PATENT PROCUREMENT STRATEGIES

§ 70. INTRODUCTION

Before drafting a United States application, one should consider the overall place of the application in the global setting of the commercial objectives of the patent owner.

Even after weighing the merits of trade secret protection as an alternative to patents, one should not simply "file a patent". Life is not that simple. Even the most journeyman researcher comes up with an "invention" quite often, but the question is whether that invention is one that should be protected by a patent, and if so, where does that invention fit into the overall business picture, both domestically and internationally. While other technologies may not always value patent rights in Europe and Japan, for a regulated chemical or biotechnology invention, the global picture is a major piece of the patent puzzle.

This section approaches patent practice from the view of the post-patenting consequences of procurement, showing what can happen to a patent in court based upon the election of varying strategies during procurement. The focal point is the procurement of claims to new chemical entities and the products of biotechnology research, this is the lifeblood of the patent department in the regulated chemical industries.

A balanced perspective to procurement strategies requires looking at patent practice from three distinct areas, that of the patent draftsman, the patent prosecutor, and the litigator or licensor. Without all three, it is impossible to effectively serve one’s client. A post-grant perspective is necessary if the drafting and procurement strategies are to lead to a broad, valid and enforceable document.

§ 71. LEARNING THE WORLD OF CHEMICAL PATENT EXAMINATION

This paper is directed to experienced practitioners from the non-chemical arts as well as new practitioners who have a basic "patent attorney examination" knowledge of the substantive requirements for patentability, but without a background of the procurement practice at the Patent and Trademark Office (PTO).

§ 72. A GLOBAL PERSPECTIVE

The world of chemical and biotechnology patent practice necessarily requires a global perspective. It is vital that the original U.S. patent application be filed just as though it were simultaneously both a European and Japanese patent application: In practical fact, it is just that, as the parent application of the eventual European and Japanese application to be filed one year later. (Under the Paris Convention, the later-filed European and Japanese applications are not given priority for what is disclosed in these later applications, but only for what is commonly disclosed also in the "parent" case, the U.S. application.) Then, during prosecution it is vital to coordinate prosecution with the European
§ 72. A Global Perspective

parallel application. No patent practitioner in the regulated chemical industries can have optimum effectiveness for either U.S. or foreign procurement unless that practitioner intimately understands both arenas.

§ 73. REGULATED PRODUCTS AND SPECIAL CONSIDERATIONS

There is comparatively little patent litigation in the regulated chemical areas, vis a vis the importance of patents to such industries. Here, patent procurement is far more significant than for many other technologies. A new chemical entity to be a commercial candidate to undergo tens of millions of dollars of regulatory testing over a period of many years requires more than a speculative patent position.

§ 74. REGULATED PRODUCTS; LATE COMMERCIAL CANDIDATES

Grant of a patent too early before the final commercial candidate has emerged requires a Karnak-mindset to guess which compounds should be the focal point of protection; it is far more prudent to benefit from hindsight by having the case pending until the regulatory period is well underway.

In other words, it is impossible at the time of filing to determine which of literally thousands of compounds embraced within the literal wording of "claim 1" of a chemical compound genus claim will be "the" compound that is to be commercially developed. The objective keys to determine the best species in other technologies may be, for example, cost of materials, advantages of the product, etc. These are secondary in the regulated chemical industries to the long screening and testing process to determine which compound can successfully undergo the regulatory gauntlet. (Health and Humans Services (HHS) and its Food and Drug Administration (FDA) is one obvious regulatory area; pesticides is another.)

§ 75. REGULATED PRODUCTS; COVERAGE TO PROTECT INVESTMENTS

Literal patent coverage of any chemical or biotechnology product is often a condition precedent to a company triggering the expenditure of several years of time and tens of millions of dollars for regulatory approval of a new entity. See § 300, Claims and Their Interpretation.

Failure to obtain literal coverage for a pharmaceutical makes commercialization a risky proposition. It is hard to imagine any company today investing the tens of millions of dollars for regulatory approval without literal patent coverage. (While it is true that there has never been a reported case of successful enforcement in the past generation of a drug patent with non-literal infringement, perhaps there have been few situations where this could be a real-life situation.)

In addition to literal coverage, the type of literal coverage is important. Optimum claim preparation includes both generic claims and also species claims to the developed species. Species protection is far more important for a regulated chemical, as a claim limited to that regulated chemical is far stronger