

## Patent-Based Exclusivity

By S. Maurice Valla

*Efforts to extend the life cycle of pharmaceutical products frequently involve innovations and improvements in product design, formulation, route of administration, and treatment indications. In addition, negotiation of agreements with competitors, including generic and biosimilar manufacturers, is frequently employed as part of a life cycle management strategy. However, recent changes in patent, regulatory, and antitrust laws have introduced greater complexity and higher risk into these strategies.*

*On October 23, 2015, a distinguished panel of BakerHostetler partners led an exclusive seminar in person and online at which they discussed these and related issues and provided suggestions for developing successful life cycle management strategies. Here, Partner Maurice Valla explains patent-based exclusivity.*

### Early Stage Development

Valla opened with the observation that patent practitioners historically focused on obtaining protection for therapeutic targets such as isolated DNA sequences or for research tools used to identify compounds that interact with those isolated DNA sequences. Now, patent practitioners face a legal landscape in which isolated sequences are no longer patentable unless the sequence has a markedly different characteristic from its naturally occurring counterpart.

Valla also discussed how patent practitioners regularly sought patent protection for correlations between a therapeutic target and disease. For example, a claim might be directed to a method of treating a disease by interacting with a particular target. The current Section 112 jurisprudence forecloses these types of claims unless the specification provides sufficient examples of the therapeutic compound to inform one of ordinary skill in the art. Valla suggested that such target/disease correlation claims might still be allowable when the target is well-characterized and the contemplated method of treatment is the administration of a biologic such as an antibody or an oligonucleotide. Unlike in small molecule therapeutics, the prevailing view is that one of skill in the art could design an antibody or an interfering RNA to a sufficiently definite target.

### Developmental Candidate Identification

Valla opined that freedom to operate should be a consideration from the very beginning of the patenting process. He advised looking at what already exists in the patent landscape in terms of the therapeutic target, drugs, and competing companies. If patents exist, ask whether those patents are still valid under the latest legal standards and how much of the patent term remains.

Valla explained that the primary concern from a legal standpoint is how broadly to draft a claim. In the past, practitioners drafted broad generic claims to cover a vast universe of species. Valla noted that the current practice involves starting with a broad generic claim, then narrowing the scope of the claim so that the identifiable species are supported by the applicant's data. In determining how aggressively to prune the broad claim, the prosecutor should adopt a pragmatic approach, considering the value of the patent and the impact of the lost scope on a doctrine of equivalents analysis. If the field is very crowded, it may be desirable to claim a narrower genus, especially where that narrow genus has unexpected advantages over the prior art.

Valla cautioned that many countries require the applicant to limit the scope of the claims to only those compounds that have actually been synthesized. This approach marks a significant shift from the conception-focused practice in the United States. In certain countries, such as China, Japan, and Taiwan, it is necessary to submit data for a representative number of compounds that shows that the compounds actually work for their claimed purpose. Given these strict data requirements, it is no longer possible to "hide the ball" by failing to identify the compound with the best binding affinity. Valla opined that these data requirements are in direct tension with the "first to file" system in the United States and elsewhere. Determining when to file an application may come down to a business decision where the applicant balances timing considerations with the importance of capturing the international markets.

### Clinical Development

The scope and direction of the claims will likely change over time as testing progresses from the benchtop to clinical trials and eventually to commercial production.

Valla said that it is desirable to claim as broadly as possible from the outset to anticipate any future changes to the product. In a situation where protection is later sought for a particular salt form of the compound, Valla advised that such claims may face obstacles where the compound is already known and there are a limited number of pharmaceutically acceptable salts. Similarly, it may be difficult to get a claim directed to a particular isomer where the racemic mixture is known in the art.

### Approaching Approval

35 U.S.C. Section 156 provides for an extension to the patent term to compensate for any delay introduced by the regulatory approval process. Valla advised that the applicant should carefully consider which patent to extend as it is only possible to extend the term for one patent per product. He suggested considering which patent is strongest in terms of validity and which patent will give the longest period of exclusivity if extended. Regardless of the length of the clinical trial process, the term of the patent can only be extended up to a maximum of 14 years post-launch. Moreover, the extension must be sought before the patent expires, although an interim extension may be available if the patent is due to expire close to the date of approval. Valla noted that the extension does not apply to the patent as a whole, but only to the product for which approval was sought. Interpreting what qualifies as the same product becomes particularly difficult when dealing with biologics where the marketed product is similar, but not identical, to the claimed product.

Regarding Orange Book listing, it is the obligation of the sponsor of the approved drug to identify the patents containing composition of matter and method for treatment claims covering the compound or the product. The obligation to identify patents does not extend to sponsors of biologic therapeutics, as the Purple Book for biologics only lists approved biologics along with their exclusivity date and any approved biosimilars.

### Prior to Launch and Follow-on Indications

Valla stressed the importance of reassessing the intellectual property landscape and the client's portfolio throughout the approval process, as the transition to commercial-scale manufacturing might yield methods of treating additional conditions. However, diagnostic-style claims may face greater scrutiny under the newly developed *Myriad* and *Prometheus* case law.

Valla suggested looking for novel testing methods or reagents, or simply drafting the claims as a method of treatment. He cautioned that method-of-treatment claims are valuable to the drug manufacturer insofar as they provide support for a product label, but they may be less valuable to third parties given the complexities of distributed infringement.

### Active Pharmaceutical Ingredient Characteristics and New Formulations

Valla also suggested that later-discovered polymorphic forms of the approved compound may provide a basis for extending exclusivity, especially where the polymorph offers some unexpected benefit over the previous compound. For example, the polymorph may have advantages in terms of bioavailability, dissolutions properties, or ease of manufacture. Valla explained that when determining whether the patents directed to these polymorphs are listable in the Orange Book, the applicant must evaluate whether the polymorph is bioequivalent to the original compound.

In addition to claiming alterations to the active pharmaceutical ingredient, Valla opined that it might be possible to claim new formulations. For example, the applicant may wish to draft claims covering new coatings or new routes of administration, keeping in mind that the new formulation must overcome an obviousness challenge or problems stemming from a lack of written description in the specification.

### Additional Protection Strategies

Valla advised that when seeking protection for a method of treatment using two drugs, the key to patentability will lie in the applicant's ability to convince the Patent Office that the drug combination yields unexpected or synergistic results. In addition to drug/drug combinations, the applicant may wish to pursue drug/device combinations such as a loaded syringe or inhaler. Such a combination would be separately patentable and would be listable in the Orange Book, and could provide an attractive avenue for gaining protection for an old drug.

Valla concluded with the observation that the applicant may also wish to seek patent coverage for an Approved Risk Evaluation and Mitigation Strategy (REMS), though courts are increasingly viewing these sorts of patents as directed to the abstract idea of a method of distributing or controlling the risk in a population.

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