KEKER VAN NEST & PETERS

Federal Circuit: Year in Review

Association of Corporate Counsel
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Introduction

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Agenda

- **Recent Decisions**
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  - Domestic Industry
  - Damages Issues
  - Skinny Labels
  - Obviousness-type Double Patenting
  - Investigating Real Parties in Interest
- **Cases to Watch**
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  - Orange Book Listing

Recent Decisions

Design Patent Obviousness

LKQ v. GM (En Banc)

102 F.4th 1280 (Fed. Cir. 2024)

Holding: *KSR* overruled *Rosen-Durling* test for design patent obviousness

- *Rosen-Durling* test:
  - Single primary reference which has "basically the same" characteristics as the claimed design.
  - Gap between primary reference and patent claim can be bridged by secondary references
    - Secondary references must be "so related" that the appearance of one reference's features would suggest their application to the other.
- In *LKQ*, Federal Circuit held that *KSR* overruled this:
  - *KSR* made clear that both § 103 and *Graham* "set forth an expansive and flexible approach" to obviousness.
  - *Rosen-Durling* is too rigid.

LKQ v. GM (En Banc)

102 F.4th 1280 (Fed. Cir. 2024)

New framework

– Use *Graham* framework – consider:

- **Scope and content of prior art** – to assess analogous art, consider whether the reference is from the same field of endeavor as the article of manufacture
- **Differences between prior art and patent** – compare visual appearance from perspective of ordinary designer in the field of the article of manufacture
- **Level of ordinary skill in the art** – "ordinary designer in the field to which the claimed design pertains"
- **Evaluate obviousness** – whether ordinary designer would have been motivated to modify the prior art "to create the same overall visual appearance as the claimed design"

– Secondary considerations – e.g., commercial success, industry praise, copying

Domestic Industry (ITC Cases)

Roku v. ITC

90 F.4th 1367 (Fed. Cir. 2024)

- Roku argued that complainant Universal had failed to prove economic prong of domestic industry because it did not allocate its DI expenses to a specific DI product
- Universal had focused its presentation on showing its investment into QuickSet technology incorporated into TV sets
- The Federal Circuit held that a complainant can satisfy the economic prong of domestic industry based on expenditures related to a subset of a product if the patents only involve that subset
- Here, there was no dispute that the patents related only to the QuickSet subset of the product, and no explanation was offered as to why domestic investments into QuickSet were not substantial

Zircon v. ITC

No. 2022-1649, 2024 WL 2037162 (Fed. Cir. May 8, 2024)

- Complainant Zircon sought to show economic prong of domestic industry based on investment into all of its electronic stud finders
- Three patents asserted and 53 electronic stud finders
  - 14 practice all three patents
  - 21 practice two patents
  - 18 practice only one patent
- Federal Circuit holds that section 337 statutory language requires that the domestic industry relate to articles protected by a patent, not a group of articles protected by various patents
- Zircon could have provided information to show that there was a domestic industry with respect to the 14 products that practiced all three patents, but did not

Zircon v. ITC

No. 2022-1649, 2024 WL 2037162 (Fed. Cir. May 8, 2024)

- Past cases all focused on articles that were protected by the same patents
- One prior case (*Certain DRAMs*) had found a domestic industry based on a group of DRAMs of different densities that were protected by one or more of the asserted patents
- But that case was before the 1988 amendments to section 337 that introduced the language of “articles protected by the patent” that is controlling today
- Therefore, to prove the economic prong of domestic industry, a complainant must include information sufficient to assess the domestic industry protected by the particular patents at issue

Damages Issues

Brumsfield v. IBG

97 F.4th 854 (Fed. Cir. 2024)

Appeal from a jury trial finding 2 patents invalid and 2 patents infringed, awarding $6.6M in damages

- Patents on commodity trading software
  - Infringing software was U.S.-made but sold and used all over the world. Foreign users operating software in their country could send orders to exchanges, which would execute the trade.
- Issues on appeal:
  - 101
  - Exclusion of damages theory at trial
    - District court excluded theory that Brumsfield could recover "foreign damages" flowing from U.S.-based manufacture of software
  - Alleged fraud in withholding evidence

Brumsfield v. IBG

97 F.4th 854 (Fed. Cir. 2024)

Holding: "foreign damages" potentially recoverable under *WesternGeco*

- *WesternGeco* (SCOTUS 2018) displaces *Power Integrations* (Fed. Cir. 2013)
  - Lost profit and reasonable royalty damages under § 284 may look to foreign conduct (even if not infringing) to determine the value of compensation owed for "the infringement"
- For reasonable royalty, "patentee must show why that foreign conduct increases the value of the domestic infringement itself … while respecting the apportionment limit that excludes values beyond that of practicing the patent."
- Causation requirement – must show "foreign damages" were proximately caused by domestic infringement
  - Proximate cause is "but-for causation plus more, including the absence of remoteness" (but exact contours not defined)

Skinny Labels

H. Lundbeck A/S v. Lupin Ltd.

87 F.4th 1361 (Fed. Cir. 2023)

- Plaintiff Takeda holds NDA for treatment of major depressive disorder (“MDD”) by Trintellix, active ingredient is a salt of vortioxetine
- Plaintiffs later obtained method of use claims for Trintellix, for treatment of MDD in patients who used other drugs but stopped because of sexually related adverse events or cognitive impairment
- Defendants submitted ANDAs to market vortioxetine for only treatment of MDD, carving out language about sexual side effects or cognitive impairment
- Plaintiffs sued for infringement based on the ANDAs, and district court found no infringement after a bench trial

H. Lundbeck A/S v. Lupin Ltd.

87 F.4th 1361 (Fed. Cir. 2023)

- The Federal Circuit affirmed, holding that the relevant use under the Hatch-Waxman Act must be the use for which an applicant is seeking marketing approval
- It may be true that some doctors will prescribe the generic to patients who previously had difficulties on other treatments
- But no inducement liability for just filing an ANDA on a label that discusses uses for which patents have already expired
- Here, information about the infringing uses were carved out of the label, and there were no allegations of materials external to the label inducing infringement
- Federal Circuit also noted that there were many non-infringing uses of the drug

Amarin v. Hikma

104 F.4th 1370 (Fed. Cir. 2024)

- Amarin sells icosapent ethyl under brand name Vascepa
- Initially indicated only for severe hypertriglycemia (triglycerides > 500) (SH indication) and not tested for effects on cardiovascular mortality of such patients (CV limitation of use)
- After further trials, approved to reduce cardiovascular risk in patients with tg > 150 (CV indication)
- Amarin removed CV limitation of use and added CV indication to label
- Hikma made generic, sought skinny label for only SH indication, ANDA approved on that basis
- Amarin sued for inducing infringement of CV indication patents, and district court dismissed, finding allegations of inducement implausible

Amarin v. Hikma

104 F.4th 1370 (Fed. Cir. 2024)

- Federal Circuit reversed, allowing inducement claims to proceed to discovery
- Held that totality of circumstances is appropriate test for inducement
- Here that included not just the label but also Hikma statements about its product being generic Vascepa and not emphasizing limitations such that a jury could find intent for the drug to be prescribed off-label
- This was especially true given that 75% of Vascepa sales were for the CV indication
- Allegations of intent had not been proven, but were at least plausible at the pleading stage

Obviousness-type Double Patenting

Allergan v. MSN

No. 2024-1061, 2024 WL 3763599 (Fed. Cir. Aug. 13, 2024)

Obviousness-type Double Patenting (ODP)

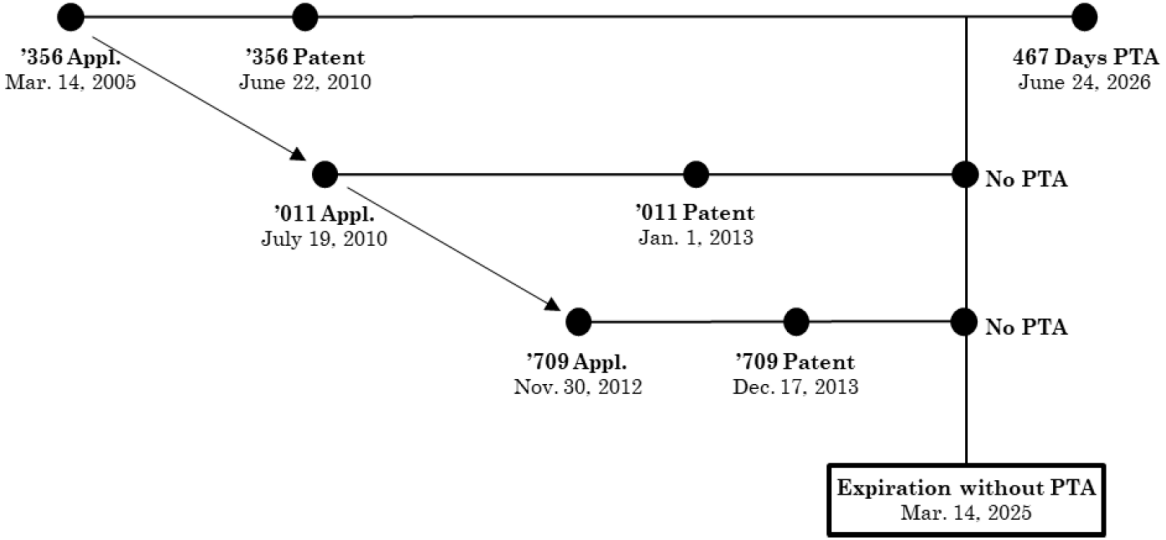
- Judicially-created doctrine that prevents obtaining multiple patents with claims that are not patentably distinct
  - An applicant can overcome an ODP rejection by filing a terminal disclaimer

- *In re Cellect:* patents with PTA could be invalidated based on ODP by earlier-expiring patents with no or less PTA

Allergan v. MSN

No. 2024-1061, 2024 WL 3763599 (Fed. Cir. Aug. 13, 2024)

Issue: Was the ’356 invalid for ODP in view of the ’011 and ’709?



- Answer: no – “later-filed, later-issued” patents cannot serve as ODP references to “first-filed, first issued” patents in their family

Investigating Real Parties in Interest

Backertop Licensing v. Canary Connect

107 F.4th 1335 (Fed. Cir. 2024)

Endorsed district court crackdown on suspected failures to disclose real parties in interest

- Background:
  - NPE and related consulting company:
    - Created plaintiff LLCs, recruited individuals to serve as owners, assigned patents with little/no consideration, and falsely reported complete assignments to PTO…
    - …but ***failed to disclose they retained substantial rights*** in patents and related proceedings
  - District court ordered production of documents and personal appearances to investigate potential fraud on the court
  - Backertop's owner refused to appear, so court held her in contempt and imposed $200/day fine
- Federal Circuit held this was within the court's inherent powers

Cases to Watch

Google v. Sonos

Case No. 24-1097

- District court found that two of the patents-in-suit were unenforceable due to prosecution laches, and that they were anticipated by the accused products themselves, as they were not entitled to a priority date before 2019
- Sonos argues on appeal
  - Prosecution laches cannot apply here because it did not extend the temporal coverage of the patents
  - Asserted new matter had been disclosed in 2007
- Google argues on appeal
  - Sonos added new matter in 2019 by taking material from an exhibit to provisional out of context
  - The patents are therefore anticipated by Google's intervening products, and the undue delay in adding new matter supports prosecution laches

Teva v. Amneal

Case No. 24-1936

Orange Book Listings

- To market a new drug, a brand must submit a new drug application (NDA) to the FDA
  - Must provide scientific data of safety & efficacy
  - Must identify any patent (1) "for which claim of patent infringement could be reasonably asserted" that (2) "claims the drug for which the applicant submitted the application" and (3) "is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent"
    - **Published in FDA's "Orange Book" (purely ministerial)**
- After NDA is approved, a generic can file an abbreviated NDA (ANDA) seeking to market a generic version
  - Must show that generic has same active ingredient and is biologically equivalent
  - For any Orange Book patents, must certify: (II) expired, (III) won't seek approval until expiration, (IV) invalid or not infringed

Teva v. Amneal

Case No. 24-1936

Background:

- Teva submitted NDA for “albuterol sulfate HFA inhalation aerosol” (for asthma)
- Teva’s Orange Book-listed patents cover inhalers and canisters (i.e., devices)

Question: Should inhaler patents be de-listed?

- District Court / Amneal: yes
  - Patents do not “claim” (i.e., recite in their claims) the drug (albuterol sulfate HFA inhalation aerosol) for which Teva submitted NDA
- Teva: no
  - Teva’s FDA-approved product (ProAir) would infringe the patents (therefore, they “claim” it)
  - “Drug” also includes “articles intended for use in … treatment”

Questions?

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Thank you!