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An Issued Life Science MPF U.S. Patent Claim: Ex parte Gleave

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Ex parte Gleave[3] is a landmark decision to the extent PTAB approved a pharmaceutical composition claim under 35 USC §112(f), otherwise known as means-plus-function (MPF) claims.

35 USC §112(f) reads "an element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof."

Section 112(f) provides a tool for patent applicants to, in a controlled way, literally cover equivalents by providing for literal infringement by structure, material, or acts that perform the same function. Historically MPF claims have been used in the mechanical and electrical/ computer fields. According to P.J. Federico's 1952 commentary on the then-brand new 1952 Patent Act, life science MPF claims were contemplated from the birth of the statutory provision:

> The last paragraph of section 112 relating to so-called functional claims is new. It provides that an element of a claim for a combination (and a combination *may be not only a combination of mechanical elements,* ***but also a combination of substances in a composition claim****, or steps in a process claim*) may be expressed as a means or step for performing a specified function, without the recital of structure, material or acts in support thereof.

Commentary on the New Patent Act (U.S.C. 1952), republished in JPOS: March 1993, http://www.ipmall.info/hosted_resources/lipa/patents/federico-commentary.asp#Application_for_Patent (emphasis added).

For patent drafters practicing in the U.S. life sciences, the means-plus-function claim format may provide more accuracy and clarity than purely structural characterization and may end up providing broader scope.[4] This alternative claim format is worth considering.

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[3]*Ex parte Gleave*, Appeal 2012-004973 (P.T.A.B. Jan. 22, 2014).

[4]For further discussion, see the seminal article on the subject: Tang, Wanli, "Revitalizing the Patent System to Incentivize Pharmaceutical Innovation: The Potential of Claims with Means-Plus-Function Clauses," 62 *Duke L.J.* 1069 (2013).

The Story of an Issued Life Science MPF Claim

The original claims in Gleave, not in MPF format, read:

> 1. A method for treatment of a cancer characterized by elevated expression of hsp27 as compared to non-cancerous tissue of the same type in an individual suffering from the cancer, comprising the step of administering to the individual a therapeutic composition effective to reduce the amount of active hsp27 in the cancer cells.
>
> 14. A pharmaceutical composition comprising a therapeutic agent effective to reduce the amount of active hsp27 in cancerous cells exposed to the therapeutic agent, and a pharmaceutically acceptable carrier.

On the filing date, however, a preliminary amendment was filed canceling all claims and presenting independent claims 25 and claim 33, introducing "means for" with emphasis added:

> 25. (new) A pharmaceutical composition comprising a therapeutic agent effective to reduce the amount of active hsp27 in cancerous cells exposed to the therapeutic agent, and a pharmaceutically acceptable carrier, wherein the therapeutic agent is an antisense oligonucleotide having a sequence complementary to SEQ. ID NO. 91, wherein the oligonucleotide comprises at least ten bases complementary to bases 744-764 of SEQ. ID NO. 91, and wherein the antisense oligonucleotide is 12 to 35 nucleotides in length.
>
> 33. (new) A pharmaceutical composition comprising a
>
> (a) ***means for*** reducing the amount of active hsp27 in cancerous cells by sequence specific interaction with Seq. ID No. 91 and
>
> (b) a pharmaceutically acceptable carrier.[5]

The preliminary amendment also presented claims 34 and 35, depending directly or indirectly from claim 33:

> 34. (new) The pharmaceutical composition of claim 33, wherein the means for reducing the amount of active hsp27 in cancer cells is an oligonucleotide, and the oligonucleotide consists of 12 to 35 nucleotides.
>
> 35. (new) The pharmaceutical composition of claim 34, wherein the oligonucleotide is an antisense oligonucleotide complementary to Seq. ID No. 91.

In presenting the new claims, Applicants made clear an intent to invoke §112(f):

> In the new claim set, claims 33-35 are also presented directed to a generic pharmaceutical composition in which the active ingredient is referred to in means plus function language. It is intended to invoke 35 USC § 112, sixth paragraph, such that this refers to the compositions disclosed in the application that accomplish this function, and equivalents thereof.

[5]The "sequence specific" language ultimately was removed from claim 33.

The PTO erroneously rejected claims 33-35 as not entitled to the effective date of the 2002 and 2003 provisional applications but rather only entitled to the actual filing date of the preliminary amendment:

> None of the applications disclose [sic] the limitations of newly added claims 33 and 34. … [T]he claim language is not supported by the instant specification or the priority documents.
>
> * * *
>
> With regards to the means plus function language of claim 33, the instant specification does not describe any means for reducing the amount of active hsp 27 via sequence specific interaction other than by antisense oligonucleotide or RNAi inhibition.
>
> Therefore, the claims are broader than the instant disclosure, as this is not a defined genus that has been described by the specification. The specification does not have a sufficient disclosure of the structure that corresponds to the claimed function. Means plus-function claims require disclosure in the specification even if the means are already well known in the art. It is not clear what structure is required to meet the limitation of resulting in sequence specific interaction, but clearly this would include triplexes, miRNA molecules, and aptamers, which are not disclosed in the specification.

The USPTO also made an erroneous written description rejection and an anticipation rejection based on Baracchini ("the oligonucleotide of Baracchini et al. meets the instant structural limitations"), a reference that would mistakenly hang over the claims all the way to the decision on appeal reversing that rejection years later.

Applicants responded, adding a new claim 36, depending from claim 33.

> 36. (new) The pharmaceutical composition of claim 33, wherein the means for reducing the amount of active hsp27 in the cells is a double-stranded RNA molecule.

Applicants also targeted the Examiner's erroneous failure to construe the claims as MPF:

> The Examiner has failed to make a determination of the scope of the claims using the standards of this section of the statute, but rather has asserted a scope that is seemingly broader than the claim scope. See MPEP § 2181. Applicants submit that this step must be performed before the Examiner can properly apply any rejection."

The PTO then issued a final rejection regarding MPF claims 33-36, maintaining the position that the claims were not entitled to the benefit of the priority date, lacked written description, and were anticipated:

> Specifically, the documents do not disclose a pharmaceutical composition comprising any means for reducing the amount of active hsp27 in cancerous cells by sequence specific interaction with SEQ ID NO: 91; and do not disclose wherein the means is an oligonucleotide consisting of 12-35 nucleotides, as it appears as if the only disclosure of oligonucleotides of this length are antisense oligonucleotides, as required by claim 35.

With respect to the MPF claim language, the examiner repeated its position from an earlier rejection.

> With regards to the means plus function language of claim 33, the instant specification does not describe any means for reducing the amount of active hsp 27 via sequence specific interaction other than by antisense oligonucleotide or RNAi inhibition. Therefore, the claims are broader than the instant disclosure, as this is not a defined genus that has been described by the specification. The specification does not have a sufficient disclosure of the structure that corresponds to the claimed function.

Responding after final, Applicants persevered and again urged that the examiner failed to correctly construe a claim in MPF format:

> Here, claims 33 and 34 are directed to a combination (a pharmaceutical composition) and one of the elements is recited in mean-plus-function format. Thus, the first thing the Examiner must do in determining the scope of the claims is to consult the specification to see the structures, materials or acts described in the specification . . . .
>
> By law, claims 33 and 34 have a scope which is the disclosed structures, plus equivalents. If the Examiner is arguing that triplexes, miRNA molecules and aptamers are equivalents of the disclosed antisense and siRNA, then these embodiments fall within the scope of the original disclosure and are entitled to the priority date of at least April 18, 2003. If on the other hand (as appears from the written description rejection) the Examiner is asserting that these are not equivalent, then these options are not within the scope of the claim, and applicants are still entitled to at least a priority date of April 18, 2003 for Claims 33 and 34. Clarification of the Examiner's interpretation of the claims is requested.
>
> Claims 33 and 34 are rejected under 35 USC § 112, first paragraph as lacking written description. The Examiner specifically identifies two means for accomplishing the stated function, but argues that the claims are broader than this. The only way this could be legally true is if the alternatives are art-recognized equivalents of the specifically named structures (i.e. antisense and siRNA). The Examiner has not taken a position as to whether or not the structures that make up the allegedly not described scope are art recognized equivalents . . . .

The failure to treat the MPF claim properly compromised, according to Applicants, the anticipation rejection also:

> In order to anticipate a means-plus-function limitation, Baracchini would have to disclose a sequence that (1) performed the function of reducing hsp27; and which (2) was identical to or the equivalent of a structure disclosed in the application. The Examiner has not made either of these showings.
>
> Baracchini's SEQ ID No. 3 is not identified as being able to reduce hsp27, and the Examiner has not argued that such activity is expected to be inherent in the Baracchini sequence. Without such a showing, there can be no anticipation.

The USPTO issued an advisory action, ruling that the reply did not place the application in

condition for allowance. Applicants engaged in a pre-brief appeal conference. The rejection was withdrawn in view of Applicant's brief in its pre-brief conference request.

That joy for Applicants proved to be short-lived. After prosecution was reopened, Applicants received yet another nonfinal rejection. In addition to making the same priority application analysis, the USPTO made a written description rejection, a prior art rejection, and a new indefiniteness rejection under §112(b).

In response, Applicants amended only claim 33 to delete "by sequence specific interaction with Seq. ID No. 91" as follows:

> Claim 33. (currently amended) A pharmaceutical composition comprising a
>
> (a) means for reducing the amount of active hsp27 in cancerous cells [by sequence specific interaction with Seq. ID No. 91] and
>
> (b) a pharmaceutically acceptable carrier.

Applicants argued that were §112(f) applied properly, the rejections would be overcome.

The USPTO responded with yet another non-final rejection based solely on 102 and 103, relying primarily on Baracchini.

Applicants filed a notice of appeal, and tried, unsuccessfully this time, another pre-brief conference request. Again, Applicants argued the examiner was not properly analyzing the claim's scope under §112(f):

> The structures that are disclosed in specification for accomplishing the stated function (reducing the amount of active hsp27 in cancerous cells by sequence specific interaction with Seq ID No. 91) are Seq ID Nos. 1-82 which are antisense oligonucleotides, and Seq ID Nos. 83-90, which are the sense strand of an *[sic]* double0-stranded inhibitory RNA molecule. Thus, the proper scope of the claims is these sequences, and the equivalents thereof. The Examiner, however, has interpreted the claims as encompassing anything capable of achieving the stated function. This is an improper application of the relevant law.

A panel of three examiners rejected these arguments, and the application proceeded to appeal.

In addition to arguing why claim 33 should be construed as a MPF claim, Applicant added a policy argument in its Appeal Brief:

> Indeed, the Examiner and her art unit appear to be making every effort to avoid having to actually apply proper mean plus function claim interpretation in this case. Although the biotech art units may see few means plus-function claims, Appellants are not aware of any art units or technology areas that are excluded from interpreting means-plus-function limitations in the manner articulated by *In re Donaldson.* The anticipation rejection should therefore be reversed.

Answering, the USPTO argued the correctness of the rejections, and, with respect to the MPF issue, concluded:

> Although applicant argues that *[sic]* manner that means-plus-function claims are interpreted by the examiner's art unit, the examiner has interpreted the claim

> in light of the disclosure of the specification.
>
> The instant claims are not limited to the specific oligonucleotides exemplified in the specification and the oligonucleotide of Baracchini et al. meets the structural limitations set forth in the instant disclosure. In order for the instant claim scope to be enabled, the compound of Baracchini et al. would result in the claimed function.

Applicants filed a reply, along with request for oral hearing.

The Board reversed the examiner's rejection, framing the issues as follows:

- Has the Examiner properly interpreted the means plus-function language in the claim?
- Does the cited prior art teach a structure disclosed in the Specification as having the recited claimed function?

Relying on *Donaldson* and other precedent, PTAB reasoned:

> Thus, as articulated in MPEP 2181, "the USPTO *must* apply 35 U.S.C. 112, sixth paragraph in appropriate cases, and give claims their broadest reasonable interpretation, *in light of and consistent with* the written description of the invention in the application." [Emphasis added.] *(See also,* Br. 3.)
>
> A structure disclosed in the specification qualifies as a "corresponding structure" if the specification or the prosecution history "clearly links or associates that structure to the *function* recited in the claim." *B. Braun Med., Inc. v. Abbott Labs.,* 124 F.3d 1419, 1424 (Fed. Cir. 1997). With means plus-function claiming, the narrower the disclosed structure in the specification, the narrower the claim coverage. *Ibormeith IP, LLC v. Mercedes-Benz USA, LLC,* 732 F.3d 1376, 1381 (Fed. Cir. 2013). In making our determination, we apply the preponderance of the evidence standard. *See, e.g., Ethicon, Inc. v. Quigg,* 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).
>
> We agree with Appellants that the structures disclosed in the Specification as having the function recited in the claims are limited to (a) the specific antisense oligonucleotides in Example 1, (b) the specific RNAi molecules of Example 5, and (c) equivalents thereof, that are effective in reducing the amount of hsp27 in cancerous cells.

The Board further concluded:

> We agree with Appellants that, "[t]he Examiner has not presented any evidence to indicate that Sequence ID No.3 of Baracchini is equivalent in function to Sequence ID No. 76 .... [T]he common sequence makes up only 1/3 of Sequence ID No. 76. The Examiner has not provided sufficient evidence that the partial sequence complementarity would necessarily have the same function, as claimed."
>
> We agree with Appellants and find that the Examiner has not shown that one of ordinary skill in the art would have, without more, accepted that complementa-

> rity of 7 /20 non-consecutive bases would necessarily provide the claimed function of reducing the amount of active hsp27 in cancerous cells. The anticipation rejection is reversed.
>
> The obviousness rejection rests on the Examiner's flawed interpretation of Baracchini in the anticipation rejection. Bertrand does not overcome the deficiencies of Baracchini. Therefore, we also reverse the obviousness rejection

With the successful appeal, the claim issued and was entitled to 903 days of patent term adjustment. U.S. Pat. No. 8722872 issued May 13, 2014 and will expire March 24, 2026 (Oct 2, 2023 + 903 days PTA).

Take-Away Messages for Practitioners

What lessons are there for practitioners from a real-life example of an issued life science MPF claim? [6]

For those drafting claims related to a regulated industry, narrow claims are not necessarily bad; they can provide satisfactory claim scope. And if broader claims are desired, carefully draft the specification to encompass all embodiments intended to be covered by the language.

Taking care to carefully link the "means for" in the claim to the specification will help avoid prior art and avoid written description and enablement issues. This may mean added difficulty for third parties challenging patentability at the PTAB or validity in district court.

Since MPF claims are construed to include statutory equivalents to what is linked in the specification, the analysis of equivalents of an MPF claim is one of literal infringement by structure, material, or acts that perform the same function., rather than the far less certain doctrine of equivalents. The potential uncertainty of the scope of literal statutory equivalents also creates challenges to third-party design-arounds.

There are challenges to consider though. Narrowness and linking to the specification may not provide satisfactory protection in specific circumstances. Defining statutory equivalents is not a very clear area of the law, and the USPTO treatment of an MPF claim may be inconsistent or even, in life sciences, reluctant to the point of necessitating appeals.

[6] See also the USPTO training materials claims 5 and 6 at https://www.uspto.gov/patent/laws-and-regulations/examination-policy/examination-guidance-and-training-materials