International In-house Counsel Journal
Vol.15, No. 59, Spring 2022, 1

Creative Claiming Strategies

XIAOGUANG MICHELLE GAO
Associate VP - Assistant General Patent Counsel, Eli Lilly, USA
ANGELA SEBOR
Director, IP, Tolmar, USA
TOM IRVING
Partner, Finnegan, USA
STACY LEWIS
Law Clerk, Finnegan, USA[1]

Innovator companies in the biopharmaceutical space are looking to their patent counsel for creative patent claiming strategies to protect their assets. In this article, using the Federal Circuit opinions in *Teva Pharms. v. Corcept Therapeutics*, *Vanda v. West-Ward*, and *Sanofi v. Watson* as a foundation, we describe a strategy of enhancing chances of success against generic or biosimilar challengers by claiming clinical trial protocols and results, and other information that appears on a drug product label, *i.e.*, by claiming what was approved by the FDA. The article will also explore creative claim strategies that take advantage of 35 U.S.C. 112(f)'s means-plus-function terminology. These strategies could help create strong US patents and provide additional protections for biopharmaceutical innovations.

I. Claim Strategy Based on Claiming Clinical Trial Results

The opinion in *Sanofi v. Watson*, 875 F.3d 636 (Fed. Cir. 2017), showcases intriguing possibilities for patent owners in the biopharma industry whose patent counsel works closely with clinical trial teams and files US patent applications that include and claim innovations arising from clinical trial results.

Under the rationale of *Sanofi v. Watson*, when a generic or biosimilar manufacturer copies a label to obtain FDA approval, an innovator biopharma company may successfully assert induced infringement of method-of-treatment claims that facially seem very narrow, but closely correspond with what the FDA approved and is included in the label, including the clinical trial results set forth in the label.

[1] These materials have been prepared solely for educational and entertainment purposes to contribute to the understanding of U.S. intellectual property law. These materials reflect only the personal views of the authors and are not individualized legal advice. It is understood that each case is fact specific, and that the appropriate solution in any case will vary. Therefore, these materials may or may not be relevant to any particular situation. Thus, the authors and FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP (including Finnegan Europe LLP, and Fei Han Foreign Legal Affairs Law Firm), ELI LILLY AND COMPANY, and TOLMAR cannot be bound either philosophically or as representatives of their various present and future clients to the comments expressed in these materials. The presentation of these materials does not establish any form of attorney-client relationship with these authors, FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP (including Finnegan Europe LLP, and Fei Han Foreign Legal Affairs Law Firm), ELI LILLY AND COMPANY, or TOLMAR. While every attempt was made to ensure that these materials are accurate, errors or omissions may be contained therein, for which any liability is disclaimed. Xiaoguang Michelle Gao, Ph.D., is Assistant General Patent Counsel at Eli Lilly and Company. Angela Sebor, Ph.D., is Director Intellectual Property at Tolmar, Inc. Tom Irving is a partner at Finnegan. Stacy Lewis is a law clerk at Finnegan.

For this strategy to work in the US, of course, the patent application must be drafted to include details of the clinical trial information and results and must be filed before any published clinical trial information or results become disabling prior art, as set out under 35 U.S.C. § 102(a)(1), in the absence of any 35 U.S.C. § 102(b)(1) exceptions.

Patent teams should therefore coordinate and communicate early and frequently with the clinical trial teams and regulatory teams of the new drug application (NDA) or biologics license application (BLA) holder/reference product sponsors to help facilitate this strategy.

Practitioners should consider including in the patent specification and claims the specific information that cannot be carved out by the generic or biosimilar manufacturer, such as key safety signals, dosage adjustments in methods of treatment, and references to the clinical studies section in the Indication and Usage section of the label.

A. Details of *Sanofi v. Watson* Opinion

The invention at issue in *Sanofi v. Watson*, *supra*, was a method of treating heart rhythm problems in patients with atrial fibrillation by administering dronedarone, an antiarrhythmic agent, which is marketed under the brand name Multaq®.

Sanofi filed a patent application on its dronedarone composition in 1998. After approximately a decade of clinical trials and successful Phase III results, Sanofi obtained FDA approval of Multaq®.

Sanofi later obtained US Patent No. 8,410,167 ("the '167 patent"), which disclosed the Phase III clinical trial results, including details of contraindicated symptoms, severe heart failure dangers, and patient cardiovascular risk factors. Claim one of the '167 patent recited those same details:

> A method of decreasing a risk of cardiovascular hospitalization in a patient, said method comprising administering to said patient an effective amount of dronedarone or a pharmaceutically acceptable salt thereof, twice a day with a morning and an evening meal, wherein said patient does not have severe heart failure, (i) wherein severe heart failure is indicated by: a) NYHA Class IV heart failure or b) hospitalization for heart failure within the last month; and (ii) wherein said patient has a history of, or current, paroxysmal or persistent non-permanent atrial fibrillation or flutter ; and (iii) wherein the patient has at least one cardiovascular risk factor selected from the group consisting of:
>
> i. an age greater than or equal to 75;
>
> ii. hypertension ;
>
> iii. diabetes;
>
> iv. a history of cerebral stroke or of systemic embolism ;
>
> v. a left atrial diameter greater than or equal to 50 mm; and
>
> vi. a left ventricular ejection fraction less than 40%.

The Clinical Studies section of the Multaq® label similarly included all of those details. The label also referred to the Clinical Studies section in the label's Indications and Usage section. The label reads: "Multaq is indicated to reduce the risk of hospitalisation for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation [see Clinical Studies (14)]." *Id*. at 642-643.

The Federal Circuit affirmed the district court holding that Sanofi's patent was valid and that the generic label provided sufficient basis for a finding of intentional encouragement of infringement, and thus inducement to infringe. *Id*. at 646.

> [T]he inference in the present case is based on interpreting the label's express statement of indications of use and the internally referred-to elaboration of those indications.

Id.

Because of the reference to the Clinical Studies section (14) within the Indications and Usage section of the label, "the label thus directs medical providers to information identifying the desired benefit for only patients with the patent-claimed risk factors." *Id*. at 645.

Using this label/patent application combination strategy, Sanofi successfully protected the innovation arising out of the Phase III clinical trial results and achieved additional scope of patent protection, with 10 more years of patent exclusivity compared to the dronedarone composition patent.

B. Vanda v. West-Ward

In the 2018 Federal Circuit decision in *Vanda Pharmaceuticals v. West-Ward Pharmaceuticals*, Vanda was also rewarded with a finding of induced infringement of its US Patent No. 8,586,610 ("the '610 patent") because of the use of a similar label/patent application claiming clinical trial results.

Claim 1 (claiming the clinical trial results set forth in the label for FANAPT®):

> A method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of:
>
> determining whether the patient is a CYP2D6 poor metabolizer by: obtaining or having obtained a biological sample from the patient; and
>
> performing or having performed a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype; and
>
> if the patient has a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount of 12 mg/day or less, and if the patient does not have a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day,
>
> wherein a risk of QTc prolongation for a patient having a CYP2D6 poor metabolizer genotype is lower following the internal administration of 12 mg/day or less than it would be if the iloperidone were administered in an amount of greater than 12 mg/day, up to 24 mg/ day.

Safety/efficacy features of the drug led to claims of "a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome." *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1136 (Fed. Cir. 2018).

The Abbreviated New Drug Application (ANDA) filer, West-Ward, submitted a proposed label that was found to be "substantially identical" to Vanda's label. *Id.* at 1122.

The Federal Circuit rejected West-Ward's argument that Vanda should present evidence of actual past direct infringement. It stated that "the contents of the label itself may permit inference of specific intent to encourage, recommend, or promote infringement". *Id.* at 1129.

> The district court made factual findings that the proposed label 'recommends' that physicians perform the claimed steps … and its

> analysis of the proposed label to assess potential direct infringement by physicians was proper under our precedent.

Id. at 1130.

The Federal Circuit affirmed the district court's finding that the label showed specific intent to encourage infringement by doctors.

Like Sanofi, Vanda successfully protected its innovative iloperidone dosing regimen based on CYP2D6 genotype and achieved an additional decade of patent exclusivity for the claimed method of treatment compared to the compound patent.

C. Claiming the Unexpected Results

In *Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc*., 18 F.4th 1377 (Fed. Cir. 2021), the Federal Circuit affirmed the Final Written Decision of the Patent Trial and Appeal Board ("the Board") holding Teva failed to show all the challenged claims in PGR2019-00048 would have been obvious.

Corcept markets a 300 mg mifepristone tablet under the name Korlym®. In approving Corcept's NDA for Korlym®, the U.S. Food and Drug Administration ("FDA") required Corcept to conduct a drug-drug interaction clinical trial of mifepristone and ketoconazole (a strong CYP3A4 inhibitor). *Id*. at 1379. The FDA also provided an Office of Clinical Pharmacology memorandum ("Lee") explaining that the drug-drug interaction study was necessary to determine whether there was a safety risk in co-administration of CYP3A inhibitors and mifepristone. *Id.*

Corcept's original Korlym® label recommended a starting dose of 300 mg once daily up to a maximum of 1200 mg once daily, but with a warning to limit the mifepristone dose to 300 mg once daily when used with strong CYP3A inhibitors. *Id*.

Based on the subsequent drug-drug interaction study, Corcept applied for and received U.S. Patent No. 10,195,214 ("the '214 patent"). Claim 1 of the '214 patent read:

> 1. A method of treating Cushing's syndrome in a patient who is taking an original once-daily dose of 1200 mg or 900 mg per day of mifepristone, comprising the steps of:
>
> reducing the original once-daily dose to an adjusted once-daily dose of 600 mg mifepristone,
>
> administering the adjusted once-daily dose of 600 mg mifepristone and a strong CYP3A inhibitor to the patient,
>
> wherein said strong CYP3A inhibitor is selected from the group consisting of [ ].

The '214 patent reflects the drug-drug interaction study by allowing up to 600 mg of mifepristone in combination with the strong inhibitor. The original label clearly contradicts that.

Corcept sued Teva for infringement of the '214 patent, and Teva then sought post-grant review of claims 1-13. Teva argued the '214 claims were obvious based on the Korlym® label and Lee, optionally in combination with FDA guidance on drug-drug interaction studies. *Id.* at 1380.

The Board rejected Teva's obviousness argument, finding that Teva failed to show that a person of ordinary skill in the art ("POSITA") "would have had a reasonable expectation of success for safe co-administration of more than 300 mg of mifepristone with a strong CYP3A inhibitor." *Id.* This conclusion followed from the Board's construction of the claims to require safe administration of mifepristone (even though that was not recited in the claims) and the Board's rejection of Teva's expert's testimony that "based on the

Korlym® label and Lee, 'it was reasonably likely that 600 mg [per day of mifepristone] would be well tolerated and therapeutically effective when co-administered with a strong CYP3A inhibitor.'" *Id*. at 1381. The Board found that testimony inconsistent with Teva's expert's later testimony that a POSITA "would have *no expectation* as to whether the co-administration of 600 mg of mifepristone with ketoconazole would be safe." *Id*. at 1381-82. (emphasis in original).

The Federal Circuit affirmed the Board's decision. Although Teva argued that the Board erred in its reasonable expectation of success analysis by requiring precise predictability of a specific dosage, the Federal Circuit disagreed. "The Board applied the correct standard, requiring only a reasonable expectation of success and tying its analysis to the scope of the claimed invention." *Id*. at 1382. Acknowledging that "[a]bsolute predictability is not required[,]" the court placed the burden on Teva to prove a reasonable expectation of success for a 600 mg dosage. *Id*. at 1381.

But Teva did not establish "that [a skilled artisan] would reasonably have expected co-administration of more than 300 mg of mifepristone with a strong CYP3A inhibitor to be safe for the treatment of Cushing's syndrome or related symptoms in patients." *Id.* The evidence showed that a POSITA would have had "*no expectation* as to whether co-administering dosages of mifepristone above the 300 mg/day threshold set forth in the Korlym label would be successful.'" *Id*. (emphasis in opinion). "Because there was no expectation of success for any dosages over 300 mg per day, there was no expectation of success for the specific 600 mg per day dosage. … Nothing about this analysis required precise predictability, only a reasonable expectation of success tied to the claimed invention." *Id*. Monotherapy doses above 300 mg per day do not change this conclusion since the claim is limited to co-administration doses. *Id*. at 1383. The Federal Circuit upheld the Board's finding that a POSITA would not have expected monotherapy and co-administration dosages to behave similarly. *Id*.

The Court concluded that substantial evidence supported the Board's finding that the condition ranges disclosed in the prior art did not overlap with the claimed invention. *Id.* at 1383. As noted above, the prior art warned against co-administration with doses of more than 300 mg per day when used with strong CYP3A inhibitors. *Id.* at 1382-1383.

Showing obviousness requires both a motivation to modify/combine the prior art AND a reasonable expectation of success in arriving at the claimed invention. Beyond looking to the prior art to determine if it suggests doing what the inventor has done, this case reinforces that one must also consider if the art provides the required expectation of succeeding in that endeavor. "Obviousness does not require absolute predictability, but a reasonable expectation of success is necessary." *In re Clinton*, 527 F.2d 1226, 1228 (CCPA 1976).

This case also highlights the importance of claim construction. Corcept's claims were construed to require safe administration of mifepristone, even though that was not explicitly recited in the claims. But the Board and the Federal Circuit focused on the clinical trial results, which Corcept had claimed. Claim construction was an important underpinning of the conclusion that the success of the claimed invention could not have been reasonably expected.

D. Why Draft a Very Narrow Claim?

Generic or biosimilar manufacturers generally need to propose the same or highly similar labeling and could be captured on the basis of inducement to infringe. The generic label, by directing doctors and patients on the use of the drug product, intentionally encourages infringement (induces infringement) of the branded drug maker's patent claims. Claims directed to innovations based on clinical trial results that are fully described in the specification are more likely to be supported under the written description and enablement

requirements. Successful execution of this strategy requires close communication with the client, careful timing and control over public disclosures, and the ability to appropriately draft a patent specification to include the requisite elements.

II. Claim Strategy Based on Means-Plus-Function Claiming

Some seventy years ago, Congress passed the 1952 Patent Act, which included 35 U.S.C. §112(6), the first statutory language describing means-plus-function ("MPF") claims. MPF claims define an element, in a combination claim, by its function instead of its structure. This statutory provision remains in action since then, though rebranded as §112(f) in the Leahy-Smith America Invents Act, 125 Stat. 284 ("AIA"). Despite the rebranding, the statutory language still reads:

> 35 U.S.C. §112(f) ELEMENT IN CLAIM FOR A COMBINATION. — 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.

The MPEP sets out a three-pronged analysis that is used to determine if a claim is a "means-plus-function" claim:

1) Claim limitation uses terms: "means" or "step" or equivalent terms for performing the claimed function;
2) Such term is modified with functional language, typically linked to transitional language, such as "for" or "such that"; and
3) Such term is <u>not</u> modified by sufficient structure, material or acts for performing the claimed function.

MPEP § 2181.

The Federal Circuit articulated the analysis as a two-part test:

> Construing a means-plus-function claim term is a two-step process. The court must first identify the claimed function. … Then, the court must determine what structure, if any, disclosed in the specification corresponds to the claimed function.

Williamson v. Citrix Online, LLC, 792 F.3d 1339, 1351 (Fed. Cir. 2015).

MPF claims, often thought of as very narrow, can in fact provide greater protection for patent applicants than can other types of claims, including for claims drawn to biopharmaceutical subject matter. That is because the statutory term "equivalents" does not refer to the doctrine of equivalents, but rather refers to literal equivalents of structure, material, or acts that perform the same function. By encompassing literal equivalents, MPF claims can better protect an inventor's rights. It can also better prevent competitors from pirating or drafting around the literal scope compared to claims that recite particular elements, since MPF claims can encompass alternatives that provide the same function as claimed.

In some circumstances, MPF claims describe the invention in a clearer, more precise, and even broader way than purely structural claims. Specifically, the functional part in the §112(f) combination covers the "corresponding structure, material, or acts described in the specification and equivalents thereof." MPF claims have been underutilized in biopharmaceutical patents, but the tide is changing, and there are some MPF biopharma claims that have sallied forth and have issued.

A. Example of an Issued MPF Claim

In *Ex parte Gleave*, Appeal 2012-004973 (P.T.A.B. Jan. 22, 2014), the PTAB reversed an examiner's rejection and allowed a pharmaceutical composition claim using MPF language.[2] Applicants amended claim 33 to read:

> 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.

This claim was rejected on several grounds, including 35 U.S.C. §112(f). With respect to the MPF language, the examiner explained:

> 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.

On appeal, the PTAB agreed with Applicants that the MPF limitation was proper:

> 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.

Appeal 2012-004973 at *7. As will readily be comprehended, such a claim could be particularly effective against a 505(b)(2) challenger or a fast follower competitor.

B. Further Examples of Issued Pharmaceutical MPF Claims

- US Patent No. 10,413,611, which claimed a pharmaceutical composition comprising at least one poloxamer and "(b) means for keeping the pharmaceutical composition in liquid phase up to a temperature of about 40° C in vitro."

  During prosecution, the examiner rejected this claim, explaining that it failed to recite a combination of elements as required by that statutory provision and thus cannot rely on the specification to provide the structure, material or acts to support the claimed function. As such, the claim recites a function that has no limits and covers every conceivable means for achieving the stated function, while the specification discloses at most only those means known to the inventor. Accordingly, the disclosure was not commensurate with the scope of the claim. The examiner was persuaded by Applicant's response that "claim 1 recites a poloxamer and a means for, meaning it is not a single means claim because it does recite a combination of elements (a poloxamer in combination with means for)." The examiner allowed the claim which issued as independent claim 1 in the '611 patent. Such a claim could be very useful against an ANDA challenger who copies the active ingredient but tries to pirate the invention by changing the formulation.

[2] For more details, see, https://www.finnegan.com/en/insights/blogs/prosecution-first/got-pharmaceutical-means-plus-function-claims.html

- US Patent No. 6,974,595
    - Independent Claim 34: A method for obtaining an average Tmax of diclofenac in a human patient between 5 and 30 minutes after administration comprising orally administering a diclofenac formulation to said patient, wherein said diclofenac formulation comprises diclofenac in acid and/or salt form and **means for enhancing said average Tmax of said diclofenac**, and wherein said diclofenac formulation is selected from:

      a powder formulation dissolved or dispersed in water; and

      a fast release layer present in a two layered diclofenac tablet that comprises a slow release layer and a fast release layer.
    - In *Nautilus Neurosciences, Inc. v. Wockhardt, United States LLC*, 2:11-cv-01997 (D. NJ Feb. 27, 2013) (not for publication), the district court found that the specification plainly links alkali metal bicarbonates (not just potassium or sodium bicarbonate) to the function recited in claim 34 "means for enhancing said average Tmax". But alkali metal carbonates were NOT linked. Alkali metal carbonates only disclosed in Examples 1-3 and only in combination with alkali metal bicarbonates. Thus, the Court is not persuaded that alkali metal carbonates qualify as corresponding structure.
    - Judgment and order of permanent injunction pursuant to settlement July 2013.
- US Patent No. 9,149,464 Bendamustine Derivatives and Methods of Using Same
    - Independent Claim: 13. A pharmaceutical composition, comprising (a) [compound], and (b)**a means for increasing the circulation time of the compound in an aqueous environment**. (emphasis added)
- US Patent No. 7,579,380 Modified Release Formulations of a Buproprion Salt
    - Independent Claim: 20. A pharmaceutical composition, comprising at least one core which is surrounded by at least one osmotic subcoat, at least one control-releasing coat which surrounds the at least one osmotic subcoat, wherein the at least one core comprises bupropion hydrobromide and at least one excipient, wherein the at least one osmotic subcoat comprises at least one osmotic agent and at least one osmotic deposition vehicle, **and a means for releasing the bupropion hydrobromide from the composition. (emphasis added)**
- US Patent No. 7,670,617 Sequential Drug Delivery Systems
    - Independent Claim 1. A pharmaceutical composition comprising an active ingredient in a dosage form comprising a first portion, a second portion and **means for sequential release of said first portion and said second portion at a desired site within a subject**;… and **wherein said means for sequential release comprise means for sequentially controlling the activity of said pH-adjusting substances so that said first pH-adjusting substance attains peak activity in the localized environment of the active ingredient before said second pH-adjusting substance attains peak activity in the localized environment, whereby the localized environment of the active ingredient attains a first pH and then a second pH; wherein said means for sequentially controlling the activity of said pH-adjusting**

substances comprises at least one coating that surrounds said second pH-adjusting substance; said first pH-adjusting substance being peripheral to said coating; and wherein said active ingredient is peripheral to said coating in said dosage form. (emphasis added)

- US Patent No. 9,446,076 Pharmaceutical Composition for the Treatment of Heart Diseases
    - Dependent Claim 9. The pharmaceutical composition of claim 1, wherein said at least one pharmaceutically acceptable excipient comprises at least one component selected from the group consisting of growth factors, cytokines, proteins involved in organogenesis signaling, pharmaceuticals, platelet lysate, serum, isotopes, **means for tracing cells in vivo**, diluents, lubricants, matrix or scaffold materials, and combinations thereof. (emphasis added)
- US Patent No. 10,335,405 Non-Burst Releasing Pharmaceutical Composition
    - Independent Claim 11. An abuse deterrent oral pharmaceutical composition comprising a tamper resistant controlled release matrix, wherein the tamper resistant controlled release matrix comprises a **means for preventing the crushing, grating, grinding, cutting, solvating, or dissolving of the tamper resistant controlled release matrix** comprising:… (emphasis added)

Overall, MPF language can be a powerful tool in drafting biopharmaceutical claims to encompass broader claim scope that covers equivalents of the structures, materials, or acts described in the specification, and thus more fully protect an inventor's rights and provide greater protection against infringement. Practitioners are cautioned, however, that 35 U.S.C. § 112(b) also applies. If one of ordinary skill in the art would be unable to recognize structure in the specification that is clearly linked as corresponding to the means plus function element, the claim will be **invalid as indefinite** under §112(b)!

C. Example from USPTO Training Materials

5. A laundry detergent composition comprising:
    a) a cleaning adjunct selected from the group consisting of a fragrance, a surfactant, and a germicide; and
    b) a variant alpha-amylase enzyme having an amino acid sequence that has at least 90% identity to SEQ ID NO: 6, with
    c) **means for causing the variant alpha-amylase enzyme to have increased thermostability relative to BSG.**
6. The laundry detergent composition of claim 5, further comprising:
    a) **means for maintaining a hue in fabrics**.

Instructor Notes for Claim 5:

- "[T]he claim limitation '(c) means for causing the variant alpha-amylase enzyme to have increased thermostability relative to BSG' invokes § 112(f):
    - Prong A is met because: claim element (c) recites 'means'
    - Prong B is met because: the term 'means' is modified by functional language ('causing the variant alpha-amylase enzyme to have increased thermostability...')
    - Prong C is met because: claim element (c) is not further modified by sufficient structure or material for performing the claimed function."

- "In this case, the recited §112(f) limitation is supported by **adequate structure in the specification linked to the function**. The specification discloses a substitution modification at one or more positions corresponding to positions 50, 61 and 105 of SEQ ID NO:6. This limitation provides structure to perform the entire claimed function because these particular sequence modifications are described as achieving the increased thermostability function."
- No §112(a) or §112(b) concerns.

Instructor Notes for Claim 6:

- "[T]he claim limitation '(d) means for maintaining a hue in fabrics ' invokes § 112(f):
  - Prong A is met because: claim element (c) recites 'means'
  - Prong B is met because: the term 'means' is modified by functional language ('maintaining a hue in fabrics')
  - Prong C is met because: claim element (c) is not further modified by sufficient structure or material for performing the claimed function."
- "**Claim 6 raises concerns under 35 U.S.C. §112(b)**. Since the claim invokes §112(f), the examiner must look to the specification to determine the structure or material that performs the claimed function. However, in this example, there is no disclosure of adequate structure to perform the claimed function of maintaining a hue in fabrics. Accordingly, the claim must be rejected as indefinite under 35 U.S.C. §112(b)."
- "Because there is no disclosure of adequate structure to perform the claimed function, the specification does not convey with reasonable clarity to those skilled in the art that the applicant had possession of the claimed invention. **A rejection under §112(a) must be made for lacking an adequate written description.**"

D. Why Would Someone in The BioPharma Field Do the MPF Gambit?

An MPF claim may allow you to cover *equivalents* of the structures, materials, or acts that perform the same function under literal infringement.

Broader literal claim scope (structures, materials, or acts described in specification and literal equivalents thereof) may help when doctrine of equivalents is fading or otherwise not available. MPF claim language may provide more accuracy and clarity than purely structural characterization and may avoid written description and enablement issues.

E. How Do I Do This?

Claim a *combination* of substances, or a *combination* of steps in a process, and meet the MPEP/ *Williamson* analyses for construing a claim as a means-plus-function claim.

III. Applying These Creative Claiming Strategies

Consider all the potential claimable subject matter:

- Actives
- Formulations
- Delivery systems
- Drug-device combos
- Methods of treatment
- Methods of making
- Diagnostics, personalized medicine

Consider the client and its strategic objectives, which requires *communication*.

A. Claim the Clinical Trial Results

- Do you have access to pivotal clinical trial data?
- Draft tailored and ***narrow claims*** that capture the innovations arising out of the clinical trial results that will be ***in the drug product label***, *e.g.*, specific indication, dosing, specified target patient population, contraindicated symptoms, warnings and risk factors.
- If you have pivotal clinical trial results, consider drafting patent claims that may, or will, in addition to claiming clinical trial results, capture salient portions of the drug product label, such as the Indications and Usage; Dosage and Administration; Contraindications, Warnings and Precautions.
- Consider the label as a whole: Use Section 1 (Indications and Usage) to point to other relevant portions of the label.
- Consider safety signals, dosing regimens, things that are difficult or impossible to carve out of a label.
- Keep in mind that the claim should be practiced by the physician and/or patient who is following the label (inducement to infringe by the Generic/Biosimilar). Beware of divided infringement.
- Make sure the specification provides adequate written description and enablement support for the claim and includes the results of the clinical study and/or other relevant data.
- *Client communication and close collaboration with the clinical trial team and regulatory team, and appropriate timing, are required for this strategy to be successful*! Make sure the drug product label actually includes the results of the clinical trial, and that features you want to claim are actually present on the label, particularly the Indications and Usage section.

B. Use MPF

- If you use means-plus-function claiming, draft the specification to cover all of the embodiments that you want to cover with this language (include alternatives).
- Link the "means for" in your claim to the specification by clearly linking the entire function recited in the claim to the structure(s), materials or acts described in your specification. This can be done during prosecution in a preliminary amendment if not explicit in the specification.
- In other words, be intentional in your decision to use MPF claims and consider using Linking Table(s) in the specification or in a preliminary amendment.

Sample Linking Tables

Claim limitation	Specification
"means for making said formulation stable at 24 months when stored at room temperature"	"there . . . exists a need for an appropriate range of concentrations for both the 5-HT3 receptor antagonist and its pharmaceutically acceptable carriers that would facilitate making a formulation with . . . increased stability." [cite exact location in specification]
	"[t]he inventors have . . . discovered that by adjusting the formulation's pH and/or excipient concentrations it is possible to increase the stability of palonosetron formulations." [cite exact location in specification]
	"exemplary embodiments that demonstrate what means (i.e., structure and/or materials and/or acts) could be used to increase the stability of palonosetron formulations" [cite exact location in specification]

Claim No.	Recited Function	Exemplified structures and/or materials and/or acts disclosed in the Specification of the application filed herewith
Claim 10	"means for making said formulation stable at 24 months when stored at room temperature"	Page 9, lines 7-9; and Example 4 (page 14)
Claim 11	"means for making said formulation stable at 18 months when stored at room temperature"	Page 9, lines 7-9; and Example 4 (page 14)

Claim limitation	Specification
"means for effectively treating ulcerative colitis in humans"	"Finally, regarding 35 U.S.C. § 112, paragraph 1, MPEP § 2181 instructs that the specification (or the prosecution history) must clearly link the structure (or materials) to the function recited in the claim[.] … That requirement of 35 U.S.C. § 112, paragraph 1, is clearly met because, as explained above, Example 4, which demonstrates that the effective treatment of UC in humans (the function of part (1) of claim 63) is clearly linked to Example 1 (the extract for achieving that function)."
"means for chemically stabilizing said benzoyl peroxide in said aqueous gel composition"	"For a material to be considered 'corresponding' to a means-plus-function, MPEP 2181 requires that the specification or prosecution history clearly ***link*** the materials to the function recited for the materials. Applicants have provided that link via, e.g., Examples 6 and 7 in the Specification, as previously discussed in the Preliminary Amendment filed … and the Amendment under 37 C.F.R. 1.111 filed… . Moreover, one skilled in the art would recognize, from at least Examples 6 and 7, materials that perform the function recited in the means-plus-function."

- Take care to avoid prior art problems as a result of covering known prior-art equivalents.
- Take care to avoid definiteness issues (and/or written description issues) as a result of not linking the "means for" part of the claim with the specification.
- Make sure that your claimed means-plus-function limitation is not the only limitation in the claim, *e.g.*, a "single means claim" which could cover every conceivable means for achieving the stated result.
- During prosecution, to address an Examiner's application of 112(f), consider leaving claims as-is and add new non-"means" claims.
- During prosecution, try not to change the linking table.
- Consider potential obviousness type double patenting issues if pursuing MPF claims in a continuation application.
- Consider the following two types of MPF composition claims:

  Example 1: Possibly Effective Against an ANDA Applicant

  1. A composition comprising:

  component A and

  means for [achieving some desirable outcome].

  Example 2: Effective Against 505(b)(2) Applicant

  1. A composition comprising:

  means for [achieving some desirable outcome]; and

  a pharmaceutically acceptable carrier.

***

Dr. Gao is Assistant General Patent Counsel at Eli Lilly and Company. She obtained her Ph.D. in Molecular Biology from Northwestern University, and J.D. from the University of Illinois. Prior to joining Eli Lilly, she was a Patent Attorney at Novartis Institutes for BioMedical Research, where she supported ImmunoOncology and Neuroscience programs. She also worked for Fish & Richardson as an associate, focusing her practice on biopharma-related patent prosecution and litigation there.

Lilly was founded in 1876 by Colonel Eli Lilly, a man committed to creating high-quality medicines that met real needs in an era of unreliable elixirs peddled by questionable characters. His charge to the generations of employees who have followed was this: "Take what you find here and make it better and better."

More than 145 years later, we remain committed to his vision through every aspect of our business and the people we serve starting with those who take our medicines, and extending to health care professionals, employees and the communities in which we live.

Tom Irving has some 45 years of experience in intellectual property law. His U.S. pharma practice includes America Invents Act (AIA) post-grant proceedings, due diligence, counseling, patent prosecution, reissue, and reexamination. In addition to advising on procuring strong U.S. patents, Tom counsels clients on a wide range of mainly pharmaceutical matters, including pre-litigation, Orange Book listings of patents covering FDA-approved drugs, infringement issues, enforceability, supplemental examination, and validity analysis. He has served as lead counsel in numerous patent interferences, reissues, and reexaminations; as lead counsel in numerous AIA post-grant proceedings; and as an expert witness in patent litigation and patent procurement.

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP is one of the largest IP law firms in the world. With offices in Atlanta, Boston, London, Munich, Palo Alto, Reston, Seoul, Shanghai, Taipei, Tokyo and Washington, DC, the firm practices all aspects of patent, trademark, and copyright law, including counselling, prosecution, licensing and litigation. Finnegan also represents clients in IP issues relating to advertising, trade secrets, European patents and trademarks, international trade, portfolio management, the Internet, e-commerce, government contracts, antitrust and unfair competition.

Angie Sebor is the Director Intellectual Property at Tolmar, Inc., a Colorado-based, fully integrated pharmaceutical company focused on developing innovative, specialty pharmaceutical products in the areas of urology, oncology, pediatric endocrinology and dermatology. Angie is a registered U.S. patent agent with a Ph.D. in Immunology and more than 25 years' experience in patent law, both as an in-house practitioner and in private practice, primarily in the areas of biotechnology and pharmaceuticals.

Tolmar is a Northern Colorado based pharmaceutical research, development, manufacturing and commercial operations company. Tolmar develops and manufactures both proprietary and generic pharmaceutical products with specific focus in dermatology, oncology, and specialty injectable therapeutic areas.