

Patenting nanomedicine: a catalyst for commercialization?

Commercial nanomedicine is part of the high-risk, high-payoff global nanotechnology phenomenon. Although the full potential of nanomedicine is years or decades away, recent advances in nano-related drug delivery, diagnosis and drug development are beginning to change the landscape of medicine. Site-specific targeted drug delivery and personalized medicine may be on the horizon.

Will these advances in the lab result in viable commercialized products to benefit society, or will certain bottlenecks delay their arrival in the marketplace? Some major factors driving commercialization in nanomedicine are greater federal funding, an expiration of blockbuster drug patents in the near future, an aging population's desire for novel drugs and therapies, and an ever-increasing understanding of the molecular basis of disease. There are also bottlenecks: large-scale production challenges; high production costs; scarcity of venture money; and a lack of clear regulatory guidelines. Add to this, the confusion at the U.S. Patent and Trademark Office (PTO) with respect to handling the flood of patent applications pertaining to nanomedicine.

For government agencies like the PTO, simply defining nanotechnology is proving to be a challenge. The National Nanotechnology Initiative (NNI) proposed a rigid definition based on a sub-100 nanometer scale. However, this definition presents difficulties for accurately accessing nanopatent statistics. Also, this sub-100 nanometer size limitation is not critical to a drug company from a formulation, pharmacokinetic or efficacy perspective since the desired property (improved bioavailability, reduced toxicity, etc.) may be achieved in a size outside of this range. Similarly, the PTO's flawed definition of nanotechnology, which is essentially copied from the NNI, has resulted in a skewed preliminary classification system for nanomedicine.

For more than a decade, all the major patent offices of the world have faced an onslaught of nanomedicine-related patent applications. This is likely to get worse. Due to the potential market value of nanomedicine-related products, researchers, executives and patent lawyers are all on a quest to obtain broad protection for new nano-scale polymers and materials that have applications in nanomedicine. Researchers around the world are steadily filing patents in hopes of creating "toll booths" for future product development.

A sort of "patent land grab" is in full swing by patent prospectors as startups and corporations compete to lock up broad nanomedicine-related patents. This land grab mentality has not only produced overlapping patents but the race to hurriedly patent



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anything "nano" has produced a pile of unduly broad patents. This proliferation will ultimately produce a web of overlapping patent thickets requiring litigation to sort out, especially if sectors of nanomedicine become financially lucrative.

The increase in the volume of patent applications and technological advancement has created additional challenges for the PTO: workforce issues like high attrition; budgetary/revenue problems with Congress; lack of collaborative or interdisciplinary patent examination; poor automation and patent search tools; and lack of focused expertise in nanomedicine. The end result of all this is too familiar to the business and patent communities: a higher cost to consumers if and when products are commercialized, and a drag on the innovation process itself.

Since there has been an explosion of overlapping and broad patent filing on nanomaterials, it is likely that companies that want to use these

building blocks in products will be forced to license patents from many different sources in order to practice their inventions. Business planners and patent practitioners should steer company researchers away from such potential patent entanglements. They may also need to analyze the patent landscape to gauge the "white space" opportunities (no overlapping patents) prior to R&D efforts, patent filing or commercialization activities. Most experts agree that the stage is set for a wave of cross-licensing agreements and bundles of intellectual property for specific nanomedicine applications licensed by groups of large corporations.

In the end, companies bringing new products to the market will certainly face considerable uncertainty regarding the validity of broad and potentially overlapping patents held by others. The ongoing land grab will definitely worsen the problem for companies striving to develop commercially viable products. Therefore, it is critical that reforms be undertaken at the PTO in order to ensure a better balance between innovation and competition, particularly in the nanomedicine space. Otherwise, cursory patent search and examination at the PTO and the resultant issuance of invalid nanomedicine patents will certainly generate a crowded, entangled patent landscape with few open space opportunities for commercialization.

If such a dismal patent climate persists, investors are unlikely to invest in risky nanomedicine commercialization efforts. For them, competing in this high-stakes patent game may prove to be too costly. In fact, the patent thicket problem in nanomedicine may prove to be the major bottleneck to viable commercialization, negatively affecting the whole nanomedicine enterprise. ■