

Does an Obvious Species Obviate the Entire Claimed Genus?

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In the patent world, a genus claim encompassing even a single prior art species is unpatentable. [See *In re Slayter*](#), 276 F.2d 408, 411 (C.C.P.A. 1960), and [Eli Lilly & Co. v. Barr Labs](#), 251 F.3d 955, 971 (Fed. Cir. 2001).

A very basic illustration of this concept is a claim to a method of rewarding a child comprising providing that child with a piece of candy. Here, "candy" is a generic term encompassing a variety of "species" (e.g. chocolate bars, licorice, jelly beans, etc.) and therefore the method is practiced by using any form of candy as the reward. Now assume that there is a prior art article that described rewarding a child by providing them with a chocolate bar. As a chocolate bar is a species of the genus candy, its use in the same method occurring in the prior art means the claim is anticipated. One can drop the claim entirely or, redefine the genus to exclude chocolate bars and/or claim any other species, so long as there is sufficient support in the patent specification.

But what if the prior art article used a chocolate cupcake instead? And what if the chocolate cupcake was used to induce the child to remain quiet and not expressly as a reward as claimed? A chocolate bar and a chocolate cupcake both contain chocolate, but it is not candy per se. Knowing that one could obtain temporary respite from an active child by providing a chocolate cupcake would probably make it obvious to use a chocolate bar as a reward instead. So that species, using a chocolate bar, is obvious. But would it also render obvious using licorice, lollipops or cotton candy as rewards? On the one hand, these are all candies, like a chocolate bar. But, on the other hand, none contains chocolate, and all are, arguably, more unlike a chocolate cupcake than a chocolate bar would be.

Back to patent law—cupcakes are not candy and thus not a species of the claimed genus candy. But the use of cupcakes to induce children to be quiet at least renders obvious one species (chocolate bars) within the claimed genus of candy as a reward. It might, or might not, render obvious using other species of candy such as cotton candy as the reward. But what about the generic claim encompassing non-chocolate species of candy in addition to the admittedly obvious chocolate bar species? Does the fact that the prior art renders a species of a genus obvious mean that the genus is obvious as well?

The U.S. Patent and Trademark Office and the U.S. Court of Appeals for the Federal Circuit have both addressed this question, and their answers were a consistent yes. In [Ex parte Kubin](#), 2007 Pat. App. LEXIS 13, at *10 (Bd. Pat. App. & Interferences May 31, 2007), *aff'd*, 561 F.3d 1351, 1361 (Fed. Cir. 2009), the Board of Patent Appeals and Interferences unequivocally stated "[a] single, obvious species within a claimed genus renders the claimed genus unpatentable under §103." In *Kubin* a known method of obtaining a particular nucleic acid molecule, and the molecule it produced, rendered obvious a genus of other nucleic acid molecules in a claimed genus. This was true even though the prior art nucleic acid molecule was not itself within the claimed genus; it merely, allegedly, rendered obvious at least one nucleic acid species claimed. Interestingly, on the flipside, the Board noted that the description of a single species may not support the patentability of a claimed genus under 35 USC §112. *Id.*

Similarly, in [Ex parte John W. Allen](#), 2012 Pat. App. Lexis 3753 (Bd. Pat. App. & Interferences Jun. 25, 2012), a claim directed to a genus of isolated polynucleotides that encode a protein with a special sequence was held to be obvious even though just one of the claimed polynucleotide sequences in the genus was considered obvious. The applicant argued that the obviousness analysis was a "double" extrapolation as one would have to first find the sequence of the protein which was not in the art (extrapolation 1) and then extrapolate back to the polynucleotide sequence (extrapolation 2) just to get to a species that allegedly rendered a claimed species obvious. *Id.* at *30-32. The Board, however, affirmed. *Id.*

[Aventis Pharma Deutschland GmbH v. Lupin, Ltd.](#), 499 F.3d 1293 (Fed. Cir. 2007), reached the same conclusion. Many drugs produced synthetically are actually a mixture of nearly identical isomers all differing by the directions of certain bound atoms or groups. See *generally* Lien Ai Nguyen et al., Chiral Drugs: An Overview, 2 Int'l J. Biomedical Sci. 85, 85-100 (2006). Sometimes this is not clinically significant. But in other cases, one of the isomers is "effective" and another not so much. For example, albuterol is used for asthma and has two isomers often labeled "R" and "S." Only the R isomer is effective. The other is inactive and may be responsible for certain side effects. A product composed of only the R isomer was marketed, but at 5 times the cost of albuterol. *Id.* An entire body of law has developed around this particular issue.

In *Aventis*, the claim in question encompassed a specific "effective" isomer, known as Ramipril, and a small group of related compounds, all in "substantially pure [] form"—meaning with no other isomers mixed in. *Aventis*, 499 F.3d at 1298. Because the claim covered more than one molecule, it was generic. The art, however, disclosed mixtures of isomers that included Ramipril. Because the claimed genus recited only "pure" isomers, it did not encompass the art. But the Federal Circuit found that this genus, and a dependent claim to substantially pure Ramipril alone, was obvious.

The court stated, "here, a claimed composition is a purified form of a mixture that existed in the prior art ... if it is known that some desirable property of a mixture derives in whole or in part from a particular one of its components, or if the prior art would provide a person of ordinary skill in the art with reason to believe that this is so, the purified compound is *prima facie* obvious over the mixture even without an explicit teaching that the ingredient should be concentrated or purified." *Id.* at 1294. The court stated: "In sum, we hold that *claims 1 and 2 of the '722 patent, which cover the 5(S) stereoisomer of ramipril in a composition substantially free of other isomers, are invalid under 35 U.S.C. §103 over the SCH 31925*

mixture, the '944 patent, and the enalapril references in the prior art." *Id.* at 1303 (emphasis added); see also [Ex parte Allen](#), 2012 Pat App. LEXIS 3753 (Bd. Pat. App. & Interferences June 25, 2012).

So evaluating the obviousness of a genus claim in view of an unclaimed species rendering a claimed species obvious closely parallels the novelty analysis where the prior art species is actually within the genus. And while what constitutes prior art may depend upon whether a first-to-invent or a first-to-file patent or application is involved, it should be of no consequence to this analysis. This particular rubric enables a streamlined obviousness challenge to a genus based on an obvious species. Going back to our original example, the entire genus candy can be obvious from the prior art use of the chocolate cupcake because it renders obvious the use of a chocolate bar.

As always, one can argue a lack of prima facie obviousness between the closest claimed species and the art or the importance of so called secondary considerations such as long felt and unsatisfied need, copying, unexpected and superior results and commercial success to support patentability. Such arguments are not available if the claim lacks novelty. But, under either theory, it is likely that claims will have to be dropped and/or amended when the challenged claim is a genus encompassing an obvious species. And prudence dictates that claims amended to overcome a novelty challenge be evaluated to see if they would withstand an obviousness challenge based on the closest remaining species.

More than ever, this suggests searching before filing to identify the best prior art and providing support for alternate claiming strategies in the specification. This will require more resources up front but could pay dividends long after in terms of more robust and defensible patent protection by not leaving the broader genus completely vulnerable to attack should a species within it be held obvious. •

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