
- Ability to quantify damage / price erosion (*Abbot v Sinocare)*

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CLAIM CONSTRUCTION
EPO & UPC:
THE EMERGING METHODOLOGY

Frédéric Portal – Bardehle Pagenberg

THE STATUTORY FRAMEWORK

- **Article 69(1) EPC:**
  - *"The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.“*

- **Article 1, Protocol:**
  - *"[…] it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.“*
  - **Article 2, Protocol:**
  - *"For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims."*

EPO vs. UPC: THE KEY DELTA

	EPO	UPC
Claims as basis	Starting point for patentability	NanoString, UPC_CoA_335/2023 "*Not only the starting point, but the decisive basis*"
Description & drawings	G_1/24: always consulted	Always used as explanatory aids - never only for ambiguity
Single vs. multiple interpretations	Tension: T_367/20 vs. T_2047/23 → G1/26 pending	Claim as a whole - single coherent construction
Construction is law	R_25/22 (Enlarged Board)	Insulet v EOFlow, UPC_CoA_768/2024
Standard	Patentability (Art. 52–57 EPC)	Infringement AND validity - same construction

EPO: "A MIND WILLING TO UNDERSTAND"

- **Synthetical propensity**
- The skilled person builds up rather than tears down - arriving at an interpretation that is technically sensible and takes into account the whole disclosure of the patent.
- "*A mind willing to understand, not a mind desirous of misunderstanding*."
- Established EPO case law:
  - T_190/99, T_920/00, T_500/01, T_1023/02, T_749/03, inter alia.
- A patent document can be its own dictionary - technical meaning takes priority over linguistic analysis (T_1354/18)

Rule	Content
Objective construction	"Mind willing to understand" = willing to objectively construe -NOT to understand the proprietor's alleged intention (T_10/22)
No illogical interpretations	Exclude illogical readings - but a broad term need NOT be read narrowly merely because a narrower reading is common in the field (T_1408/04, T_5/14)
Broadest technically sensible meaning	A non-specific definition is given its broadest technically sensible meaning in the context of the claim (T_79/96, T_596/96, T_1266/19)

EPO: CLAIM CONSTRUCTION AS A MATTER OF LAW

- Claim interpretation is a question of law within the exclusive competence of the deciding body. It is not for parties or experts to determine.
  - Enlarged Board, R_25/22; T_1473/19; T_1513/12; confirmed in R_14/23, T_1973/23, T_837/24

Principle	Rule	Key Decisions
Parties' agreed interpretation	Not binding on the Board - interpretation affects third parties	T_1513/12; T_2319/18; T_583/23
Expert evidence	May establish technical facts (e.g. meaning of a term in prior art) - but cannot determine the correct construction	T_1473/19; T_450/20; T_1494/21
File wrapper / prosecution history	No file wrapper estoppel under the EPC - Prosecution arguments may indicate a construction is not technically unreasonable	T_1837/06; T_1042/15; T_325/23

G_1/24 AND THE TENSION G1/26 MUST RESOLVE: CASE BACKGROUND

- Case: T_0873/24 - ArcelorMittal v POSCO
- Board: Technical Board of Appeal 3.3.05
- Date of referral: 3 February 2026
- Referred to: Enlarged Board of Appeal → G_1/26 (pending)
  - The controversy - one patent claim feature, three different outcomes:
  - The disputed feature (EP 3 587 104, claim 1 as granted):
    - "wherein the ratio of titanium to nitrogen is in excess of 3.42“ (no units specified)

G 1/24 AND THE TENSION G1/26 MUST RESOLVE: CASE BACKGROUND

Approach	Treatment of the feature	Outcome on Art. 123(2) EPC
1st - Description used only to define the skilled person	Ratio = open; molar ratio technically possible → not disclosed in the application as filed	Added matter
2nd - No broadening or limitation from the description	Ratio = open; molar ratio compatible with technical context	Added matter
3rd - Holistic: broadening or narrowing in view of the patent specification	Context of the entire patent shows weight ratio only → weight ratio is the correct construction	No added matter

- **Three approaches - diametrically opposite legal conclusions - same claim feature.**
  - Source: T 0873/24, Technical Board of Appeal 3.3.05, Interlocutory Decision of 3 February 2026.

G1/26: THE QUESTIONS REFERRED TO THE ENLARGED BOARD

- Question 1 — Admissibility of the referral itself:
  - May a decision be considered to be "required" for the purposes of Article 112(1) EPC, if the referring Board demonstrates that the point of law in question arises out of the context of the case pending before it and, in the circumstances of the proceedings, it is reasonable for the Board to examine it and decide on it next?
- Question 2(a) — Can description-only features restrict the claim?
  - Does the fact that the claims are the starting point and the basis for assessing the patentability of an invention generally preclude a feature which is only disclosed in the description or the drawings of a patent from being read into the meaning of a granted claim, in particular if this leads to a restrictive reading of terms used in the claim?
- Question 2(b) — If NO to 2(a): holistic unitary process?
  - Is claim interpretation the result of both reading the claims and consulting the description and drawings as a unitary process and does the claim being the starting point and the basis for assessing the patentability rule out only those interpretations which can be derived from the patent as a whole but would clearly contradict the general technical understanding of the terms used in the claim?

G1/26: THE QUESTIONS REFERRED TO THE ENLARGED BOARD

- Question 3(a) — Scope of Art. 123(2) EPC assessment:
  - When assessing compliance with Article 123(2) EPC, must a term used in a claim be assessed against all interpretations that make technical sense to the skilled reader on the basis of the claim alone?
- Question 3(b) — If NO to 3(a): narrower scope?
  - Is it sufficient that only the interpretations of the subject-matter of the claim established against the background of the patent specification as a whole are directly and unambiguously derivable from the application as filed?

The UPC Foundational Principles - NanoString v 10x Genomics

UPC_CoA_335/2023 | Order of 26 February 2024 (rectified 11 March 2024)

- *"The patent claim is **not only the starting point**, but the **decisive basis** for determining the protective scope of a European patent under Art. 69 EPC in conjunction with the Protocol on the Interpretation of Art. 69 EPC.*
- *The interpretation of a patent claim does **not depend solely on the strict, literal meaning** of the wording used. Rather, the **description and the drawings must always** be used as explanatory aids for the interpretation of the patent claim and not only to resolve any ambiguities in the patent claim.*
- *However, this does **not** mean that the patent claim **merely** serves as a **guideline** and that its subject-matter also extends to what, after examination of the description and drawings, appears to be the subject-matter for which the patent proprietor seeks protection.*
- *The patent claim is to be interpreted from the point of view of a **person skilled in the art**.*
- *In applying these principles, the aim is to combine **adequate protection** for the patent proprietor with **sufficient legal certainty** for third parties.*
- *These principles for the interpretation of a patent claim apply equally to the assessment of the **infringement and the validity** of a European patent."*

THE SKILLED PERSON & THE CLAIM AS A WHOLE

- **VusionGroup v Hanshow, UPC_CoA_1/2024, Order of 13 May 2024**
  - "*Claim features must always be interpreted in the light of the claim **as a whole**.*“
- **Insulet v EOFlow, UPC_CoA_768/2024, Order of 30 April 2025**
  - *"The interpretation of a patent claim is a matter of law. Therefore, the **Court** cannot leave the judicial task of interpreting the patent claim to an expert but **has to construe the claim independently**."*
  - *"The skilled person is a notional entity that cannot be equated with any real person in the technical field of the invention. The decisive factor is not the individual knowledge and abilities of a person, but rather the **general specialist knowledge** that is customary in the **relevant field** of technology, as well as the average knowledge, experience, and abilities in this specialist field. It is for the Court, not the expert, to assess these circumstances."*

FUNCTIONAL FEATURES: ABBOTT & DYSON

- **Means-plus-function - Abbott v Sibio, UPC_CoA_382/2024, Order of 14 February 2025**
  - *"As a general principle of claim interpretation, means-plus-function features must be understood as any feature suitable for carrying out the function."*
- **Structural + functional balance - Dyson v Dreame, UPC_CoA_789/2025 and UPC_CoA_813/2025, Order of 6 March 2026**
  - *"While the function of a structural element must be considered when interpreting a claim feature relating to such an element, the interpretation must likewise take into account the physical and spatial configuration of the elements as taught by the patent.“*
- **Key takeaway**
  - Function and structure must be balanced - not either/or.
  - Particularly relevant for: antibody claims | dosage regimens | medtech | platform biotech | Markush

NUMERICAL VALUES: KODAK v FUJIFILM

- **Kodak v Fujifilm, UPC_CoA_312/2025 et al., Decision of 2 June 2026**
  - *"There is no general rule that the skilled person would always and automatically take into account fluctuations which are due to the manufacturing process and the measurement method and in doing so would automatically add deviations to the – as such precise – numerical value in a claim feature. This may be a result of claim interpretation but is not inherent to the use of a numerical value in a claim.“*

- **Life sciences relevance**
  - Dosage claims | Purity specifications | Concentration ranges | Bioavailability thresholds | Particle size distributions

MEDICAL USE CLAIMS: INHERENT THERAPEUTIC EFFECTIVENESS

- **Amgen v Sanofi and Regeneron, UPC_CoA_528/2024 and UPC_CoA_529/2024, Decision of 25 November 2025**
  - *"When the claims are drafted in 'medical use-format', it is an **inherent claim feature** that the claimed product must be **objectively suitable for the claimed use**, i.e. be therapeutically effective. This requires that the claimed treatment causes a noticeable improvement of the medical condition of the patient suffering from the disease mentioned in the claim, i.e. the **treatment must be meaningful**."*
  - *"The fact that the skilled person does not derive any minimum required effect from the claim or the description does not lead to another conclusion, since the feature of therapeutic effect does not follow from the claim language that is to be interpreted, but from the use of the medical use claim format."*

INVENTIVE STEP & TECHNICAL EFFECT: KEY PRINCIPLES

- **Three pillars of the UPC inventive step analysis**

Principle	UPC Holding
Realistic starting point	No rigid "closest prior art" formalism - multiple realistic starting points may exist - hindsight-based prior art selection is rejected
"Would" not "Could"	The skilled person must would have arrived at the invention with a reasonable expectation of success - not merely could have done so
Holistic assessment	Inventive step is assessed on the invention as a whole - not by rigid feature-by-feature dissection

CONCLUSIONS

#	Takeaway
1	• The UPC is building an autonomous claim construction methodology - not copying EPO, German, English, or French approaches. • The 2025–2026 CoA decisions are functioning as genuine precedents. • The EPO's G1/26 will determine whether the EPO follows the same holistic approach.
2	• One construction governs infringement and validity. • A broad reading helps infringement; it also exposes validity. • You cannot hold both simultaneously. • Plan your strategy accordingly - and monitor parallel EPO/UPC proceedings carefully.
3	• In life sciences: technical effect is substantive, not cosmetic. • Medical use claims carry an inherent therapeutic effectiveness requirement. • Inventive step turns on "would" not "could." • And numbers mean what they say - unless the description says otherwise.

ENFORCEMENT OF SECOND MEDICAL USE PATENTS

Dr Kai Rüting - Vossius

Why it matters

- Skinny labels vs reality:
  - indication is not on the prescription
  - pharmacist will cross dispense
  - generic medicine will be used for patented indications
- Enforcement of 2nd medical use patents
  - is difficult in practice
  - differs across Germany and Europe
  - concerns the intersection of IP law and public policy
  - affects every multi-indication drug protected by multiple patents
  - impacts drug pricing, timing of market entry, and R&D incentives

Background – Cross-label use

- **Skinny label**, cf Article 11 of Directive 2001/83 EC:

  "The summary of the product characteristics shall contain, in the order indicated below, the following information: …

  4. clinical particulars:

  4.1 therapeutic indications,

  4.2 posology and method of administration …

  For authorizations under Article 10 [generics], those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed need ***not to be included****."*

- **Problem**: activities for promoting the product also for the patented (but off-label) indication

Background –
Prescription, substitution and discount contracts in Germany

Physician prescribes drug

↓

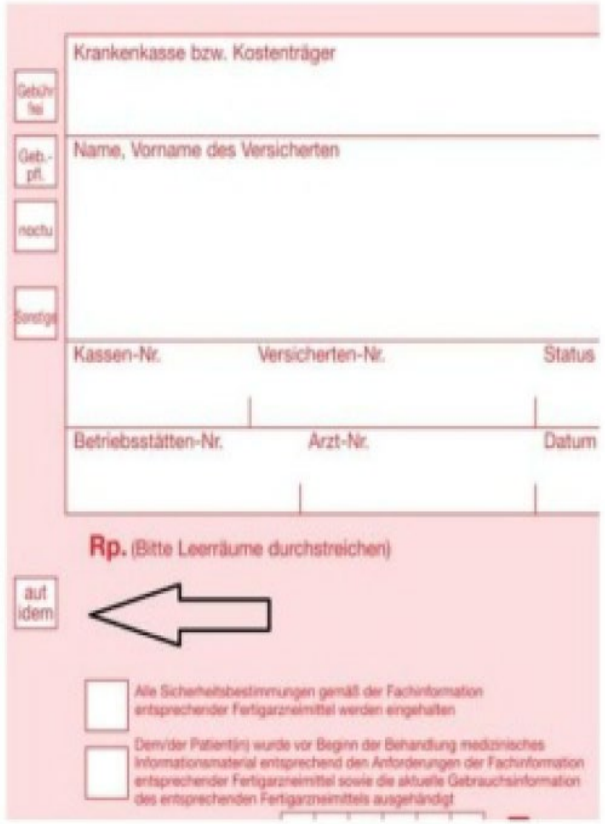
Pharmacist dispenses drug

↓

Public health fund reimburses drug

No indication on prescription
Mandatory substitution by cheaper Gx:

- Pharmacies are legally obliged to substitute a drug or active substance prescribed by physicians with one of the drugs listed in a discount contract
- Substitution applies as long as the discounted drug and the original drug overlap in at least one indication for which an MA exists
- And as long as physician does not exclude this option by checking the aut idem box

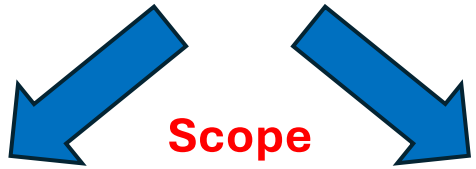


Reimbursement irrespective of label

Background – Infringement of 2nd medical use claims in Germany

Use of compound X for the (manufacture of) new therapeutic application Y

Purpose-limited product claim (German Federal Supreme Court)



Manifest Arrangement:

- If the substance is formulated, tailored, packaged
- And this arrangement allows conclusion of patented use

Patented use without manifest arrangement

Düsseldorf case law – Fulvestrant (CoA, Jan 9, 2019, I-2 U 28/18)

"Scenario 1"

"(...) the trial judge has to ascertain that

- Firstly there has been a **sufficient use** according to the patent, and that
- Secondly this fact can **by no means have remained hidden** from the generic company.

with the **number of proven uses** as covered by the patent the chances are increasing that the trial court will ascertain this fact, whereas single cases of use will generally not lead to a liability if there is no manifest arrangement."

"Scenario 2"

"special, formidable advantages of the patent protected uses compared to other therapeutic purposes which imply the use of the medication according to the patent" (obiter dictum)

Düsseldorf case law – Fulvestrant (cont'd)

- Patented use without manifest arrangement:
  - Use of circumstances leading to patented use; use must be so extensive that solid knowledge of the use is inferred
  - Formidable advantages of patent-protected use
- Conclusions:
  - No subjective approach
  - Skinny labeling does not exclude liability
- BUT:
  - Unlike in "manifest arrangement"-cases, the infringement has (still) to take place during the time of the oral hearing (or in the previous years)
  - Infringement is only possible if the specific use is covered by the SmPC => High hurdle

Regional Court Munich – Nilotinib (Dec 4, 2024, 21 O 14559/24) - Facts

- Patent: Nilotinib for use in treatment of leukemia wherein the drug is orally administered dispersed in apple sauce
- SmPC for originator product:
  - Nilotinib must not be used with food
  - In case of problems with swallowing, the capsule should be opened and administered together with a spoon of apple sauce
- SmPC of Gx:
  - “In case of swallowing problems, use different drugs with Nilotinib”
  - “Do not open the capsule”
- Administration together with Nilotinib was discussed during approval proceedings and found as safe regardless of whether it is mentioned in the SmPC because it is assumed that the product will be taken together with apple sauce

Regional Court Munich – Nilotinib (cont‘d) - Decision

- Manifest arrangement (-) due to lacking statements in SmPC
- Patented use without manifest arrangement (+):
  - Reimbursement system: Pharmacies must substitute with cheaper generic version and due to refunding system it is very unlikely that doctors will not check “aut idem” box
  - Knowledge of the doctors:
    - Nilotinib and administering in case of swallowing issues are well known and tested
    - SmPC would not hinder doctors from prescribing because generic version is identical copy and there are no medical explanations for prohibition of opening the capsule and using it with apple sauce

Regional Court Munich – Nilotinib (cont'd) - Decision

- Remedies: Injunction? How to enjoin?
  - No participation in discount contracts unless such contracts make sure that drug is not used in patented manner
  - Warning notices on patent protection and patent infringing use towards wholesalers and in the relevant databases
- Munich CoA:
  - lifted enforceability of decision due to lack of imminent infringement and undue remedies (6 U 4098/24, March 5, 2025)

Regional Court Munich – Safinamide (Sept 17, 2025, 21 O 7785/25) - Facts

- EP 2 474 521:
  - High purity degree safinamide for treatment of Parkinson's disease
  - in patients
    - that are classified as poor metabolizers or
    - who are concomitantly assuming other drugs which are known to interact with CYP450 system and/or are known to have HERG channel blocking properties
  - => specific indication + patient group
  - Original product: Xadago
- Gx tried to obtain carve-out for patient group of poor metabolizers => was rejected by regulatory authorities

Regional Court Munich – Safinamide (cont'd) - Arguments

- Arguments - 2 scenarios for patent infringement:
  - **Manifest arrangement:**
    - the standard is that doctors are guided to the patented use
    - SmPC addresses CYP450 system (but does not mention co-treatment with other drugs as claimed)
    - SmPC indicates that there is no significant impact on enzymes => doctors assume that drug can be dispensed for poor metabolizers
  - **Patented use without manifest arrangement:**
    - Guidelines to doctors on treatment of Parkinson's disease mention co-treatment
    - Doctors know that impurities in safinamide have disadvantage for poor metabolizers => use advantage of high purity
    - Reimbursement system: If doctors prescribe Xadago, regulatory laws require mandatory substitution by Gx

Regional Court Munich – Safinamide (cont'd) – Decision (Dec 30, 2025)

- PI granted *ex parte* in June 2025; confirmed after oral hearing
  - Manifest arrangement: fulfilled for both patient groups
  - Poor metabolizer (+): SmPC indicates that Safinamide does not induce or inhibit enzymes => clear indication for doctors that drug is suitable and determined for use with poor metabolizers
  - Co-medication (+): SmPC states that there is no substantial inducement or inhibition of CYP450 system => this constitutes an unambiguous hint that there will be no significant interaction with co-medication
- Patented use without manifest arrangement?

Regional Court Munich – Safinamide (cont‘d) - Key take aways

- Munich proposes less strict requirements than Düsseldorf courts:
- General indications in SmPC without explicit link to the patented requirements seem to be sufficient => doctors will make their conclusions
- Left open the issue of patented use without manifest arrangement but it seems that – different to Düsseldorf – they would not require a considerable extent of the patented use

Sanofi/Regeneron v Amgen on PCSK9 (LD DUS, 13 May 2025, UPC_CFI_505/2024) - Facts

- EP 3 536 712:
  - Second medical use claim
  - PCSK9 inhibitors for reducing lipoprotein(a) (Lp-a)
- Amgen marketed PCSK9 inhibitor Repatha® (evolocumab) for standard cardiovascular indications
- Lp(a)-reduction was mentioned in the SmPC as a pharmacodynamic effect, but not as a therapeutic indication

Sanofi/Regeneron v Amgen (cont'd) – Decision

- UPC established **two-part infringement test** for second medical use:
  - **objective element**: the product is offered or marketed in a way that leads or may lead to the patented second use. Assessment uses market facts & behavior – not abstract test
  - **subjective element**: infringer knew or should reasonably have known that users apply it for the patented use
- **Multi-factor assessment**:
  - Prescribing practice in relevant markets
  - Market shares and patient numbers
  - SmPC / Label carve-out relevant, but not decisive and not sufficient
  - Commercial conduct of the defendant:
    - either positively de facto encouraging the patented use
    - or negatively by taking measures to prevent the product from being used for the patented use

Sanofi/Regeneron v Amgen (cont'd) – Decision

- Appying the infringement test:
  - No infringement: patented effect viewed as incidental / "windfall effect"
  - Repatha® SmPC lacked any mention of Lp-a reduction
    - Section 4.1 (therapeutic indications) and section 5.1 (Pharmacodynamics properties)
  - Expert evidence: physicians do not prescribe Repatha for Lp-a
  - No evidence of marketing encouragement for Lp-a use => both objective and subjective elements not met

Sanofi/Regeneron v Amgen (cont'd) – Key take aways

- Skinny labels relevant, but not decisive alone
- UPC adopts fact-specific multi-factor analysis => case specific test
- Automatic pharmacological effects alone insufficient
- Patentee must prove both market reality and defendant knowledge
- Development of case law is in progress => UPC appeal decision required

Hikma v. Amarin US Supreme Court - Facts

- Issue: What is the standard for pleading induced infringement by a skinny label?
- VASCEPA® approved for Indication #1
- Patents on Indication #1 invalidated
- VASCEPA® approved for Indication #2
- Hikma launches generic with carve-out of Indication #2
- Amarin sues Hikma for induced infringement based on Hikma's label, press releases, and website

Hikma v. Amarin Supreme Court - Facts

- Hikma's press releases and website:
  - Stated that Hikma's product was the "generic version" of VASCEPA®
  - Did not state the product was only approved for Indication #1
  - Stated that the product was approved "in part" for Indication #1
  - Described product as "AB rated" to VASCEPA® for a broader indication than label language
  - Referenced Amarin's VASCEPA® sales, over 75% of which were for Indication #2

Hikma v. Amarin Supreme Court - Decision

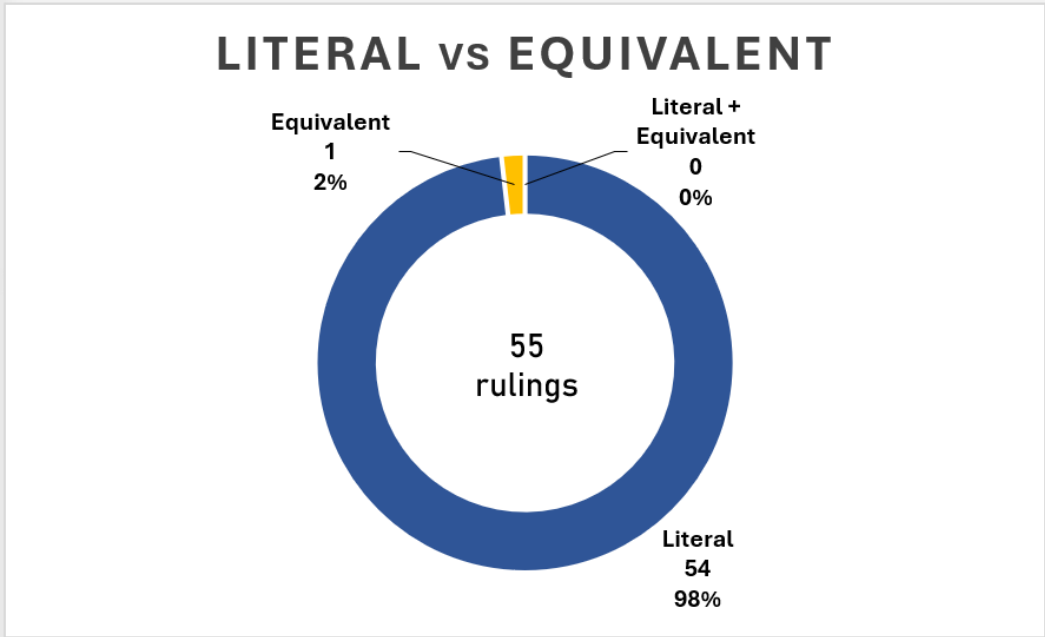
- Induced infringement under 35 U.S.C. §271(b) requires: direct infringement + knowledge + active steps
  - only “active steps” were disputed before the Supreme Court
- Standard for “active steps”:
  - **affirmative, purposeful conduct** – not passive omissions or ordinary distribution acts
  - implicit encouragement may suffice, but **must be clear and affirmative**
- Application to Hikma:
  - label / “generic equivalent”: obvious alternative explanation = law or industry practice
  - omissions (no Indication #2 / no Indication #1-only clarification): no affirmative act
  - patient leaflet, therapeutic category and AB rating: too vague
  - sales figures in investor press releases: too many speculative steps – possible, not plausible

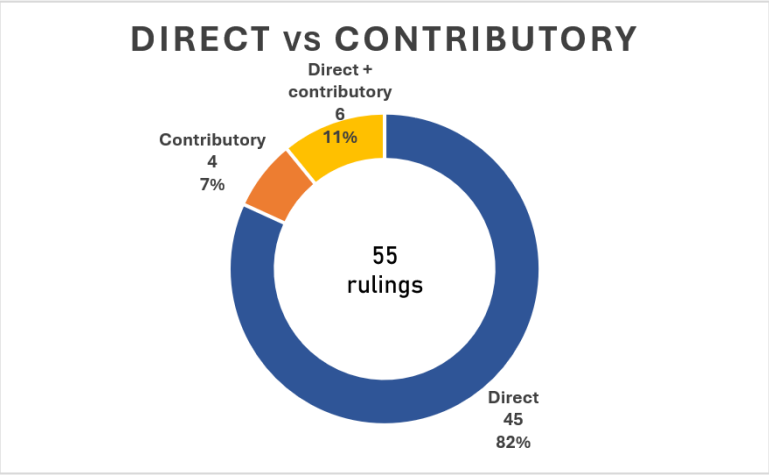
EQUIVALENT INFRINGEMENT

Thomas Bouvet – Jones Day

UPC APPROACH

- Statistics (decisions on the merits) : equivalent rulings are still "*a needle in a haystack*"





UPC APPROACH (1/5)

- The Hague LD, 22 November 2024, ***Plant-e Knowledge / Arkyne Technologies*** UPC_CFI_239/2023) (EN)
  - First UPC decision on equivalence
  - "Dutch" test
  - only a first-instance decision applying a national test BUT **consistently applied since then**:
    - The Hague LD, 11 September 2025, ***Washtower / BEGA*** (UPC_CFI_479/2025) (EN) (plastic L-shaped strip **found to be equivalent** to metal strip (PI proceedings))
    - (implicitly) The Hague LD, 18 November 2025, ***Advanced Cell Diagnostics / Molecular Instruments*** (UPC_CFI_187/2024) (EN) (no equivalent infringement)
    - Helsinki LD, 29 April 2026, ***AIM Sport Development / TGI Sport*** (UPC_CFI_214/2023 / UPC_CFI_403/2025) (EN)
    - Düsseldorf LD, 27 May 2026, ***Wonderland / Cybex*** (UPC_CFI_807/2024) (EN)
    - Paris LD, 29 May 2026, ***TIRU / Valinea Energie, Maguin*** (UPC_CFI_130/2025) (FR)
  - **no CoA ruling yet: will be key** (validation of Dutch test vs departure from it)

UPC APPROACH (2/5)

- The Hague LD, 22 November 2024, ***Plant-e Knowledge / Arkyne Technologies*** UPC_CFI_239/2023) (EN)
  - Four-Prong Test (**cumulative** requirements)
    1. **Technical Equivalence**: *Does the variation perform the same function and solve the same problem?*
       In this case, the court found that Bioo's devices, though described as Soil-MFCs, performed the same function as the patented P-MFC: generating electricity using microbial oxidation of organic matter. The plants, though deemed "optional" by Bioo, contributed to the process by replenishing organic matter, akin to the claimed invention.
    2. **Fair Protection for the Patentee**: *Is extending the patent's scope to cover the variation justified?* The court's approach is that a fair balance must be struck between preventing patents from being designed-around through minor changes while the substance of the invention is reproduced, while safeguarding against an overly broad and generous interpretation.
       Here, the court held that interpreting the patent to include Bioo's implementation was warranted, given that: (i) Plant-e's invention was a significant contribution to the state of the art and (ii) the accused devices clearly relied on the principles of the patented invention.
    3. **Reasonable Certainty for Third Parties**: *Would a skilled person understand that the variation is within the patent's scope?*
       In other terms, the skilled person must read into the literal wording of the patent claims that there is an additional room for equivalents, in particular when no reason can justify to limit the scope of protection of the claim.
       Here, the court noted that Bioo's communications about its technology, including grant applications, emphasized the role of plants, aligning closely with Plant-e's patented claims. A skilled person would thus reasonably infer that the accused technology fell under the scope of the patent.
    4. **Novelty and Inventiveness**: *Is the alleged equivalent novel and inventive over prior art?*
       This fourth prong corresponds to the Formstein or Gillette defenses, which provide that there is no infringement if an accused product or process, while falling within the scope of a patent claim (the validity of which has been unsuccessfully challenged), were known or obvious from the prior art (aka "no infringement can result from merely practicing the prior art").

UPC APPROACH (3/5)

- Brussels LD, 17 January 2025, ***Jozef Frans Nelissen / OrthoApnea S.L., Vivisol*** (UPC_CFI_376/2023) (NL)(EN)
  - no clear test set out
  - Court found that the accused product performed the patented function but with different means
  - no equivalent infringement

UPC APPROACH (4/5)

- Several LDs check whether the **main core requirement shared by all national equivalence tests** is satisfied:
  - Mannheim LD, 6 June 2025, ***DISH Technologies L.L.C., Sling TV L.L.C. / AYLO*** (UPC_CFI_471/2023) (DE)(EN): "***According to all doctrines of equivalence or equivalence tests of the UPC contracting member states**, equivalent patent infringement is ruled out if there is no technical-functional equivalence of the substitute means in the sense that the modified means do not fulfil **essentially the same function in order to achieve essentially the same effect**. If the same function is not taken as a basis, at least essentially the same effect is taken as a basis*"
  - Paris LD, 1 August 2025, ***N.J Diffusion / Gisela Mayer*** (UPC_CFI_363/2024) (FR): "*In light of the case law of the UPC (see Mannheim UPC LD, 6 June 2025 - 471/2023- Headnote 3; Brussels UPC LD, 17 January 2025, para. 98 - CFI 376/2023), this Division considers, on the one hand, that it is appropriate to adopt the most harmonised interpretation possible within the JUB when ruling on claims of infringement by equivalence and, on the other hand, that, in any event, **in view of the different tests applied within the contracting Member States of the AJUB, it is appropriate to first answer a question that is the lowest common denominator and constitutes the first criterion for examining equivalence: Do the modified (or substitute) means essentially fulfil the same function to achieve essentially the same effect?***"
  - Vienna LD, 19 February 2026, ***Messerle / Sabert*** (UPC_CFI_26/2025) (EN): "*While there is no harmonized approach to determining an equivalent use of the teaching of the patent among the Local Divisions of this Court yet (see: Local Chamber in The Hague, decision on the merits of 22 November 2024, UPC_CFI_239/2023; Local Chamber in Mannheim, decision on the merits of 6. Juni 2025, UPC_CFI_471/2023; Local Chamber in Paris, decision on the merits 1. August 2025, UPC_CFI_363/2024) it seems to be accepted – also apparently in all doctrines of equivalence or equivalence tests of the UPC member states (Local Chamber in Mannheim, decision on the merits of 6. Juni 2025, UPC_CFI_471/2023 mn 167 with reference to the Year Book 2023 / I of the International Association for the Protection of Intellectual Property (AIPPI) and Brussels Local Chamber, Beslissing ten gronde of 17 January 2025, para.; see LG München I (7. Zivilkammer), order on the merits of 25. September 2025 – 7 O 9383/25 for a summary of the doctrines of equivalence or equivalence test of the EU member states and also Enclosure I) - **to rule out equivalent patent infringement if there is no technical-functional equivalence of the substitute means in the sense that the modified means do not fulfil essentially the same function in order to achieve essentially the same effect. If the same function is not taken as a basis, at least essentially the same effect is taken as a basis***"

UPC APPROACH (5/5) – Procedural aspects

- adding an equivalence argument does not change the nature/scope of the dispute and so does not require leave under R. 263 RoP (CoA, 21 November 2024, ***OrthoApnea, Vivisol / Jozef Frans Nelissen*** (UPC_CoA_456/2024) (EN))
- Estoppel: claim construction should not result in giving the claims, in particular through equivalence, the scope they had prior to amendments during prosecution / opposition:

  Paris LD, 24 October 2025, ***Raccords et Plastiques Nicoll / First Plast*** (UPC_CFI_612/2024) (FR)

  > *"However, **RPN admitted during the proceedings for the grant of EP 938** that the two parallel, L-shaped longitudinal walls of prior art US 628 and JP 021 did not constitute spacer elements, but a single spacer element (RPN No. 10-2, pages 2, 3, and 5) **and amended its application** by introducing the feature of longitudinal alignment of the separator elements and the openings **to avoid the objection of lack of novelty**. Indeed, RPN stated (Exhibit RPN No. 10-2, page 6) that unlike the prior art (US 628), where "the elements 20 are spaced apart in the transverse direction and mutually aligned on both sides of the slot, and thus also in the transverse direction," in patent EP 938 "the spacer elements (...) are aligned with one another, i.e., relative to one another, and separated by the opening in the upper surface of the receiving body 10, in the longitudinal direction"*

  Munich LD, 13 September 2024, ***Philips IP Ventures / Belkin*** (UPC_CFI_390/2023) (DE)(EN)

  > *"The patent specification must be read in a meaningful context and, in case of doubt, the patent claim must be understood in such a way that there are no contradictions with the statements in the description and the pictorial representations in the drawings. **However, a patent claim may not be interpreted in accordance with a broader description if the description is not reflected in the patent claim.** If and to the extent that the teaching of the patent claim is consistent with the description and the drawings cannot be reconciled and an irresolvable contradiction remains, **those elements of the description that are not reflected in the patent claim may not be used to determine the subject matter of the patent**. In this respect, the patent claim takes precedence over the description. If several embodiments are presented in the description as being in accordance with the invention, the terms used in the patent claim are, in case of doubt, to be understood in such a way that all embodiments can be used to fulfil them."*
  >
  > *"In a letter dated 10 February 2014, the applicant declared this to the EPO: (...). It has thus expressed that, in accordance with the patent, it is not merely a matter of an acknowledgement of receipt (...) "*

NATIONAL APPROACHES

- **Protocol on the Interpretation of Article 69 EPC**
  Article 2: Equivalents

For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims

	DEFINITION	RESULT	SKILLED PERSON	ESTOPPEL	PRIOR ART
FR	Different means / identical function	Similar nature Same technical advantage	Not taken into account	No	Function must be novel
DE	Different means / Same effect (*Schneidmesser* questions)	Similar nature Same technical advantage	Equivalent means must be obvious to skilled person	No	Formstein defence
NL	Function, way and result must be the same	Same degree	Obvious that the same results are obtained	Yes	Gillette defense
IT	Different means / identical function	Same technical problem	Equivalent means must be obvious to skilled person	No	Function must be novel

THE FRENCH TEST

- **French very broad three prong test:**
  - when the patent covers a new function
  - An equivalent is:
    - different in shape
    - fulfils the same function
    - to achieve a result of the same nature, even if to a different degree
- **Cass. Com. November 2, 2011, pourvoi n° 10-30.907**

*"Whereas, in so determining, after finding, on its own grounds and on adopted grounds, that **the patent covered a new function** consisting in maintaining the assembly of the slats of the barrel bottom by force-fitting without resorting to any other means of fastening, without investigating, as it was invited to do, whether, **despite the difference in shape** due to the presence of a sealing ring between the slats, the method of combining this joint with slats whose side faces had grooves, did not **fulfil the same function with a view to achieving a result of the same nature, even if this was to a different degree**, the Court of Appeal deprived its decision of a legal basis."*

NATIONAL APPROACHES – FRANCE

- **Paris Court of Appeal, 17 December 2025, Docket No 24/02201 (1/3)**

  "On infringement

  Eli Lilly argues that Viatris sold a generic drug in France containing the active ingredient pemetrexed in combination with vitamin B12 (and folic acid) to treat malignant pleural mesothelioma and bronchial cancer; that the active ingredient in Pemetrexed Mylan is the same, the use of an alternative salt form such as diarginine salt, which has no effect on the drug's efficacy or side effects, has no bearing on the assessment of infringement; that the essential features of EP 508 are reproduced; and that infringement therefore exists.

  Viatris argues that the alleged infringement consists of supplying the product resulting from the pemetrexed manufacturing process with the alleged intent of using it in combination with vitamin B12; that the drug in question, Pemetrexed Mylan, contains the diarginine salt of pemetrexed in the form of a solution for dilution for infusion, so that it is not pemetrexed disodium, to which Eli Lilly limited its claim in response to the examiner's objections; that the company is accused of referring to vitamin B12 in its Summary of Product Characteristics (SmPC), whereas vitamin B12 is mentioned for its effect on the product's safety, so that it is not permissible, for safety reasons, to remove this reference; that infringement is therefore not established."

NATIONAL APPROACHES – FRANCE

- **Paris Court of Appeal, 17 December 2025, Docket No 24/02201 (2/3)**

  "***Infringement is determined based on similarities and occurs when the essential elements of the invention are present in the product in question*** *(Cass. Com. March 20, 2024, No. 22-22.406).*

  In this case, Patent EP 508 protects the administration of pemetrexed disodium, in combination therapy with vitamin B12, and optionally with folic acid, for the treatment of tumor growth. The Mylan pemetrexed drug at issue has pemetrexed as its active ingredient, used in the form of pemetrexed diarginine. It is further established that the difference between pemetrexed disodium and pemetrexed diarginine is a secondary one, as the salt cations—whether sodium or arginine ions—play no role in either the production of therapeutic effects or the development of side effects, the only active component of the drug being the pemetrexed anion, to which they are similarly bound.

  It therefore follows from the summary of product characteristics for Pemetrexed Mylan that it must be used in combination with vitamin B12 and folic acid to treat malignant pleural mesothelioma and bronchial cancer. ***It follows from the foregoing that Pemetrexed Mylan reproduces the essential features of claims 1 through 14 of European Patent EP 508****. Since direct infringement is thus established, the argument based on infringement by equivalence becomes moot."*

NATIONAL APPROACHES – FRANCE

- **Paris Court of Appeal, 17 December 2025, Docket No 24/02201 (3/3)**

  1st instance : infringement by **equivalence**

  Appeal: difference between pemetrexed disodium and pemetrexed diarginine is a secondary difference, because the sodium or arginine cations played no role in either therapeutic effects or side effects > **direct** infringement by reproduction of the **essential means**

  Reminiscent of older / parallel French doctrine sometimes described as *infringement despite secondary differences*

  Does this reasoning avoid the safeguards of equivalence analysis, especially the question whether "disodium" was a deliberately limiting claim feature?

NATIONAL APPROACHES – Germany

- **FCJ, March 12, 2002, Docket No X ZR 168/00 – Schneidmesser I**

General principles

1. **Same effect**: The variant must solve the problem according to the patent with means having essentially the same effect as the element specified in the patent claim.

2. **Discoverability**: The skilled person must be able, due to their expert skill, to find the variant as having essentially the same effect as the element in the patent claim.

3. **Equivalence**: The skilled person must be able to find the variant as having the same effect by considerations oriented to the technical teaching protected by the patent claim.

4. **No Formstein Defense**

NATIONAL APPROACHES – Germany

1. Same Effect

FCJ, January 15, 2015, Docket No X ZR 81/13 – Kochgefäß I

> *"To assess equivalence, it is necessary to examine the patent claim to determine which of the effects that can be achieved with its features must, according to the invention, be present together to solve the underlying problem. The totality of these effects represents the solution claimed by the patent; further subdividing them into "essential" and "additional" effects is misguided."*

3. Equivalence

FCJ, May 10, 2011, Docket No X ZR 16/09 – Okklusionsvorrichtung

> *"If the description discloses several ways in which a particular technical effect can be achieved, but only one of those ways has been included in the patent claim, the use of one of the other ways does* ***not generally constitute infringement*** *of the patent by equivalent means.."*

Specified by FCJ, June 14, 2016, Docket No X ZR 29/15 – Pemetrexed

> *"As a general rule, it cannot be assumed that the patent owner made a choice. Rather, there must be specific grounds for assuming that a choice was made."*

Specified by FCJ, August 23, 2016, X ZR 76/14 – V-förmige Führungsanordnung

> With reference to pemetrexed, that alternatives that are merely identifiable or generally implied are not automatically excluded from the scope of equivalence.

NATIONAL APPROACHES – Germany

3. Equivalence

FCJ, November 17, 2020, Docket No X ZR 132/18 – Kranarm

"*An embodiment that differs in design from a feature specified in the patent claim cannot automatically be regarded as having the same effect simply because the protection sought by the patent (...) is not achieved in the section of the line specified in the patent claim, but is achieved in another section.*"

4. Formstein defense

FCJ, April 29, 1986, Docket No X ZR 28/85 – Formstein

If the plaintiff alleges patent infringement by means that are modified but have the same effect, the defendant may also defend itself by arguing that the contested embodiment is not patentable because it was anticipated or suggested by the prior art as of the priority date of the patent in suit .

→ In substance, this is the argument of the free state of the art, which can only apply in the event of an extension of the scope of protection by equivalent means. In conclusion, it is a prerequisite that the contested embodiment, with all its features (including the equivalently infringed one), must have already existed in the prior art as of the priority date of the patent.

NATIONAL APPROACHES – Germany

Equivalence in Life Sciences

CLAIM	ACCUSED PRODUCT
Use of **pemetrexed disodium** (...)	**Pemetrexed dihydrochloride with tromethamine** as equivalent to pemetrexed disodium (HRC Munich, May 18, 2017, Docket No 6 U 3039/16) **Pemetrexed-Diarginin** as equivalent to pemetrexed disodium (Munich Regional Court I, July 24, 2020, Docket No 21 O 8568/20)
(...) comprising fast-release **tablet** (...)	(...) comprising fast-release **hard capsule** (...) (HRC Munich, February 13, 2025, Docket No 6 U 2277/244 e – Rivaroxaban I)
An ophthalmic formulation of (...) (d) 5-40 mM of **sodium phosphate buffer**; and (...)	Using **histidine as a buffer** instead of sodium phosphate (Munich Regional Court I, September 25, 2025, 7 O 9382/25 - VEGF-Antagonisten; 7 O 16055/24 - VEGF-Antagonisten III)

NATIONAL APPROACHES – Germany

Recent Case Law - Munich Regional Court I, September 25, 2025, 7 O 16055/24 - VEGF-Antagonisten III

Same effect: The non-literal feature was the buffer in feature 1.4, claimed as 5–40 mM sodium phosphate. The court saw the buffer's function as setting or stabilizing the formulation's pH within the required range and found histidine to have the same relevant properties as sodium phosphate for that purpose.

Discoverability: Histidine and phosphate had substantially overlapping pH ranges. The court also noted that ranibizumab, the only comparable intravitreal protein drug in advanced development at the priority date, used 10 mM histidine as buffer. Required stability studies did not preclude discoverability, as the court viewed them as routine testing rather than inventive work.

Equivalence: The route to histidine remained oriented to the patented teaching because the patent required a buffer to set pH but did not assign sodium phosphate any additional function or special advantage. The court rejected a conscious limitation to sodium phosphate, found no exclusionary selection decision, and treated the case as a typical case of equivalent infringement.

Formstein defense: The defence failed because the relevant prior-art document, D10, disclosed aflibercept with histidine but did not disclose an ophthalmic VEGF-antagonist formulation for use in intravitreal administration. The court distinguished mere suitability for intravitreal administration from the claimed limitation that the formulation be intended for that use.

Long-arm Jurisdiction: The court held that a finding of equivalence under German law has strong indicative value for other EPC states, because equivalence is rooted in Art. 2 of the Protocol on Art. 69 EPC. Unless the defendant shows concrete reasons why a particular national law would lead to a different result, the German equivalence analysis can therefore guide the assessment in the other asserted states.

National Approach – United Kingdom: General

- The Supreme Court held in *Actavis UK Ltd v Eli Lilly & Co* [2017] UKSC 48 that a patent may be infringed by equivalence. A three-stage test is used to determine the issue [66]:

i. Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, i.e. the inventive concept revealed by the patent? - Yes

ii. Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention? - Yes

iii. Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention? - No

- If there is no 'literal' infringement (the product or process of the 'infringing' product does not fall within the relevant claim of the patent as a matter of normal interpretation), the patentee must establish the answer to the first two questions is 'yes', and third 'no'.
- *Ice Scape v Ice World* [2018] EWCA Civ 2219. Start with purposive construction. For Q1 court must focus on "the problem underlying the invention", "the inventive core", or the "inventive concept". It is the feature of the patent distinguishing it from prior art and/or the common general knowledge.

National Approach – United Kingdom: Case Study (1/3)

- Formycon and Samsung v Regeneron and Bayer [2025] EWHC 2527 (Pat)
  - The litigation related to aflibercept, a successful drug developed by Regeneron for treating wet age-related macular degeneration by injection into the eye (Eylea).
  - The patents subject to the dispute were not to aflibercept itself, which formed part of the prior art, but rather to specific formulations for intravitreal use which specified the concentration of drug, four excipients and their concentrations, and pH.
  - Formycon and Samsung developed aflibercept biosimilars for commercialisation after patent expiry.
  - By trial, Regeneron relied upon a narrow amended dependent claim. That claim detailed specific amounts of aflibercept and certain excipients. Regeneron accepted there was no infringement under 'normal' interpretation. However, they alleged Formycon and Samsung Bioepis infringed under the doctrine of equivalents.
  - Squeezes between obviousness and infringement

	Claim	Formycon Product	Samsung product
VEGF antagonist	Aflibercept 40mg/ml	Aflibercept 40mg/ml	Aflibercept 40mg/ml
Co-solvent(s)	0.03 polysorbate 20	0.03% polysorbate 20	0.03% polysorbate 20
Tonicity Agent	Sodium chloride about 40mM	40 mM sodium chloride	None
Buffer	Sodium phosphate 10mM	10 mM histidine	7.78 mM sodium phosphate
Stabilizing agent	5% sucrose	5% sucrose	8% sucrose
pH	6.2-6.3	6.2	6.2
	Suitable for intravitreal administration	Suitable for intravitreal administration	Suitable for intravitreal administration

National Approach – United Kingdom: Case Study (2/3)

- Actavis 1: Inventive Concept – does the variant achieve substantially the same result in substantially the same way as the invention?

  - **CGK**: two levels at which excipients operating: (i) first level, individually performing primary function, (ii) second level, interacting with one another to achieve stability. Second level is unpredictable.
  - **Inventive concept:** here a **narrow inventive concept** focused on second level. Claim 5 excipients, suitable for intravitreal administration + clinically useful stability. Reflected in narrowing of claims and claim 5 embodying two examples.
  - **Formycon Product:** The Formycon product achieved stability, but it did so in a different way from the invention at the relevant level of generality. A 10mM histidine buffer substituted the sodium phosphate buffer. While the same primary function would be achieved at the first level (taking in and releasing hydrogen ions (maintaining pH)) stability at the second level resulted from "*a very particular combination of excipients and the way in which they do or do not interact*" [488]. Histidine would behave differently, and how stability was achieved was unknown.
  - **Samsung Product:** The Samsung product also achieved osmolality + stability in a different way: only 7.78mM sodium phosphate buffer, no sodium chloride, increased sucrose to 8%. **Osmolality** – patent = balance of NaCl and Sucrose. Samsung product = absence of sodium chloride "*not just a question of degree*" [511]. **Stability** – higher sucrose + lower phosphate buffer = stability in a different way.
  - **Overall:** Products do **not** achieve the same result in the same way at the second level. ([488] and [514] respectively).

National Approach – United Kingdom: Case Study (3/3)

- Actavis 2: is it obvious to a person skilled in the art, knowing a substantially similar result is achieved, that a variant does so in substantially the same way as the invention?
  - SP would **not** understand how stability at Regeneron's second level was achieved, just that it was, and specifically would not be able to assess what role ionic interactions played without experiments [489].
  - **Experiments to investigate how a variant works are not permissible for Actavis Q2**. It is recognised an affirmative answer to Actavis Q2 almost always follows if Q1 is answered 'yes'. "*Fundamentally, I think that allowing experiments for [AQ2] would abolish it completely. It is already often said, with considerable justification, that [AQ2] will only ever avail a defendant when their product is a "black box". Allowing experiments to determine how it works would leave nothing to [AQ2] at all.*" [438]
- Actavis 3: Strict Compliance
  - If inventive concept broad: Regeneron had drafted a claim that was consistently very narrow for all the excipients, exception "**about** 40mM NaCl". Claim 5 = dependent claim. Claim 5 = examples 3 and 4. These structural features of the specification and claims indicated that Regeneron intended strict compliance with the literal meaning of the claim.

Thank you!

Hogan Lovells

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