USPTO's Lax Policy Leads to Humira Formulation Thicket

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Keywords: Patents, Biologics, Formulations, Comparative Law, Written Description

Abstract: Biosimilar drugs enter the United States market well after they enter the European market. That is likely because pharmaceutical companies have many more patents in the United States than in Europe. But why is patent coverage of biological drugs so much more extensive in United States? This case study seeks to answer this question for drug formulation patents.

The high price of health care in the United States has reached a crisis. The cost of biologic drugs is one component of the problem. Biologic drugs were made possible by advances in biotechnology. These new cell-derived large molecule drugs have already proven to be effective at treating a wide range of serious illnesses including various autoimmune diseases and cancers. However, biologics are extremely expensive. In 2017, biologic drugs represented 2 percent of all US prescriptions, but 37 percent of net drug spending.[1]

One reason for their high price is that it costs more to develop and manufacture biologics than traditional small molecule drugs. However, this rationale does not explain why biologics cost more than twice as much in the United States as they do in Europe.[2] While there may be multiple reasons for this disparity, several commentators have suggested that differences in US and European Union patent coverage are an important contributing factor.[3] While biologic drug companies are able to get patent coverage for the active ingredient in both jurisdictions, companies are more successful at extending their patent coverage in the United States. That is because the US issues more patents that build on the original active ingredient patent. Examples of follow-on patents include formulations, methods of treatment, and manufacturing technique patents. Follow-on patents allow drug companies to delay generic drugs from entering the market.[4] In the case of biologic drugs, that means biosimilars (the generic version of a biologic drug) enter the market well after a biologic drug's active ingredient patent expires.

Abbvie's lucrative Humira drug provides a concrete example of how follow-on patents can delay biosimilar entry. The original active ingredient patents expired in 2016. Soon thereafter, Boehringer obtained FDA approval for its Humira biosimilar, Cyltezo.[5] However, Abbvie brought suit alleging infringement of 74 Humira patents.[6] The case eventually settled without Cyltezo entering the US market. Biosimilar competition in the United States only began in 2023. In the interim, Humira earned $114 billion.[8]

The situation is different in the EU. Biosimilar versions of Humira entered the EU market years ago.[9] Not surprisingly, patent coverage of Humira is significantly thinner in the EU than the U.S., particularly in follow-on patents.[10] Importantly, earlier biosimilar competition in the EU is not unique to Humira. The same phenomenon has been seen in other biological drugs.[11] Of course, biosimilar market entry leads to increased competition and lower prices.[12]

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DOI: 10.1017/jme.2024.132

https://doi.org/10.1017/jme.2024.132 Published online by Cambridge University Press

While many commentators have studied the impact of secondary patenting in the pharmaceutical industry, no one has sought to explain why there is such a disparity between patent coverage in the United States and the EU. Presumably, biological drug companies seek extensive patent coverage in both jurisdictions. Differences in how the United States Patent and Trademark Office (USPTO) and the European Patent Office (EPO) handle patent applications likely prevent biological companies from obtaining the kind of patent thickets in the EU that they receive in the United States. But what are the specific policies that result in fewer EU patents?

This current study seeks to identify these policies by comparing the US and EU prosecution histories of formulation patents covering Humira. The USPTO and EPO are counterpart authorities. They each make decisions on what is patentable and what is not for their respective jurisdiction (the United States vs. the EU member states). Their policies directly affect the scope of patent coverage that drugs like Humira can obtain. Importantly, biologic drugs include more than their active ingredient. They also include a combination of excipients (e.g. buffers, stabilizers, detergents and tonicity agents) that perform different functions like stabilizing the active ingredient for long-term storage and rendering the drug suitable for delivery to the patient. These excipients provide the opportunity for additional patents. In the United States, biological companies frequently sue biosimilar companies on these kinds of patents. Therefore, it is important to understand why these formulation patents are granted and what these patents cover.

This current study seeks to identify these policies by comparing the US and EU prosecution histories of formulation patents covering Humira. The USPTO and EPO are counterpart authorities. They each make decisions on what is patentable and what is not for their respective jurisdiction (the United States vs. the EU member states).[13] Their policies directly affect the scope of patent coverage that drugs like Humira can obtain. Importantly, biologic drugs include more than their active ingredient. They also include a combination of excipients (*e.g.* buffers, stabilizers, detergents and tonicity agents) that perform different functions like stabilizing the active ingredient for long-term storage and rendering the drug suitable for delivery to the patient. These excipients provide the opportunity for additional patents. In the United States, biological companies frequently sue biosimilar companies on these kinds of patents.[14] Therefore, it is important to understand why these formulation patents are granted and what these patents cover.

This study found two differences in the way that that the USPTO and EPO treated formulation patent applications for Humira. First, the primary difference between the two patent offices is that they treat prophetic examples dramatically differently. The written description for these patents contained both working examples with data, and a laundry list of ingredients (*i.e.* prophetic examples) that had no accompanying test results. The USPTO allowed broad claims that covered far more than the working examples. The claims covered the prophetic examples and beyond. In contrast, the EPO requires independent claims to contain the "essential features" of invention. In practice, this meant that the EPO only allowed claims that were narrowly tailored to cover the working examples. Claim limitations corresponded to the specific excipients found in the working examples.

The second difference was how the two patent offices treated functional claims. These are claims that include limitations that are drafted to describe a result or function as opposed to the structure (e.g. a chemical compound) that the applicant used to achieve the function. Functional claims can be extremely broad because a whole range of known and unknown structures/compounds may satisfy the functional limitation. During the prosecution of these formulation patents, the US patent office often allowed claim limitations

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https://doi.org/10.1017/jme.2024.132 Published online by Cambridge University Press

that recited functional definitions. However, when the EPO was faced with functional claim language, it objected stating "that these features are results to be achieved" which "lacks clarity under Article 84 of the European Patent Convention (EPC)." While this policy difference undoubtedly led to broader patents in the US than the EU, the EPO's essential features requirement was the larger factor.

The upshot is that a combination of these two policy differences led to vastly different patent portfolios in the US and EU. Humira's US patents did not just have greater claim scope than their EU counterparts, the US patents were also far more numerous than their EU counterparts (22 US formulation patents vs. 2 EU formulation patents). As a result, Abbvie had a substantially greater ability to prevent biosimilar competition in the United States than in Europe. The broad US patent claims left little space for biosimilar companies to design around and develop alternative formulations that might stabilize the biological drug.

Humira Formulation Patent Claim Coverage in the US vs Europe

Abbvie's Humira drug is used to treat a variety of inflammatory diseases. The original active ingredient patent covering the Humira (adalimumab) antibody was filed on February 9, 1996[15] and the formulation patents were filed six years later. This study examines the prosecution histories of the family of formulation patents. The Humira patents were located using the IPD Analytics commercial database.[16] US prosecution file wrappers were downloaded from USPTO PAIR.[17] European prosecution file wrappers were downloaded from the EPO register.[18] These patents and applications all claim priority from WO2004016286 which is entitled "Formulation of Human Antibodies for Treating TNF-alpha Associated Disorders."

A. Working and Prophetic Examples

The study first compares the raw numbers of patents in the US and EU. A list of all these patents is found in Table A1 of the Appendix. As expected, there are far more patents disclosing essentially the same subject matter in the United States (22) than the EU (2). Recall, these are all patents that have the same written description and priority dates.

But raw numbers do not tell the full story. It is also important to look at claim scope. Humira's formulation patents in the US have dramatically broader claim scope than they do in the EU. These differences start with how differently the USPTO and EPO view the relationship between the claims and the written description of the patents, also known as the specification. Because patents in both the US and EU claim priority from WO 2004/016286, they share the same specification. The specification describes one formulation with a high level of detail:

> Ingredients were weighed out as follows: 240.0 g mannitol, 26.1 g citric acid monohydrate, 6.1 g sodium citrate, 30.6 g disodium phosphate dihydrate, 17.2 g sodium dihydrogen phosphate dihydrate, 123.3 g sodium chloride, 20.0 g polysorbate 80, and 19,715.7 to 19,716.1 g of water.[19]

The specification then goes on to provide the results of various "Freeze/Thaw" studies for two versions of this formulation (with and without polysorbate 80) (WO 2004/016286 Table 2). The results of both Freeze/Thaw studies showed that the two embodiments should work and that the version with polysorbate 80 was superior because it "improved the physicochemical properties" of the formulation. These two embodiments are called working examples.[20] Based on the test data in the application included in the specification, one might reasonably expect that these formulations should work for their intended purpose.

While the buffer described in the working example is a specific combination of citrate buffer and phosphate buffer, the specification also provides:

> Examples of buffers that will control the pH in this range include acetate (e.g. sodium acetate), succinate (such as sodium succinate), gluconate, histidine, citrate and other organic acid buffers.[21]

Notably, this is the only description of these alternate buffers in the specification. Moreover, unlike the working examples, there is no test data. These kinds of examples have been labeled prophetic examples because the applicant hopes, but does not know, that they will stabilize the drug. But even that description seems a little generous because the applicant does not explain why it would expect these buffers to work with adalimumab, let alone any of the other listed excipients.

This story repeats itself for the other excipients required in the formulation: the stabilizer, the surfactant, and the salt. For example, the working examples require a specific stabilizer, mannitol (which is one type of polyol). The working examples also describes the specific amounts (concentrations) of mannitol required to stabilize the drug. But the specification also provides a laundry list of other possible stabilizers. Specifically, it lists various: sugar polyols ("fructose, mannose, maltose, lactose, arabinose, xylose,

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https://doi.org/10.1017/jme.2024.132 Published online by Cambridge University Press

ribose, rhamnose, galactose and glucose"), non-reducing sugars ("sucrose, trehalose, sorbose, melezitose and raffinose", sugar alcohols ("mannitol, xylitol, erythritol, threitol, sorbitol and glycerol") and sugar acids ("L-gluconate and metallic salts"). The specification does not provide any test results for compounds in this list, nor does it explain why one of these excipients would work.[22] Rather, the applicant appears to have just disclosed a list of well-known compounds. Indeed, some members of this list like "sucrose" and "sorbitol" are extremely common stabilizers and used in formulations for other drugs.[23]

The USPTO and EPO have significantly different policies when dealing with working examples (with test data) and prophetic examples (a laundry list of different excipients that might work). This difference leads to Humira's US patents having dramatically broader claim scope than their EU counterparts.

B. Broader US Claims

Table 1 compares two of the broader claims in the two jurisdictions, claim 1 of US9750808 (the US '808 patent) and claim 1 of EP1528933 (the EP '933 patent)

Both claims begin by reciting a concentration of the active ingredient, adalimumab (which is a human anti-human Tumor Necrosis Factor alpha (TNFα) IgG1 antibody having an internal designation name of D2E7).

However, claim 1 of US '808 patent is incredibly broad. It simply requires a "buffer system." The other limitations are not meaningful. For example, the claim requires that the formulation be isotonic, but the FDA requires that antibody formulations for human therapy are stable and isotonic. The claim also requires that the formulation have a pH of 4 to 8. But the FDA does not permit acidic formulations (lower than pH4) or alkaline formulations (higher than pH8) to be injected into the human body. Perhaps more importantly, the claim is not limited to the specific excipients used in the working examples. There are no limitations directed to phosphate and citrate (the buffer), mannitol (the stabilizer), polysorbate 80 (the surfactant), or sodium chloride (the salt). Nor are there any limitations to the working concentration of each excipient.

By comparison, claim 1 of the EP '933 patent identifies specific ranges for five different excipients. Both the excipients and the amount of the excipients correspond to the preferred working example found in the specification. This is not a coincidence. Abbvie tried to obtain broader patent coverage in the EU. But Abbie's attempts resulted in objections under EPC Article 84. Among other requirements, Article 84 requires that claims contain the "essential features" of the invention.[24] This requirement prevented Abbvie from obtaining broader genus claims. For example, at one point, Abbvie tried to include a limitation that simply called for a particular amount of a "surfactant", but the EPO objected, saying that:

> All claims comprise some but not all necessary technical features for which a technical effect has been shown (c. f. example 2) ... However, it is clear from the description that the specific formulation(s) disclosed in the examples are essential to obtain the desired result(s) for [antibody Humira].[25]

The EPO made this objection because polysorbate 80 was the only surfactant included in a working example. Therefore, it was necessary for carrying out the invention as described in the specification. Abbvie was eventually forced to amend its limitation from ".1 to .10 mg/ml surfactant" to ".1-5 mg/ml of polysorbate 80." Notably, the broader version of the limitation would have covered numerous prophetic examples, but the narrower version does not. It only covers the specification's working example.

But this is not the only way Abbvie attempted to broaden its claim coverage in Europe. In three instances, the EPO objected to claims that "defined a result to be achieved." These objections were in response to claim language that recited the following results:

- a shelf life of at least 18 months,
- maintain stability following at least 3 freeze/thaw cycles, and
- have enhanced stability of at least 12 months at a temperature of 2-8°C.

In essence, the EPO raised objections to functional language in the claims. With limited exceptions, functional language is generally not allowed under Article 84.[26] As a result, all these limitations were removed from the final EP claims. While these specific functional limitations do not appear in the US formulation patents either, other less obvious functional language was included. Independent claims contained limitations broadly directed at a "buffer system" or a "surfactant" without any further structure.[27] That means that any ingredient that functions as buffer or surfactant arguably satisfy these limitations.

Both the "essential features" objections and the "result to be achieved" objections are based on Article 84 of the EPC. The US counterpart to Article 84 is 35

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https://doi.org/10.1017/jme.2024.132 Published online by Cambridge University Press

Table 1
Claim Breadth Comparison

Claim of 1 of US9750808 (the US '808 patent)	Claim 1 of EP1528933 (the EP '933 patent)
1.A stable liquid aqueous pharmaceutical formulation comprising: a human anti-human Tumor Necrosis Factor alpha (TNFα) IgG1 antibody at a concentration of 45 to 105 mg/ml, wherein the antibody is D2E7 [Humira], and a buffer system; • wherein the formulation is isotonic, • suitable for single-use subcutaneous injection, • and has a pH of 4 to 8.	1.A liquid aqueous pharmaceutical formulation having a pH of 4 to 8 and comprising (a) 20 to 130 mg/ml of [Humira], (b) 10-14 mg/ml of mannitol, (c) 0.1-5 mg/ml of polysorbate 80, (d) 1-1.5 mg/ml of citric acid monohydrate, (e) 0.25-0.5 mg/ml of sodium citrate, (f) 1.25-1.75 mg/ml of disodium phosphate dihydrate, (g) 0.7-1.1 mg/ml of sodium dihydrogen phosphate dihydrate, and (h) 6.0-6.4 mg/ml sodium chloride.

Table 2
Written Description and Claim Clarity Statutes

EPC Article 84	35 U.S.C §112
The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.	(a) The specification shall contain a written description of the invention, and of the manner and process of making and using it … (b) The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention. * * *

U.S.C §112(b). The text of these statutes is reproduced above in Table 2.

Despite their textual similarity, these statutes have been interpreted to mean something quite different in practice. During the prosecution in Europe, the EPO issued objections under Art 84 EPC in every office action and oral interview until the claims were narrowed to the specific formulation that corresponded to the working example. In contrast, the USPTO never rejected a claim as functional. Moreover, across the 22 US patents in this family, rejections based on Section 112(a) were rare, and did not significantly narrow the claim scope of the patents in question.

Finally, I try to depict the difference in the US and EU Humira formulation patents. To appreciate the magnitude of the difference, one needs to consider the large number of broad US patent claims against the small number of narrow EU patent claims. Appendix A (Tables A2 and A3) includes all the independent claims from both US and EP patent families. In addition, claim 1 from each patent was coded along six dimensions to determine how broad or narrow the coverage is. These dimensions are: (1) the antibody, (2) the buffer, (3) the stabilizer, (4) the surfactant, (5) the salt and (6) the pH level. These results are found in columns 3–8 of the tables in Appendix A. Table 3 (p. 432) shows only columns 2–5 of one entry from Appendix A. The text of claim 1 of EP2359856 is found in the "Independent Claims" column. The antibody, buffer, and stabilizer limitations have been pulled out of the claim and used to populate the remaining columns.

The full appendix contains the same information on the two EU formulation patents and the twenty-two US formulations patents with three additional columns reflecting the surfactant, the salt and the pH level.

For those that do not have the patience to wade through Appendix A, Figure 1 summarizes the table graphically. The four sets of blue/red circles are intended to represent the four coded excipients: the buffer, the stabilizer, the surfactant, and the salt (omitting the antibody and the pH level). Bold language in the circle indicates that at least one independent claim

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https://doi.org/10.1017/jme.2024.132 Published online by Cambridge University Press

Table 3
Illustration of Coding of Claim Limitations

Independent Claims	Antibody	Buffers	Stabilizers
1.A liquid aqueous pharmaceutical formulation for injection in the form of a 0.8 mL solution comprising: a) 40.0 mg the anti-human Tumor Necrosis Factor alpha antibody D2E7 b) 9.6 mg mannitol c) 1.044 mg citric acid monohydrate d) 0.244 mg sodium citrate e) 1.224 mg disodium phosphate dihydrate f) 0.688 mg sodium dihydrogen phosphate dihydrate g) 4.932 mg sodium chloride h) 0.8 mg polysorbate 80 i) 759.028 - 759.048 mg water j) 0.02 - 0.04 mg sodium hydroxide, which gives a total of 817.6 mg per 0.8 ml solution.	40 mg adalimumab	• 1.044 mg citric acid monohydrate • 0.244 mg sodium citrate • 1.224 mg disodium phosphate dihydrate • 0.688 mg sodium dihydrogen phosphate dihydrate	9.6 mg Mannitol

expressly covered this excipient. In practice, different concentrations of excipients may or may not work in any particular formulation. The two EU patents recite specific concentrations of specific excipients, and their coverage is narrowly tailored to the working examples as illustrated by the red circles.

In contrast, the numerous US formulation patents (represented by the blue circles) recite larger classes of excipients. Again, bold is used to indicate the claim limitation corresponding to this class. For example, a common stabilizer limitation in the US patents was "a polyol." Thus, polyol appears in bold in the 2nd blue circle from the left. The specification also lists 22 polyols, making that limitation extremely broad. Those 22 polyols are all included in the blue circle to indicate that the stabilizer limitation broadly covered all these alternatives.

In still other examples, claims would state "a buffer" or "a surfactant." Presumably, this functional language would be satisfied by any excipient that serves as a buffer or as a surfactant. Notably, this functional language was only found in claims of the US formulation patents. A few claims even omitted entire excipient categories. These claims are even broader because any excipient or no excipient in this category would satisfy the claim limitation. Because the US formulation patents covered so many alternatives, the blue circles (US claim coverage) were made substantially larger than the red circles (European claim coverage) indicating substantially broader claim coverage.

In short, the Humira formulation US patents were vastly broader than their European counterparts. At the same time, they appeared to cover many different alternative formulations. It is important to keep in mind that the specification only discloses two working embodiments, *i.e.* two combinations of excipients that stabilize adalimumab. This likely explains why biosimilar companies could not enter the US market when Humira's active ingredient patent expired in 2016 and instead had to delay their launch by six years. In effect, the formulation patent claims in the US were so broad that that they effectively extended Humira market's exclusivity.

In contrast, the EPO only issued two Humira formulation patents to Abbvie. The European claims were limited to the combination of specific excipients that were exemplified by experimental data. The narrower claims allowed biosimilar competitors to design around the patents by screening for alternative combinations of excipients that stabilize the same drug. Not surprisingly, biosimilars to Humira entered the European market 5 years earlier than the US market.[28]

Discussion

By studying the prosecution histories of Humira's formulation patents in both the US and EU, this study found that two policy differences caused dramatically disparate patent coverage in the two jurisdictions. Far more formulation patents were issued in the US (22) than the EU (2). Moreover, the US formulation patents also had significantly broader claim coverage than the EU patents.

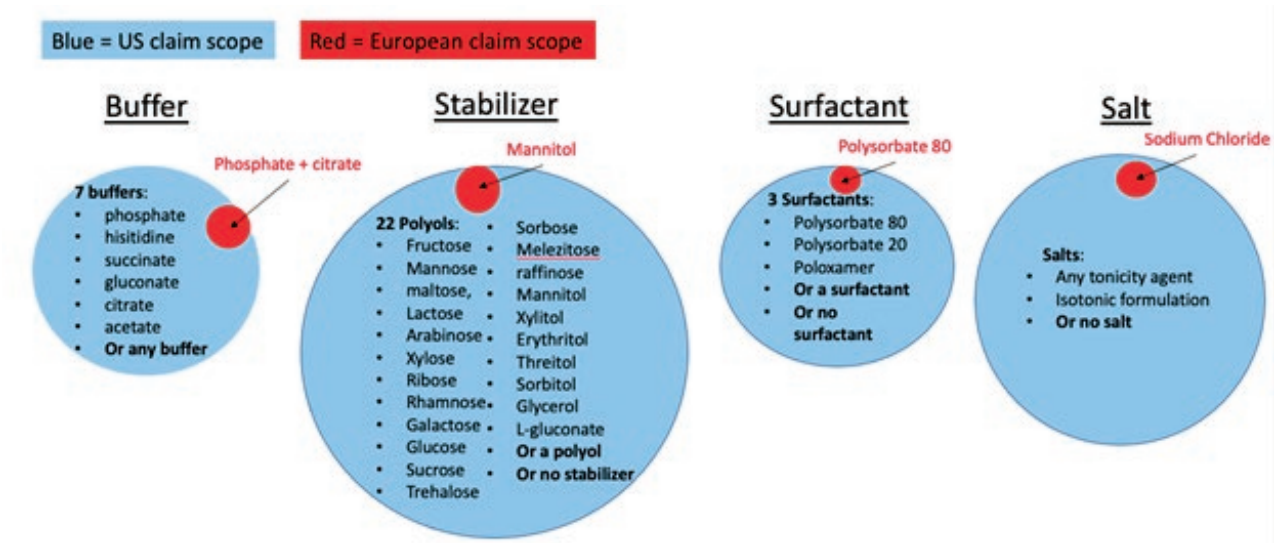
The primary policy difference concerns the level of support that claims must find in a patent's specifica-

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https://doi.org/10.1017/jme.2024.132 Published online by Cambridge University Press

Figure 1

Scope of US Formulation vs EU Claims



tion. Both the EU and the US have laws that require the claims to be rooted in the specification. They are Article 84 of the EPC and 35 U.S.C. § 112 respectively. While these laws are textually similar, the EPO and USPTO implement them in very different ways. Using the essential features test, the EPO required Humira's EU claims to contain the specific excipients (and amounts) found in the specification's working examples. In contrast, the USPTO allowed much broader generic claim language. These claims covered both the working examples and a laundry list of prophetic examples.

While the essential features test may sound unfamiliar to US patent practitioners, the Federal Circuit has occasionally invalidated claims under § 112(a) using similar reasoning.[29] In these cases, when a claim does not contain an essential feature of the invention described in the specification, the Federal Circuit has said that a claim does not satisfy the written description test. The EPO's essential features test applies this analysis more rigorously, at least with respect to formulation patents.

The second policy difference relates to how the jurisdictions treat functional claims. The EPO repeatedly rejected claim language with functional language, but the USPTO did not reject functional language.[30] While objections based on functional language figured less prominently than objections based on the lack of essential features, both policies worked together to force Abbvie to narrow its EU claims. The EU claims that were eventually issued covered the working examples found in the specification and did not cover the laundry list of prophetic examples.

At first blush, these results may seem inconsistent with Tu & Holman's recent study suggesting that the USPTO currently requires antibody claims to cover specific antibodies with well-defined structures.[31] But Tu & Holman only looked at antibody patents (*i.e.* covering the active ingredients), not formulation patents. Moreover, their study noted that antibody patents previously granted broad genus protection. The changes at the USTPO may be a response to the maturation of the antibody field. As the technology has become more well understood, antibody patent coverage has narrowed. However, the current study suggests that the USPTO handling of formulation patents may not have evolved in the same way.

Of course, by itself, broader patent protection does not suggest a problem. The question is whether the claim breadth is deserved. The US Supreme Court recently addressed this issue in the context of antibody claims. In *Amgen Inc. v Sanofi*, Amgen had obtained two patents with claims that covered all antibodies that: 1) bind to a naturally occurring protein known as PCSK9, and 2) block PCSK9 from impairing the body's mechanism for removing LDL cholesterol from the bloodstream.[32] Amgen's specification identified the amino acid sequences of 26 antibodies that perform these two functions. Although Sanofi also sold an anti-cholesterol drug with an antibody that operated on PCSK9, it used a different antibody. When Amgen sued, Sanofi argued that Amgen's broad claims were invalid because they failed to satisfy 35 U.S.C § 112's

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https://doi.org/10.1017/jme.2024.132 Published online by Cambridge University Press

enablement requirement. In response, Amgen said that scientists could follow the company's "roadmap" or its proposal for "conservative substitution" to make alternative versions of the claimed antibodies. Because both methods employed a form of trial and error, the Supreme Court said that the "two approaches amount[ed] to little more than two research assignments." In short, the specification did not give information that distinguished those antibodies that would work from those that would not. Accordingly, the Supreme Court sided with Sanofi and found the broad claims were invalid for lack of enablement.

This study shows that the USPTO has allowed formulation claims that appear very similar to the antibody claims the Supreme Court rejected in *Amgen v. Sanofi*. Specifically, Amgen's formulation patents include a list of prophetic examples. Some of these examples may serve as a proper formulation for adalimumab while others may not. The Amgen patents do not help distinguish the working examples from the non-working ones. The only way to identify the formulations which work is to test them. Under the reasoning of *Amgen v. Sanofi*, it seems that these claims should have been rejected. To use the Supreme Court's language, Amgen's prophetic examples simply provide a "research assignment."

This result reflects sound policy. Claims should only cover an inventor's real contributions to the field. In the case of Humira's formulation patents, the working examples reflect actual research and development. But providing a laundry list of alternative prophetic examples does not suggest any type of effort or ingenuity. This is particularly true in the context of formulations where there appears to be a limited set of known excipients to try. Granting broad generic claims that covered both the working and prophetic examples only served to prevent biosimilar companies from developing their own alternative formulations to Humira. The result was that Humira's US market exclusivity lasted many years after the patent protection on the active ingredient expired.

The USPTO does not necessarily need to adopt the EPO's approach to avoid issuing the broad formulations patents observed in this study. There are many different potential policy levers that the USPTO could rely upon. One approach might be to adopt some form of essential features requirement. But the EPO's version of this test — where the claims need to closely track a working example's excipients — is only one way to implement this concept. The USPTO could adopt a test with a looser relationship between the working examples and claim breadth. Indeed, *Amgen v. Sanofi* could be considered to reflect a kind of compromise approach. Thus, the USPTO could simply rely on *Amgen v. Sanofi* to change the way it approaches formulation patents.

The USPTO could also take a stricter approach to allowing functional claim limitation. That does not necessarily mean eliminating functional claiming. Section 112(6) allows for claim limitations to use means plus function language. When a claim uses this language, the limitation does not cover any structures that perform the recited function. Rather, the limitation covers both: (1) structures disclosed by the specification that perform the recited function, and (2) such structures' "equivalents." Lemley & Sherkow have recently suggested that antibody patents include claims with means plus function limitations.[33] One

By examining USPTO and EPO patent file histories, this study has identified two USPTO policies that resulted in a thicket of broad US patents protecting Abbvie's Humira drug. In contrast to their EU countaerparts, the US patents covered both working examples and a laundry list of prophetic examples. While this study only examined the formulation patents of one biologic drug, Humira, the differences between US and EU coverage were dramatic. This article argues that coverage of the prophetic examples in these formulation patents was undeserved, and thus contributed to the delayed introduction of biosimilars into the US market. The article concludes with various policy suggestions aimed at curbing the problem of overbroad formulation patents in the future.

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https://doi.org/10.1017/jme.2024.132 Published online by Cambridge University Press

problem with this approach is that using an equivalence test injects undesirable uncertainty into the analysis. Moreover, overbroad claims are still likely to be a problem. Still, their proposal could eliminate some of the worse abuses of functional claiming.

The USPTO could also scrutinize patents more rigorously when a specification simply provides a laundry list of potential excipients. On the one hand, by merely identifying a laundry list of excipients, an applicant is suggesting that a list is all the information those skilled in the art need to make a suitable formulation. But if that is all that is needed, it is likely that making a formulation out of these excipients is obvious. In fact, the US Supreme Court has suggested that an invention may be obvious under Section 103 of the patent laws when the solution was obvious to try.[34] On the other hand, if the applicant can provide evidence that using the listed excipients is non-obvious, the patent's specification needs to explain about how to combine these excipients. Otherwise, the patent has failed to enable a person of ordinary skill in the art to practice the invention as required by Section 112 of the US patent laws. In either case, the patent is invalid. That does not mean that biologic companies cannot obtain formulation patents. They just need to describe more working examples when they want broader claim coverage.[35]

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Note

The author has no conflicts of interest to disclose.

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https://doi.org/10.1017/jme.2024.132 Published online by Cambridge University Press

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