The United States Law Week

INSIGHT: The Scope of a Sextillion—How Courts Misapply Law of Enablement to Life Sciences

By Kristina Caggiano Kelly and Paul A. Calvo

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A Federal Circuit ruling in 2019 is the latest in the trend toward courts heightening the enablement requirement for life science patents, Sterne, Kessler, Goldstein & Fox attorneys write. They say the trend could ultimately have catastrophic effects on innovation in the pharmaceutical and small molecule therapeutic industries.

A troubling trend is emerging in patent litigation involving 35 U.S.C. § 112 law.

Courts are seeming to require an ever-increasing and unnecessary amount of disclosure to support patent claims to a broad genus of compounds in the biological and chemical fields.

This trend threatens to disrupt the delicate balance between rewarding innovation and ensuring that patentees provide prompt and adequate disclosure for future practitioners.

For instance, the Federal Circuit in *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.* (Fed. Cir. 2019), treated as dispositive the number of effective candidates compared to the size of the genus, and the fact that the accused product was not exemplified. "[B]ecause the claim allows for nearly any substituent to be attached at any position (other than 2'-up), a person of ordinary skill in the art would understand that “billions and billions” of compounds literally meet the structural limitations of the claim,” the court said.

Other cases like *Enzo Life Scis. Inc. v. Roche Molecular Sys Inc.* (Fed. Cir. 2019) and *Wyeth & Cordis Corp. v. Abbott Labs.* (Fed. Cir. 2013), similarly compare the number of possible embodiments within a genus claim to the number of examples provided in the specification as part of a de facto quantitative analysis. The elevation of that comparison to an essentially dispositive inquiry underestimates routine practices in the biological and chemical arts, loses sight of the purpose of the enablement requirement, and misapprehends the reality of very large numbers.

Understanding Large Genus Claims

The prospect of a genus containing millions or even billions of possible embodiments may seem insurmountable in the abstract. But navigating a genus containing millions of possible embodiments with thousands of effective candidates is actually very common and routinely managed, even in the so-called “unpredictable arts” like pharmaceuticals.

Routine testing can narrow the field to classes, subclasses, and even optimal individual embodiments in “relatively short order.” That a skilled artisan could practice any given embodiment in relatively short order after reading the patent specification is the true measure of enablement, regardless of how many possible embodiments the artisan has to choose from.

The court in *Idenix* used the analogy that determining which of the large number of 2′ methyl-up nucleosides fell into the smaller group of compounds that effectively treat HCV left a skilled artisan to search for needles in a haystack. That analogy, although commonly used in criticizing patent disclosures, does not really capture what a skilled artisan actually does when practicing an invention. The purpose of this article is to provide a more apt analogy that illustrates how large genus claims are enabled and practiced.

By way of illustration, artist Martin Silfen creates paintings of geometric designs using 16 different panels that can be put together to create, among other possible configurations, a 4 x 4 image. Any panel can occupy any of the 16 positions in the 4 x 4 grid.

Within each position, each panel has 4 possible orientations, i.e., rotated 0°, 90°, 180°, or 270°. Because each panel is slightly different, every arrangement of panels results in a different overall image. Some images may be dramatically different from one another, but many are only slight variations. A photograph of one such painting appears below (reproduced with permission from artist).

Martin Silfen

Although there are a large number of different possible arrangements, nothing more than the information already provided above is needed to enable a person of ordinary skill in the art of hanging paintings (almost any homeowner with a flair for interior decorating) to practice the full scope of a claim directed to a piece of décor comprising these 16 panels.

Indeed, disclosing one species (the image depicted above) and explaining how the panels can be arranged (16 positions, four rotational orientations), clearly describes, enables, and demonstrates possession of the genus of images that results from all possible arrangements. I have a Silfen painting in my house, and the process of selecting and mounting the *perfect* arrangement of panels took about an hour.

It is important to note that interior design, like biology and chemistry, is an "unpredictable" art. Some arrangements of panels will be aesthetically pleasing, and others will not. There is no real way to know which embodiments will look good until the panels are viewed in a given arrangement. But such iterative trial and error does not undermine the conclusion that the full scope of the claim is enabled, because a skilled artisan could make *any* of the possible embodiments with no further instruction.

What Is 'Full Scope' Enablement?

Perhaps the most enlightening part of the analogy comes from the math underlying the actual number of arrangements in Silfen's paintings. Recall that the court in *Idenix* treated as dispositive the fact that there were "billions and billions" of potential molecules that fell within the scope of the genus, while the specification only disclosed a handful of examples.

For the simple 4 x 4 painting above, the number of potential arrangements is calculated: 16! x 4^16. That equals over 89 sextillion unique images. If a skilled artisan generated 1 arrangement per second, it would take 20,000 times the age of the known universe to try them all. Even if every panel was identical, with four rotational orientations, the total number of unique images would still be 4^16 = 4,294,967,296.

But this seemingly daunting number of embodiments should not give pause to a properly focused an enablement inquiry. A skilled artisan does not need to spend 20,000 times the age of the known universe trying every embodiment in order to practice the "full scope" of the claim. Rather, one must simply test a few dozen arrangements using routine techniques and select one that works. Similarly, in *Idenix*, "a jury could have found that the synthesis of an individual compound was largely routine."

The true measure of enablement is thus whether a skilled artisan could practice *any* embodiment without undue experimentation—not whether he can actually make *every* embodiment. The former provides the proper incentive balance to reward innovation, while the latter allows our difficulty conceptualizing very large numbers to cloud the analysis.

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