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CAN UTILITY DOCTRINE RESURRECT THE GENUS CLAIM?

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I. INTRODUCTION

This Comment offers a comparative law perspective on Professor Karshtedt’s article “The Death of the Genus Claim,” co-authored with Mark A. Lemley & Sean B. Seymore,1 which argues that current U.S. law is overly restrictive in its approach to genus claims. While I agree that the current state of U.S. law is unsatisfactory, I argue that their proposal, that a genus claim should be valid if the person having ordinary skill in the art (“PHOSITA”) can identify some species within it that will work without undue effort, does not adequately guard against overbroad claims. I argue that the root of the problem lies in the reliance of U.S. law on enablement doctrine to police claim scope. Canadian and European law rely instead on utility doctrine, which requires the patentee to establish that a reasonable prediction can be made at the time of filing that the invention will work across the full scope of the claim. U.S. utility doctrine is functionally very similar to Canadian and European utility doctrine, and I conclude by suggesting that U.S. utility doctrine could readily be repurposed to police claim scope. Doing so would address my objections to the proposal by Karshtedt et al., and at the same time would address their main concerns with current U.S. enablement doctrine.

This Comment is based on a series of email exchanges I had with Professor Karshtedt discussing an earlier draft of this paper. Given the

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brevity of this comment, I will assume familiarity with the relevant U.S. doctrine. I will focus my critique on the normative discussion by Karshtedt et al. of what they feel the law should be. I will not address whether their description of either current or prior law is correct.

II. THE DEATH OF THE GENUS CLAIM

Whether a claim is enabled in U.S. law turns on a holistic consideration of the Wands factors, which include the breadth of the claim and the amount of experimentation necessary to practice the claimed invention.\(^2\) Karshtedt et al. argue that genus claims are now very difficult to sustain as a result of “some subtle but important doctrinal shifts” in the Federal Circuit jurisprudence.\(^3\) With respect to enablement doctrine, they argue that at one time the law was such that “the inventor of a genus can claim that genus as long as there’s enough information that the PHOSITA can identify some species within it that will work and determine how to make those species without too much effort.”\(^4\) In their view, that is all that should be necessary to satisfy the enablement requirement: “the PHOSITA doesn’t need to find every species that works to make and use the invention. It is enough to get hold of just one, or perhaps a few, structural analogs within the genus that accomplish the claimed or intended purpose” without undue effort.\(^5\) They argue that enablement doctrine has now shifted so that the claims are not enabled if “routine but undue” experimentation is required, with the result that a genus claim will be invalidated “unless the patentee can show exactly which species within the genus will work as intended.”\(^6\) It is no longer enough to identify some working species without undue effort; the PHOSITA must be able to identify all working species within the genus without undue effort.\(^7\) Given the unpredictability of the chemical and pharmaceutical arts, satisfying this new full-scope enablement requirement is effectively impossible, hence the death of the

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\(^2\) See In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988); see also Karshtedt et al., supra note 1, at 8–9.

\(^3\) Karshtedt et al., supra note 1, at 4.

\(^4\) Id. at 17. They also consider the emergence of the written description requirement to be an important shift which has also contributed to making it more difficult to claim a genus; see generally id. at 17–20, 25–46. I will ignore the written description requirement in the interest of space; the key point for my purposes is their assessment that under current U.S. law the PHOSITA must be able to identify all working species within the genus. My analysis does not turn on the doctrinal mechanism unpinning this result.

\(^5\) Id. at 30–31.

\(^6\) Id. at 4.

\(^7\) See id. at 35.
They argue that this shift in the law is misconceived and the law “should go back to the way it was.”

III. THE PUZZLE OF CLAIM 7

I begin with a simple example to challenge Karshtedt et al.’s thesis that it should be enough for the PHOSITA to be able to identify a few working species without undue effort.

Suppose P has synthesized a new small molecule compound, “viridimycin,” and has fully characterized it structurally. P carried out a routine plaque reduction assay in mouse cells against murine retroviruses and discovered viridimycin has an antiretroviral effect. P further carried out a routine test against HIV in the ATH8 cell line and discovered that viridimycin eradicates HIV \textit{in vitro}. This gives excellent grounds for believing that viridimycin will be therapeutically effective against HIV in humans. However, P has no idea why it is effective. P nonetheless expects that at least some analogues will also be effective, but because P does not know what the active moiety is, P has no idea which analogues will be effective. P files a patent application with Claim 1 to viridimycin; Claim 2 is to a set of analogues claimed by structure, defined by specifying a particular variable substituent; Claim 3 defines a different set of analogues, specifying a different variable substituent; and so on with Claims 4 through 10. P has no basis for thinking there is anything special about any of these substituents but is simply hoping that at least one of the claims will capture the key moiety. As it happens, P got lucky with Claim 7 and most of the compounds within that claim are effective against HIV. All the compounds of the other claims (except for viridimycin itself) do not work.

Claim 1 is clearly valid and Claims 2 through 10, excluding Claim 7, are clearly invalid. What about Claim 7?

The approach proposed by Karshtedt et al. suggests that Claim 7 is valid. So, in critiquing decisions focusing on the number of species within the genus as a reason to reject the claim, they say:

The genus is very large and it would take an impossible effort to identify all the species within its scope that work. But there’s no reason anyone needs to make that much effort (except that more and more Federal Circuit cases seem to require it). Anyone who wants to know if their chemical is within the scope of the claim can readily make that assessment: by hypothesis, the boundaries of the chemical genus are well-specified, and it doesn’t take much effort to

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8 See id. at 30, 57, 58, 62.
9 Id. at 5.
determine whether or not any particular chemical works for its intended purpose.\textsuperscript{10}

In my hypothetical, the boundaries of Claims 2 through 10, including Claim 7, are well-specified. Moreover, it doesn’t take much effort to determine whether any particular species is active against HIV—just a simple plaque reduction assay, which, if positive, can then be followed up with a cell line assay.

Similarly, in responding to the concern expressed by one court that synthesis of tens of thousands of candidate compounds would require undue effort, Karshtedt et al. say:

That does indeed sound like a lot of work. But why would the PHOSITA have to synthesize tens of thousands of candidates? Even if half or more of the species in the genus don’t work (and there was no evidence that this was actually the case in \textit{Wyeth}), on average (i.e., working at random) the PHOSITA might have to try two or three candidates before finding one that does.\textsuperscript{11}

Yes, the PHOSITA needs to find a species that works. But the PHOSITA doesn’t need to find every species that works to make and use the invention. It is enough to get hold of just one, or perhaps a few, structural analogs within the genus that accomplish the claimed or intended purpose.\textsuperscript{12}

Thus, their approach asks whether the PHOSITA can find a species that works without too much experimentation. This test is satisfied by Claim 7. Yes, the PHOSITA will run into a number of failures, but the number of experiments required before the PHOSITA finds a working compound will be modest. There are eight different classes of compounds, and most within Claim 7 will work. That means the PHOSITA will need only about 10 to 20 experiments before identifying the genus of Claim 7 as the key genus; most experiments thereafter will be successful.

This implies that Karshtedt et al. would say that Claim 7 should be valid. This result seems counterintuitive. Claims 2 through 10 were all just guesses; the only difference between them is that Claim 7 was a lucky guess. And as Karshtedt et al. say, “the patentee shouldn’t be permitted to lock up an entire new field of research if these teachings . . . generalize solely thanks to luck.”\textsuperscript{13} Claim 7 illustrates a tension between the idea that a lucky guess shouldn’t be patentable and their proposed test for enablement.

\textsuperscript{10} \textit{Id.} at 58.
\textsuperscript{11} \textit{Id.} at 30 (commenting on \textit{Wyeth} v. Abbott Lab’ys, 720 F.3d 1380 (Fed. Cir. 2013)).
\textsuperscript{12} \textit{Id.} at 31.
\textsuperscript{13} \textit{Id.} at 60. In our email exchange Professor Karshtedt called this example “provocative” and seemed to acknowledge its force but he did not expressly say that Claim 7 should be invalid.
The closest Karshtedt et al. come to addressing this issue is with a rule against what they refer to as “improper generalization,” which is the flip side of the “common property” exception to lack of enablement that emerged from *Incandescent Lamp.* As they describe it:

Following *Incandescent Lamp,* in the 1928 case *Corona Cord Tire Co. v. Dovan Chemical Corp.*, the Supreme Court invalidated a broad genus claim to a class of chemicals (guanidine derivatives) because the patentee hadn’t shown that there was “any general quality common to disubstituted guanidines which made them all effective” for use in the process of the invention. Here, too, there was evidence that a substantial number of the claimed embodiments didn’t work.

In a case of improper generalization, “the problem is that the patentee has defined a genus of things that don’t really have anything in common. The genus may well be small, but some species are not at all like the others given the purpose or nature of the invention, and just wouldn’t work.” In that case, “the patentee didn’t invent a genus because she didn’t actually identify a group of chemicals with a relevant property in common.”

The concept of improper generalization does not deal with the puzzle of Claim 7; the compounds of Claim 7 do have a relevant property in common. The problem with Claim 7 is not that the compounds do not share a common property; the problem is that the patentee did not know that at the time of filing.

Karshtedt et al. conclude their discussion of improper generalization by saying that “[a]s long as the technology is advanced enough that the PHOSITA can assess which species work and which ones don’t, she has the information needed to make and use the invention.” In my hypothetical, the PHOSITA can indeed assess which species within Claim 7 work and which ones do not. This confirms that the common property requirement does not address the puzzle of Claim 7.

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15 Karshtedt et al., supra note 1, at 12, citing *Incandescent Lamp,* supra note 14, at 472 (stating that if the patentees “had discovered in fibrous and textile substances a quality common to them all, or to them generally, as distinguishing them from other materials, such as minerals, etc., and such quality or characteristic adapted them peculiarly to incandescent conductors, such claim might not be too broad); *Corona Cord Tire Co. v. Dovan Chem. Corp.*, 276 U.S. 358, 385 (1928) (stating the patentee could not claim the broad genus because “[h]e makes no showing that there is any general quality common to [the claimed compounds] which made them all effective. . . . Claims for their exclusive use cannot therefore be sustained.)
16 Karshtedt et al., supra note 1, at 59.
17 Id. at 60.
18 Id.
IV. The Utility-Based Approach to Claim Scope

U.K. and Canadian law, as well as the case law of the European Patent Office (“EPO”), adopt an approach to overbreadth that is very different from U.S. law. Claim scope is controlled primarily by utility doctrine (known as “plausibility” in Europe) instead of enablement.

The purpose of the utility requirement is understood in the same way in the EPO, U.K., Canadian and U.S. law: it serves to prevent speculative claims which might allow the patentee to prematurely monopolize an area of research.19 When the doctrine is applied to a single compound, as in Brenner v. Manson, the question is whether enough is known about the potential usefulness of the compound at the time of filing to warrant a patent.20 The requirement that the information about utility be known at the time of filing is crucial to the function of the utility requirement. If utility could be established purely on the basis of post-filing evidence, “major pharmaceutical corporations could . . . patent whole stables of chemical compounds for all sorts of desirable but unrealized purposes in a shot-gun approach hoping that, as in a lottery, a certain percentage of compounds will serendipitously turn out to be useful for the purposes claimed.”21

All four jurisdictions all take the same approach to speculative claiming when the compound itself is claimed. The compound will normally have been synthesized and subjected to various tests to establish its properties. The question is whether the tests carried out on that compound at the time of filing are sufficient to establish the usefulness of the compound itself.22 EPO, Canadian, and U.K. law apply the same reasoning to control claim scope. When the inventor claims a genus of related compounds, the question is whether the tests carried out on the preferred compounds are sufficient to establish the utility of the untested

19 In U.S. law, see Brenner v. Manson, 383 U.S. 519, 534, 536 (1966), stating that a patent granted prematurely “may confer power to block off whole areas of scientific development, without compensating benefit to the public,” and famously noting that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion”; in Canadian law see AstraZeneca Canada Inc. v. Apotex Inc., 2017 SCC 36 at para. 56, stating that the purpose of the utility requirement is to “avoid granting patents prematurely, and thereby limiting potentially useful research and development by others,” and see also Apotex Inc. v. Wellcome Foundation Ltd., 2002 SCC 77 at paras. 37, 42, 45, 66, 69, 83, 84 [hereinafter Apotex v. Wellcome]; in EPO jurisprudence see T 0870/04 BDP1 Phosphatase / MAX-PLANK at paras. 21–22 and T 0898/05 Hematopoietic receptor / ZYMOSGENETICS at para. 7; and in U.K. law see Human Genome Sciences Inc v. Eli Lilly and Company, [2011] UKSC 51 at para. 91 (accepting the EPO jurisprudence), and paras. 102, 107 [hereinafter HGS v. Lilly].

20 Brenner, 383 U.S. at 534–35 (holding that a valid patent cannot be granted until the invention is developed to the point “where specific benefit exists in currently available form”).

21 Apotex v. Wellcome, supra note 19, at para. 80.

22 There is some jurisdictional variation as to whether utility must be established as of the priority date (in European law) or the filing date (in Canadian law). This does not affect the basic point.
compounds within the genus. Either way, the question is whether the inventor’s discoveries establish the usefulness of the claimed invention at the time of filing. The rationale is the same in either case: if the utility of the claimed compounds cannot be predicted then the patentee had not actually invented anything, but merely made a “lucky guess.” The result is that, for a genus claim to be valid, the PHOSITA must be able to make a reasonable prediction at the time of filing that most or all of the compounds within the genus will work.

Canadian law, which is based on pre-1977 U.K. law, provides a particularly straightforward framework. For a genus claim to be valid, it must be possible to make a “sound prediction” of utility across the full scope of the claim at the time of filing. This requires (1) a factual basis for the prediction; and (2) “an articulable and sound line of reasoning from which the desired result can be inferred from the factual basis.” In other words, at the time of filing, the patentee must have a theory of why the compound works, as well as a factual basis for believing that the theory is correct. The factual basis for predicting the utility of the untested members of the genus comprises the tests that were carried out on the preferred compounds, along with the common general knowledge. This means that the claim will be valid if there is a reasonable basis for extrapolating from the established utility of the preferred compounds to the likely utility of the untested members of the genus.

The EPO applies the European Patent Convention (“EPC”), which does not have a utility requirement as such, but instead requires that the invention be “susceptible of industrial application.” In consequence of the U.K.’s accession to the EPC, the utility requirement as such was removed from U.K. law in 1977 in favor of the requirement of industrial applicability. Nonetheless, a doctrinal requirement functionally equivalent to utility has emerged in the form of “plausibility.” The plausibility requirement originated in the EPO Board of Appeals as a direct response to over-broad claims, “in particular claims to whole classes of chemical compounds supported by a description which fails to show which

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23 Apotex v. Wellcome, supra note 19, at para. 69.
25 Apotex v. Wellcome, supra note 19, at para. 70; a third requirement is “proper disclosure.” There is an open question as to whether proper disclosure requires disclosure of the factual basis for the prediction in the specification itself. The answer to this question does not affect the argument of this Comment.
27 Id., art. 52, 57.
compounds can be expected to work.” The effect of the plausibility doctrine is that a genus claim is only valid in U.K. and EPO law if it is “possible to make a reasonable prediction the invention will work with substantially everything falling within the scope of the claim or, put another way, the assertion that the invention will work across the scope of the claim must be plausible or credible.” Importantly, this prediction must be possible at the time of filing. While plausibility doctrine originated to deal with genus claims, it is also used to address the Brenner v. Manson scenario when claiming a single compound at an early stage of development.

European plausibility doctrine is thus functionally equivalent to the Canadian utility requirement, whether applied to a single compound or to a genus claim. While European law requires a “‘plausible,” or “reasonably credible” prediction that the invention is useful, and Canadian law requires a “sound” prediction that the invention is useful, the key points in both are that (1) it must be possible to make a prediction that the invention will work across the full scope of the claim and (2) it must be possible to make this prediction at the time of filing. For convenience, I will refer to this as the “utility-based approach” to claim scope.

28 Warner-Lambert Company LLC v. Generics (UK) Ltd., [2018] UKSC 56 at para. 23 [hereinafter Warner-Lambert]. The seminal decision is T 939/92 Triazoles / AGREVO [1996] EPOR 171 [hereinafter AgrEvo], which concerned a genus claim to a group of chemicals for use as herbicides, in which the EPO Board of Appeal held at para. 2.6 that it was necessary to establish that “it would be credible that substantially all claimed compounds possessed [the desired herbicidal] activity.” While AgrEvo used the term “credible,” the term “plausible” was used synonymously in the subsequent EPO Decision T 1329/04 Factor-9 / JOHN HOPKINS [sic] at paras. 6, 11, and “plausible” or “plausibility” has become the accepted term. While now well-established, the concept of plausibility does not have a clear doctrinal home; it was originally developed in AgrEvo as an aspect of the inventive step requirement (see also Conconi Medsystems Inc. v. Angiotech Pharmaceuticals Inc., [2008] UKHL 49 at para. 37 and Idenix Pharmaceuticals Inc. v. Gilead Sciences Inc. & Ors, [2016] EWCA Civ 1089 at paras. 104–29, both discussing plausibility in the context of obviousness); it has also been considered to be an aspect of sufficiency, which corresponds to enablement in U.S. law (see Warner-Lambert, supra note 28, at para. 39); industrial applicability (see HGS v. Lilly, supra note 19, at para. 109); as well as an independent ground of invalidity (see Idenix Pharmaceuticals Inc. at para. 140). None of this affects the points that it is functionally the same as the Canadian utility requirement.


30 HGS v. Lilly, supra note 19, at para. 107 (summarizing the principles set out by the EPO Board of Appeal).

31 Apotex v. Wellcome, supra note 19, at para. 56.

32 There are of course differences of detail. For example, where Canadian law requires that the prediction of usefulness must be “sound”, European law requires only that it be “plausible,” suggesting a lower threshold in European law. See Apotex v. Wellcome, supra note 19, at para. 57; HGS v. Lilly, supra note 19, at para. 107. It is not clear whether this translates into a different threshold in practice.
The effect of the utility-based approach is that a valid genus claim must reflect a common quality or unifying principle, just as in U.S. law. But that is not enough; the patentee must know that principle at the time of filing. This provides an intuitively appealing explanation of what it means to “invent” a genus. A person who defines and claims a thousand different genuses has not really invented anything simply because one happens by chance to have a common quality across its scope. To invent a genus is to identify a class of compounds which one knows, or has a good basis for believing, have a common quality. It is the information about the common quality which is conveyed by the patentee that constitutes invention of the genus. A patentee who selects a genus that happens by luck to have a common quality has not conveyed any valuable information. The requirement that the patentee must be able to make a sound prediction of utility at the time of filing is what distinguishes an invention from a lucky guess. A claim to a single compound is invalid as speculative unless there is a reasonable basis at the time of filing for believing that it is useful. Similarly, a claim to a genus is invalid as speculative unless there is a reasonable basis at the time of filing for believing that the compounds of the genus are useful.

The utility-based approach easily resolves the puzzle of Claim 7: Claims 2 through 10 are all invalid because P did not have any basis for predicting that the compounds claimed in the genus would work across the full scope at the time of filing. That is just as true of Claim 7 as it is of any of the other claims 2 through 10. The compounds of Claim 7 did in fact work across the full scope, but the question on the utility-based approach is whether the applicant knew that at the time of filing—and the answer is no.

Recall that Karshtedt et al.’s main objection to current U.S. law of utility is that it gives the patentee the impossible task of identifying all useful species within the genus. The utility-based approach addresses that objection. In European law, all that is required is a “reasonable prediction” and “[i]f it is possible to make such a prediction then it cannot be said the claim is insufficient simply because the patentee has not demonstrated the invention works in every case.”

The utility-based approach is distinct from “how to make” enablement, which is referred to as “classical insufficiency” in U.K. law. It is not possible in this Comment to delve into exactly how Canadian and

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33 See Regeneron, supra note 29, at para. 100 (stating that if it is possible to make a reasonable prediction the invention will work across the scope of the claim “[t]he products and methods within the claim are then tied together by a unifying characteristic or a common principle”).

34 Id.

European law deal with “how to make” enablement and, in any event, I am not suggesting that the United States adopt Canadian or European law wholesale. I will simply point out that if utility is used to control claim scope, there is no difficulty in applying a more relaxed approach to enablement. In particular, the utility-based approach to claim scope can be combined with Karshtedt et al.’s approach to enablement. Claim 7 would still be invalid for lack of utility, and in my view, rightly so. However, suppose that P had identified the active moiety in viridimycin and so there was a good basis for predicting that everything in the scope of Claim 7 would work. Many of the species within the genus would not be useful, notwithstanding the common principle, because the activity of the active moiety can be affected by other structural elements. In that case, we could say that the genus claim would clear the utility hurdle, but validity would turn on how difficult it is to identify operable species within the genus. \(^{36}\) In effect, it would be possible to apply Karshtedt et al.’s test for enablement, requiring only that the PHOSITA is able to find some species to satisfy the enablement requirement without undue effort, in combination with utility doctrine which ensures that the patentee actually invented a genus with a common principle.

V. A Utility-Based Approach in U.S. Law?

I have argued that a utility-based approach is sound in principle and would help resolve many of the difficulties plaguing U.S. law of overbreadth. This is not to say that the EPO, U.K., or Canadian approach should be imported directly into U.S. law. I am not suggesting that any of these bodies of law is correct in every detail on this point. \(^{37}\) Rather, the effective use of the utility requirement to control claim scope in these jurisdictions suggests a parallel approach might be equally successful in U.S. law.

There is no evident doctrinal difficulty in adapting U.S. law of utility to the overbreadth context. As discussed above, when applied to the timing question regarding a single compound, U.S. law of utility is functionally equivalent to Canadian and European law, though of course with differences of detail. \(^{38}\) Professor Karshtedt and I had several lengthy email

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\(^{36}\) I should emphasize that this is not exactly the way either Canadian or European law operates.

\(^{37}\) For example, in principle a genus claim is invalid in Canadian law if even a single inoperative species is found within the genus; see *Apotex v. Wellcome*, supra note 19, at para. 56. This is arguably too strict a standard, though it tends not to have a major impact in practice because competitors, including generics, do not usually do research sufficient to establish that a species is inoperable and a mere prediction that some species are inoperable is not sufficient to invalidate the genus claim.

\(^{38}\) So, the threshold for establishing utility for a single compound is arguably lower in European law than in U.S. law. Compare *Brenner*, 383 U.S. with *HGS v. Lilly*, supra note 19.
exchanges trying to understand why U.S. utility law has not been used to police claim scope. We never arrived at a satisfactory answer. It is my great sorrow, both intellectually and personally, that I will not be able to continue to explore this question with him. Nonetheless, in our preliminary discussions we could identify no clear reason why U.S. utility doctrine could not be applied to claim scope in the same manner as Canadian and European utility doctrine. My sense is that an idiosyncratic path-dependent turn in litigation strategy led to the emergence of enablement rather than utility as the primary doctrine for policing claim scope. Perhaps it is not too late to revive utility doctrine as a means of controlling claim scope.