

Patent litigation in Europe:

The UPC and the Doctrine of Equivalents



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Today's speakers...

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Partner, European Patent Attorney

Specialist areas

- Small molecule APIs
- Peptides and small proteins
- Radiopharmaceuticals and –diagnostics
- 2nd medical use and dosage regimens
- IP Strategy & pharmaceutical patent litigation

Edit Szodorai, PhD



European Patent Attorney, Senior Associate

Specialist areas

- Biologics and small molecule APIs
- Antibodies, ADCs
- Protein engineering
- Vaccine development
- Advanced cell and gene therapies (ATMPs).

Previous EP litigation presentations by AWA

- The past couple of years AWA have often presented on European patent litigation, e.g. **apixaban** and **rivaroxaban**, and also how the application of the G2/21 Enlarged Board of Appeal (EBA) decision has shaped European court decisions.
- A few weeks ago we gave a webinar on how UK developed their first real *Doctrine of Equivalence* through the *Actavis vs. Eli Lilly (2017) case on pemetrexed*.
- **Today we will continue on this theme** by discussing how the Unified Patent Court is handling DoE questions.

The legal battle in *Actavis vs. Eli Lilly*

Actavis' generic pemetrexed products used **different salt forms** — none literally Eli Lilly's patented "pemetrexed disodium"

1

Pemetrexed diacid

Not the literal claim wording

2

Pemetrexed ditromethamine

Not the literal claim wording

3

Pemetrexed dipotassium

Not the literal claim wording

Actavis sought declarations of non-infringement in the UK, France, Spain and Italy — arguing that a claim limited on its face to "**pemetrexed disodium**" could not cover a different salt of the same active anion.

UK doctrine of equivalents: quick post-*Actavis* summary

PRE-2017: ~only a claim construction inquiry → POST-2017: normal interpretation + a distinct equivalents inquiry

PRE-ACTAVIS

One route to determine claim scope

QUESTION

What would the skilled person understand the patentee to mean by the claim language, read in context?

AUTHORITIES/case law

Catnic • **Improver** • Kirin-Amgen

PRACTICAL CONSEQUENCE

The **purposely construed claim** marked the boundary of protection (i.e. "claim construction").

POST-ACTAVIS

Two routes to determine claim scope

STEP 1 — NORMAL INTERPRETATION

Does the variant fall within the claim's normal meaning?

STEP 2 — EQUIVALENTS

If not: is the variation **immaterial**?

PRACTICAL CONSEQUENCE

A variant may infringe even if it is outside the claim's **normal meaning**.

Equivalence moved from an aspect of construction to a separate basis for infringement.

From the "Protocol" (*Improver*) to the *Actavis* questions

PRE-ACTAVIS · IMPROVER

1

Material effect?

Does the variant have a **material effect** on the way the invention works?

2

Obvious absence of effect?

If not, would that absence have been obvious at publication?

3

Strict compliance intended?

Would the skilled person nevertheless regard compliance with the claim language as essential?

POST-ACTAVIS · THREE QUESTIONS

1

Same result, same way?

Does the variant achieve substantially the same result in substantially the same way?

2

Obvious equivalence—assuming it works?

At priority, would that be obvious to the skilled person who knows the variant works?

3

Literal compliance essential?

Would the skilled reader conclude that strict compliance with the literal meaning was intended to be essential?

Question 2 is the important shift: Obviousness is assessed on the **counterfactual assumption** that the variant is known to work

Applying the updated test: The outcome of *Actavis vs. Eli Lilly*

All three Actavis variants

- share the pemetrexed anion and
- achieve the same anti-tumor effect via the same mechanism with vitamin B12, and
- were therefore found to be an “immaterial variation” (~an equivalent).

The Supreme Court thus found the Actavis products to infringe Eli Lilly's patent by equivalence.

The UPC and DoE – *status September 2026*

The UPC should build its own **doctrine of equivalents** but has still only limited case law to build on...

1

UPC is a new, single court...

The Unitary Patent and the UPC have been operational since **1 June 2023**, giving a single court jurisdiction over a single patent right across participating EU member states.

2

... with a statutory duty to apply the EPC Protocol.

Article 24(1)(c) UPCA requires the UPC to apply **Article 69 EPC** and its **Protocol** when determining the extent of protection.

3

Equivalence is therefore “built-in”...

Article 2 of the Protocol* requires “**due account**” to be taken of any element equivalent to one specified in the claims but does not say how.

*** Protocol 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.*

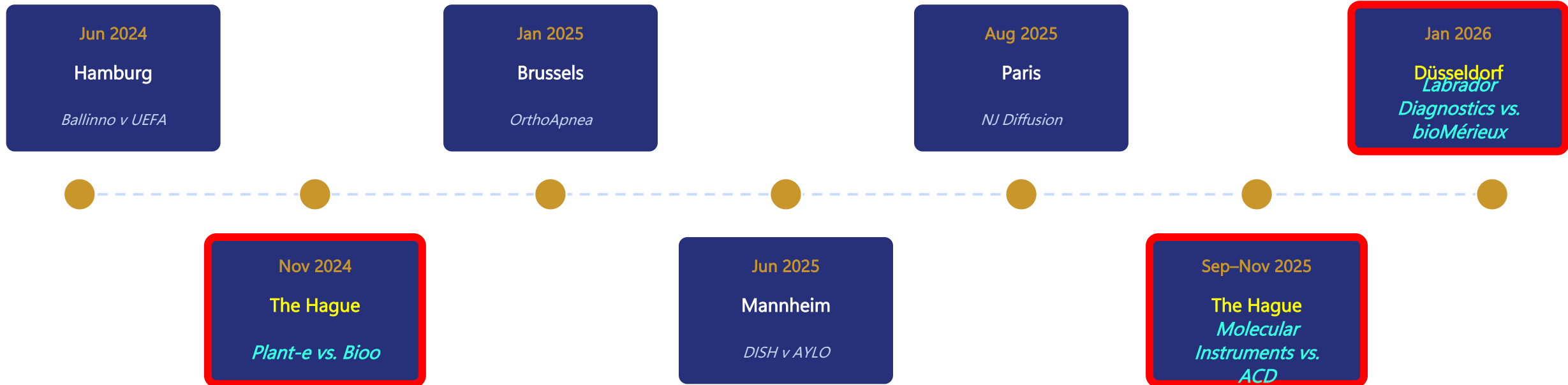
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... but so far no statutory test

Neither the UPCA nor its Rules of Procedure defines an “**equivalent element**” or sets out a test. The UPC must therefore develop its own doctrine, informed by — but not bound by — national traditions.

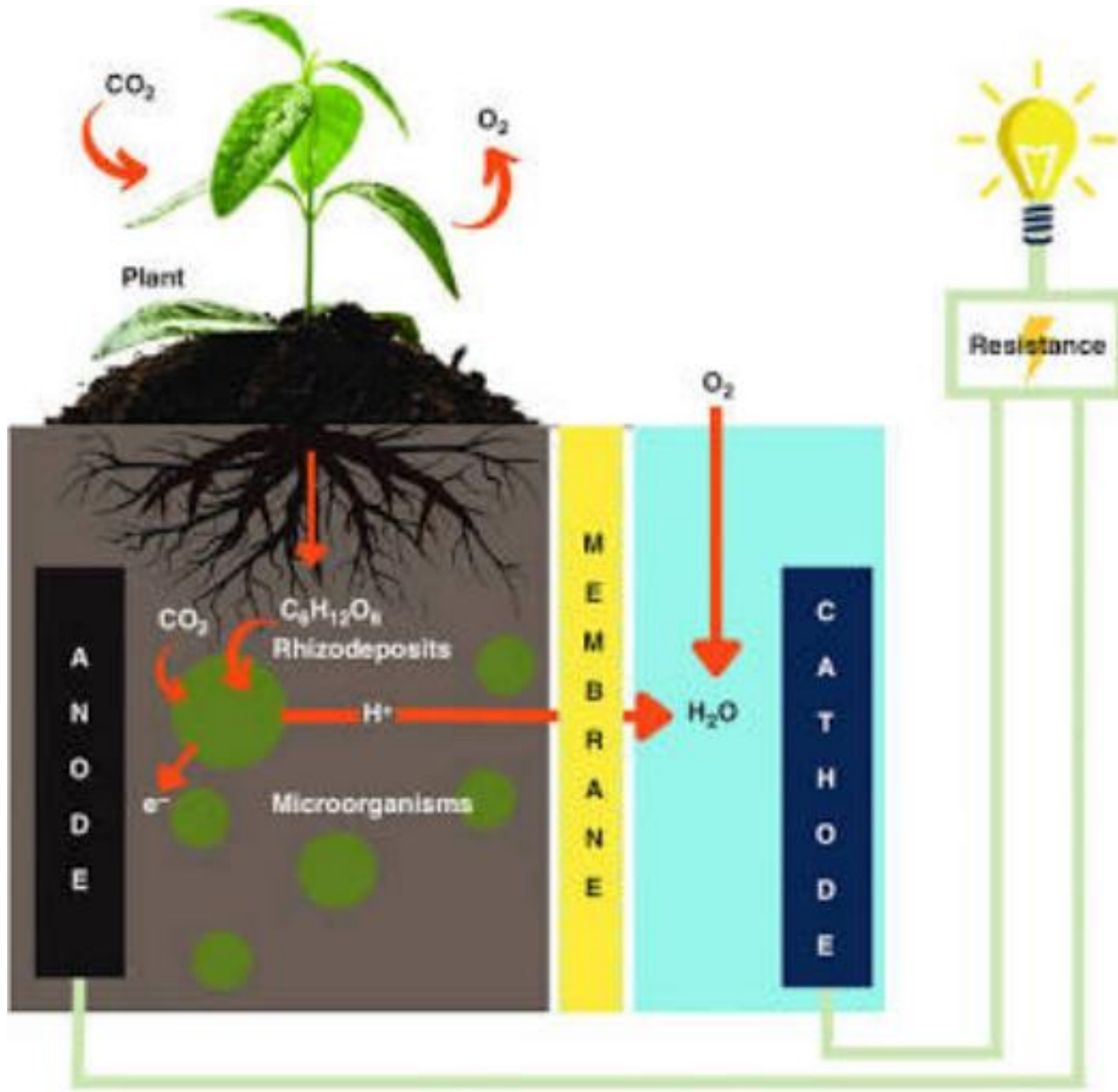
Timeline of Key UPC Equivalence Decisions

Seven decisions across six local divisions in under two years. Today we will look at three of these



No UPC Court of Appeal decision on the substance of equivalence has yet been handed down.

Plant-e vs. Bioo: PMFC



Plant-e vs. Bioo: Background & the Patent

1

The parties...

Plant-e Knowledge B.V. (patent owner) and Plant-e B.V. (licensee), both Dutch, against Arkyne Technologies S.L. of Spain, trading as "Bioo."

2

The patent:

EP2137782 claims a Plant-based Microbial Fuel Cell (P-MFC):
a living plant sits in an anode compartment, with micro-organisms in its root zone oxidising organic matter to generate electricity; a cathode compartment completes the circuit.

3

How the dispute arose

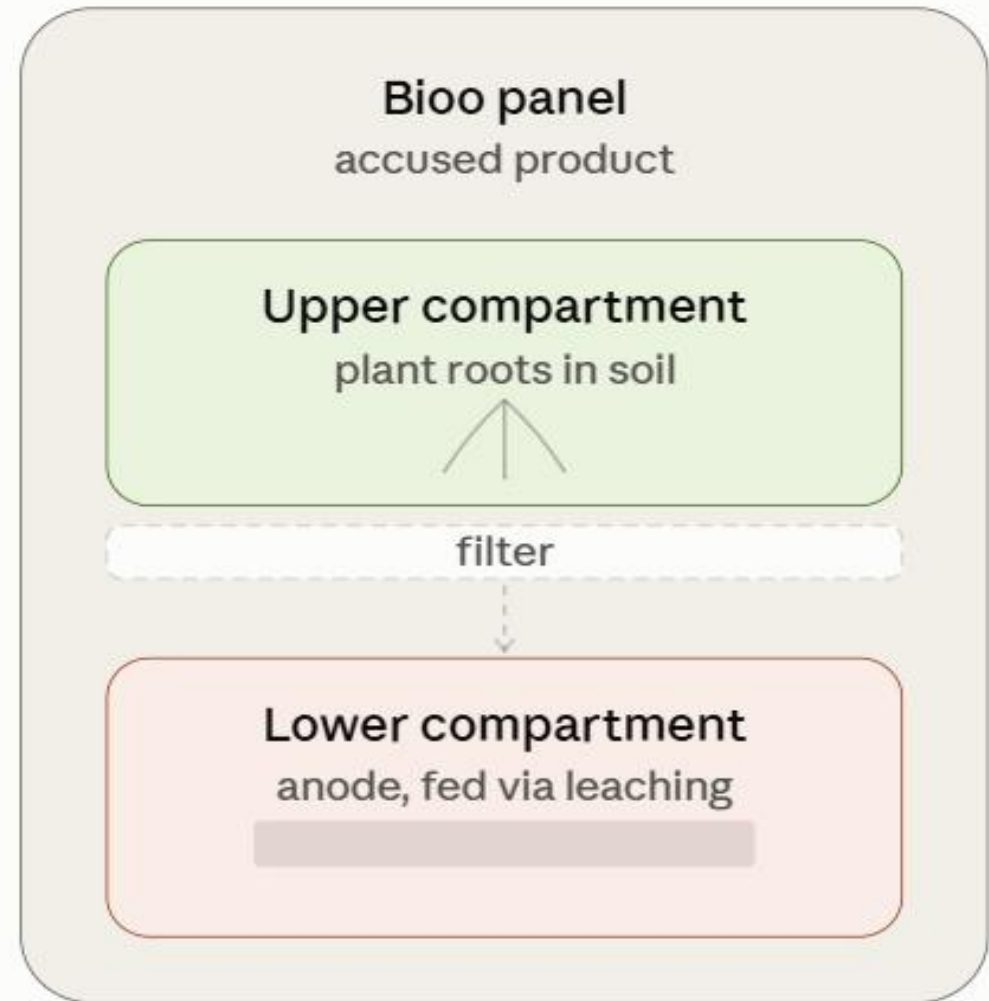
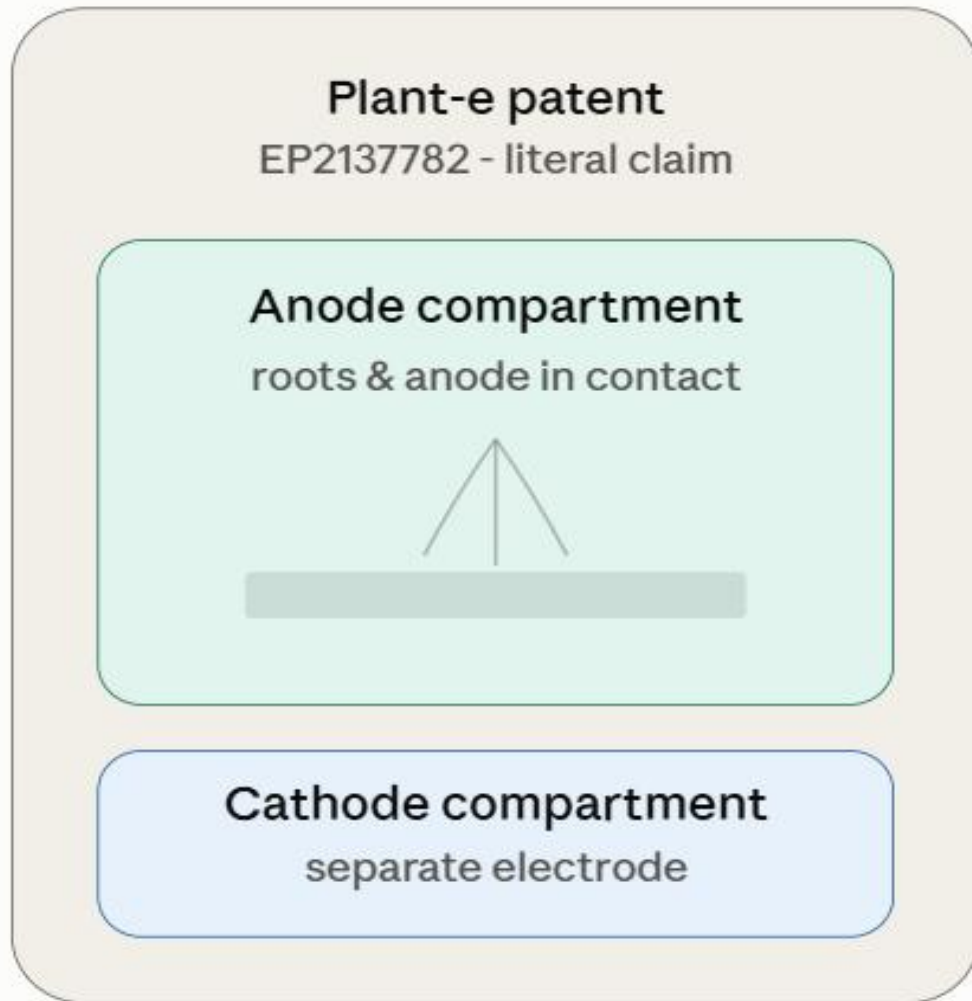
Plant-e discovered Bioo's products via a crowdfunding campaign in the late 2010s. A non-exclusive licence followed in 2018 — terminated by Bioo in 2019, citing disappointing sales. Bioo filed its own patent application in 2020 and launched new products in 2022.

4

The products in suit

The Bioo Panel (a buried garden/park fuel cell with lighting) and Bioo Bench (a phone-charging bench). Bioo counterclaimed for revocation, but the Plant-e patent was upheld valid.

Plant-e vs. Bioo: architecture of P-MFCs



The Hague LD: Plant-e v Bioo

UPC_CFI_239/2023 · 22 November 2024 — the first UPC on the merits to describe and use an explicit test

Infringement?

1

Technical equivalence

Does the variant solve essentially the same problem and perform essentially the same function in this context?

Yes

2

Fair protection for the patentee

Is extending protection to the variant proportionate, given the patentee's contribution to the art?

Yes

3

Legal certainty for third parties

Would the skilled person understand from the patent that its scope is broader than the literal claim wording?

Yes

4

Novelty and inventiveness

Is the accused product itself novel and inventive over the prior art — a Gillette/Formstein-style screen?

Yes



Comparison *Actavis* vs. "Dutch test" used by UPC

UK *Actavis* Questions:

Yes

- *Does the variant achieve substantially the same result in substantially the same way as the invention (i.e., the inventive concept)?*

Yes

- *Would it be obvious to the person skilled in the art that the variant achieves substantially the same result?*

No

- *Would the skilled person have understood from the language of the claim that the patentee intended that strict compliance with the literal meaning was an essential requirement?*

Yes

Dutch Four Principles used at UPC:

Yes

- *Technical Equivalence:* Does the variant fulfill the same technical function?

Yes

- *Fair Protection:* Appropriate to extend protection to the variant based on patent's contribution?

No

- *Legal Certainty:* Would third parties reading the patent expect the scope to include the variant?
- *Prior Art (Formstein Defence):* Does the variant lack novelty or inventive step over the prior art?

Reasons for finding infringement by equivalence

No literal infringement

The **Bioo Panel** implemented every claimed feature except one: **the plant's roots (with the micro-organisms) were not located inside the anode compartment as the claim required.**

1 — Technical equivalence

Even without direct root-to-anode contact, Bioo's system generated electricity through the same microbial oxidation process — *i.e. solving the same problem, the same way*. Bioo's "different substrate" argument was rejected as amounting to a scientifically impossible perpetual-motion claim.

2 — Fair protection

The Court treated Plant-e's invention **as genuinely groundbreaking** — a new category of fuel cell — making it proportionate to extend protection to Bioo's re-engineered variant.

3 — Legal certainty

A skilled reader would understand the invention's core idea **as plant-driven electricity generation broadly**, not the precise root placement, so third parties had fair warning the scope could extend this far.

4 — Novelty screen

Bioo **could not show its variant was itself obvious over the prior art** — no Gillette/Formstein defence was made out, so the equivalence finding stood.

Plant-e v Bioo: Outcome and Significance

1

No literal infringement

Bioo's product did not implement **every** claimed feature of EP2137782 in literal terms.

2

All four steps satisfied

Applying the **Dutch four-step test**, the Court answered every question in the affirmative.

3

Patent upheld and infringed

EP2137782 was found valid and infringed by equivalence — **no successful Gillette/Formstein defence.**

4

Multi-country injunction

The Court granted relief across the UPC's participating territories in a single judgment.

As of September 2026, this remains the only UPC merits judgment to have upheld infringement by equivalence.

ACD v Molecular Instruments: Background

A transatlantic rivalry over RNA imaging, fought in parallel at the UK High Court and the UPC

1

The parties...

Advanced Cell Diagnostics, Inc. ("ACD," part of the Bio-Techne group) develops assays for detecting and quantifying RNA molecules *in situ*, including its multiplex fluorescent/ chromogenic ISH platform.

Molecular Instruments, Inc. ("MI") makes molecular kits for multiplexed bioimaging in research, drug development and diagnostics.

2

...and the patents:

EP1910572 ("EP'572") — twelve method claims for *in situ* detection of nucleic acid targets within a cell, starting with fixing and permeabilising it.

EP2500439 ("EP'439") — a related kit claim, from the same parent application.

3

The UK round came first...

ACD sued **MI** in the UK in 2022 (HP-2022-000026). In April 2024, Mr Justice Meade found both patents invalid for obviousness on "overwhelming" evidence and ordered ACD to pay MI £1.35 million in costs.

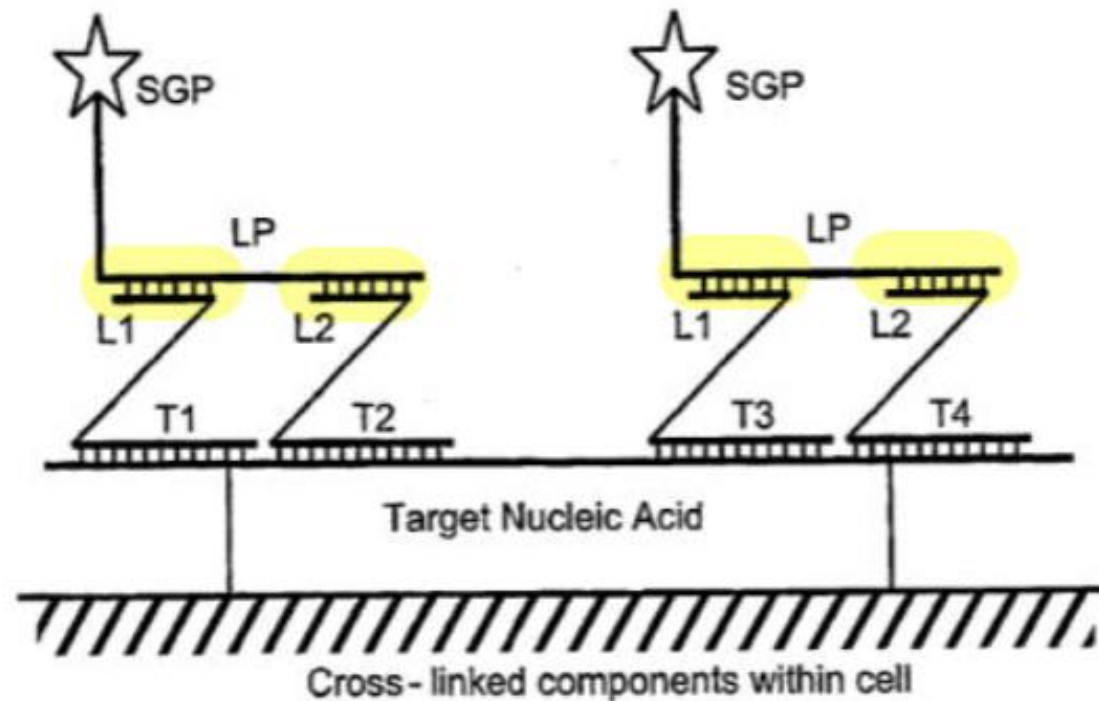
4

...followed by the UPC:

ACD filed a fresh infringement action at the UPC's Hague division in 2024 (UPC_CFI_187/2024 & 507/2024), targeting MI's HCR™ RNA-ISH products offered into UPC territory, including the Netherlands.

The disputed feature

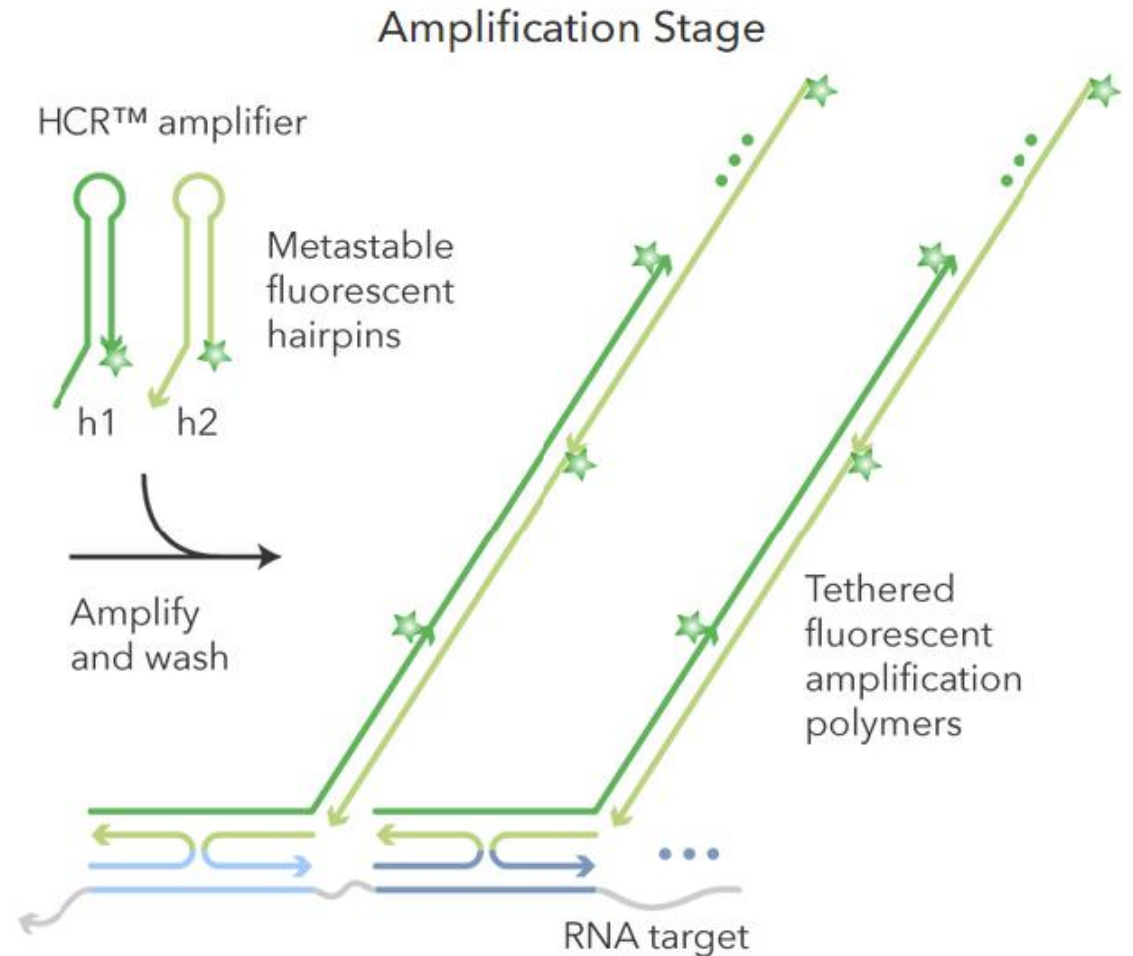
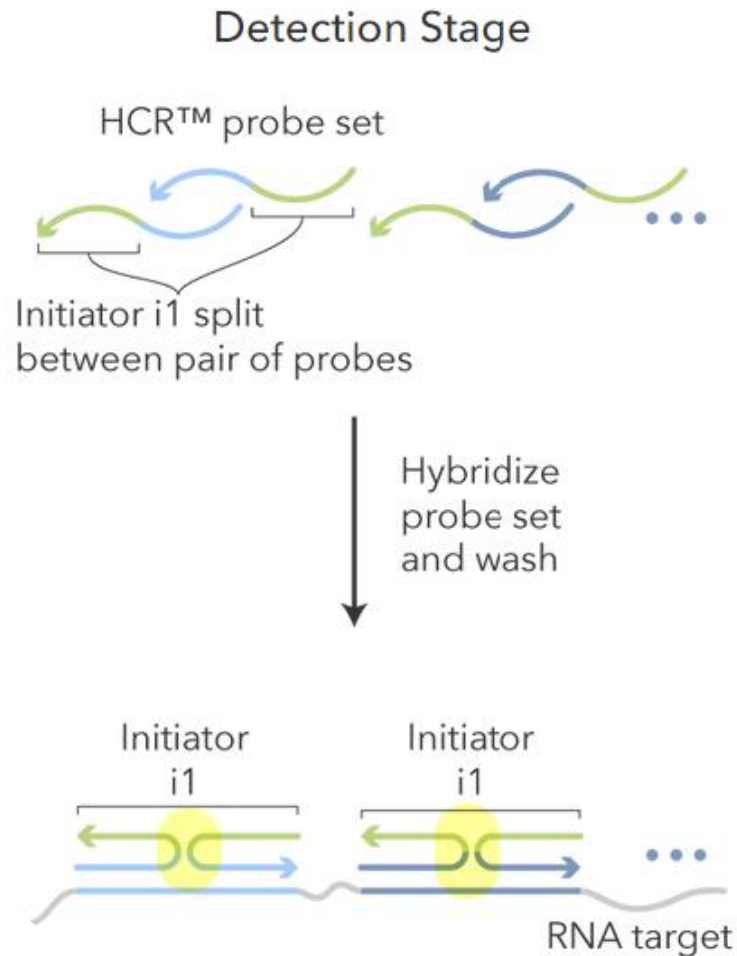
Feature 1(h): "and the L sections are complementary to **nonoverlapping regions** of the label probe (...)"



EP572

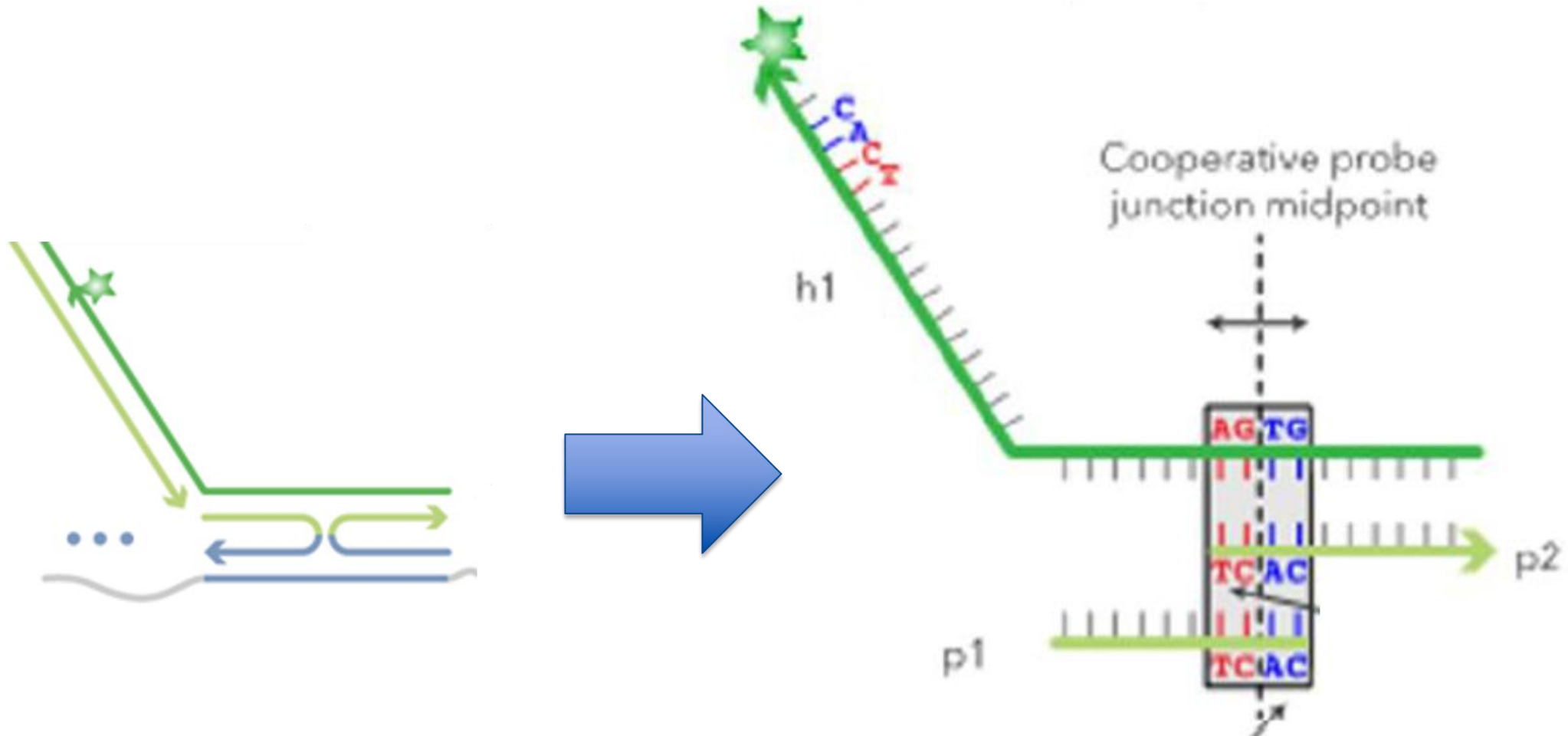
The accused product

HCR-FISH



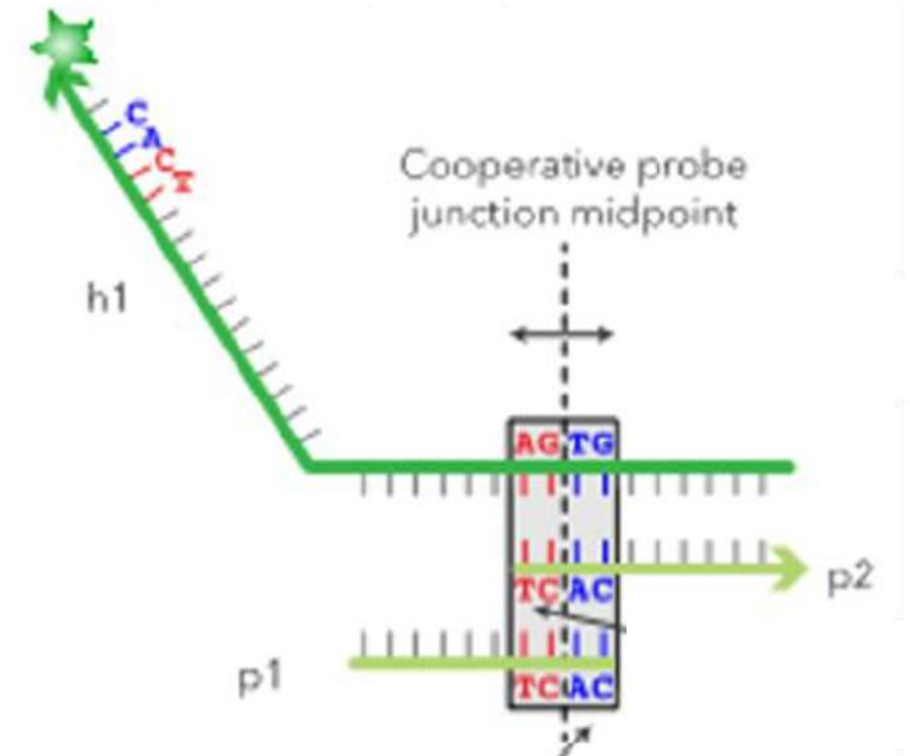
NO LITERAL INFRINGEMENT

UPC_CFI_187/2024 & 507/2024 · 18 November 2025 — 4 overlapping nucleotides



NO INFRINGEMENT BY EQUIVALENCE

UPC_CFI_187/2024 & 507/2024 · 18 November 2025



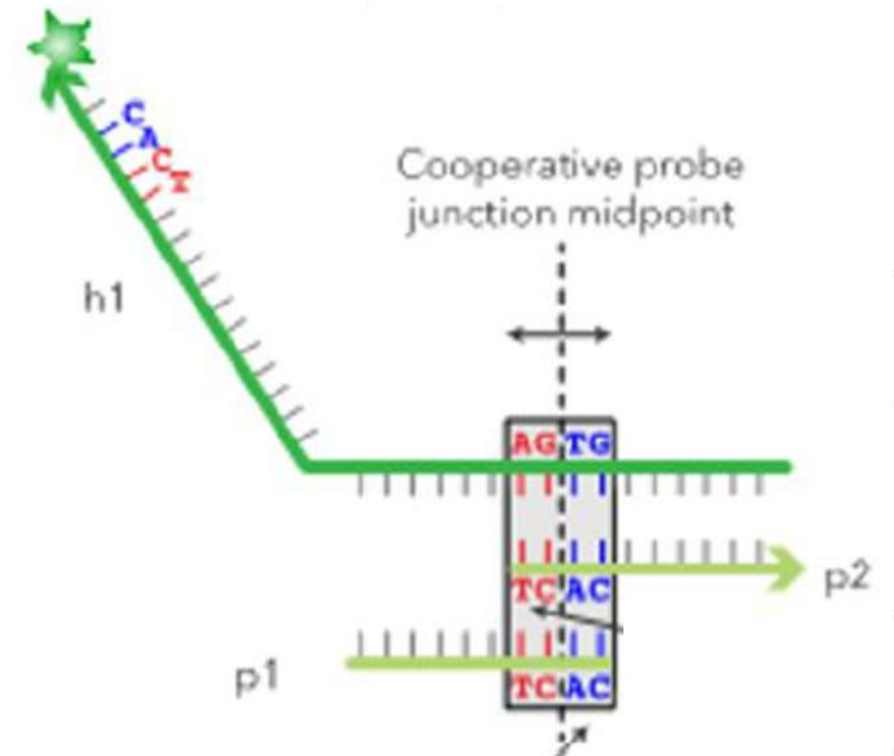
3. **LEGAL CERTAINTY:** If this is equivalent, how much overlap would still be equivalent?

NO INFRINGEMENT BY EQUIVALENCE

UPC_CFI_187/2024 & 507/2024 · 18 November 2025

2. **FAIR PROTECTION**: All ingredients were known, just not in combination. Not a very significant step in the development of *in situ* assays.

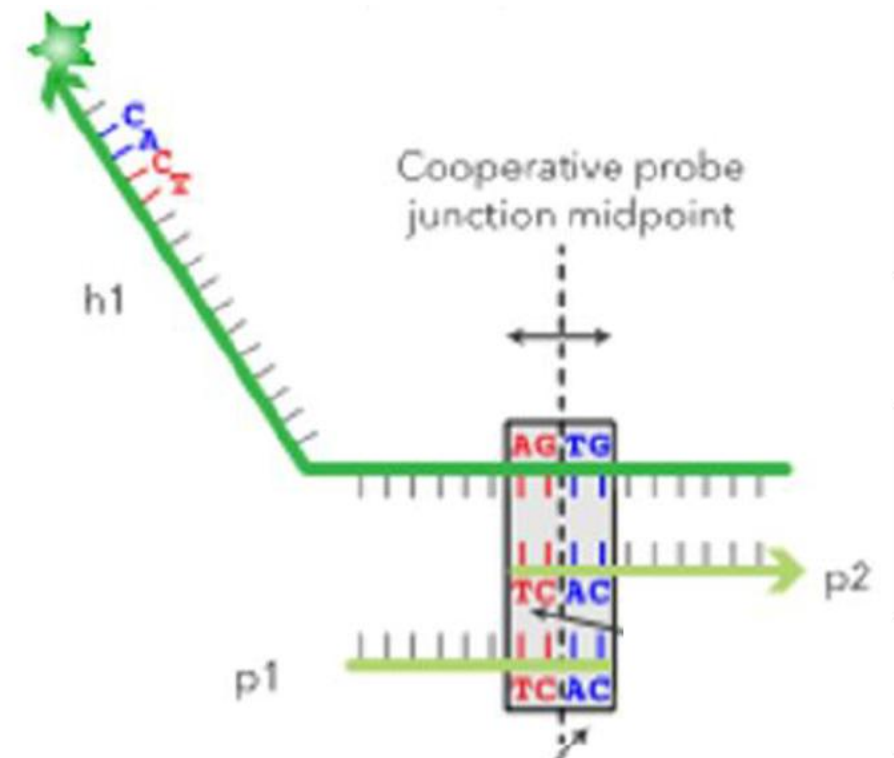
3. **LEGAL CERTAINTY**: If this is equivalent, how much overlap would still be equivalent?



NO INFRINGEMENT BY EQUIVALENCE

UPC_CFI_187/2024 & 507/2024 · 18 November 2025

1. **TECHNICAL EQUIVALENCE**: 2-4 nt overlap is not a mere workaround, but energetic relaxation which reduces the kinetic barrier to branch migration, speeding up the opening of the first h1 hairpin and initiation of HCR signal amplification.
2. **FAIR PROTECTION**: All ingredients were known, just not in combination. Not a very significant step in the development of *in situ* assays.
3. **LEGAL CERTAINTY**: If this is equivalent, how much overlap would still be equivalent?



UK vs UPC

Same parties & same patents but opposite reasoning on validity & infringement — both cases ultimately favoring MI

UK

- The capture probes bind *distinct* regions of the labelled probe.
- Focus is the *formation of two stable duplexes*, not strict non-overlap.
- *Performance improvement* with MI's overlapping configuration.
- However, "non-overlapping" should be interpreted *purposively*, in light of its intended function.

INFRINGEMENT
BUT NOT VALID

UPC

- How much overlap is equivalent?
- A 1-4 nt overlap may achieve a *similar technical effect*, including increased specificity.
- However, the overlap serves a *recognised technical function* of its own and is *not merely a workaround* of the claimed invention.

VALID
BUT NOT INFRINGED



Labrador Diagnostics vs. bioMérieux: Background

The Theranos legacy, a multi-front litigation campaign, and a split UPC case

1

The Theranos legacy

EP 3 756 767 B1 covers an automated immunoassay instrument. It is one of several patents Fortress Investment Group acquired from Theranos's estate after the blood-testing company's collapse and now holds through Labrador Diagnostics LLC.

2

The target

Labrador asserted the patent against bioMérieux's VIDAS® immunoassay platform — widely used diagnostic instruments in clinical laboratories — across bioMérieux's French, German, Italian and other European operating entities.

3

A multi-front campaign

Parallel actions ran in France, Germany and the UPC. A related Theranos-derived patent (EP341) was revoked by the EPO Boards of Appeal in September 2024, and Labrador withdrew its French action on that patent as a result.

4

A split, bifurcated UPC case

The UPC referred bioMérieux's revocation counterclaim to the Milan Central Division, which upheld EP767 in amended form in October 2025 — after bioMérieux ran roughly 50 separate invalidity attacks — while Düsseldorf retained the infringement claim, decided in January 2026.

Claim 1 as amended

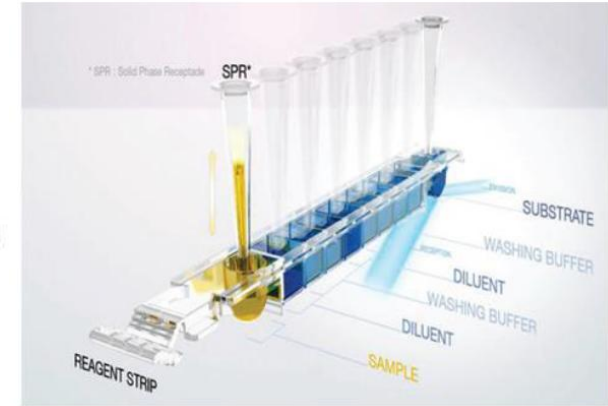
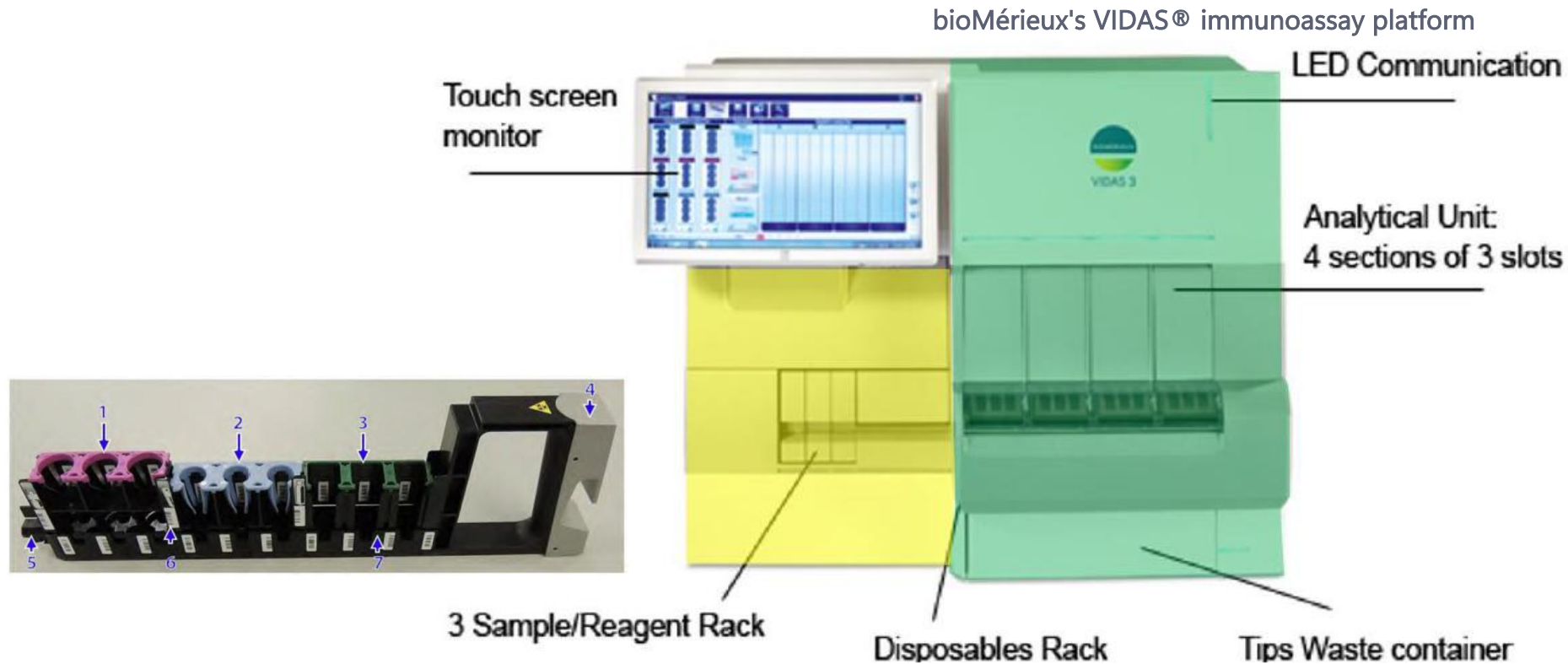
1. An instrument for detecting a biological analyte, comprising:

*first means for receiving a **device** inserted into the instrument, the device comprising:
an **array of reagent units**, each reagent unit of the array of reagent units for containing a reagent for an assay to detect the biological analyte, and
a sample unit comprising a sample applied by a user; and*

*second means configured to, with the device received by the first means:
move at least one of a first pipette tip comprising sample or a reagent unit of the array of reagent units relative to the other of the first pipette tip or the reagent unit, for transfer of sample from the sample unit to the reagent unit;
and*

*move at least one of the reagent unit or second pipette tip relative to the other of the reagent unit or the second pipette tip, for transfer of sample from the reagent unit to the second pipette tip, the second pipette tip comprising a capture surface configured to bind with the biological analyte,
a detection assembly for detecting a signal indicative of the presence, absence or concentration of the biological analyte bound to the capture surface configured to bind with the biological analyte.*

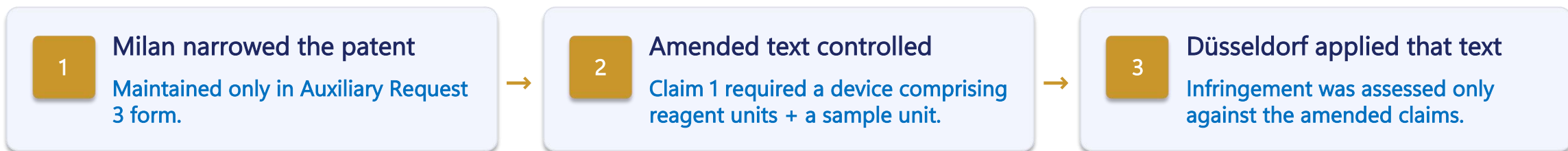
The accused instrument



*first means for receiving a device inserted into the instrument, the device comprising:
an array of reagent units, each reagent unit of the array of reagent units for containing a reagent for an assay to detect the biological analyte, and
a sample unit comprising a sample applied by a user; and*

Labrador v bioMérieux: equivalence became irrelevant

EP 3 756 767 B1 · VIDAS 3 · Düsseldorf LD



CLAIM 1 — THE AMENDED CLAIM NO LONGER MATCHED THE STRUCTURE

AMENDED CLAIM

A connected "device" comprising:

- reagent-unit array
- user-applied sample unit

VIDAS 3

Reagent strips and sample vials were spatially separate.

Only a functional link through operation.

CONSEQUENCE

No "connected device" according to the amended claim.

The infringement case **ended** at claim 1 before a consideration of equivalents was required.

CLAIM 2 — SEPARATE BASIS

Method claim

bioMérieux supplied the instrument; laboratory customers performed the assay steps.

No direct use / no offer for use.

Practical take-aways



1 Plead and evidence **technical-functional equivalence** as the baseline in any UPC action — it is the **one requirement that** every UPC division currently applies.

2 Party agreement on national test: **Consider early** whether pushing for (or resisting) the **Dutch four-step test** serves your client.

3 **“Forum shopping” may matter** until the Court of Appeal harmonises the doctrine — track how each local division has ruled so far.

4 For FTO in UK, *Actavis* is highly relevant, **but for FTO opinions covering UPC-designated states**: Do not assume *Actavis* will be consulted. Calibrate FTO risk to the narrower, 4-step Dutch DoE approach.

5 Watch closely for the first **UPC Court of Appeal** ruling on the substance of equivalence — it will likely set the definitive framework for years to come.

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