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## The Death of the Genus Claim

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**THE DEATH OF THE GENUS CLAIM\***

*Dmitry Karshedt\*\**, *Mark A. Lemley\*\*\** & *Sean B. Seymore\*\*\*\**

ABSTRACT

The central feature of patent law in the chemical, biotechnology, and pharmaceutical industries is the genus claim — a patent claim that covers not just one specific chemical but a group of related chemicals. Genus claims are everywhere, and any patent lawyer will tell you they are critical to effective patent protection.

But as we show in this Article, the law has changed dramatically in the last thirty years, to the point where it is nearly impossible to maintain a valid genus claim. Courts almost always hold them invalid, either at trial or on appeal. Remarkably, courts do this without acknowledging that they've fundamentally changed an important area of law. More remarkably, it's not clear that patent lawyers and patent owners have noticed this shift. Invention, investment, patenting, and patent litigation continue much as they have before, but the genus patents that are thought to be the basis of this activity generally end up invalid.

We document this surprising shift in the law. We explain why we think it represents both bad law and bad policy. We also discuss why it hasn't seemed to matter to the relevant stakeholders, and what that fact says about the relevance of patent doctrine more generally.

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## I. INTRODUCTION

The most fundamental rule of patent law is that what the patentee owns is defined not by what she actually built or described, but by the patent claim — the legal definition of the invention drafted by her patent lawyer. Lawyers draft those claims as broadly as the law appears to allow. In particular, lawyers are careful not to limit the claim to a particular thing or “species,” even though that’s normally what the patentee actually built or conceived. Instead, patent lawyers lead with a “genus claim” — a broad claim that covers a group of structurally related products that incorporate the basic advance of the patented invention.<sup>1</sup> They do this to make sure that no one can copy their basic idea by making a small change to it to avoid infringing the patent.

Nowhere is this more true than in the chemical arts.<sup>2</sup> Pharmaceutical, biotechnology, and chemical companies rely more heavily on the patent system than do other industries.<sup>3</sup> Some scholars have concluded that the system works well in those industries but not others.<sup>4</sup> And those industries make heavy use of genus claims. A chemical patent, for instance, might include one or more claims to a particular compound — a species — but almost invariably it starts with a claim to a group of chemicals — the genus. It bears emphasizing that these genus claims are thought important to prevent competitors from capturing the benefit of an invention while avoiding infringement by making a minor change to one aspect of it. The U.S. Patent and Trademark Office (“USPTO”) grants broad genus claims as a matter of course in the chemical industries.<sup>5</sup> And those industries regularly attempt to enforce such claims in court.<sup>6</sup>

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1. See *In re Kalm*, 378 F.2d 959, 963 (C.C.P.A. 1967) (“When one speaks of a ‘genus’ in the chemical arts, one ordinarily speaks of a group of compounds closely related both in structure and properties.”). The U.S. Court of Customs and Patent Appeals (“CCPA”) was a five-judge Article III appellate court on the same level as the U.S. Courts of Appeals. The Federal Courts Improvement Act of 1982 abolished the CCPA. See Pub. L. No. 97-164, § 122, 96 Stat. 25, 36 (1982) (codified as amended in scattered sections of 28 U.S.C.). Soon after its creation, the U.S. Court of Appeals for the Federal Circuit adopted CCPA decisional law as binding precedent. See *South Corp. v. United States*, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc).

2. In this Article, we sometimes use the terms “chemical,” “pharmaceutical,” and “biotechnological” somewhat interchangeably to refer to industries focused on the development and use of new molecules and compounds. We view the term “chemical” as encompassing both biotechnology as well as more traditional organic and inorganic chemistry. Our Article is focused on those fields, and our argument does not extend to non-chemical industries. At various points, we do distinguish rules that apply differently to certain subfields, such as specialized rules for certain biotechnological inventions. We make clear when we are doing so.

3. See *infra* Part IV.

4. See *infra* Part IV.

5. See Sean B. Seymore, *Patenting the Unexplained*, 96 WASH. U. L. REV. 707, 729 (2019) (noting that genus claims are “ubiquitous” in these industries).

6. See *infra* Part III.

When they do, however, something surprising happens. As we show in this Article, courts almost invariably hold genus claims invalid under 35 U.S.C. § 112(a) for failure to enable or describe the full scope of the claimed invention. In the last thirty years, the U.S. Court of Appeals for the Federal Circuit (the court with exclusive jurisdiction over patent appeals) has struck down claim after claim on the theory that whatever the patentee has done to justify a broad claim to a group of chemicals, it isn't enough. It regularly reverses district courts that have found adequate support for the genus claim.<sup>7</sup> Not once but three times has the Federal Circuit thrown out a jury verdict of over a billion dollars because it concluded the genus claims at issue were invalid.<sup>8</sup> In fact, we find only a small minority of Federal Circuit decisions that have upheld a genus claim in the chemical industry in the past thirty years, and each of those has some idiosyncrasy that explains why it bucks the trend.<sup>9</sup> That trend, as reflected in dozens of cases, is unmistakable: biotechnology, chemical, and pharmaceutical genus claims lose in court.

It's unclear whether patent lawyers and scholars have discovered this shift in the jurisprudence. Patent lawyers continue to draft genus claims, the USPTO grants them, and patent owners attempt to enforce them in court. Lawyers and scholars sometimes lament individual decisions they disagree with. But the whole system seems to proceed merrily along on the assumption that the role of genus claims in supporting these industries is secure. It isn't.

We argue that the death of genus claims is the result of some subtle but important doctrinal shifts, and that those changes reflect a misunderstanding of the purposes that patent law is supposed to serve. The Federal Circuit has abandoned a practical focus on whether others could make and use the claimed invention, instead favoring a fruitless search for the exact boundaries of that invention. This "full-scope possession" theory invalidates a genus claim unless the patentee can show exactly which species within the genus will work as intended — an impossible task for a genus of any nontrivial size.<sup>10</sup> Given the importance of patents to the biotechnology, chemical, and pharmaceutical industries, and the importance of genus claims to those patents, we find the death of genus claims in modern courts troubling. If the doctrine continues down this path, it may threaten innovation in an important sector of the economy.

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7. *See infra* Part III.

8. *See* *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1332 (Fed. Cir. 2021); *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 271 F. Supp. 3d 694, 696 (D. Del. 2017) (considering motion to enhance the jury's \$2.54 billion damages award), *patent invalidated by* 941 F.3d 1149, 1165 (Fed. Cir. 2019); *Centocor Ortho Biotech, Inc. v. Abbott Lab'ys*, 636 F.3d 1341, 1341–42 (Fed. Cir. 2011).

9. *See infra* Section III.C.

10. *See infra* Section III.C.

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