

Prosecuting Bispecific Antibody Patents Worldwide: A Fine-Dining Guide for Patent Chefs

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PRACTICES Intellectual Property, Patents, Patent Prosecution and Counseling, Life Sciences, Biotechnology

Introduction

A client calls and says, “We’re cooking up a bispecific antibody. We want to mix and match binding sequences like a molecular gastronomy tasting menu. Some will go into CAR-T dishes. And of course, we want patents everywhere—from the United States to Latin America to the Persian Gulf. What ingredients do you need?”

If this sounds familiar, welcome to the Michelin-starred madness of bispecific antibody (bsAb) patenting, where every jurisdiction is a different kitchen with its own rules, recipes and temperamental food critic extraordinaire—aka patent examiner.

Claim Language: Mise en Place Matters

The fundamental ingredient of any antibody claim is the binding domain—your CDR sequences. Whether you’re plating heavy/light chain pairings or serving heavy-chain-only tapas, a proper patent menu should include:

- The exact CDR set (the “signature dish”);
- A 95% identity variant of the variable region (the “seasonal variation”); and
- The full variable region at 100 percent identity (the “chef’s original”).

For multispecific antibodies with unusual architecture—binding units tucked between domains like amuse-bouches between courses—describe each polypeptide subunit from N-terminus to C-terminus. Identify each binding unit by target, format, location and CDR composition. Don’t forget any mutations that affect effector function, heterodimerization or purification—these are your secret sauces.

Round it out with full-length sequence claims: the tasting menu from first bite to final dessert.

For CAR-T dishes, treat the extracellular binding domain as the key flavor component. If a jurisdiction refuses claims involving “cells,” simply present the CAR or its encoding polynucleotide—same dish, just as a deconstructed bento box.

Supporting Data: Restaurant Critics are Everywhere

Patent offices, especially in Europe, want evidence—not promises—that your new antibody sequence tastes better than the prior art. Novelty alone won’t win you a star. You will need data showing technical effect, such as:

- Stronger binding (umami!);
- Better specificity (no off-notes);

- Improved epitope targeting (precise plating);
- Agonism/antagonism shifts (controlled seasoning);
- Therapeutic improvements (the customer feels great afterward);
- Reduced toxicity (no one gets food poisoning); or
- Changes in ADCC/CDC (enhanced “bite”).

Since more jurisdictions are adopting Europe’s standards, gather your data early—before the examiners start acting like judges on a culinary competition show and saying you only made 11 of the 12 requested opera cakes.

Method-of-Treatment Claims: International Menu Translations

In the U.S., you can serve method-of-treatment claims straight from the kitchen. Elsewhere, the maître d’ insists on Swiss-type claims, first-medical-use phrases or second-medical-use formats. Write your specification like an international menu so you can plate whichever format each jurisdiction demands.

Prosecution Strategy: Avoiding Double-Patenting Kitchen Chaos

Each country’s patent prosecution is its own kitchen, complete with its own version of double-patenting health codes. A reliable recipe:

1. **Serve the product claims first**—those reciting both binding units by sequence.
2. **Then bring out the broader platform claims**—those featuring only one binding unit by sequence, and generically referencing the other, e.g., “a second binding unit that binds to a tumor associated antigen (TAA).”
3. **Add provisos** to the platform claims to carve out combinations already claimed in the parent, e.g., “...provided the second binding unit does not bind Target 2.”

It is the patent equivalent of keeping two dishes distinct so the reviewer does not accuse you of serving the same entrée twice.

Conclusion

Prosecuting bsAb patents is like running a high-end kitchen: you need precise ingredients (claims), impeccable flavor combinations (data) and a menu tailored to each region’s preferences (jurisdictional formats). But above all, stay close to your development team—they’re the sous-chefs who know what is really cooking. The sooner you start collaborating, the less likely you will have a kitchen fire during your dinner service!