

Portfolios With 4 Legs To Stand On: Animal Drug Patent Tips

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Business is booming in the animal health industry. Sources estimated \$23.9 billion in sales in the animal medicines and vaccines sector during 2014 and predict a continued growth of 4 percent.[1] Increased demand for animal protein, coupled with increased companion animal ownership and spending on medicines, are key drivers of this growth.[2]

Merial Ltd. has commanded the lion's share of the flea and tick protection market with its Frontline products. This success is in part because Merial has excluded multiple competitors by repeatedly asserting a single patent that claims the marketed "spot-on" formulation. While successful for Merial, this single-patent approach is not typical in the human pharmaceutical industry. Instead, human pharmaceutical companies tend to rely upon a multilayered fortress of protection, often called a "patent thicket," to obtain overlapping scope designed to deter competitors.

A thicket typically is best developed via a prosecution strategy that includes multiple types of claims, multiple terminologies, multiple conceptual approaches and multiple claim scopes, in multiple patents. Some animal pharmaceutical companies are following this model for their products. One example is Zoetis Inc.'s Apoquel (oclatinib). A family of patents protects Apoquel via claims directed to the compound and its polymorphs, methods of making the compound, compositions comprising the compound, and methods of treatment. Close examination of the filing strategies and drafting considerations that lead to the creation of portfolios like this provides insight for other animal health companies looking to expand market share.

Initial Filing Strategies

Developing strong patent protection requires making strategic decisions before filing the foundational provisional or nonprovisional application(s). Frequently, companies initiate diligence in developing a new product by studying freedom-to-operate around a target molecule, a disease, or a disorder, or by looking at white space to identify gaps in competitor's product offerings. Many times where the company acquires or develops a platform technology, its researchers screen for efficacious active ingredients to treat diseases or disorders. Once a company identifies a promising active ingredient, and particularly without an existing freedom-to-operate analysis in hand, a company would be wise to



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initiate a patentability analysis to determine whether to file a patent application. Such filings typically cover, e.g., the lead active ingredient, either specifically or as part of a genus, and/or methods of treatment using the active.

Next, when deciding what types of claims and claim scope to pursue, the company must carefully weigh broad versus narrow coverage for the active ingredient(s). While a broad genus claim could provide claim coverage for all tested active ingredients, a company may find itself "barking up the wrong tree," as a broad genus claim may present increased difficulty and cost to prosecute. In fact, a confluence of changes to the patent law have created a difficult environment for procuring broad genus claims due to: (1) patent eligibility issues, (2) written description/enablement issues, and (3) the expanded scope of prior art for post-America Invents Act filings.

Patent eligibility, a hot topic over the last several years, has become a bear for patent owners due in large part to the U.S. Supreme Court's interest in redefining what is a patent eligible as opposed to a law of nature, natural phenomenon or abstract idea. Several recent decisions in this area have far-reaching implications for the protection of, e.g., diagnostic methods for animals or biomarkers.

In *Mayo Collaborative Services v. Prometheus Laboratories Inc.*, the Supreme Court ruled as invalid diagnostic method claims directed to using a particular level of 6-thioguanine as an indicator of whether a drug dose should be modified, stating that the claims do not do "significantly more than simply describe ... natural relations."^[3] In *Association for Molecular Pathology v. Myriad Genetics Inc.*, the Supreme Court held that isolating a genomic DNA sequence was insufficient to provide patent eligibility.^[4] Most recently, in *Ariosa Diagnostics Inc. v. Sequenom Inc.* (cert. pending), the Federal Circuit ruled that method claims for detecting paternally inherited cell-free fetal DNA from a blood sample of pregnant women were patent ineligible.^[5] This triad has had, and is having, a profound impact on what is patent eligible and what — among matter that was previously thought eligible — no longer is. Purified natural products such as antibiotics are foremost on the list of concerns for animal pharmaceutical companies.

Another important factor to consider when determining the breadth of claim coverage to pursue is whether in vitro data is sufficient to satisfy the written description and enablement requirements, especially when planning to file the patent application globally. This is a fact intensive determination that will depend on the nature of each invention. For example, the advent of biologics as active ingredients has produced a significant body of case law unique to the field. These decisions have increased the difficulty in attaining and protecting broad claims with an adequate written description. And that task has become more challenging with the Federal Circuit's decision in *AbbVie Deutschland GmbH & Co. v. Janssen Biotech Inc.* ^[6] In *AbbVie*, the court further expanded the requirement in the immunological arts to actually reduce to practice as many embodiments as possible in the application. Where a patent applicant does not, she runs the risk of a successful invalidity attack at the time of infringement for lack of written description of an infringing species not reduced to practice at the time of application filing.

And in view of the expanded scope of prior art for post-March 16, 2013, filings ushered in by the America Invents Act, a broad genus claim may be more difficult to obtain due to the new definition of prior art under AIA 35 U.S.C. § 102. For example, whereas pre-AIA prior art geographically limited certain disclosures to the U.S. (i.e., if the invention was known or used by others, in public use, or on sale in the U.S. less than one year before the date of the application), the new 35 U.S.C. § 102 encompasses public disclosures occurring anywhere in the world before the effective filing date of the claimed invention. So it behooves companies to monitor and coordinate its global disclosures.

For these reasons, it may be necessary to limit claims to narrower classes of active ingredients. And within sets of claims of varying scope, the company should always include its lead active(s). Similarly, strategic decisions must guide drafting of the specification and considerations of what information to include. Too little detail may result in inadequate written description or fail to buttress patent eligibility, while too much detail regarding speculative methods of treatment, dosage regimens, biomarkers, animal species, and formulations may prevent patent protection for those types of inventions best suited for follow-on applications that will have later expiration dates. Thus, a company must carefully consider the level of detail to pursue in its foundational application(s).

Expanding the Portfolio

Subsequent filing decisions will likely arise as more data is generated during further testing of promising active ingredients. Innovators need to constantly consider whether the new data supports a new patent application filing using many of the same analyses that guided the initial filing strategy. Follow-on patent applications may include claims directed to new dosing regimens, formulations, delivery routes, and drug combinations. For example, specific dosing regimens or formulations may be more effective for particular species or breeds. And those findings may help overcome patent eligibility or obviousness issues a company may face during patent prosecution. As an example, the Federal Circuit in *Prometheus Labs. Inc. v. Roxane Labs. Inc.* helpfully noted that "[s]ingling out a particular subset of patients for treatment (for example, patients with a particular gene) may reflect a new and useful invention that is patent eligible despite the existence of prior art or a prior art patent disclosing the treatment methods to patients generally. An obvious rejection likely would not be appropriate where the new patient subset displayed unexpected results." [7] Depending on the results of the animal studies, data may show that such results are unexpected and therefore patentable.

Furthermore, when deciding whether to file a subsequent patent application, in addition to considering whether the claims are novel or nonobvious, obviousness-type double patenting must be considered. A later-filed, but earlier-expiring, patent can be used as a reference patent in an obviousness-type double patenting rejection. [8] This is particularly relevant if an earlier-filed patent enjoys the benefit of a pre-General Agreement on Tariffs and Trade filing date (an issue seen less frequently now that we are more than 20 years post-GATT) or patent term adjustment. Thus, having a carefully thought-out lifecycle management strategy for animal health products is imperative.

Conclusions

Obtaining patent portfolios with four legs to stand on requires forethought and careful planning. From the outset, companies should endeavor to understand the state of the prior art, carefully consider claim scope and mindfully determine the level of detail to disclose in the foundational application(s). When building a portfolio, companies must constantly consider whether the new data supports a new patent application filing and be mindful of creating obviousness-type double patenting situations. Drafting the right type and scope of layered claims and strategically filing the appropriate divisional or continuation applications can provide the tools needed to control segments of the booming animal health market.

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[1] Animal Health Industry Global Market Review 2014, Health for Animals (2014), <http://healthforanimals.org/our-industry/animal-health-industry-global-market-review-2014/>.

[2] Animal Health Growing Industry, Zoetis, <http://www.zoetis.com/animal-health/growing-industry.aspx> (last visited March 13, 2016).

[3] 566 U.S. ___, 132 S. Ct. 1289 (2012).

[4] 569 U.S. ___, 133 S. Ct. 2107 (2013).

[5] 788 F.3d 1371 (Fed. Cir. 2015).

[6] 759 F.3d 1285 (Fed. Cir. 2014).

[7] 805 F.3d 1092, 1098 (Fed. Cir. 2015).

[8] *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014).

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