



*Amgen v. Sanofi
and Regeneron*

Argued March 27, 2023

Decided May 18, 2023

Agenda

What is this case about?

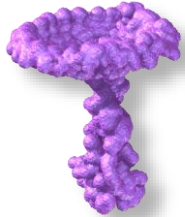
What was the law before the case?

What was decided at the Supreme Court?

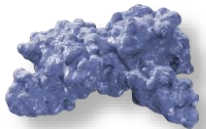
Proteins Involved in LDL Regulation:



LDL is referred to as bad cholesterol



Proteins called LDL Receptors (LDLRs) **lower** LDL blood levels by **transferring** LDL from blood into liver cells and are recycled

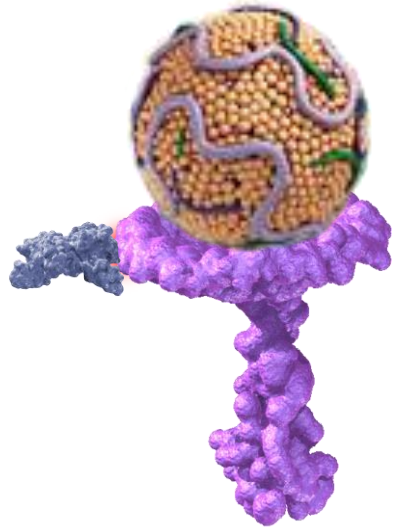


Another protein called PCSK9, however, targets LDLRs for **destruction**, preventing them from recycling and transferring more LDL from the blood into liver cells

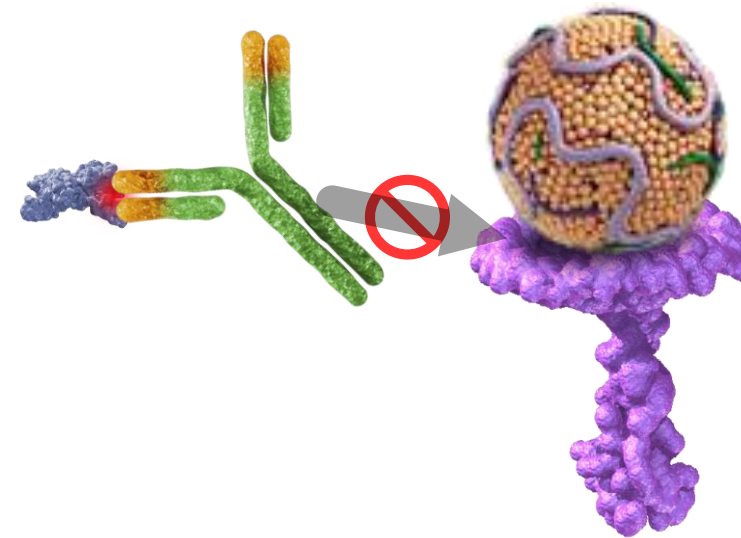


PCSK9 antibody **inhibits** PCSK9 and allows LDLRs to recycle, thus **lowering** LDL levels in the blood

Antibody Binds PCSK9 and Blocks it from Binding LDLR

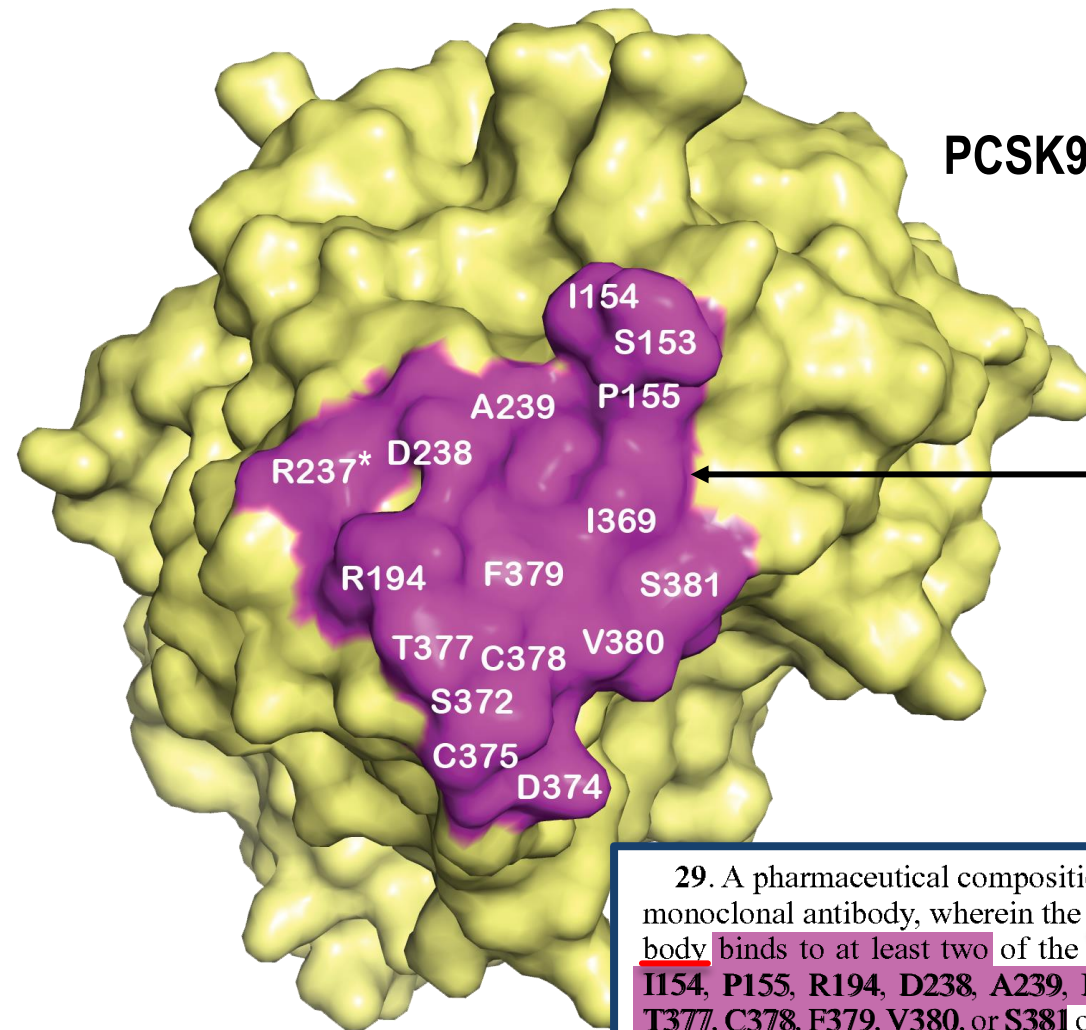


Problem:
PCSK9 targets LDLR for **destruction**,
which leads to high cholesterol



Solution:
Inhibit PCSK9 with an antibody, which allows
LDLR to be recycled, lowering cholesterol levels

The Amino Acids in Amgen's Claims



LDL-R binds to this purple region of PCSK9. Amgen refers to this area as the "sweet spot."

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%.

The Law of Enablement

Cannot require undue experimentation

“To prove that a claim is invalid for lack of enablement, a challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention **without undue experimentation.**”

In re Wands, 858 F.2d 731, 736–37 (Fed. Cir. 1988)

Specification must enable the full scope

“[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the **full scope** of the claimed invention without undue experimentation.”

In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993)

The Law of Enablement

The *Wands* Factors

“Whether undue experimentation is needed ... is a conclusion reached by weighing many factual considerations,” which are:

- (1) the quantity of experimentation necessary,
- (2) the amount of direction or guidance presented,
- (3) the presence or absence of working examples,
- (4) the nature of the invention,
- (5) the state of the prior art,
- (6) the relative skill of those in the art,
- (7) the predictability or unpredictability of the art, and
- (8) the breadth of the claims

In re Wands, 858 F.2d 731, 736–37 (Fed. Cir. 1988).

Amgen failed to teach how to make an entire class of antibodies – those that bind 9 or more of the claimed amino acids.

	Amgen Antibodies													Competitor Antibodies			
PCSK9 Residue	21B12	31H4	1A12	8A3	11F1	3B6	9C9	9H6	17C2	23B5	25A7	30A4	12H11	Alirocumab	1D05	AX132	J16
S153	■		■										■	■		■	
I154			■				■	■						■			
P155			■				■	■						■		■	
R194	■					■			■		■						
D238	■						■	■		■				■			
A239			■								■			■			
I369			■				■	■						■			
S372																■	
D374	■	■			■									■		■	
C375						--	--	--	--	--	--	--					
T377	■		■			■			■		■						
C378						--	--	--	--	--	--	--		■			
F379	■						■	■		■		■		■		■	
V380		■		■	■									■			
S381				■	■								■				■

PCSK9 Supreme court case – key issues

Questions presented to the Supreme Court by Amgen:

- Is enablement a question of fact or law? (The Supreme Court declined to hear this issue.)
- Does the enablement statute require a patentee to enable the full scope of an invention without undue experimentation? (This is the issue that was decided.)

OTHER ISSUES:

Problems with functional claims – describe what an invention does, rather than what the invention is.

Problems with broad genus claims – under current law, the full scope of the claim must be enabled without undue experimentation. Lowering the standard would allow patentees to claim more than they invented.

Consistency with the law on small molecules – claims to any small molecule that binds a protein and inhibits its function are invalid according to decades of Federal Circuit case law.

Oral argument



Justice Neil Gorsuch

JUSTICE GORSUCH: “Do you agree that a patent fails the enablement test if it would force a person skilled in the art to undertake undue experiments to produce the claimed invention?”

MR. LAMKEN: “I think that's a fair statement of the law.”

JUSTICE GORSUCH: “I'll take that as a yes.”



Jeff Lamken
Counsel for Amgen

Oral argument



Justice Elena Kagan

JUSTICE KAGAN: “And everybody agrees also, I take it from your answers to Justice Gorsuch's question, that there is a requirement that the full scope of the invention has to be enabled?”

MR. LAMKEN: “I think that's right.”



Jeff Lamken
Counsel for Amgen

Oral argument



Justice Neil Gorsuch

JUSTICE GORSUCH: “If we agree on the law, what's left for this Court?”

MR. CLEMENT: “Nothing, except maybe a DIG (Dismissed as Improvidently Granted).”



**Paul Clement
Counsel for Sanofi
and Regeneron**

Oral argument



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**Paul Clement
Counsel for Regeneron
and Sanofi**

PCSK9 case – take away

AMGEN'S FUNDAMENTAL PROBLEM:

- Amgen wanted the Court to decide accept the law vs. fact issue, then decide that enablement is an issue of fact. (This would be a reversal of current law.) Then Amgen could argue that deference should have been given to the two jury verdicts that were Amgen's favor.
- However, when the Court declined to hear the law vs. fact issue, Amgen had to make a strategic choice. Both juries were instructed that a patentee must enable the full scope of an invention without undue experimentation, and Amgen did not object to the jury instructions. Disposing of the legal standard would necessarily dispose of the jury verdicts.
- In the end, this did not really change the law. Amgen agreed that the full scope of the claims must be enabled without undue experimentation. Therefore, the case was reduced to the factual dispute that the Supreme Court was not inclined to address.



U.S. Supreme Court's Decision in
Goldsmith v. Andy Warhol Foundation:
How will current AI cases be impacted by this decision?

Dorothy R. Auth
November 14, 2023
NYIPLA Patent One-Day

C A D W A L A D E R

Why is Copyright important?

- Software is covered by copyright
- AI raises issues
- Movies, books, podcasts, art – wherever there is human creative expression, there is copyright



copyright

all rights reserved

Goldsmith v. AWF Facts

- Goldsmith took a photo of Prince for a Newsweek article about the rising pop star
- Goldsmith granted a one-time license as an “artist reference” to Vanity Fair who hired Andy Warhol to create a work from photo for article about Prince
- AWF licensed to Condé Nast for \$10,000 the previously-unpublished “Orange Prince” (also from Goldsmith’s photo) without Goldsmith’s permission
- Goldsmith notified AWF of potential infringement; AWF sued Goldsmith for declaratory judgement or fair use; Goldsmith countersued for copyright infringement



Legal Standard Under the U.S. Copyright Act

Copyright Act encourages creativity by granting to the creator “a bundle of exclusive rights,” including the right to reproduce the copyrighted work and to prepare derivative works, which is defined in §101 to include

“any other form in which a work may be recast, transformed, or adapted.”

Fair Use as codified in §107 sets out four factors for consideration:

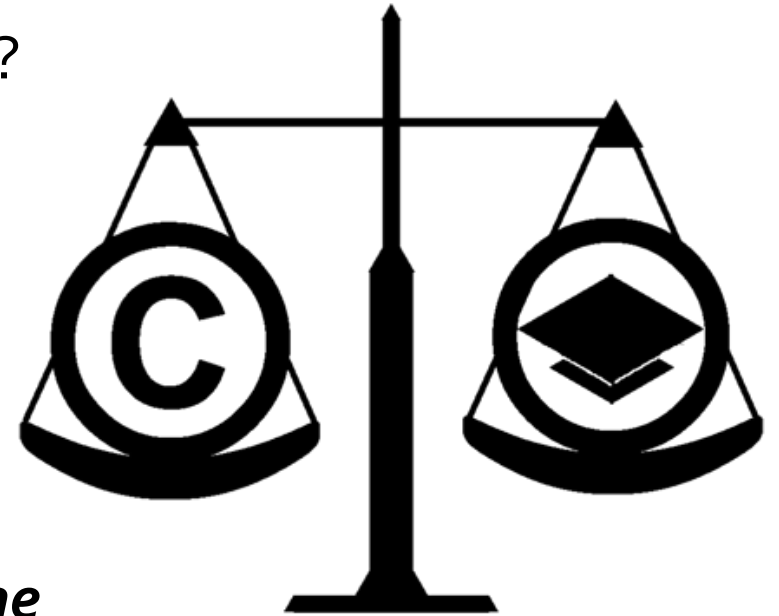
1. the purpose and character of the use, including commercial or nonprofit educational purpose
2. nature of the copyrighted work
3. the amount and substantiality of the content used from the original work
4. effect of the use on potential value of original work, *i.e.*, actual or potential market substitution



First Fair Use Factor: Purpose & Character of the Use

- Is it transformative?
Does it have a further purpose or different character?
 - What is sufficient to be transformative?
 - Is there something more?
- What is the purpose of the use?
- Is the use of a commercial nature or for non-profit/educational use?

Does the new use "merely supersede the objects of the original creation or instead add something new, with a further purpose of different character"?



Goldsmith v. AWF District Court Decision



District Court held on SJ for AWF, finding Warhol's work to be transformative, *i.e.*, Warhol, because *his works are distinctive*, is transformative

Second Circuit reversed, holding the Prince Series was substantially similar to Goldsmith's photograph.

- Held: District court erred, grounding ruling in a *subjective* evaluation of the underlying artistic message rather than an *objective* assessment of the work's purpose and character.



United States Supreme Court 598 U.S. 508 (2023)



Question Presented: Whether “the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes” weighs in Goldsmith’s favor.

Held: Fair Use Favors Goldsmith

- Specific use for both Goldsmith and AWF was as an image of Prince in articles about Prince, *i.e.*, the same purpose
- Both were commercial uses
- No justification for use – no parody, commentary or education



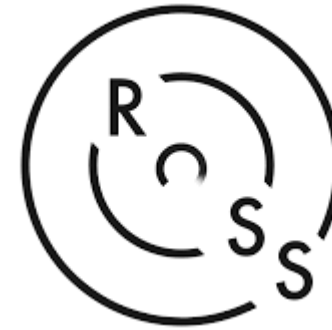
To Square with *Google*

Google v. Oracle Am. 593 U.S. 1071 (2021)

- Computer code is treated differently than other works.
 - “The fact that computer programs are primarily functional makes it difficult to apply traditional copyright concepts in that technological world”
 - Transformational use based on:
 - Limited use of declaring code – *“taking only what was needed to allow users to put their accrued talents to work in a new and transformative program”*
 - Different purpose – originally developed for computer systems but transformed for use in smart phones.



Impact on Copyright Law: Follow-up case



Thomson Reuters v. ROSS Intelligence — 529 F.Supp.3d 303 (D. Del 2022)

- Ross is a natural language search engine where users enter questions and receive quotes from court opinions.
- To train its AI engine, Ross had a third-party draft legal memos with legal questions and answers. Thomson Reuters contends these questions were essentially Westlaw headnotes (which are copyrighted) with a question mark at the end.
- Thomson Reuters cited *AWF* emphasizing both parties are using the headnotes for commercial purposes. The court rejected this emphasis because **“in a technological context”** like that in *Google*, it is appropriate to **“place[] much more weight on transformation than [on] commercialism.”**



Impact on Copyright Law: Follow-up case

Getty Images v. Stability AI – D. Del 2023

- Getty Images alleges Stability AI copied more than 12 million photographs from its collection, along with the associated captions and metadata, in order to build its AI engine.
- Stability AI created an image-generating model that uses AI to deliver computer-synthesized images in response to text prompts.



Takeaways

- Purpose & Character of Use
 - Different Purpose? Educational?
 - Justification of use – Parody? Commentary?
 - Commercial Use
 - Transformative nature





May 22, 2023, 4:00 AM

Judges Don't Need to Be Art Critics After *Warhol* Decision



Dorothy Auth
Cadwalader, Wickersham & Taft



Howard Wizenfeld
Cadwalader, Wickersham & Taft

Cadwalader's Dorothy Auth and Howard Wizenfeld say the US Supreme Court examined the first fair use factor for determining copyright infringement and focused on the nearly identical commercial uses of the original work and its copy in finding their purposes were too similar.

The Supreme Court May 18 relieved courts of the qualification to be an art critic in addressing copyright infringement cases involving works of art.

The court in *Andy Warhol Foundation vs. Goldsmith* stated fair use “is an objective inquiry into what a user does with an original work, not an inquiry into the subjective intent of the user, or into the meaning or impression that an art critic or judge draws from a work.”

Courts have struggled with fair use—that is, the question of how different a new work must be from an original work to be considered sufficiently different under copyright law.

The court in no uncertain terms stated that judges should not be art critics in evaluating whether an allegedly infringing work qualifies as fair use.

At issue was Warhol's use of a copyrighted photograph of the artist Prince, originally shot by Lynn Goldsmith. Warhol created a number of silkscreen portraits from Goldsmith's photograph without authorization, including one where Prince's photograph was set against an orange background. After Prince's death, the Andy Warhol Foundation licensed this “Orange Prince” to Condé Nast for use in a special edition magazine about Prince's life.

When Goldsmith saw the article and recognized that Orange Prince included her work, she notified AWF of her concern. AWF filed for declaratory judgment of noninfringement or in the alternative, fair use. Goldsmith counterclaimed for infringement.

The district court ruled in favor of AWF on the issue of fair use. The Second Circuit Court of Appeals reversed, holding all four fair use factors fall in favor of Goldsmith.

AWF petitioned the Supreme Court on only the first of the four fair use factors, “the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes,” arguing that Orange Prince satisfies this first factor because it conveys a different meaning or message from Goldsmith’s photograph.

Writing for the majority, Justice Sonia Sotomayor clarified that imbuing a work with a new message or meaning by itself is insufficient to satisfy the first factor. Rather, under the first factor, a court must examine the “purpose and character of a new use, including whether such use is of a commercial nature or is for nonprofit educational purposes.”

The court explained the first fair-use factor focuses on “whether and to what extent” the use of the copyrighted work has a “purpose or character different from the original,” and whether that use is commercial in nature. “[T]he commercial character of a secondary use should be weighed against the extent to which the use is transformative or otherwise justified.”

Comparing the two works under this framework, the court determined that Condé Nast’s purpose of the use was “substantially the same” as that of Goldsmith’s photograph. Both works were used in magazines to illustrate Prince’s face in stories about the artist. Because Condé Nast paid AWF for the work, its use was commercial in nature.

Although the Orange Prince work may provide a different expression from Goldsmith’s original photograph, the court found this insufficient to satisfy the requirements of fair use. AWF took the position its work conveyed a new meaning: “the dehumanizing nature of celebrity.”

Even so, this meaning did not alter the purpose of the use—as an image in an article about Prince. Accordingly, the Orange Prince “shared the objectives, of Goldsmith’s photograph, even if the two were not perfect substitutes.”

With this decision, the Supreme Court has strengthened the protection of copyrights. It is not enough to claim that a work subjectively confers a new expression, meaning, or message to a prior work to receive fair use protection. Instead, under the first factor, an artist must objectively show that the purpose or character of the use in the new work differs from that of the original work.

Overseeing such objective, contextual fights are a strength of the judiciary. As noted in the concurrence: “Nothing in the law requires judges to try their hand at art criticism and access the aesthetic character of the resulting work.”

After all, they’re judges, not art critics.

The case is *Andy Warhol Found. for the Visual Arts, Inc. v. Goldsmith*, U.S., No. 21-869, opinion 5/18/23.

This article does not necessarily reflect the opinion of Bloomberg Industry Group, Inc., the publisher of Bloomberg Law and Bloomberg Tax, or its owners.

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Cadwalader’s A.J. Harris contributed to this article.



Review of the Supreme Court Decision in:
Jack Daniel's Properties Inc. v. VIP Products LLC, Dkt.22-148, 599 U.S. 140, 143 S.Ct. 1578
(June 8, 2023).

William Thomashower, Esq.
Pryor Cashman LLP
New York City

NYIPLA One Day CLE Nov. 8, 2023

SCOTUS clarifies trademark law and the parody defense for claims of infringement and dilution.*

- **Factual Background:** The case involved trademark infringement and trademark dilution claims brought by the owners of the Jack Daniel's® brand and trade dress for whiskey against VIP Products, makers of a line of dog squeaker chew toys. The pet products company designed and sold a soft dog chew toy mimicking the trademark, trade dress, bottle shape, colors and label of the Jack Daniel's "Old No. 7 Brand Tennessee Sour Mash Whiskey." VIP's principal defense was that it had a right to use "Bad Spaniels, The Old No. 2 On Your Tennessee Carpet" and other features similar to Jack Daniel's as an expressive attempt at humor and parody.

* Presented By: William Thomashower, Esq., Counsel, Pryor Cashman LLP ("PC"). This paper is not to be taken as legal advice for a specific matter or client and the views expressed are solely those of the author and not necessarily those of PC or the NYIPLA.

- As in most trademark cases, the sight, sound and appearance of the trademarks and accused product are important. And a “Picture is Worth a Thousand Words.”
- But it is also settled law that trademark comparisons for purposes of determining “likelihood of confusion” are not to present the products side by side, because that is usually not how they will be experienced by the relevant consumer, except in the case of a direct comparative advertising.



The Decision described VIP's product as follows:

“Bad Spaniels is about the same size and shape as an ordinary bottle of Jack Daniel's. The faux bottle, like the original, has a black label with stylized white text and a white filigreed border. The words "Bad Spaniels" replace "Jack Daniel's" in a like font and arch. Above the arch is an image of a spaniel. (This is a dog toy, after all.) Below the arch, "The Old No. 2 On Your Tennessee Carpet" replaces "Old No. 7 Tennessee Sour Mash Whiskey" in similar graphic form. The small print at the bottom substitutes "43% poo by vol." and "100% smelly" for "40% alc. by vol. (80 proof).“

“The toy is packaged for sale with a cardboard hangtag (so it can be hung on store shelves). Here is the back of the hangtag [image omitted].
At the bottom is a disclaimer: ‘This product is not affiliated with Jack Daniel Distillery.’
In the middle are some warnings and guarantees.” *Id. at 1585.*

VIP argued that the dog toy was a humorous, expressive parody of the original Jack Daniel's bottle. To be sure, VIP had taken some liberties with their parody, by using not merely humorous but off color, negative imagery, with words like "The Old No. 2 On Your Tennessee Carpet" and "43% poo by vol." and "100% smelly". Would a less negative parody have escaped liability?

Lower Court Rulings

- VIP moved for summary judgment on both the infringement and dilution claims, relying on the *Rogers* test for “expressive works.” As the Supreme Court explained it, “the so-called *Rogers* test requires dismissal of an infringement claim at the outset unless the complainant can show one of two things: that the challenged use of a mark “has no artistic relevance to the underlying work” or that it “explicitly misleads as to the source or the content of the work.” *Rogers v. Grimaldi*, 875 F.2d 994, 999 (C.A.2 1989) (NEWMAN, J.).” *Id.* at 1586. The District Court rejected this argument finding that the features “cribbed” from the Jack Daniel’s product were used to identify the “source” of the product, a core trademark function.

Lower Court Rulings

- The District Court conducted a bench trial and ruled largely on survey evidence that consumers were “likely to be confused” as to the source of the VIP “Bad Spaniels” toy. The court also thought that the toy, by creating “negative associations” with “canine excrement,” would cause Jack Daniel’s “reputational harm.
- **Infringement:** The “Ninth Circuit reversed, ruling that the District Court had gotten the pretrial legal issues wrong. In the Ninth Circuit’s view, the infringement claim was subject to the threshold *Rogers* test because Bad Spaniels is an “expressive work”: Although just a dog toy, and “surely not the equivalent of the *Mona Lisa*,” it “communicates a humorous message.” 953 F.3d 1170, 1175 (2020) (internal quotation marks omitted).” *Id.* at 1586. On remand the District Court found Jack Daniel’s could not meet the *Rogers* tests for liability.
- **Dilution:** The “Court of Appeals also held that the exclusion in the dilution statute for “noncommercial use” shielded VIP from liability. § 1125(c)(3)(C). The “use of a mark may be ‘noncommercial,’” the court reasoned, “even if used to sell a product.” 953 F.3d, at 1176 (internal quotation marks omitted). And here it was so, the court found, because it “parodies” and “comments humorously” on Jack Daniel’s.” (citations omitted). *Id.* at 1586.

NYIPLA Amicus Brief

- The NYIPLA Amicus Committee submitted an *amicus* brief “in support of neither party” which urged that the *Rogers* test should not replace the likelihood of confusion test and humor alone, as “found” by the Ninth Circuit, was insufficient to show parody for a claimed non-commercial use exception to dilution.

The Amicus brief also argued that:

“Many factors can aid in determining whether a parody is successful or confusing, including (a) how clear it is that the parodist's product was not authorized by the brand;

(b) the nature of the challenged product and common uses of parody in the relevant industry;

(c) the reasons why, if any, the parody targets the brand;

(d) the nature of the brand’s products including particularly whether or not the brand licenses a variety of products and/or licenses products similar to those sold by the parodist; and

(e) survey evidence indicating how the public actually perceives the parodist's use of the mark.” (citing K. McCarthy, *Free Ride or Free Speech? Predicting Results and Providing Advice for Trademark Disputes Involving Parody*, 109 Trademark Reporter 691 (July-Aug. 2019)).

SCOTUS RULING

- 1. The Supreme Court disagreed with Ninth Circuit and vacated and remanded the case. While expressly not deciding the merits of the *Rogers* test, the Court rejected that defense in the specific context shown **where an alleged trademark infringer used a similar or identical trademark or trade dress of another in such a way as to designate the source or origin of its own goods or services.**
- 2. In such cases, alleged infringers may still have the ability to assert a parody defense for infringement claims, but even for parody products which are "expressive" or "humorous" and also could "in part" indicate the senior user's brand as a source of origin, the courts should undertake a proper likelihood of confusion and parody analysis under the relevant circuit standard **without applying *Rogers*.**
- 3. The Court indicated that the likelihood of confusion analysis will be able to take into account the interest in free expression. And when the trademark or trade dress are used as a designation of source of origin, the parody "fair use" defense does not apply to trademark dilution claims, which will be judged under the "blurring" and "tarnishment" standards in the Lanham Act.

Thus, the Supreme Court agreed with the District Court, that the VIP product was not merely an “expressive parody” but, said the Court, the record showed that VIP used its cribbed “Bad Spaniels” trademark and similar trade dress to “identify and distinguish [VIP’s] goods” and to “indicate [their] source.”

The Court also cited other of VIP’s parody squeaker dog toys as used the same way -- as trademarks and trade dress to indicate VIP as the “source” -- for example, in its dog toys like “Jose Perro” (cf. Jose Cuervo) and “HeinieSniff’n” (cf. Heineken). “And it has chosen to register [as trademarks] the names of still other “parody” dog toys, including Dos Perros (#6176781) [like Dos Equis], Smella Arpaw (#6262975)[like Stella Artois], and Doggie Walker (#6213816) [like Johnnie Walker].” *Id.* at 1591 (footnote omitted).

Does this Doom all Parody Products by confusing consumers as to their source? No.

Importantly, while the Court stated that the *Rogers* test should not be applied where the parody mark is used to identify the source, dissimilarities in the marks or use could avoid full scale litigation on “likelihood of confusion” factors:

“That is not to say (far from it) that every infringement case involving a source-identifying use requires full-scale litigation. Some of those uses will not present any plausible likelihood of confusion—because of dissimilarity in the marks or various contextual considerations. And if, in a given case, a plaintiff fails to plausibly allege a likelihood of confusion, the district court should dismiss the complaint under Federal Rule of Civil Procedure 12(b)(6). See 6 McCarthy § 32:121.75 (providing examples).” *Id.* at 1594, fn. 2.”

“Yet to succeed, the parody must also create contrasts, so that its message of ridicule or pointed humor comes clear. And once that is done (*if* that is done), a parody is not often likely to create confusion. Self-deprecation is one thing; self-mockery far less ordinary. So although VIP's effort to ridicule Jack Daniel's does not justify use of the *Rogers* test, it may make a difference in the standard trademark analysis. Consistent with our ordinary practice, we remand that issue to the courts below.” *Id.* at 1592.

The Court also reversed dismissal of the dilution claim and remanded.

The Court noted that given VIP's use as a "trademark" indicating source, "Jack Daniel's claim of dilution by tarnishment (for the linkage of its whiskey to less savory substances)" was not entitled to the exclusion for "parody" as a "humorous message".

"[T]he 'fair use' exclusion specifically covers uses "parodying, criticizing, or commenting upon" a famous mark owner. § 1125(c)(3)(A)(ii); see *supra*, at 1584-1585. But not in every circumstance. Critically, the fair-use exclusion has its own exclusion: **It does not apply when the use is "as a designation of source for the person's own goods or services."** § 1125(c)(3)(A). In that event, no parody, criticism, or commentary will rescue the alleged dilutor. " *Id.* at 1592 (emphasis added).

THE COURT'S CONCLUSION

"Today's opinion is narrow. We do not decide whether the *Rogers* test is ever appropriate, or how far the "noncommercial use" exclusion goes. On infringement, we hold only that *Rogers* does not apply when the challenged use of a mark is as a mark. On dilution, we hold only that the noncommercial exclusion does not shield parody or other commentary when its use of a mark is similarly source-identifying. It is no coincidence that both our holdings turn on whether the use of a mark is serving a source-designation function." *Id.* at 1592-93.

Some Post-Decision Consequences

1. On the Supreme Court's remand to the Ninth Circuit, the Circuit on August 14, 2023 vacated the District Court's Decision which the Circuit had affirmed for VIP, and remanded to the District Court.
2. In 2022, the Ninth Circuit relying on *Rogers*, had affirmed summary judgment dismissing a trademark infringement claim against a commercial use. *Punchbowl, Inc. v. AJ Press, LLC*, 52 F.4th 1091 (9th Cir. 2022). The NYIPLA Amicus Brief had criticized this opinion because the defendant had used the accused mark as a brand. After the June 8, 2023 Decision in *Jack Daniel's*, the Ninth Circuit withdrew its 2022 decision "in light of" *Jack Daniel's* and indicated the case would be set for re-argument. (Slip. Op. Dkt. 21-55881, 9th Cir., Sept. 1, 2023).
3. In *Jth Tax LLC d/b/a Liberty Tax v. AMC Networks, Inc. and Sony Pictures Tel. Inc.*, No. 22 Civ. 6526 (PGG) (S.D.N.Y. Sept 25, 2023), the district court granted a motion to dismiss a trademark infringement claim, applying *Rogers* as still good law in the Second Circuit, where an expressive work does not use a mark "as a designation of source for the infringer's own goods," and acknowledging that *Jack Daniel's* "declined" to reach *Rogers'* application in that context.

TIP OF THE ICEBURG: MORE AND DIFFERENT DOG TOY PARODIES BY OTHERS





In re Collect

The Intersection of Obviousness-type
Double Patenting and Patent Term
Adjustment

Paul Coletti
Johnson & Johnson
November 8, 2023

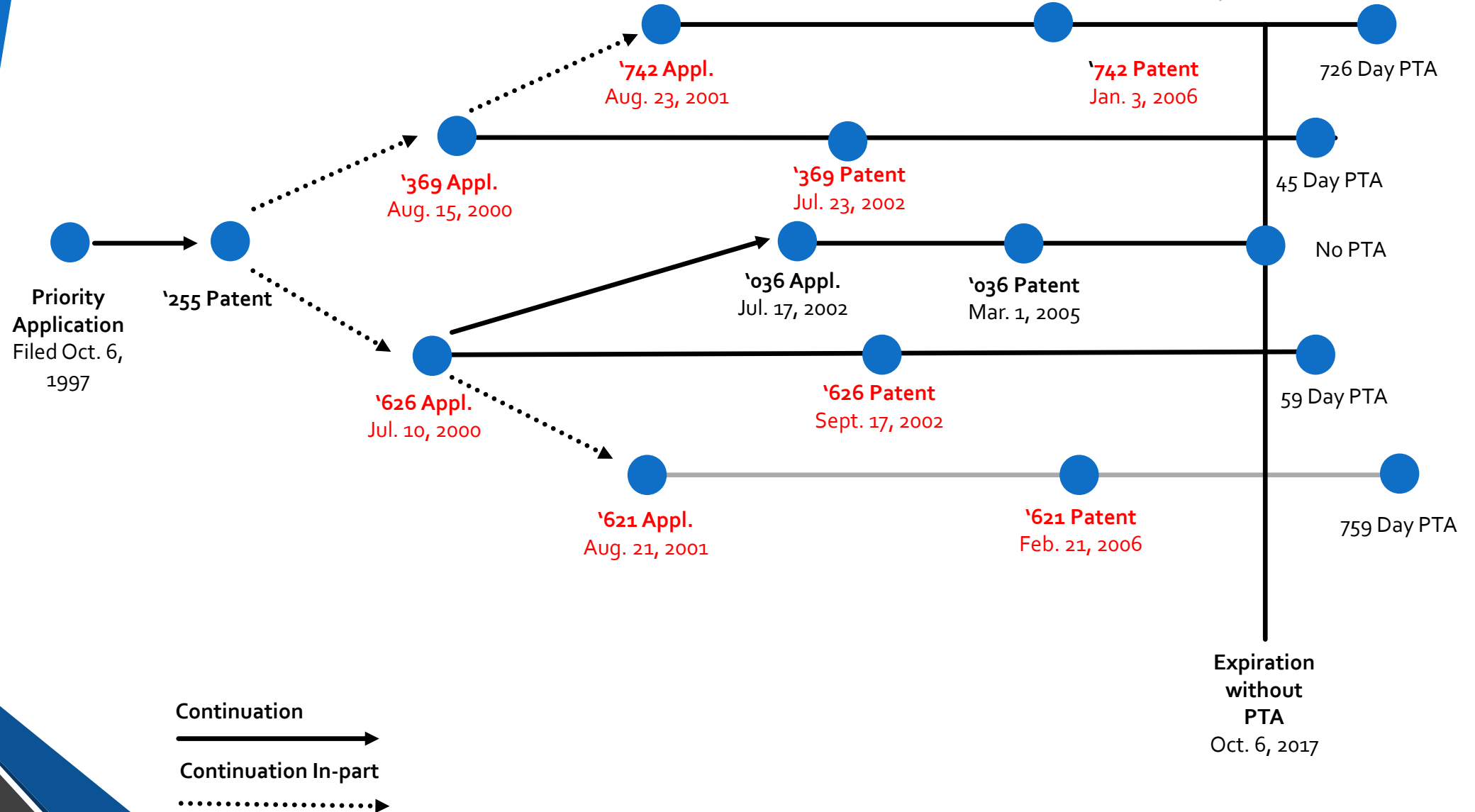
The issue

How does Patent Term Adjustment (PTA) - added to the term of a patent due to USPTO delays - affect application of the doctrine of Obviousness-type Double Patenting (ODP) over a patent in the same family?

PROCEDURAL HISTORY

- Collect owns a family of patents - all but one patent have varying amounts of PTA
- Collect sued Samsung for infringement of 4 of the patents and Samsung filed an ex parte reexam, alleging the patents are invalid for ODP
- The reexam examiner rejected the claims for ODP **even though the original examiner had not raised this rejection**
- Collect appealed to the PTAB, which affirmed the examiner
- Collect then appealed to the Federal Circuit, which affirmed the PTAB

Collect Patent Family



Patent	Claims	ODP Ref Patent
'742	22, 42, 58, and 66	'369
'369	1, 17, 19, 21, 22, 27, 49, 55, and 61	'036
'626	1, 5, 11, 33, 34, 58, and 64	'369
'621	25, 26, 27, 28, 29, and 33	'626

- All of the challenged patents and reference patents were expired, so no Terminal Disclaimer could have been filed
- Collect did concede claims of the various patents were patentably indistinct
- The '255 patent was never asserted against the challenged patents

Cellect raised 3 arguments on appeal:

- **The Board erred by not considering whether a patent is unpatentable for ODP based on expiration without reference to duly granted PTA**
- The Board erred in failing to consider equitable concerns underlying the finding of ODP during the reexamination procedure
- The Board erred in finding a substantial new question of patentability in the underlying reexaminations

Merck & Co. v. Hi-Tech Pharamcal Co., 482 F.3d 1317 (Fed. Cir. 2007)

- ODP rejection made during prosecution and TD filed
- ***Patent later awarded 1233 days of PTE***
- Court: “patent term extension under § 156 is not foreclosed by a terminal disclaimer,” and “Hatch-Waxman patent term extension is from the expiration date resulting from the terminal disclaimer and not from the date the patent would have expired in the absence of the terminal disclaimer”

Novartis AG v. Ezra Ventures LLC, 909 F.3d 1367 (Fed. Cir. 2018)

- Patent contained claims challenged as patentably indistinct from those of a reference patent and expired after the reference patent solely because of statutorily-mandated PTE awarded to the challenged patent (no TD filed)
- Court: “as a logical extension of our holding in *Merck & Co. v. Hi-Tech* that double patenting also should be considered **before a PTE**”
- Thus, the ODP analysis is conducted before PTE is applied

CELLECT'S POSITION

- In these cases, the Federal Court indicated that the correct analysis is: first determine the expiration date of the patent, including any ODP/TD consideration; and only then add PTE to that expiration date
- Cellect urged the court to similarly find that patents subjected to ODP are still entitled to PTA and that the PTA should be calculated in a similar manner – first consider when the patent would expire based on ODP/TD and then add any statutorily granted PTA to that date

USPTO'S POSITION

- Collect does not dispute that the challenged and reference patents are commonly owned and that the challenged claims were patentably indistinct over claims in the reference patents
- **The statutory language and precedent indicates that PTA and PTE should be treated differently when determining whether or not claims are unpatentable under ODP**
- Novartis' statement that judge-made doctrine, such as ODP, cannot be used to cut off statutorily granted term extension is limited to PTE determinations
- **The statutory language is clear that TDs cut short PTA but not PTE**

THE COURT'S FINDINGS

- The Federal Circuit agreed with the USPTO that these types of term adjustments should be treated differently
- 35 U.S.C. § 154 (PTA):

No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.
- 35 U.S.C. § 156 (PTE):

The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b)

The Court held that Section 154 expressly limits the grant of PTA by any disclaimer of patent term (i.e., in a TD), therefore the proper calculation is

- First calculate the expiration date of each challenged and reference patent including any PTA
- Then consider ODP and any TDs with all patentably indistinct patents expiring on the earliest expiration date
- The Court also consider that there may be situations, as in the present case, where no TD was filed. It determined that TDs are generally filed in response to ODP and so its holding applies to such situations

- **Note: each application is different. The following considerations are not to be construed as legal advice.**
- Review pending portfolios to determine if any ODP rejections are outstanding:
 - Traverse ODP rejections on the merits, when possible
 - Traverse on procedural grounds, when possible
 - *"Applicant traverses this rejection and requests reconsideration. A double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103" except that the patent principally underlying the double patenting rejection is not considered prior art. In re Braithwaite, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. In re Braat, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Applicant submits that the cited combination fails to establish a prima facie case of obviousness, and therefore the obviousness-type double patenting rejection is improper."*

PRACTICE CONSIDERATIONS

- Review pending portfolios to determine if any ODP rejections are outstanding (con't):
 - Withhold agreement until claims are otherwise found allowable
- Consider abandoning earlier expiring case
 - Closely review applications to determine most valuable claims as part of analysis

- Consider listing co-pending applications
 - List applications and status
 - Include statement such as:
 - “The foregoing statuses were pulled from the USPTO’s Patent Center on _____ [date when data is pulled, not when amendment filed]. The Examiner is encouraged to review and monitor each of these file wrappers, including the issued and pending claims, all art of record, and any rejections. Details of these cases are available through the Office’s records. No representation is made or intended that the foregoing cases are material to patentability of the present claims, or that the foregoing is a comprehensive list of copending applications.”
- Evaluate patent strategy for new portfolios early and often:
 - Consider possible claim categories to be pursued and whether to attempt to trigger restriction
- Evaluate potential intra-family ODP concerns
 - Cases do not need to be part of the same family to raise ODP

Backup

- In 1995, the US harmonized patent term with the rest of the world and all applications filed on or after June 8, 1995 had a patent term of 20 years from date of filing
 - Submarine patents were sunk
 - ODP remained viable because, at least, of the safe-harbor provision of Section 103 (*but for the fact that the reference is not available prior art, this would otherwise be double-patenting*)
 - Can occur in unrelated cases having different expirations
 - Opponents argued that judicially-created doctrine cannot overrule statutory prohibition on double patenting
 - Proponents respond that a variation on an invention is not the same invention, therefore not prohibited by statute
 - Cannot legally assert obviousness if reference is not available as prior art due to 103 safe harbor

- Note that decision was unanimous and there were no concurring opinions
 - Original case heavily briefed by industry
 - BIO, PhRMA, IPO, the Association for Accessible Medicine, Samsung, and Alvogen submitted amicus briefs
 - BIO, PhRMA, IPO argued to overturn PTAB
- *En banc* rehearing has not been granted
 - Petitions for rehearing were due on November 13, 2023
 - Amicus briefs are due on November 27, 2023
- Assuming it stands, it affects everyone
 - Re-evaluate competitive patents for advantage where possible
 - Adopt best practices to minimize *Collect* considerations going forward

Collect is already having an impact

Allergan v. MSN (D.DE. 19-1727)

- Unlike *Collect*, the challenged patent was first filed and first to issue relative to the ODP reference patents
- To address common ownership, Allergan filed a TD in the non-expired ODP reference patent (already expired before the challenged patent because the challenged patent obtained PTA) – No term given up
- Claim 40 of the challenged patent was found invalid for ODP in view of the two referenced patents
- Court said that the fact that the challenged patent was first filed and first issued was immaterial
 - Look at expiration dates, under *Gilead*, and whether the claims are patentably distinct
- Allergan has appealed