INSIDE: Obviousness-Type Double Patenting ◆ Patent Thickets ◆ Procedures of the Federal Bench

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Dominick T. Gattuso and Karen Pascale

This latest edition of *Delaware Lawyer* covers a number of issues relating to intellectual property. As many of our readers know, the District Court of Delaware is home to five Article III judges, with one on senior status, and four magistrate judges.

In 2023 — the last year for which complete data is readily available — approximately 42% of the civil case filings involved intellectual property disputes, making the District Court of Delaware the top district for patent infringement suits filed under the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), commonly referred to as the Hatch-Waxman Act (a/k/a ANDA litigation). That news may not surprise the federal litigators among our readers. However, it might come as a surprise to others, who may ask: Why is there so much patent litigation?

Patents are arguably the engine that drives innovation. Indeed, the protection that patents (and other forms of intellectual property rights) afford inventors is enshrined in Article I, Section 8, Clause 8 of the United States Constitution, which recognizes that patents and other forms of intellectual property rights are necessary to ensure progress in science and the arts.

At its most basic, in the U.S., a patent is simply a property right granted by the U.S. Patent and Trademark Office. Exceptions aside, most U.S. patents are valid for 20 years, starting from the date of the patent application. Once issued, a patent affords the inventor, or "patentee," a monopoly for the patentee's unique invention. Many products are often protected by dozens and dozens of patents. That patent protection affords the inventor/patentee options. The patentee could provide a license to a third party, thereby allowing the third party to "practice" that aspect of the patented invention without risk of infringing the licensed patent. Alternatively, the patentee can sue the alleged infringer, asserting that the alleged infringer is violating the inventor's patent.

Because patent rights are governed by federal law, patent suits are filed in federal district courts. To minimize personal jurisdiction challenges, patentees often sue alleged infringers where they reside, are incorporated or have their principal place of business. As the state of incorporation of more than 2 million entities, including more than 60% of Fortune 500 companies, the District Court of Delaware is an obvious location to file suit against an alleged patent infringer.

In our first article, Emily Rapalino and Kelly Grosshuesch with Goodwin's IP Litigation group provide helpful guidance on obviousness-type double patenting. Double patenting can occur when an inventor obtains a second patent on an invention where the second patent is not "patentably" distinct from the earlier patent. While there are two forms of double patenting, Rapalino and Grosshuesch focus on obviousness-type double patenting, or ODP. Obviousness-type double patenting may occur when an inventor seeks a second patent for an obvious modification of a previously patented invention. If the modification is considered obvious to a person skilled in the art (i.e., the science at issue), the modification may not satisfy the criteria for patentability, resulting in the patent application being denied or the patent invalidated. ODP is intended to prevent an inventor from extending the rather substantial protections afforded under the original patent simply by making minor tweaks to the invention, thereby balancing the cost of innovation with the value of competition in the marketplace.

In our second article, Mary LaFleur Miklusak with Crowell & Moring LLP wades into a hot topic concerning patent infringement suits filed under the Hatch-Waxman Act (the "Act"). Brand-name pharmaceutical manufacturers may obtain dozens of patents on various aspects of their drug products, creating a web of patents, also known as a patent thicket, which may afford a brand-manufacturer a lengthy monopoly on the drug product. However, as Miklusak explains, to hasten the introduction of generic versions of costly drugs to the market, the Act allows generic drug manufacturers to "carve out" patent indications from their labels in certain instances. This label carve-out is known as a "skinny label." Though useful, skinny labels can be risky. Miklusak discusses a number of recent decisions from the United States Court of Appeals for the Federal Circuit addressing the use of skinny labels.

In our third article, Nate Hoeschen with Shaw Keller LLP provides a helpful, informative update on the District Court of Delaware's latest procedures and practices relating to patent litigation. As state and federal litigators know well, courts employ various rules, procedures and guidelines, some written and some not, that attorneys must follow throughout the litigation process. Failing to follow those rules and procedures can result in the rejection of a filing, the loss of a claim or defense, or even sanctions. Hoeschen begins with a review of sealed filings and redactions. After that primer, Hoeschen pivots to claim construction issues in the District Court, providing helpful guidance concerning the number of claim terms the judges will construe during a *Markman* hearing and when the judges will consider whether a claim term is indefinite.

And with that, we leave our readers to it. Enjoy this edition. And, as always, thank you for your readership.

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Kelly Grosshuesch is an associate in Goodwin's IP Litigation group. She joined the firm in 2020. Grosshuesch focuses her practice on intellectual property litigation, with experience in multiple areas of technology, including electronics and pharmaceuticals.

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Mary LaFleur Miklusak is counsel at Crowell & Moring LLP. Miklusak graduated from Indiana University in 2016 with a bachelor's degree in chemistry and then graduated from Chicago-Kent College of Law in 2019. Her practice focuses on patent litigation in a variety of fields, including pharmaceuticals, biotechnology and medical devices. Miklusak has specific technical experience with biochemistry, biopharma, drug development and research, inorganic chemistry, and organic chemistry and synthesis. She has been a practicing Hatch-Waxman litigator since 2018 and has represented numerous clients in district courts and at the Federal Circuit. Many of those cases involved allegations of induced infringement due to skinny labels, including the *H. Lundbeck A/S v. Lupin Ltd.* case discussed in her article.

Emily Rapalino, a partner in Goodwin's IP Litigation group, is a member of the firm's Life Sciences Disputes group and focuses her litigation practice on patent litigation, particularly in the areas of pharmaceuticals and biotechnology. She holds undergraduate and graduate degrees in biology and combines scientific technical knowledge and expertise with litigation strategy to advise clients on a broad range of pre-litigation and litigation matters in district court and before the Patent Trial and Appeal Board.

Emily Rapalino and
Kelly Grosshuesch

A Changing Landscape

Recent Litigation Regarding Obviousness-Type Double Patenting

Recent case law and other developments have changed the landscape for obviousness-type double patenting (ODP) inquiries and present new considerations for patent owners and patent challengers.

I. What Is ODP?

The doctrine of ODP requires a patent examiner to reject a claim as invalid, or a later district court to hold a claim invalid, when the patent claims subject matter "that [is] not patentably distinct from the claims in a commonly owned earlier patent." [1]

In essence, "obviousness-type double patenting is intended to prevent a situation in which a patent expires and the public is nevertheless barred from practicing obvious modifications of the invention claimed in that patent because the inventor holds another later-expiring patent with claims for obvious modifications of the invention."[2]

ODP thus prevents a patentee from claiming an obvious variant of an invention claimed in an earlier reference patent without filing a terminal disclaimer over the reference patent.

II. What Qualifies as an ODP Reference Patent?

To qualify as a proper ODP reference, the reference patent must be an "earlier patent" than the challenged patent. What qualifies as an "earlier patent," however, has been the subject of much debate and recent litigation.

A. Meaning of 'Earlier Patent'

Prior to the Uruguay Round Agreements Act of 1994 (URAA), a patent's term was measured from its issue date.[3] Therefore, in analyzing ODP pre-URAA, courts looked at the issue date of a patent to determine if it was an available reference.[4] The URAA changed how patent terms were calculated — defining a patent's term as 20 years from the patent's effective filing date.[5]

Post-URAA, the Federal Circuit has held a patent's issue date is no longer relevant for ODP, holding that looking to issue date alone post-URAA would allow for "significant gamesmanship during prosecution."[6] The Federal Circuit instead looked to the expiration date to hold an earlier-filed, earlier-expiring, but later-issued patent was an available ODP reference to challenge a later-filed, later-expiring, but earlier-issued patent.[7]

B. Later-Filed, Earlier-Expiring Reference Patents

Recent case law has further clarified whether a reference patent is considered to be filed "earlier" for ODP purposes.

The Federal Circuit considered the effect of patent-term adjustment (PTA) on patent expiry dates in ODP analyses in *In re Cellect LLC*.[8] In *Cellect*, the challenged patents, all members of the same family, had each been granted PTA and, therefore, had different expiration dates.[9] The ODP reference patent was also a member of the same family, but had not been granted PTA and therefore expired before the other, challenged, patents in its family.[10] The Federal Circuit held "[t]he expiration date used for an [ODP] analysis where a patent has received PTA is the expiration date after the PTA[11] has been added."[12] The court also reiterated that the patent expiry date in an ODP analysis where a patent has been granted a patent-term extension (PTE) is the expiration date before the PTE is added.[13]

Courts have since split in how to interpret the Federal Circuit's decision in *Cellect*. Indeed, the Federal Circuit's decision was interpreted differently by at least two judges in the District of Delaware.

In *Acadia Pharms. Inc. v. Aurobin-*

do Pharma Ltd., Judge Williams held a later-filed but earlier-expiring patent could not serve as an ODP reference to challenge an earlier-filed patent.[14] *Acadia* addressed whether a later-filed, later-issued, but earlier-expiring divisional patent could serve as an ODP reference against its parent patent.[15] Judge Williams found the divisional could not be used as an ODP reference to invalidate its parent, holding "references must be earlier-filed to be available as a reference."[16]

Judge Williams reasoned, "if a later-filed patent is used as a reference, the logic and purpose of [ODP] is flipped on its head," as instead of "preventing a patent owner from unjustifiably extending the term of a patent, [ODP] would operate to cut off a patent term that would have been valid but for a later-filed patent."[17] Further, Judge Williams noted the *Cellect* decision had no bearing on the question at issue in *Acadia*, because "the court [in *Cellect*] did not independently consider whether the reference patents were available."[18]

Just a few months earlier, in *Allergan USA, Inc. v. MSN Labs. Private Ltd.*, the district court, relying on *Cellect*, found a patent invalid for ODP where the reference patents and challenged patent were part of the same family and had the same priority date.[19] The reference patents were filed after and issued after the challenged patent.[20] But, due to the challenged patent's PTA, the later-filed, later-issued reference patents expired before the earlier-filed challenged patent.[21] The district court found the challenged patent invalid for ODP based on the reference patents, holding "[t]he 'first-filed, first-issued' distinction is immaterial," but rather "[w]hen analyzing ODP, a court compares patent expiration dates."[22] The district court further held "*Cellect* recognizes no exception to the rule it announced," and ODP "should not [b]e influenced by equitable concerns."[23]

On appeal, however, the Federal Circuit reversed the holding in *Allergan* and clarified the scope of its holding in *Cellect*.[24] In its decision, the Federal Circuit explained that *Cellect* does not address, let alone resolve, any variation of the question presented here — namely, under what circumstances can a claim properly serve as an ODP reference — and therefore has little to say on the precise issue before us.[25]

The Federal Circuit then held that because the reference patents were filed after the challenged patent, they were not available as ODP references, reasoning that holding otherwise would "run afoul of the fundamental purposes of ODP" and further would "effectively abrogate the benefit Congress intended to bestow on patentees when codifying PTA."[26] The Federal Circuit's decision made clear that a patent must still be earlier-filed to be an available ODP reference and that *Cellect's* holding is narrow. Patent owners therefore need not rush to file terminal disclaimers for *later-filed* patents in patent families with PTA, and patent challengers should avoid bringing later-filed, earlier-expiring patents as ODP references.

III. Proposed Changes to Terminal Disclaimer Rules

Another development that impacts ODP law is the withdrawal of a proposed rule regarding terminal disclaimers.

In May 2024, the United States Patent and Trademark Office (USPTO) proposed a change to the rules governing terminal disclaimers, whereby all terminal disclaimers would need to include an agreement that the terminally disclaimed patent will only be enforceable if it is not tied to, and has never been tied directly or indirectly to, a patent by one or more terminal disclaimers in which any claim has been held unpatentable or invalid.[27] That is, if a patent is terminally disclaimed to another patent that has been found unpatentable or invalid, the terminally disclaimed patent is also unenforceable.

The USPTO explained that "[t]his action is being taken to prevent multiple patents directed to obvious variants of an invention from potentially deterring competition and to promote innovation and competition."[28] In other words, this is an effort by the USPTO to address "patent thickets" that, in their view, stymie competition and innovation. The comment period on the proposed rule closed July 7, 2024 with a total of 352 comments.[29] Many of the comments critical of the proposed rule noted that it is inconsistent with the policy of assessing patentability on a claim-by-claim basis and would "result in manifest unfairness in having claims in a granted patent rendered invalid due to a finding of invalidity of another claim in a different albeit related patent without consideration of the claims on their own merits."[30]

In December 2024, the USPTO withdrew its proposed rule, noting that it received "more than 300 comments from a variety of stakeholders, including commenters both supporting and opposing the proposal" and explaining that due to resource constraints, USPTO decided not to move forward with the proposed rule at this time.[31]

IV. Takeaways

The Federal Circuit has significantly clarified the application of ODP to post-URAA patents in the last few years. Patent challengers should keep in mind that while issue date is no longer relevant to the "earlier patent" eligibility inquiry, a reference patent must still be filed before the challenged patent to be an available ODP reference.

In addition, when possible, patent owners should opt to file applications as divisionals in response to an examiner's restriction requirement, to make use of the ODP safe harbor, protecting against an ODP challenge for divisional applications.[32]

Although the USPTO withdrew its proposed rule that would have changed the rules governing terminal disclaimers, we will need to wait and see whether there is any future activity from the USPTO to further its stated goal of promoting innovation by preventing multiple patents on obvious variants from deterring competition. What direction the USPTO takes will depend, at least to some extent, on the next director appointed by the new administration. ◆

NOTES

1. *See Eli Lilly and Co. v. Barr Lab'ys, Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001).
2. *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1214 (Fed. Cir. 2014).
3. *See Allergan USA, Inc. v. MSN Labs. Private Ltd.*, 111 F.4th 1358, 1367 (Fed. Cir. 2024).
4. *Id.* at 1215.
5. *Id.*
6. *Id.* at 1214.
7. *Id.* at 1216-17.
8. 81 F.4th 1216 (Fed. Cir. 2023).
9. *In re Cellect LLC*, 81 F.4th at 1219-20 (Fed. Cir. 2023).
10. *Id.*
11. When both a terminal disclaimer and PTA apply, the extension is applied after the end date is modified by the terminal disclaimer. *See Novartis AG v. Ezra Ventures LLC*, 909 F3d. 1367, 1373-74 (Fed. Cir. 2018).
12. *In re Cellect LLC*, 81 F.4th at 1229-30.
13. *Id.* at 1226.
14. 706 F. Supp. 3d, 477 (D. Del. 2023).
15. *Acadia Pharms. Inc. v. Aurobindo Pharma Ltd.*, 706 F. Supp. 3d, 477, 487 (D. Del. 2023).
16. *Id.* at 487-88.
17. *Id.*
18. *Id.*
19. 694 F. Supp. 3d 511, 539-40 (D. Del. 2023), *rev'd*, 111 F.4th 1358 (Fed. Cir. 2024).
20. *Id.*
21. *Id.*
22. *Id.* at 540.
23. *Id.*
24. *See Allergan USA, Inc. v. MSN Labs. Private Ltd.*, 111 F.4th 1358 (Fed. Cir. 2024).
25. *Id.* at 1368-69.
26. *Id.* at 1371.
27. Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting, 89 FR 40439 (May 10, 2024).
28. *Id.*
29. *Id.*
30. Comment by AbbVie, Docket No. PTO-P-2024-0003, July 9, 2024.
31. Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting; Withdrawal, 89 FR 96153 (December 4, 2024).
32. 35 U.S.C. § 121.

Mary LaFleur Miklusak

Cutting Through Patent Thickets

The State of the Skinny Label

High prescription drug prices have been, and continue to be, a concern for many Americans. This issue will remain a contentious topic of debate in the U.S. healthcare system for years to come, absent real legislative changes. While generic alternatives to brand-name drugs can help lower prescription drug prices, bringing those generic alternatives to market is increasingly difficult.

Background

Brand-name drug manufacturers often seek and obtain a web of overlapping patents that protect different aspects of a prescription drug. Over the past few years, brand manufacturers filed more than 500 patent applications on five of their top 10 selling drugs in the United States after the initial patents on those drugs were approved by the U.S. Food and Drug Administration (FDA).[1] This practice has been referred to as creating a "patent thicket." Two aspects often covered by these patent thickets are subsequent FDA-approved indications or new patient populations, which typically result in an extension of the

Typically, the FDA requires a generic manufacturer's drug label to be identical to the brand drug's label, including the approved indications. This requirement encourages patent thickets.

brand's monopoly beyond the expiration of the original patents covering the active pharmaceutical ingredient in the product.

Typically, the FDA requires a generic manufacturer's drug label to be identical to the brand drug's label, including the approved indications. This requirement encourages patent thickets. To hasten the introduction of generic drugs to the market, Congress created an exception to this label requirement in the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), commonly referred to as the Hatch-Waxman Act, thereby allowing generic manufacturers to "carve out" patented indications from their labels, leaving only unpatented indications in the generic's label.[2] This carved-out label is sometimes called a "skinny label."

The Hatch-Waxman Act sets forth the statutory basis for the skinny label in 21 U.S.C. § 355(j)(2)(A)(viii). A generic applicant may seek FDA approval for an intended use that is not covered by an unexpired patent by submitting (i) "a statement that the [unexpired] method of use patent does not claim" the use for which the generic applicant is seeking FDA approval, and (ii) a drug label proposed to the FDA for approval that removes (or "carves out") those indications that are still covered by the brand's unexpired patent(s), thereby leaving only the unpatented indications in the generic's proposed label. If the generic's skinny label is approved by the FDA, then the generic drug product is only approved for the unpatented uses.

Skinny labels thus allow gener-

ic drugs to enter the market more quickly by avoiding patents that cover only new indications and the time-consuming, costly litigation associated with challenging those patents. Unsurprisingly, generic manufacturers have embraced the power of the skinny label in response to ever-growing patent thickets. One recent study reported that "[w]e identified a total of 56 brand-name drugs first available as generics from 2015 to 2019 that were susceptible to skinny labeling, 24 (43%) of which had generic formulations with skinny labels."[3]

Skinny labeling has provided some success in increasing competition in the healthcare system and providing earlier access to less expensive generic drugs. By one assessment, skinny-label generics saved Medicare nearly $15 billion between 2015 and 2020.[4] But the power of the skinny label is not limitless.

Leading Precedent

Brand manufacturers have advocated fiercely against the use of skinny labels, presumably to protect the brands' monopoly on successful drugs. In numerous patent infringement suits, brands have alleged indirect infringement by generic manufacturers' skinny labels.

Indirect infringement comes in two forms: induced infringement and contributory infringement. To prove induced infringement under 35 U.S.C. § 271(b), brands must "present evidence of active steps taken [by generics] to encourage direct infringement" by others.[5] For example, a brand may allege that a generic label induces infringement by encouraging physicians to prescribe the generic drug for a patented use, even though the generic label does not expressly include that patented use. To prove contributory infringement under 35 U.S.C. § 271(c), brands must prove that the generic drug product is "especially made or especially adapted for use in an infringement . . . and [is] not . . . suitable for substantial noninfringing use." For example, a brand may assert that a generic is liable for contributory infringement because patients prescribed the generic drug will use it in a directly infringing manner, notwithstanding the skinny label.

Takeaways From Favorable Cases for Brand Manufacturers

In the last few years, brands have secured important victories in federal courts, thereby limiting the effectiveness of skinny labels.

In one leading case, *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*,[6] the accused patent was directed to the administration of carvedilol to treat congestive heart failure (CHF). The proposed label of the generic (Teva) initially carved out the CHF indication but was later required by the FDA to include that indication. Teva also issued press releases and marketing materials referring to its drug as a "generic version" of and "equivalent" to the brand-name drug. The U.S. Court of Appeals for the Federal Circuit found that the proposed label, containing the CHF indication, combined with Teva's public statements and marketing materials, were sufficient evidence for the jury to conclude that Teva induced infringement by encouraging physicians to practice the CHF indication.

Similar evidence was considered in *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*[7] There, the accused patents were generally directed to administration of icosapent ethyl to reduce cardiovascular risk. The proposed label carved out the indication to reduce cardiovascular risk. However, Hikma, the generic manufacturer, issued press releases referring to its drug as a "generic version" of the brand-name drug and marketed its product on its website as an equivalent to the brand-name drug. The Federal Circuit held that Amarin's allegations regarding Hikma's proposed label, combined with Hikma's public statements and marketing materials, were sufficient to plausibly state a claim for induced infringement and remanded the case to the district court for further proceedings.

The *GSK* and *Amarin* cases illustrate an important lesson for generic manufacturers. Representations made by generics should be carefully considered, including statements throughout the entirety of the label and statements outside the label, such as in the generic's marketing materials and websites. Those statements, individually and collectively, can be used by brands as evidence of indirect infringement.

In another leading case, *Salix Pharms., Ltd. v. Norwich Pharms. Inc.*,[8] the accused patents were generally directed to the administration of rifaximin to treat irritable bowel syndrome and hepatic encephalopathy (HE). The HE patents were found valid and infringed. One month after final judgment, the generic defendant submitted a proposed skinny label carving out the HE indication and requested relief from judgment under Rule 60 of the Federal Rules of Civil Procedure.

The district court denied the motion to modify the final judgment, holding that the generic defendant "fully litigated the merits of its noninfringement and invalidity case, lost, and now seeks a way around the final judgment through Rule 60(b)" and that consideration of the amended skinny label would be inequitable and inappropriate. On appeal, the Federal Circuit held that, under Rule 60(b), the district court "may" reconsider

its finding of infringement in light of the generic's skinny label but was not required to do so. A petition for a writ of *certiorari* to the United States Supreme Court was filed but later denied.

The *Salix* case illustrates another important lesson — the timing of submission of the skinny label may impact a court's willingness to consider (or reconsider) findings of infringement. It is arguably in a generic's best interest to submit a skinny label as early as possible to ensure a fulsome non-infringement case can be developed and presented to the court. If a generic submits a skinny label late in the case, brands may have a stronger argument that the existence of a skinny label alone is not sufficient to support a finding of non-infringement (or reverse a finding of infringement) and it may be too late for a generic to develop a case proving the contrary.

Takeaways From Favorable Cases for Generic Manufacturers

Though *GSK*, *Amarin* and *Salix* tell a cautionary tale, skinny labels remain viable provided generics proceed carefully, as the following cases illustrate.

In *Grunenthal GmbH v. Alkem Labs. Ltd.*,[9] the accused patent was directed to the administration of tapentadol to treat "polyneuropathic pain." The generic defendant's proposed label included an indication for "moderate to severe chronic pain" and carved out an indication for "neuropathic pain associated with diabetic peripheral neuropathy (DPN)." The Federal Circuit held that, although the generic's proposed label's broad indication for "moderate to severe chronic pain" included polyneuropathic pain, the label did not actively encourage treating that particular use and did not inevitably lead to treating that particular use.

Further, the proposed label's broad indication encompassed substantial non-infringing uses.

In another leading case, *HZNP Meds. LLC v. Actavis Labs. UT, Inc.*,[10] the accused patent required that all three method steps be performed: (i) apply a topical diclofenac medication to the knee, (ii) wait for the knee to dry, and (iii) apply a topical product to the knee after drying. The generic defendant's proposed label warned "wait until area is completely dry before covering with clothing or [a topical product]." The Federal Circuit found the generic's proposed label's warning operated in an "if/then" matter. It did not require performance of the third method step but merely permitted it, and thus was insufficient to encourage infringement.

In a third leading case, *H. Lundbeck A/S v. Lupin Ltd.*,[11] one of the accused patents was directed to administration of vortioxetine to treat major depressive disorder (MDD) in patients who previously used other drugs but had to cease using those drugs due to sexual dysfunction, and another accused patent was directed to the administration of vortioxetine to treat cognitive impairment. The generic defendant's proposed label "carved out" those two methods of use and only

covered the treatment of MDD generally. The Federal Circuit held that brand manufacturers cannot rely on a label directed to a use covered by expired patents (i.e., MDD generally) to demonstrate the required specific intent to encourage infringement of new patents covering additional, narrower uses (i.e., the "carved out" uses). Further, the proposed label's broad indication encompassed substantial non-infringing uses.

Grunenthal, *HZNP* and *Lundbeck* demonstrate the importance of considering the breadth of the label's indications and the patent's claim language. Brand manufacturers should be cautious in drafting indications and claim language so broadly that they encompass indications covered by older, expiring patents, which can be carved out. Brands should also consider avoiding permissive language in the label. Non-permissive language may increase the likelihood of finding an infringing use, thereby making a complete carve-out more difficult. By drafting indications and claim language more narrowly, brands arguably make it more difficult for generics to create label carve-outs, even narrow ones, or to argue substantial non-infringing uses exist.

Conclusion

The skinny label will likely remain a powerful tool for generic manufacturers in the years to come, despite brand manufacturers' success in limiting the use of skinny labels. The skinny label is but one measure to aid in reducing the ever-growing cost of healthcare in the United States. However, absent additional legislation offering more protection for the use of skinny labels, brand manufacturers could further limit the viability of skinny labels through careful drafting of indications and patent claims. ◆

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NOTES

1. Banks, Pharmaceutical Care Management Association's (PCMA) Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights (PTO-P-2022-0025) (Jan. 31, 2023).
2. 21 U.S.C. § 355(j)(2)(A)(viii).
3. Walsh, et al., *Frequency of First Generic Drug Approvals with "Skinny Labels" in the United States*, 181(7) JAMA INTERN. MED. 995-97 (Mar. 29, 2021).
4. Joszt, *Competition from Skinny-Label Generics Saved Medicare Nearly $15B Over 5 Years*, AJMC (Apr. 29, 2024).
5. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, Case No. 2018-1976 (Fed. Cir. 2021), Case No. 14-cv-00878 (D. Del.) (Stark, J.).
6. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, Case No. 2018-1976 (Fed. Cir. 2021), Case No. 14-cv-00878 (D. Del.) (Stark, J.).
7. *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, Case No. 2023-1169 (Fed. Cir. 2024), Case No. 20-cv-01630 (D. Del.) (Andrews, J.).
8. *Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, Case No. 2022-2153 (Fed. Cir. 2024), Case No. 20-cv-00430 (D. Del.) (Andrews, J.).
9. *Grunenthal GmbH v. Alkem Labs. Ltd.*, Case No. 2017-1153 (Fed. Cir. 2019), Case No. 13-cv-04507 (D.N.J.) (Cecchi, J.).
10. *HZNP Meds. LLC v. Actavis Labs. UT, Inc.*, Case No. 2017-2149 (Fed. Cir. 2019), Case No. 14-cv-07992 (D.N.J.) (Hillman, J.).
11. *H. Lundbeck A/S v. Lupin Ltd.*, Case No. 2022-1194 (Fed. Cir. 2023), Case No. 18-cv-00088 (D. Del.) (Stark, J.).

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Demystifying the Procedures of the Federal Bench

One of the hallmarks of Delaware federal practice is the bar's intimate familiarity with the practices and preferences of our relatively small number of judges. In the last 10 years, however, our federal bench has seen 100% turnover, with Judges Andrews, Robinson, Sleet and Stark passing the torch to Judges Connolly, Hall, Noreika and Williams. (Judge Andrews, however, maintains significant caseload despite taking senior status.)

Many of the new judges' preferences and procedures can be gleaned from the standing orders and model schedules listed on the District of Delaware's website. Some issues, however, only become apparent through concerted research into specific questions. This article will identify a few such issues and hopefully save you a bit of trouble and heartache.

Redactions

One common area where our judges' practices differ is redacted filings. Unlike some other districts, the Delaware CM/ECF guidelines have long provided a straightforward method for filing sealed and redacted documents. Typically, the protective order allows or requires designated material to be filed under seal, and a redacted

version is due within seven days. Easy-peasy.

The tides began turning in 2019, when the Third Circuit issued its opinion in *In re Avandia Marketing*, which clarified the standard for sealing filings and reiterated the "strong presumption of openness" for court documents.[1] In the time since, Delaware judges have taken subtly different approaches to ensuring that redacted and sealed filings comply with *Avandia* and its progeny.

Judge Connolly Closely Examines Dockets With Suspicious Redactions

Only a few months after the *Avandia* decision, Judge Connolly raised the issue of over-redaction *sua sponte* in *Genentech, Inc. v. Amgen Inc.*[2] The inciting incident there was the sealed filing and subsequent redaction of a stipulation extending a deadline. Because such a stipulation usually consists of no more than an anodyne recitation of vacations, unrelated hearings and technical difficulties, it's not terribly surprising that filing it under seal raised eyebrows. As it happens, the defendant's e-discovery vendor had been offline due to a ransomware attack, which they apparently wished to keep under wraps. So, all reference to the attack was removed in the redacted version.

We will never know what might have occurred if this was the only issue in the case, because this redaction caused Judge Connolly to look further into the parties' recent sealed filings, which revealed that they had also redacted exhibits that consisted of transcripts of public hearings held in open court. Added together, this caused Chief Judge Connolly to issue an order requiring the parties to submit all of their sealed filings in the case to a special master — Widener Law School's First Amendment expert Rod Smolla — "to address whether the sealed and redacted filings in these cases comply with Supreme Court and Third Circuit law and the Federal Rules of Civil Procedure." Ultimately, the parties had to resubmit several thousand pages of documents with reduced or eliminated redactions as well

The number of terms the court is willing to construe at *Markman* has long been a contentious issue in the district. Opinions on the subject go back at least as far as 2009, when Chief Judge Sleet issued an order limiting all patent actions to no more than 10 disputed terms per patent.

as significant briefing and declarations justifying all of the remaining redactions. All in all, it amounted to quite a bit of work.

In the years since *Avandia* and *Genentech*, Judge Connolly has issued similar *sua sponte* orders in other cases addressing over-redaction by the parties. As in *Genentech*, these orders usually followed the parties sealing a routine filing that would normally be filed publicly. Rule 7.1 corporate disclosure statements are currently the most common culprits.[3]

Judge Andrews Rejects Filings That Redact Entire Exhibits

Judge Andrews has drawn a brighter line. Beginning in fall of 2019, he began issuing orders rejecting filings that redacted exhibits in their entirety, with a docket entry like:

> The redacted filing . . . is REJECTED because **parts of it are redacted in their entirety**. Absent a compelling reason, **supported by a statement under oath by a party, redactions in their entirety are impermissible**; redactions must be done so as to redact the least possible amount of the materials submitted. Failure to make a good faith attempt at such redactions may result in sanctions, the most common of which would be simply unsealing the entire filing. **Redacting in its entirety a document that contains publicly available materials is *prima facie* evidence of bad faith.**[4]

Very few parties have attempted to save their redactions *ex post facto* by filing a motion to seal and the vast majority have failed, even when accompanied by the requested declaration.[5]

Judge Hall has recently begun issuing identical orders in cases assigned to her, although only a few such orders have been issued at the time of this writing.[6]

Other Judges Have Not Rejected Filings *Sua Sponte*

It appears that neither Judge Williams nor Judge Noreika has yet rejected a proposed redacted filing *sua sponte*.

Markman Terms

The number of terms the court is willing to construe at *Markman* has long been a contentious issue in the district. Opinions on the subject go back at least as far as 2009, when Chief Judge Sleet issued an order limiting all patent actions to no more than 10 disputed terms per patent.[7] Given the court's wide discretion to manage its docket in this regard, the judges have taken various approaches to limiting the number of terms construed.

Judge Noreika Strictly Limits Cases to 10 Terms

Shortly after taking the bench, Judge Noreika began issuing her "standard" order on *Markman* proceedings in cases assigned to her. This order, which was issued after *Markman* briefing had been completed, required the parties to meet and confer and "attempt to reach agreement on

any remaining disputed terms where possible and on an attempt to focus the dispute over the remaining terms in light of the joint claim construction brief." To encourage a more substantive meet and confer, the order also required the parties to "file a letter with the Court identifying by name each individual who participated in the meet and confer, when and how that meet and confer occurred and how long it lasted."[8]

In the middle of 2020, however — following an instance where the parties submitted more than 30 terms for construction — Judge Noreika took a different tack and began simply ordering parties to reduce the number of terms to 10. This limit has been universally applied, even in cases where the parties only modestly exceeded the 10-term limit.

Other Judges May Order Reduction, But Do Not Enforce Universal Limit

Similar to Judge Noreika's early practice, Judge Connolly and Judge Hall both require the parties to meet and confer in order to reduce the number of claims to be construed. This requirement appears in both judges' form scheduling orders. (Neither Judge Andrews nor Judge Williams include this requirement.)

None of the other judges have taken the further step of strictly limiting the number of terms. They have all, however, taken steps to rein in the most egregious cases. Judge Andrews, for instance, canceled a *Markman* hearing where the parties proposed construing 16 terms.[9] Similarly, when parties before Judge Connolly submitted a claim chart with 15 terms, he required them to reduce to no more than five terms each.[10] Judge Hall issued a similar order requiring a reduction to 10 terms when the parties proposed 19 for construction.[11] Judge Williams did the same when he received briefing on 24 terms.[12]

In sum, litigants should propose no more than 10 terms for construction before Judge Noreika and keep within spitting distance of that number before the remaining judges lest they face a reduction or the cancellation of the claim construction proceedings.

Indefiniteness at *Markman*

Another common *Markman* stumbling block is the briefing of indefiniteness during claim construction, which some of our judges permit and others forbid. (Judge Sleet considered it "an end-run around the court's scheduling order regarding the filing

of dispositive motions."[13]) Given the limit on the number of terms and the limited space for briefing, it's important to know which is which.

Judge Connolly Will Not Consider Indefiniteness at *Markman*

Judge Connolly has explicitly stated that he will not hear argument on indefiniteness at *Markman*.[14] At least twice, however, he has ordered early summary judgment briefing and a hearing on the issue when it appeared ripe during discussion at the *Markman* hearing.[15] Usually, though, the parties just note in their joint claim construction chart that they understand Judge Connolly does not consider indefiniteness at this stage, and reserve their rights to raise it at summary judgment.

Judges Noreika, Williams and Andrews Consider Indefiniteness at *Markman*

Each has considered indefiniteness numerous times and found at least one term indefinite at the *Markman* stage. Nevertheless, it is frequently reserved for summary judgment.

Judge Hall Will Consider Indefiniteness in Most Circumstances

Judge Hall has likewise decided indefiniteness issues numerous times at *Markman*. In cases to be tried to the bench, however, she has canceled hearings where the only dispute related to indefiniteness.[16] ◆

NOTES

1. *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019).
2. *Genentech, Inc. v. Amgen Inc.*, C.A. No. 17-1407-CFC, 2020 U.S. Dist. LEXIS 54775, at *7 (D. Del. Mar. 30, 2020).
3. *See, e.g., WSOU Investments, LLC v. SalesForce, Inc.*, C.A. No. 23-mc-27-CFC (D. Del. Feb. 23, 2023) (Oral Order).
4. *Conformis, Inc. v. Medacta USA, Inc.*, C.A. No. 19-1528-RGA, D.I. 185 (D. Del. Aug. 16, 2021) (Oral Order) (bold added).
5. *See ViaTech Techs., Inc. v. Adobe Inc.*, C.A. No. 20-358-RGA, D.I. 164 (D. Del. Sept. 23, 2022) (Oral Order).
6. *Otsuka Pharmaceutical Co., Ltd. et al. v. Mylan Laboratories Limited*, C.A. No. 22-464-JLH (D. Del. Mar. 12, 2024).
7. *Grape Tech. Grp., Inc. v. Jingle Networks, Inc.*, C.A. No. 08-408-GMS (D. Del. Oct. 20, 2009).
8. *See Virentem Ventures, LLC v. YouTube, LLC*, C.A. No. 18-917-MN, D.I. 171 at 4 FN2 (D. Del. Dec. 13, 2019).
9. *Applied Biokinetics LLC v. KT Health, LLC*, C.A. No. 22-638-RGA-JLH (D. Del. June 2, 2023).
10. *MG FreeSites Ltd v. ScorpCast, LLC*, C.A. No. 20-1012-CFC-JLH, D.I. 120 (D. Del. Feb. 18, 2022).
11. *Robocast, Inc. v. Netflix, Inc.*, C.A. No. 22-305-JLH, D.I. 242 (D. Del. Apr. 5, 2024) (Oral Order).
12. *HID Global Corporation v. Vector Flow, Inc.*, C.A. No. 21-1769-GBW, D.I. 138 (D. Del. Jan. 3, 2023) (Oral Order).
13. *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, No. 02-148-GMS, 2003 WL 124149, at *1 n.1 (D. Del. Jan. 13, 2003).
14. *See Volterra Semiconductor LLC v. Monolithic Power Systems, Inc.*, C.A. No. 19-2240-CFC-SRF, at 18:16-24 (D. Del. May 12, *2021*) (transcript).
15. *HIP, Inc. v. Hormel Foods Corp.*, C.A. No 18-615-CFC, D.I. 115 (D. Del. Apr. 22, 2019).
16. *Ingenus Pharms., LLC v. Accord Healthcare, Inc.*, C.A. No. 23-377-JLH, D.I. 37 (D. Del. Feb. 28, 2024) (Oral Order).

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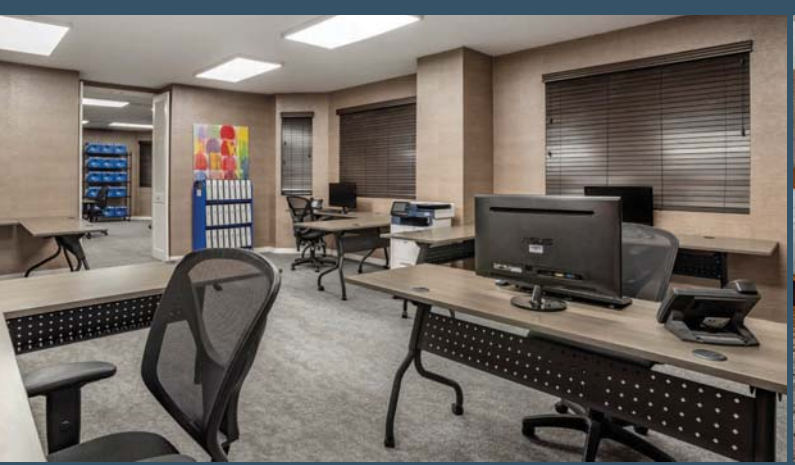

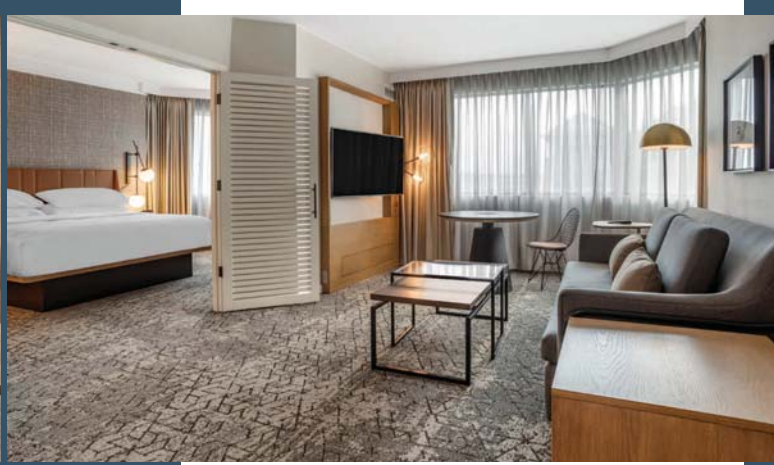

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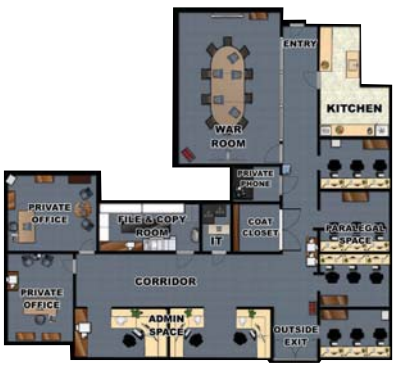

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