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IMPORTANT IP CASES FROM 2023

Jan. 26 |

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Webinar開始の前に

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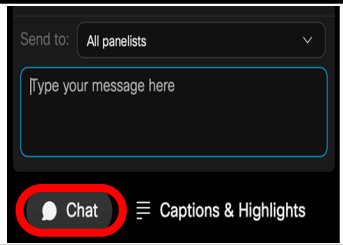

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Amgen Inc. v. Sanofi (U.S. 21-757)
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Amgen v. Sanofi

実施可能要件 - Enablement

35 U.S.C. § 112 – Specification

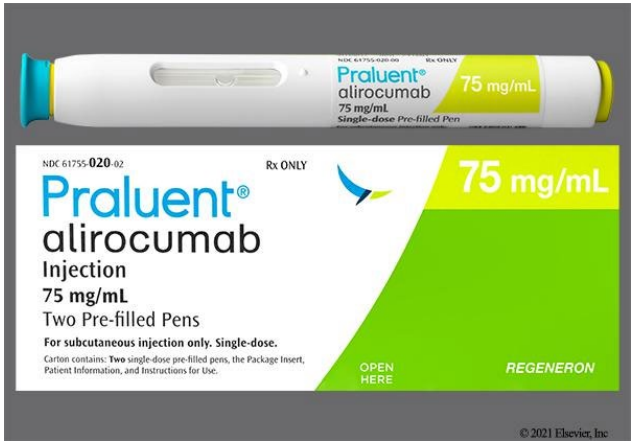
(a)IN GENERAL.—The specification shall contain a written description of the invention, and of **the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains**, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

Amgen v. Sanofi

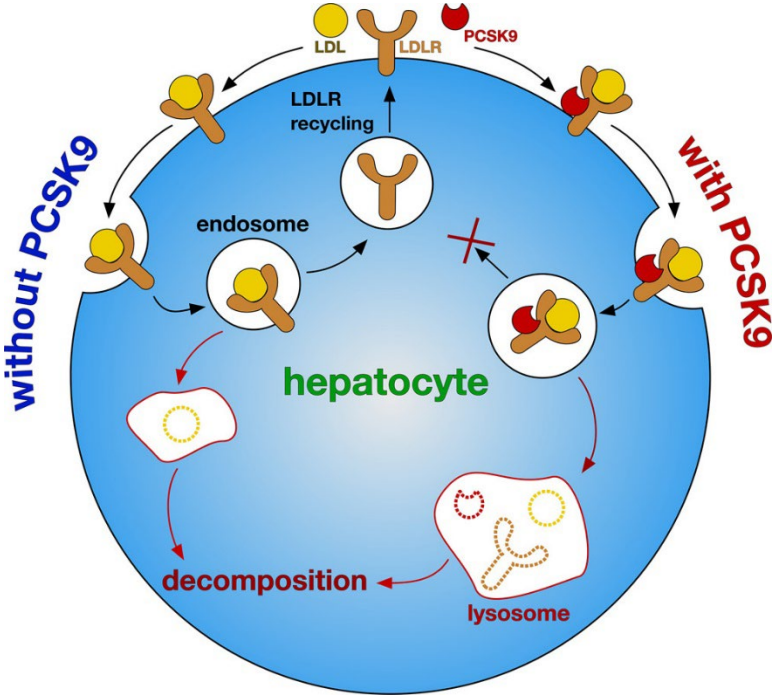
US8,829,1165

Claim 29. A pharmaceutical composition comprising an isolated monoclonal antibody,

wherein the isolated monoclonal antibody binds to at least two of the following residues S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of PCSK9 listed in SEQ ID NO:3 and blocks the binding of **PCSK9 to LDLR** by at least 80%.



Amgen v. Sanofi



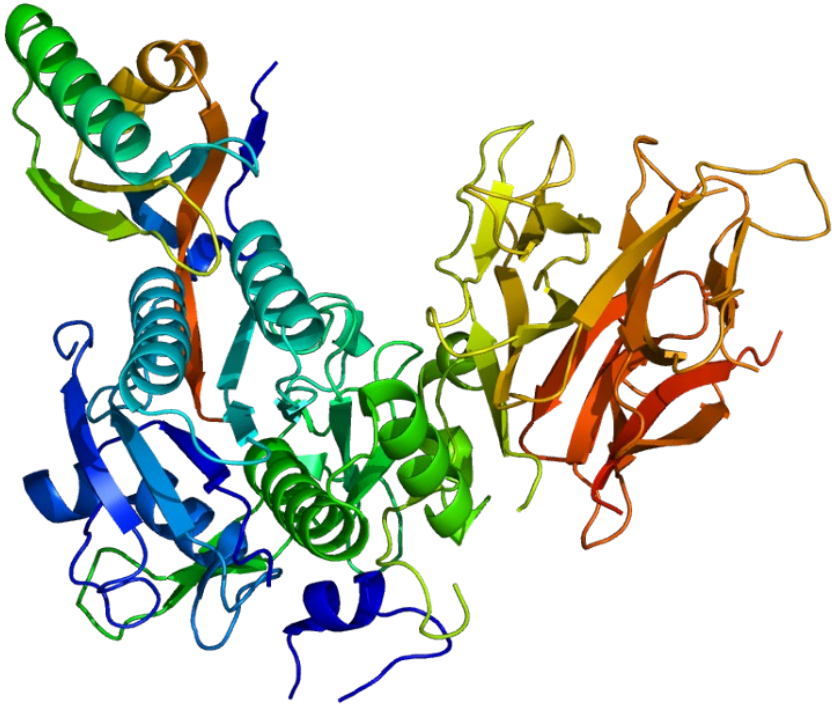
PCSK9: ヒトプロタンパク質転換酵素サブチリシン
LDLR: LDL(コレストロール)受容体タンパク質

Amgen v. Sanofi

US8,829,1165

…wherein the isolated monoclonal antibody binds to at least two of the following residues S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of PCSK9 listed in SEQ ID NO:3 and blocks the binding of PCSK9 to LDLR by at least 80%.

*No recitation of any structural limitations of the *antibody*



Amgen v. Sanofi (Fed. Cir. 2021)

"What emerges from our case law is that the enablement inquiry for claims that include functional requirements can be particularly focused on the breadth of those requirements, especially where predictability and guidance fall short. In particular, it is important to consider the quantity of experimentation that would be required to make and use, **not only the limited number of embodiments that the patent discloses, but also the full scope of the claim**."

Amgen v. Sanofi (US 2023)

Issue: Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to "make and use" the claimed invention, or whether it must instead enable those skilled in the art "**to reach the full scope of claimed embodiments**" without undue experimentation—i.e., to cumulatively identify and make all or nearly all embodiments of the invention without substantial "**time and effort**."

Amgen v. Sanofi (US 2023)

- **Amgen expressly claimed more than 32,000 combinations of residues and was required to enable every combination**

"Regardless of the exact number of embodiments, it is clear that the claims are far broader in functional diversity than the disclosed examples."

- **Determining where a particular antibody binds requires x-ray crystallography, a time-consuming and unpredictable methodology**

"[E]ven assuming that the patent's "roadmap" provided guidance for making antibodies with binding properties similar to those of the working examples, no reasonable factfinder could conclude that there was adequate guidance beyond the narrow scope of the working examples that the patent's 'roadmap' produced."

Amgen v. Sanofi (US 2023)

- **Performing amino acid substitutions according to the specification's instructions would lead to "millions of candidates" that must be tested.**
  - Teaching non-working means of practicing the claimed invention can undermine enablement

"[I]f the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid."

Parus Holdings v. Google LLC (Fed. Cir. 2023)

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Parus Holdings, Inc. v. Google LLC

35 U.S. Code § 311 - Inter partes review

(b)Scope. A petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under **section 102 or 103** and only on the basis of prior art consisting of patents or printed publications.

Parus Holdings, Inc. v. Google LLC

- **PTAB did not exceed its statutory authority when it determined that the patent claims at issue in the IPR lacked written description support** and thus could not claim priority to the application filing date
- PTAB's analysis was sufficiently based on Section 103 arguments because the PTAB could not make a determination under Section 103 without first establishing what qualified as prior art, which Respondent disputed its legitimacy

Parus Holdings, Inc. v. Google LLC

Federal Circuit Decision

[12] **[13]** For a claim to be entitled to the "the filing date of an earlier application under 35 U.S.C. § 120, each application in the chain leading back to the earlier application must comply with the written description requirement of 35 U.S.C. § 112." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997). Each application in the chain must therefore "reasonably convey[ ] to those skilled in the art that the inventor had possession of the [later-claimed] subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). "Sufficiency of written description is a question of fact, reviewed for substantial evidence." *Gen. Hosp. Corp. v. Sienna Biopharms., Inc.*, 888 F.3d 1368, 1371 (Fed. Cir. 2018).

For a claim to be entitled to the filing date of an earlier application, each application in the chain leading back to the earlier application must comply with the written description requirement of 35 U.S.C. §112

Parus Holdings, Inc. v. Google LLC

Federal Circuit Decision

[15] **[16]** By raising an argument in its Preliminary Response, but not its Response, a patent owner waives said argument. *In re Nuvasive, Inc.*, 842 F.3d 1376, 1380 (Fed. Cir. 2016). Even if Parus had not waived such argument, it is without merit. As we decided in *Arthrex*, § 311(b) "merely dictates the grounds on which an IPR petition may be based, not the issues that the Board may consider to resolve those grounds." 35 F.4th at 1344–45. As in that case, Appellees complied with § 311(b) by asserting invalidity grounds under § 103. Because Parus asserted that Kurnagov-262 is not prior art by claiming priority from the application from which it stems, the Board needed to determine whether the challenged claims satisfied the written description requirement. The Board therefore did not exceed its statutory authority.

§311 (b) merely dictates the grounds on which an IPR petition may be based, not the issues that Board may consider to resolve those grounds. Appelles complied with §311(b) by asserting invalidity grounds under §103.

In re: Cellect LLC (Fed. Cir. 2023)

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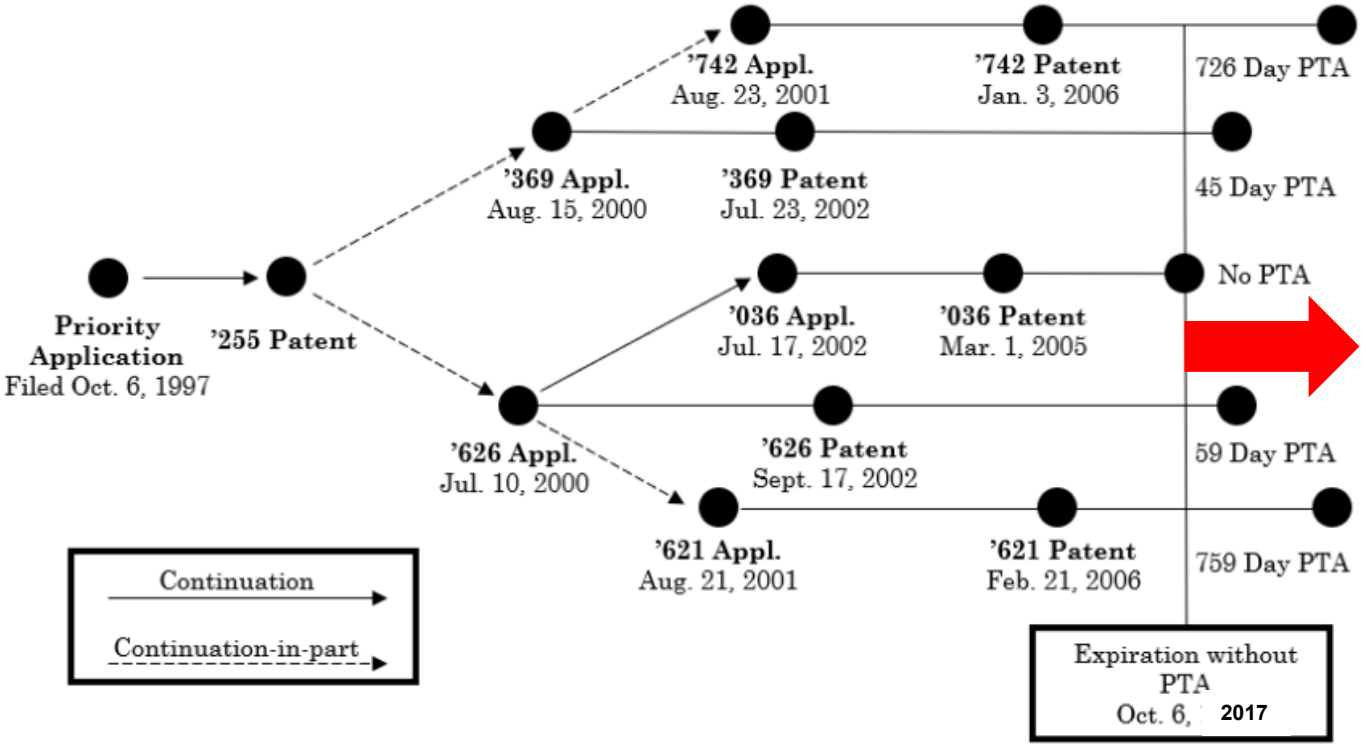
In re: Cellect LLC



In re: Cellect LLC

First, we note that an ODP (Obviousness-type Double Patenting) determination depends on an assessment of obviousness, i.e., whether the claims of a later-expiring patent would have been obvious over the claims of an earlier-expiring patent owned by the same party. If so, absent a terminal disclaimer, the later-expiring claims are invalid.

In re: Cellect LLC

There, we noted that, "if a patent, under its original expiration date without a PTE, should have been (but was not) terminally disclaimed because of [ODP], then this court's [ODP] case law would apply, and the patent could be invalidated," but that "**if a patent . . . is valid under all other provisions of law, then it is entitled to the full term of its PTE.**" *Novartis,* 909 F.3d at 1373, 1374

Patent Term Adjustment: 35 U.S.C. 154 (Examination Delay)
Patent Term Extension: 35 U.S.C. 156 (Regulatory Delay)

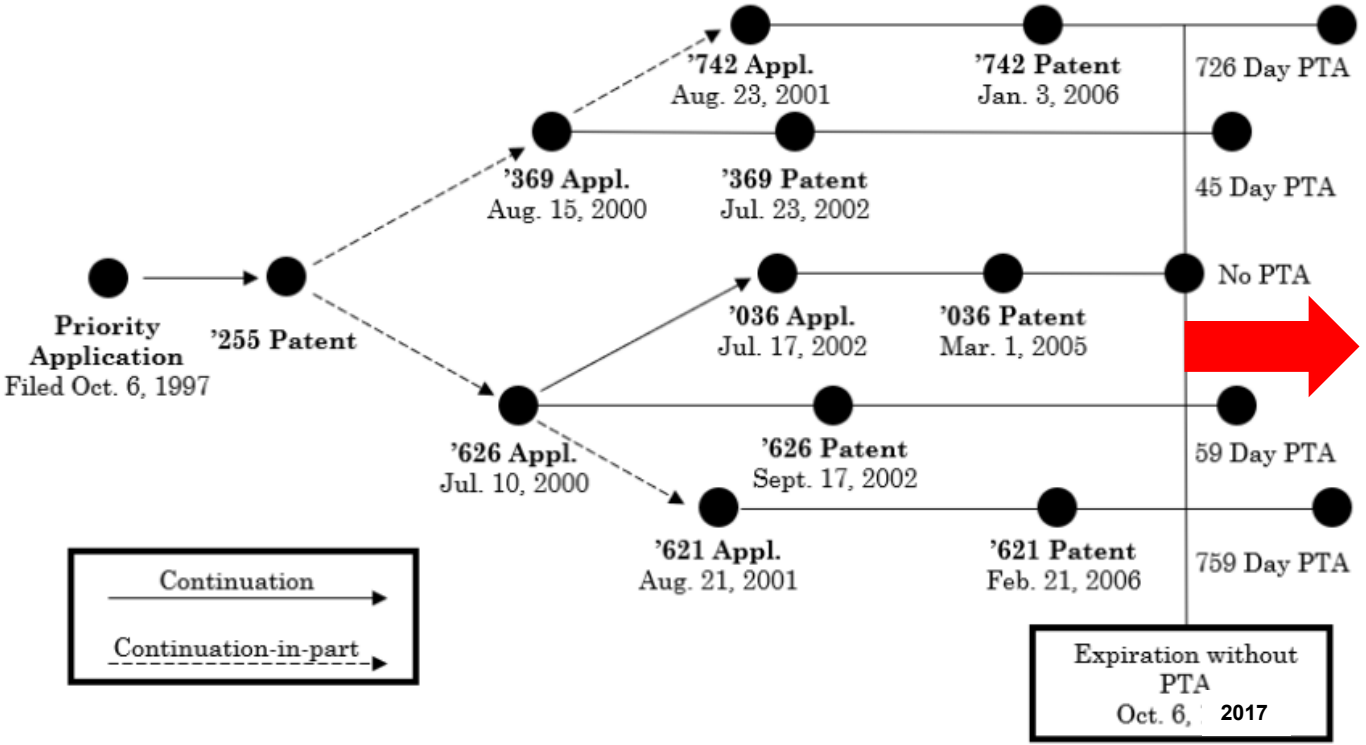
In re: Cellect LLC

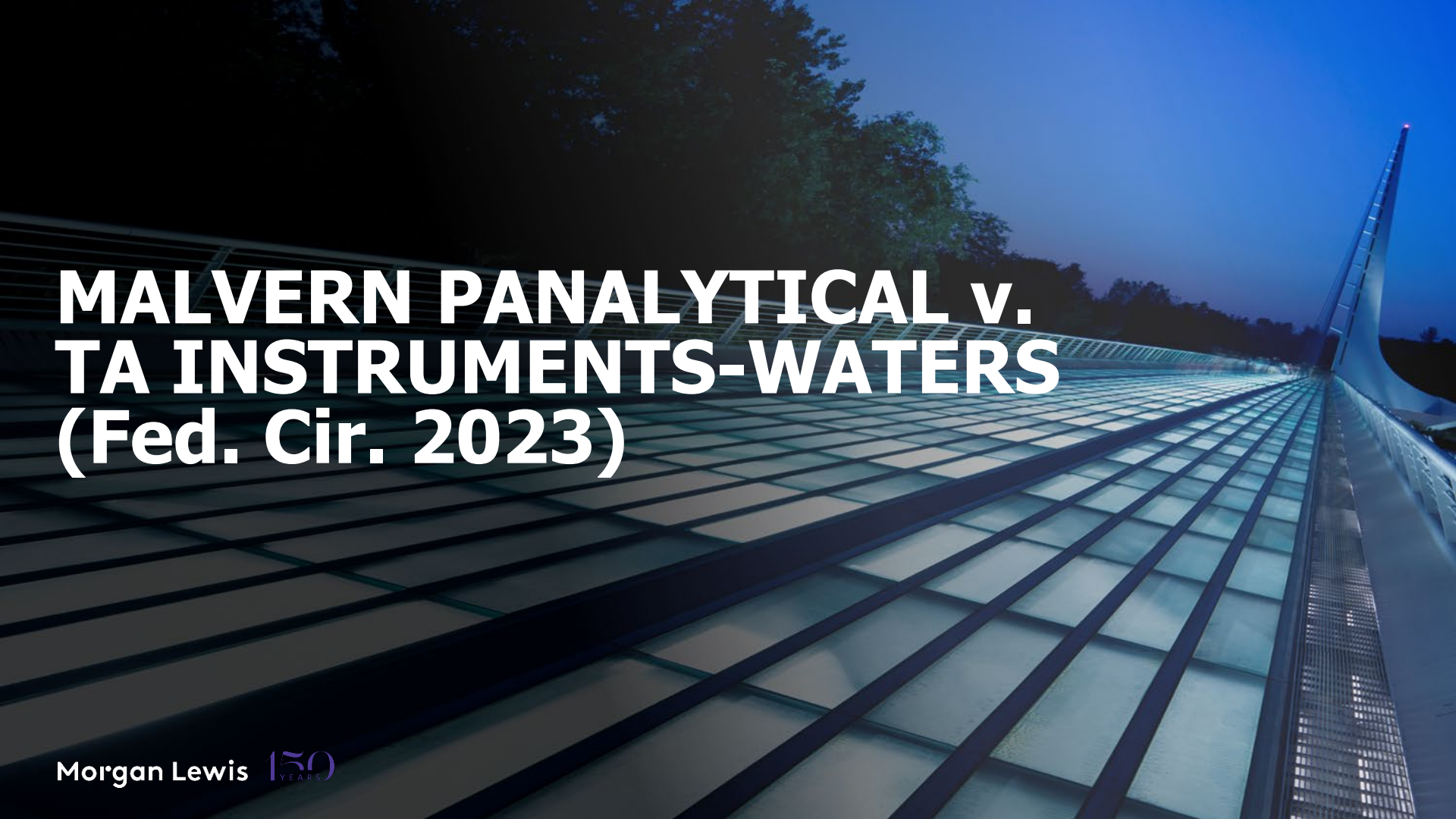
We agree with the USPTO that PTA and PTE should be treated differently from each other when determining whether or not claims are unpatentable under ODP. PTA and PTE are dealt with in different statutes and deal with differing circumstances.

In re: Cellect LLC

To say that PTA and PTE should be factored into an ODP analysis in the same manner merely because they both provide statutorily authorized time extensions that restore patent term due to various administrative delays, as Cellect argues, is an **unjustified attempt to force disparate statutes into one**.

In re: Cellect LLC





MALVERN PANALYTICAL v. TA INSTRUMENTS-WATERS (Fed. Cir. 2023)

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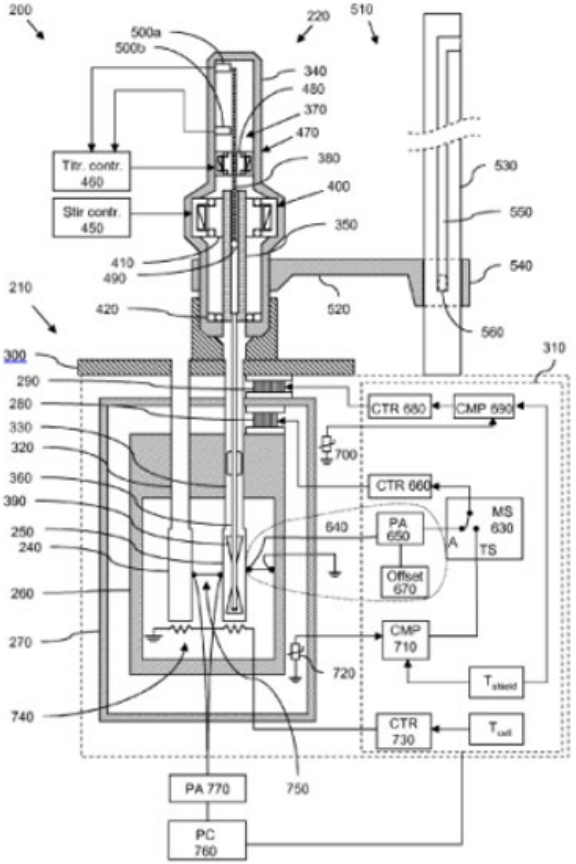
Malvern Panalytical v. TA Instruments-Waters

Title: Isothermal titration microcalorimeter apparatus and method of use

<u>Claim Construction</u>

“pipette guiding mechanism”



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Malvern Panalytical v. TA Instruments-Waters

District Court: "pipette guiding mechanism"

"mechanism that **manually** guides the pipette assembly" based on intrinsic evidence in the form of statements made during prosecution of an unrelated U.S. Patent No. 9,103,782 ("the '782 patent") owned by the same assignee

Malvern Panalytical v. TA Instruments-Waters

Distritc Court's Decision

The district court looked to the '782 patent applicant's statements during prosecution of the '782 patent to ascertain the scope of the "pipette guiding mechanism," concluding that the '782 patent applicant limited the "pipette guiding mechanism" to only manual embodiments. *Id.* The district court attributed the statements of the '782 patent applicant to Malvern because the '782, '549, and '175 patents had a common assignee and because both parties and the district court treated the common assignee as Malvern. *Id.* at *4 n.2. The district court considered statements made during the '782 patent prosecution when interpreting the '549 and '175 patents because it concluded that Malvern agreed the statements cited in the IDS during supplemental examination were incorporated into the intrinsic record. *Id.* In part relying on this prosecution history, the district court limited "pipette guiding mechanism" to manual guiding mechanisms.

The district court considered statements made during the '782 patent prosecution when interpreting because it concluded that Malvern agreed the statements cited in the IDS during supplemental examination were incorporated into the intrinsic record.

Malvern Panalytical v. TA Instruments-Waters

Federal Circuit Decision

We conclude that merely listing the '782 patent office actions in the IDS of the '175 patent supplemental examination was insufficient to inform the meaning of "pipette guiding mechanism" in the unrelated '175 and '549 patents. On this basis alone, we conclude that the district court erred when it used the '782 patent prosecution history statements to limit "pipette guiding mechanism" to manual guiding mechanisms.

"In the absence of an incorporation into the intrinsic evidence, this court's precedent takes a narrow view on when a related patent or its prosecution history is available to construe the claims of a patent at issue and draws a distinct line between patents that have a familial relationship and those that do not." *Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1167 (Fed. Cir. 2004). However, even once a reference has been incorporated into the intrinsic record, such as by citation in an IDS, *see Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1303–04 (Fed. Cir. 1997), the amount of characterization of that reference in the IDS impacts how informative we consider that reference when evaluating a patent. For example, listing of references in an IDS does no more than admit "that references in the disclosure may be material to prosecution of the pending claims," but it does not admit materiality. *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1279 (Fed. Cir. 2003). Likewise, a patentee has not necessarily admitted that a listed reference's characterization or use of a claim term bears on the proper construction of that term in the patent. *See id.*

We conclude that Malvern's bare listing of the '782 patent office actions in the IDS during the '175 patent supplemental examination did not amount to an admission that the '782 patent prosecution history is material (or controlling) in construing "pipette guiding mechanism." The sum total of the references to the '782 patent prosecution history is seven lines in the IDS citing office actions from the '782 patent prosecution.[5] Malvern's bare references to the '782 patent office actions in the IDS for the '175 patent supplemental examination are insufficient to impact our understanding of the specification and claim language. On this basis alone, the '782 patent prosecution history statements cannot limit the scope of "pipette guiding mechanism."

Malvern Panalytical v. TA Instruments-Waters

Federal Circuit:

"pipette guiding mechanism" means a mechanism that guides the pipette assembly **manually or automatically**, which is a plain and ordinary meaning of the term.

Ortiz & Associates Consulting v. Visio Inc. (N.D. Tx. 2023)

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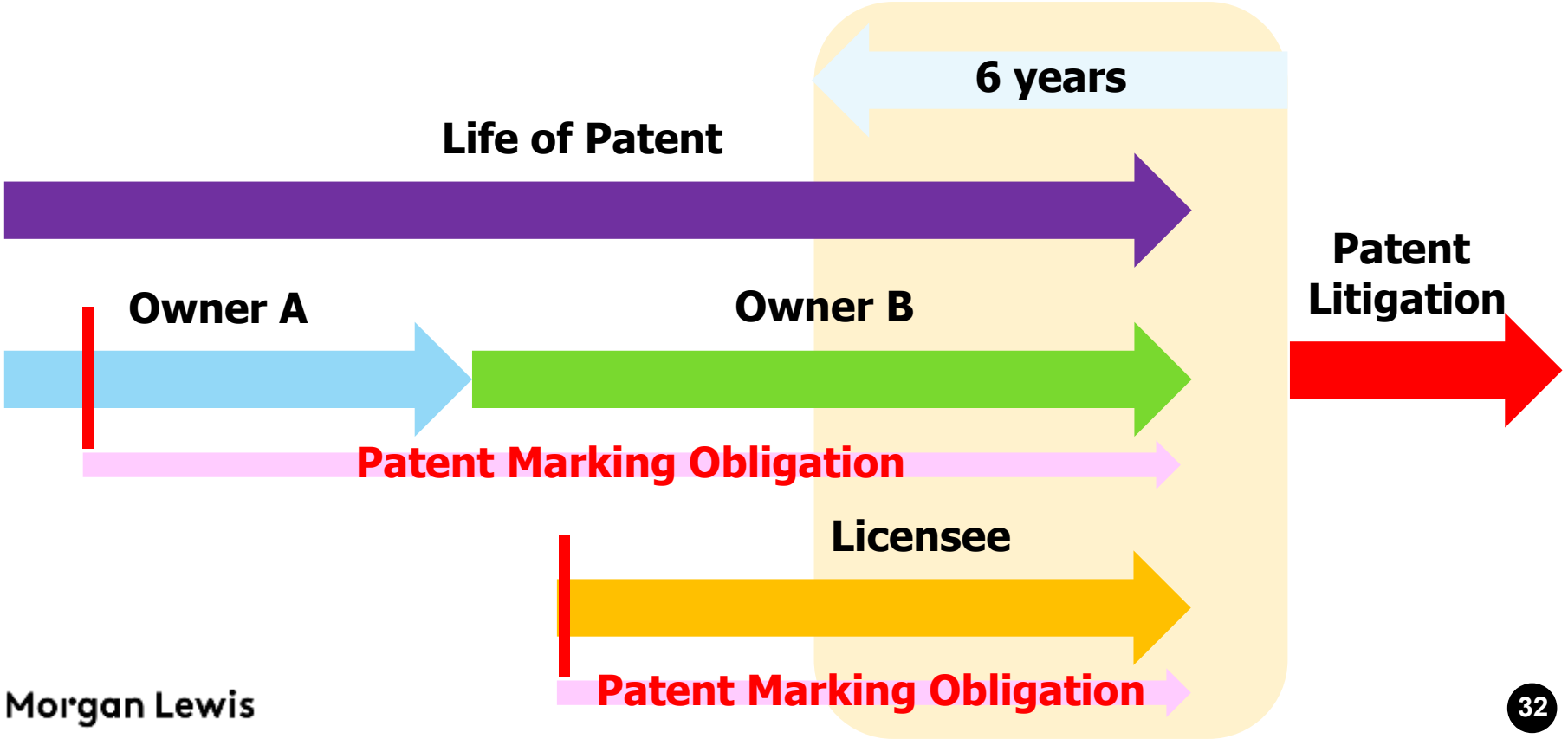
Ortiz & Associates Consulting v. Visio Inc.

- Dismissing patent litigation case with prejudice due to lack of damages (i.e. failing to plead facts sufficient to state a claim for relief under Rule 12(b)(6))
- 12(b)(6) dismissal was based on failure to comply with the patent marking statute. The parties agreed that the asserted patent had expired and the NDTX Court dismissed pre-suit damages due to lack of marking of licensed products of a Defendant who settled the prior case

Ortiz & Associates Consulting v. Visio Inc.



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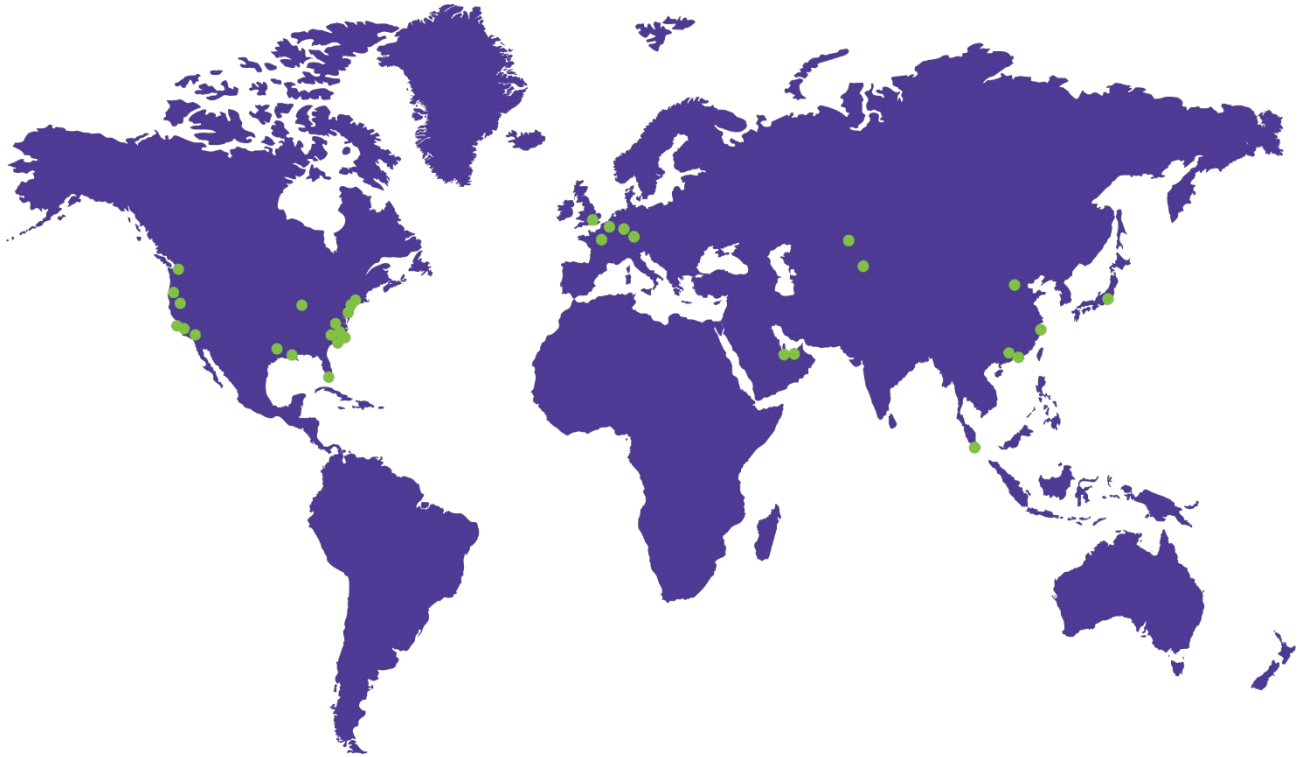

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