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Claim Construction

AbbVie Deutschland and Unknown Embodiments: Has the Written Description Requirement for Antibodies Gone Too Far?

By Jorge Goldstein

A recent decision from the Court of Appeals for the Federal Circuit, *AbbVie Deutschland GMBH & Co. v Janssen Biotech, Inc.*,[1] sheds serious doubt on the continued viability of a fundamental 1977 case, *In re Hogan*.[2] For more than 35 years, *Hogan* has been authority for the proposition that future embodiments, unknown at the filing date, cannot be used to hold claims invalid for lack of enablement. In the guise of an analysis under the written description requirement (WD), the Federal Circuit in *AbbVie Deutschland* seems to have sidestepped the *Hogan* rule and, examining the after-developed accused product, concluded that the patent holder in *AbbVie Deutschland* did not have written description of a genus of products that encompasses the accused product. The court then invalidated the claim.

It is the purpose of this paper to shed light on the apparent tension between *AbbVie Deutschland* and *Hogan*, and try and understand whether *Hogan* is doomed. I believe that unless the court clarifies the extent of the *AbbVie Deutschland* holding, generic claims in the promising field of therapeutic antibodies will be increasingly difficult to obtain and—worse—to defend against hindsight-driven challenges.

[1] 759 F.3d 1285 (Fed. Cir. 2014).
[2] 559 F.2d 595 (CCPA 1977).

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AbbVie Deutschland and Antibodies to Interleukin-12

In *AbbVie Deutschland*, the Federal Circuit held an antibody claim invalid for lack of written description since it encompassed a broad genus of embodiments, while the written description was limited to a smaller subgenus. At issue was claim 19 of U.S. Patent No. 6,914,128:

> A neutralizing isolated human antibody, or antigen-binding portion thereof that binds to human IL-12 and disassociates from human IL-12 with a k_{off} rate constant of $1\times10^{-2}s^{-1}$ or less, as determined by surface plasmon resonance.

The specification teaches that such antibodies are useful in treating psoriasis. The claim encompasses a large class of human antibodies against the (previously known) interleukin-12 (IL-12) antigen. The antibodies are defined by a functional limitation, their k_{off} rate.[3] The written description in the AbbVie patent, which includes about 300 human antibodies, is limited to those that have V_H3-class heavy chains and lambda-class light chains. The described antibodies share 90 percent or more amino acid sequence similarity in the variable regions.

[3] A low k_{off} rate is a function of high stickiness.

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Centocor marketed an antibody under the brand name Stelara® (''Stelara''), which in principle, literally infringed the claim. Stelara is a neutralizing human anti-IL-12 antibody, has the low k_{off} rate required by the claim and is used for treating psoriasis. Stelara, in contrast to the 300 described V_H3/lambda-type antibodies in the AbbVie patent, has V_H5-class heavy chains, and kappa-class light chains. Stelara only has about 50 percent sequence similarity in the variable regions to the antibodies described in the '128 patent.

The Federal Circuit bypassed enablement and based its holding squarely on lack of written description. In its analysis, the court looked at the accused antibody, finding nothing legally dubious in doing so. The Federal Circuit defined Stelara's class combination as V_H5/kappa, concluded that the claimed genus was not sufficiently described to encompass the accused class and invalidated the claim. Concluded the court (emphasis added):

> On review of the record, there is no evidence to show *any described antibody to be structurally similar to, and thus representative of, Stelara.* There is also no evidence to show whether one of skill in the art could make predictable changes to the described antibodies to arrive at other types of antibodies such as Stelara.

This condones the violation of a fundamental tenet in the law of future embodiments established by *Hogan*: it is not permissible to examine embodiments not known at the filing date and invalidate a claim based on lack of enablement for such embodiments. The appellate court failed to even mention *Hogan*. By sidestepping enablement, the court seems to be implying that the *Hogan* concepts are not relevant to written description.

The absence of any recognition of the principles of *Hogan* is disturbing. I will demonstrate that *Hogan* and its progeny—at least in the area of enablement—are still controlling authority. Then I will briefly review the law of written description (WD) for antibody claims, and finally I will address whether *Hogan* has any relevance to the *AbbVie Deutschland* situation.

Hogan and Its Progeny

Hogan had filed a first patent application in 1953 disclosing and claiming a ''solid homopolymer of 4-methyl-1-pentene.'' Years later, while still in prosecution, there appeared in the literature additional solid polymers of methyl-1-pentene, such as amorphous and elastomeric forms. It turned out with hindsight that Hogan had discovered the first of several such solid polymers, namely the crystalline one, and had (with good reason) called it ''solid.'' The U.S. Patent and Trademark Office (USPTO) rejected the claims premised on insufficient enabling disclosure under 35 U.S.C. § 112 for the term ''solid,'' in that it encompassed both the disclosed crystalline and the later discovered amorphous forms. The Court of Customs and Patent Appeals (CCPA) held that this was clear error, explaining that the later state of the art could not be used to test an earlier application for compliance with 35 U.S.C. § 112. The court reasoned:

> [T]o now say that appellants should have disclosed in 1953 the amorphous form which on this record did not exist until 1962, would be to impose an impossible burden on inventors and thus on the patent system.

The court reversed and remanded so that the USPTO could evaluate the claims under the state of the art at the time of the initial application. It added:

> The business of the PTO is patentability, not infringement. . . . The courts have consistently considered subsequently existing states of the art as raising questions of infringement, *but never of validity*.

The *Hogan* rules are clear: one cannot enable that which is not known on the filing date and, if the claims issue with terms which at the infringement date dominate embodiments unknown to exist at filing, the only questions left for the court are those of claim interpretation and application, ''but never of validity.'' The rules of *Hogan* have been applied consistently over the years. See for example:

- *United States Steel Corp. v. Phillips Petroleum Co.* (1989).[4] (Claim to crystalline polypropylene not invalid over later discovered high molecular weight and high viscosity crystalline polypropylene.)
- *Schering Corp. v. Amgen, Inc.* (2000).[5] (Claim to recombinant DNA molecules coding for interferon of the ''alpha-type'' was not invalidated for failure to enable or describe future invented consensus sequences.)
- *Amgen, Inc. v. Hoechst Marion Roussel* (2003).[6] (Claim to mature erythropoietin incorrectly believed to be of 166 amino acids at filing was not invalidated for lack of description or enablement of the later discovered and accused mature erythropoietin of 165 amino acids.)
- *Scripps Clinic & Research Foundation v. Genentech, Inc.* (1991)[7] and *Amgen v. HMR* (2003).[8] (Product claims not invalidated for failure to enable future methods of making the products.)
- *Chiron Corp. v. Genentech, Inc.* (2004).[9] (Claim to monoclonal antibodies did not lose its first filing date for failure to describe or enable later developed humanized or chimeric antibodies.)
- *Biogen Idec, Inc. & Genentech, Inc. v. Glaxo Smith Kline LLC et al* (2013) (''*BiogenIDEC*'').[10] (Claim to a method of treating leukemia with antibodies was not invalidated for failure to enable or describe the accused antibodies, which are against a later-discovered epitope.)

In all of these cases the court has strictly followed the *Hogan* edict, resolving questions of infringement by, ''but never of validity'' over, later-developed or -discovered products. The claims were not held invalid for lack of enablement or written description. In most instances, product claims were construed narrowly to encompass only the product that the inventor had described on the filing date. The claims survived, but in such narrow fashion that they were not literally infringed.

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[4] 865 F.2d 1247 (Fed. Cir. 1989).
[5] 222 F.3d 1347 (Fed. Cir. 2000).
[6] 314 F.3d 1313 (Fed. Cir. 2003).
[7] 927 F.2d 1565 (Fed. Cir. 1991).
[8] See note 6.
[9] 363 F.3d 1247 (Fed. Cir. 2004).
[10] 713 F.3d 1090 (Fed. Cir. 2013).

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The Plant Cases

There is another, contrasting, line of cases where the court has invalidated claims for failure to enable future embodiments. When, at the time of filing, those of skill in the art know of, or can reasonably foresee, embodiments but do not know how to enable them, the USPTO and the courts are justified in rejecting generic claims for lack of enablement.

The classic biotechnology examples in this context are a trio of plant transformation cases, one an *ex parte* appeal from the Board, *In re Goodman;*[11] and the other two arising during litigation, *Plant Genetic Sys. v. DeKalb Genetics Corp.*,[12] and *Monsanto Co. v. Syngenta Seeds, Inc.*[13] (''the Plant Cases''). The claims in these cases included the term ''plant cell.'' In theory, this term would be literally infringed by highly desirable monocotyledonous plants, such as transgenic maize, commercialized by the accused infringers. The specifications, however, were only enabled for dicotyledonous plant cells, such as transgenic tobacco. The Federal Circuit held that the desirable embodiments of monocot plant cells, while prophetically described at the filing date, were not then enabled by the patent specifications or by the state of the art. Because the terms were broad enough to include both monocots and dicots, the claims were held unpatentable/invalid under 35 USC § 112, first paragraph.

* * *

Given the two lines of cases on the *Hogan* issue, it is reasonable to ask why the court in *AbbVie Deutschland* held the claim invalid (as in the Plant Cases) rather than saving it and construing it narrowly to avoid a finding of literal infringement (as in *Schering v. Amgen, Amgen v. HMR, BiogenIDEC v. GSK*, or others). The court seemed to be unconcerned that the embodiments of additional not-described V_H and V_L chain combinations were not predictable at filing. The implicit reasoning of the court is that it is not a *Hogan*-type concern for the court that an applicant cannot describe embodiments at filing because the embodiments are *unpredictable*. *Hogan* immunity from invalidity seems to come up when *unforeseeable* embodiments are not enabled; the claims are then not invalidated. The Plant Cases suggest that when *foreseeable* embodiments are not enabled, *Hogan* immunity does not exist and the claims are invalidated. The court in *AbbVie Deutschland* implicitly held that the embodiments of different class combinations are foreseeable (even if unpredictable) and should have been described. In sum, *AbbVie Deutschland* is like the Plant Cases and *Hogan* immunity does not apply. The question is whether this is the correct conclusion. I don't think so.

Before we analyze this issue, however, let's briefly review the law of written description (WD) of antibodies and see if it (in contrast to the law of enablement) has addressed the issue of *Hogan*-type immunity (i.e., no need to describe future unknown embodiments). It has not.

[11] 11 F.3d 1046 (Fed. Cir. 1993).
[12] 315 F.3d 1335 (Fed. Cir. 2003).
[13] 503 F.3d 1352 (Fed. Cir. 2007)

The Written Description Requirement for Antibodies

A careful review of the case law on the written description of antibody claims reveals that the *Hogan* issue has not arisen. The 1997 case of *Regents v. Eli Lilly*[14] marked a fundamental re-statement on the law of written description in biotechnology. Before *Regents*, WD was rarely used to find generic claims invalid for failure to describe a representative number of embodiments. While *Regents* dealt with insulin genes, not antibodies, three cases after *Regents* have applied the *Regents* written description rules to therapeutic antibodies. None of these cases, however, addressed future unknown embodiments. The cases are:

- *Noelle v. Lederman*[15] (When the antigen is novel and well characterized, written description is sufficient for an antibody claimed broadly without immunological limitations.);
- *In re Alonso*[16] (When the antigen is novel but not characterized, written description is not sufficient for a claim to a method of treating neurofibrosarcoma by administering a monoclonal antibody, where only one antibody had been deposited, and one antibody was not representative of a genus.); and
- *Centocor Ortho Biotech, Inc. et al. v. Abbott Laboratories, et al.*[17] (When the antigen is known, written description is not sufficient for an antibody claimed with full human variable regions, and with immunological limitations, since human variable regions are unpredictably different than mouse ones, and the specification only described mouse ones).

Noelle and *Alonso* deal with novel antigens, which is not the case with *AbbVie Deutschland*. *Alonso* further holds that, in the absence of an identified or characterized novel antigen, one antibody will not support a broad claim, even a claim without immunological limitations.

Centocor Ortho is closer to, and has several facts in common with, *AbbVie Deutschland*, although it is readily distinguishable. The antigens in *Centocor Ortho* (TNF-α) and in *AbbVie Deutschland* (IL-12) were known; the claims in both cases were to human antibodies and included immunological limitations. Both cases thus present issues of representativeness: The *human* claim limitations in *Centocor Ortho* were unsupported solely by the described *mouse* regions; these were not representative of the human claims. And, while the specification in *AbbVie Deutschland* described many *human* antibodies, the court held that these were not representative of the whole human genus either; the described 300 human V_H3/lambda-type antibodies were not representative of the V_H5/kappa-type of the later-invented Stelara. In essence, the court in *AbbVie Deutschland* analogized the failure to describe the subgenus of V_H5/kappa-type human antibodies within the broad genus of claimed human antibodies, with the failure to describe *any* human antibodies to

[14] 119 F.3d 1559 (Fed. Cir. 1997).
[15] 355 F.3d 1343 (Fed. Cir. 2004).
[16] 545 F.3d 1015 (Fed. Cir. 2008).
[17] 636 F.3d 1341 (Fed. Cir. 2011).

support a claim to human antibodies in *Centocor Ortho*. These are different issues. In *Centocor Ortho*, human antibodies (while claimed) are not even described; in *AbbVie Deutschland*, 300 human antibodies are described, yet they are deemed not to be representative of the accused subgenus, including Stelara.

Despite the superficial fact similarities in *AbbVie Deutschland* and *Centocor Ortho*, neither directly addressed the *Hogan* issue: To what extent must one describe future unknown embodiments? Central to this issue is the answer to an epistemological question: What is an applicant charged as *knowing* on the filing date?

To Know or Not to Know on the Filing Date

In analogy to the Plant Cases, it is tempting to say that antibody classes such as those of the V_H5/kappa-type were known at the filing date. And, since they were not described, the result would be invalidity, not merely narrow claim construction. This is too simplistic an explanation. It stretches the concept of ''known at the filing date'' to the limit.

It certainly was known at the filing date that, generally, there are seven classes of variable antibody heavy chains, V_H1 to V_H7; and two classes of variable light chains, V_L lambda and V_L kappa. But it was not known that anti-IL-12 antibodies with V_H chains other than V_H3, and V_L chains other than lambda, could be made with a k_{off} rate below the claimed limits. Such knowledge was not reasonably foreseeable. The materials here are variable regions, which, by definition, are different from class to class, yet all bind to the IL-12 antigen and its epitopes. It is not possible ahead of time to know which ones will and which ones will not bind tightly. These are not embodiments that an applicant can predict at the filing date.

The court in *AbbVie Deutschland* seems to be implying that the knowledge in the art at filing was such that it placed an obligation on AbbVie to describe different V_H and V_L chains by structure, or else pay the steep price of invalidity. The court affirmed the logical rule that an applicant need not describe the *exact* later-developed accused antibody—an otherwise unworkable standard. However, the court consulted the later developed antibody and, with the benefit of hindsight, ruled that at least the patent holder should have described antibodies of Stelara's class combinations, the V_H5/kappa-type. Yet it is impossible for an applicant to know at filing that a competitor would make a V_H5/kappa-type antibody, and that she better describe general antibodies of that type. AbbVie did not know that, and could not know that. Yet, after *AbbVie Deutschland*, it would appear that if an applicant wishes to describe a group that is representative of the entire genus of antibody variable chain classes, she needs to describe representative examples of all possible embodiments, including all (or most) permutations of V_H and V_L classes.

The rule is actually harsher than that. Structurally describing the sequence of antigen-binding V_H or V_L antibody chains is not a simple matter of prophecy. While an actual reduction to practice is not necessary for a proper written description, see *Falkner v Inglis*,[18] prophetic description only works when the technology is predictable, not as unpredictable as that in *AbbVie Deutschland*. To describe a sample of antibodies that is representative of a broadly claimed genus, one must first reduce to practice and test an antibody from every class combination (or a representative number of class combinations). Only then can one describe a genus.

Super-Enablement Is Upon Us

After *AbbVie Deutschland*, it is not enough to simply *list* the possible class permutations (e.g., V_H1/lambda, V_H1/kappa; V_H2/lambda; V_H2/kappa, and so on) and affirm that there will be antibodies in each of those permutations. The *names* of possible (as of yet unknown) gene combinations are not sufficient written description. See *Regents v. Eli Lilly*. For gene sequences that are not previously known in the prior art, it is not enough to name them; they need to be sequenced, or at least deposited.[19] But since AbbVie did not reduce to practice a representative number of sequences within the whole genus, its description was *a priori* not achievable.

In analogy to *In re Wands*,[20] the holder in *AbbVie Deutschland* could demonstrate enablement by showing that it was routine experimentation to generate antibodies of different types, including the V_H5/kappa-type, and then screen for the ones that bind to IL-12 with the proper k_{off} rate. However, written description and enablement are different inquiries, as the Federal Circuit has pointed out several times. See, for example, *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*[21] *Wands*-type routine experimentation to enable the whole genus of anti-IL-12 antibodies is not the same as written description of the same genus.

In 2003, in a prescient concurring opinion in *Moba v. Diamond Automation*,[22] Judge Randall Rader called the pre-condition of actual reduction to practice before proper written description a ''super-enablement'' requirement. The judge warned of ''serious consequences for biotechnology.'' It seems clear that the WD requirement, when taken to the extremes of *AbbVie Deutschland*, has fulfilled Judge Rader's admonition. The super-enablement rule (that many if not most class permutations of antibodies need to be reduced to practice and described by sequence or deposit) places an onerous burden on patent applicants in immunology—especially in a first-to-file environment as the one we are in now.

I am forced to conclude that *Hogan* immunity to invalidity will not be available to broad antibody claims. The existence of different antibody classes is foreseeable, even though the precise V_H/V_L sequences that bind to IL-12 with a low k_{off} are unpredictable. While that is the law, I believe it is not the right result for immunologists.

Immunologists Are Not Organic Chemists

Since *Regents v. Eli Lilly*, the Federal Circuit has focused its analysis of written description of a genus

[18] 448 F.3d 1357 (Fed. Cir. 2006).

[19] See *Enzo Biochem, Inc. v Gen-Probe, Inc.*, 323 F. 3d 956 (Fed. Cir. 2002) (A biological deposit including a DNA sequence is sufficient to provide written description for the sequence. The Federal Circuit remanded to the lower court to decide if a collection of three such deposited DNAs may constitute sufficient written description of a genus.)

[20] 858 F.2d 731 (Fed. Cir. 1988).

[21] 598 F.3d 1336 (Fed. Cir. 2010).

[22] 325 F.3d 1306 (Fed. Cir. 2003).

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claim in biotechnology on the need to provide structure, in the form of genetic or protein sequences, or chemical structures of molecules such as agonists or antagonists. The court's firmness on the presence of structure is reminiscent of, and seems inspired by, chemical patent law.

The insistence on structure is understandable in organic chemistry. Very few if any product claims in organic chemistry are defined functionally. Without structure, terms like ''statin'' or ''Non-Steroidal Anti-Inflammatory Agent,'' generic as they are, carry no meaning to a pharmacologist, aside from function. There are large internal variations in the structures of statins or NSAIDs. Most chemical product claims are therefore defined either by structural formulas having a basic core with a large variety of attached functional groups, or alternatively, by lists of structurally defined compounds, representative of a genus (*Markush* claims). The latter is analogous to the situation in *AbbVie Deutschland*, a ''representativeness'' case. In the world of antibodies, however, things are different.

The word ''antibody'' already carries a distinct *structural* connotation. It is true that the therapeutic antibody in AbbVie's claim is defined partly by the k_{off} rate, which is functional. But the claim is not *entirely* functional; it is a combination of structure *and* function. There are in the claim two distinct molecular structures; one the antibody, the other the known antigen. All antibodies have two heavy chains, all of them have two light chains, and all of them assemble in the same three-dimensional manner. The antibodies claimed in AbbVie's patent, *a priori*, also share a common counter-molecule, their binding partner IL-12. In addition to these two structural limitations, the claim also has a distinct *functional* condition, that the antibody binds to IL-12 with a certain low k_{off} rate.

Antibodies within the class of IL-12 binders have more in common structurally with each other than statins or NSAIDs have with each other. Yes, in terms of class combinations, antibodies come in 14 different varieties. However, the classification of V_L and V_H chain sequences does not detract from the fundamental concept that antibodies to IL-12 are molecules with a common framework that bind to a common known antigen. To argue, like the court does, that an immunologist does not have possession of the genus of antibodies that bind to IL-12 with certain stickiness until she has detailed sequence information of the variable chains, is placing structure over function, a legal habit that comes directly from organic chemistry. The immunological reality is that it simply does not matter what the precise V_L and V_H sequences are. The right combinations of chains are selected by standard screening assays and, whatever their detailed sequence, all converge on the one structural limitation that matters in immunology: they all bind to the IL-12 antigen. The court should have seen the antibody claims in *AbbVie Deutschland* as a hybrid of well-understood structures (common antibody scaffolds and common well-characterized antigen) *and* function (binding to the antigen with certain stickiness). After all, the Court in *Noelle* recognized the descriptive role of a well-characterized counter-antigen in the description of antibodies that bind to it.

The fact that the sequence of the variable chains is unpredictable does not mean that immunologists invent narrowly and are precluded from obtaining broad claims. The unpredictability of variable chain sequences is not as relevant to the scope of a generic claim in immunology as is the potential unpredictability of an extensive *Markush* group of chemicals. The extensive *Markush* group may demonstrate too much structural variety for a given function, whereas, due to the converging method of V_H and V_L chain production, all of them necessarily bind the antigen, regardless of primary sequence.

It places an unrealistic burden on immunologists to expect that, in order to get generic patent protection, they need to provide an exhaustive list of structures that perform a function, especially to expect that the list should include representatives of future, yet-to-be-developed accused products. To invalidate for lack of WD their antibody claims because, with hindsight, they do not show representative variable chain sequences in an accused product is akin to invalidating a claim to the first inventor of a hinged door (supported by a bronze or steel hinge) because the inventor did not describe a later accused hinged door with a hinge made of a yet-to-be-invented titanium alloy. It simply does not matter what the material of the hinge is, the invention is a hinged door, regardless of the material.

Because ''super-enablement'' is a hybrid of written description *and* enablement, a hybrid approach should be sufficient for generic antibody claims to well-characterized antigens, with functional limitations, such as a k_{off} rate. The two types of claim limitations in antibody claims—structural and functional—show possession of a large class of (macro) molecules, which are basically identical to each other in their own structures and that of their binding partner, except for the sequences of their variable regions. It should be perfectly acceptable then to combine a detailed sequence description of multiple human variable chains (300 would certainly qualify) *together* with a well-described assay to screen for antibodies with the claimed k_{off} rate. The public notice role of the WD requirement under 35 USC § 112, 1st paragraph, delineating the scope of the claim, is fully met by a combination of structure *and* function, even without a list of sequences (or deposits) of V_L or V_H chains in 14 different permutations.[23]

[23] The parallel decision to *AbbVie Deutschland* in the Canadian courts in 2014 held that similar claims to those in the U.S. (also based functionally on k_{off} rates) were not invalid for lack of written description. See *AbbVie Corp. v Janssen*, 2014 FC 55, 168. This reflects a fundamental difference in the way Canadian and U.S. courts look at written description. The Canadian court was heavily influenced by what I might describe as ''the broader concept.'' The ''concept,'' which was embodied in Janssen's later Stelara patent, was that anti-IL-12 antibodies with low k_{off} rates could treat psoriasis. Said the court:

> AbbVie was the one who confirmed that if an antibody did bind to IL-12, then psoriasis could be treated . . . AbbVie was the first to confirm that, if you want to treat psoriasis, you must get an antibody that binds to IL-12 and it must have at least a certain level of stickiness and potency.

In contrast to the Federal Circuit, the Canadian court did not focus on future embodiments that were not yet known (such as multiple additional class permutations of variable heavy and light chains), and did not look at whether the specification described the class of the accused antibody. The Canadian court transcended the structural details of antibody chains and focused instead on the fundamental contribution of the patent holder: treating psoriasis with anti-IL-12 antibodies. That seems like the right result.

Conclusions

AbbVie Deutschland has brought us to the point where the burden on applicants who wish to obtain and sustain the validity of a broad antibody claim defined by immunological limitations and by a known antigen is to reduce to practice as many antibody classes as foreseeable. Only then can the applicants describe them (by sequence or deposit) and assert the full scope of the genus. And since, after *AbbVie Deutschland*, it should be possible to look at the accused product and conclude that, as of the filing date, the patent holder did not possess a class containing it, the claim can be more easily invalidated for lack of written description at infringement time. The words of *Hogan* should remind us of the challenge presented to the patent system by such an approach (emphases added):

> There cannot, *in an effective patent system*, be such a burden [describing at filing that which was not discovered until much later] placed on *the right to broad claims*. To restrict appellants to the crystalline form disclosed, under such circumstances, would be a poor way to stimulate invention, and particularly to encourage its early disclosure.

It is too late to rein in super-enablement. *Regents v. Eli Lilly* and its progeny control the law on WD in immunology. In the vernacular, the horse has left the barn. And, while I have concluded that *Hogan* immunity from invalidity was not available to AbbVie, it is not too late to remind the court of certain invariant concepts of *Hogan*.

Given the court's acknowledged evaluation of the structure of the accused antibody and, in consequence, the invalidation of the *AbbVie Deutschland* claim as not supported by description of even one antibody within the Stelara class, it is possible to see the case as ignoring *Hogan* so drastically that *Hogan* has been marginalized. *AbbVie Deutschland* has achieved by failure of written description what *Hogan* warned could not be done by failure of enablement. It has cast serious doubt on the right to broad claims in immunology.

To paraphrase *Hogan*: the right to broad claims cannot be so burdened. The super-enablement rule will not stimulate invention or encourage its early disclosure. The *AbbVie Deutschland* rule will favor well-established biopharma companies that have the resources for multiple parallel reductions to practice ahead of filing, at the expense of the small, often start-up, companies that provide so much of our biotech innovation. In the knowledge that the well-established companies will be able to compete well in the marketplace with one successfully protected antibody species, such companies care a lot less about their own generic protection than the possibly blocking generic protection obtained by their smaller brethren.[24]

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[24] Not surprisingly, Eli Lilly and Co. filed an *amicus* brief in *AbbVie Deutschland* and the court acknowledged it, as well as acknowledging a brief from Prof. Liivak (''We were aided in our consideration of this issue by *amicus curiae* briefs filed by Eli Lilly and Co. et al. and Professor Oskar Liivak of Cornell Law School.''). *AbbVie Deutschland*, footnote 6, at 1307. In turn, Prof. Liivak has written a paper, ''Finding Invention,'' 40 *Fla. State University Law Review* 57 (2012), in which he discusses what he calls ''the antibody exception,'' concluding that today's patent system ''allows claims that improperly extend well beyond the actual invention disclosed.'' See, pp. 89-91, where Prof. Liivak quotes extensively from another Eli Lilly *amicus* brief filed in *Centocor Ortho*. Since *Regents v . Eli Lilly* in 1997 through *Ariad v. Eli Lilly* in 2010, and in multiple *amicus* briefs in between and since, Eli Lilly and Co. has played a critical role in refocusing the requirements under 35 USC § 112, first paragraph, in biotechnology away from enablement and onto written description.

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