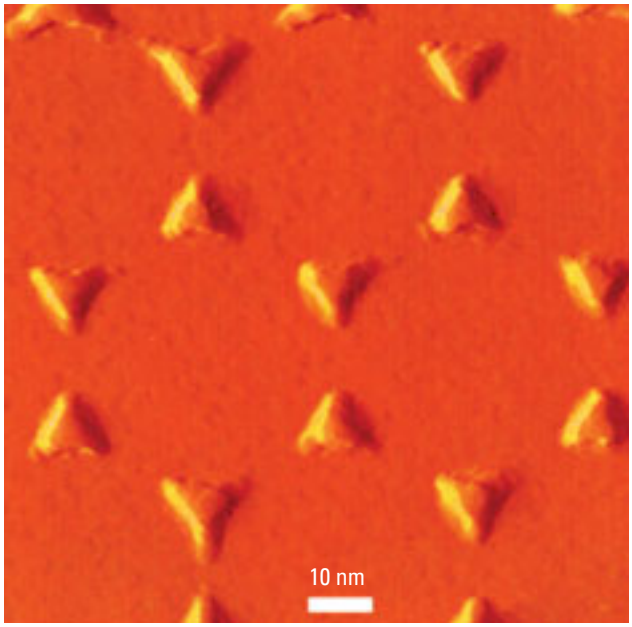
Unpredictable inventions

Patenting bionanotechnology inventions presents certain enablement challenges.

BY MARK L. HAYMAN

Although the U.S. Patent and Trademark Office (PTO) has seven technology centers—ranging from biotechnology to chemistry to materials engineering—none is specifically dedicated to nanotechnology. In the past three years, the number of nanotechnology-related patent applications has mushroomed to several thousand per year, up from several hundred six years ago. For now, the PTO processes nanotechnology patent applications through its existing examining groups.

However, it is problematic that nanotechnology, like all new technologies, presents unique legal issues. For example, the cross-disciplinary aspect of some nanotechnology patent applications can complicate the process of obtaining quality patents, because a working knowledge of diverse scientific disciplines and technologies may be required in both drafting and examining a patent application. In particular, problems of "enablement" may arise when patenting cross-disciplinary nanotech inventions, such as biosensor devices.



Connect the dots. An optical biosensor is based on triangular silver nanoparticles. (Adapted with permission from Haes, A. J.; et al. *J. Am. Chem. Soc.* **2002**, *124,* 10596–10604.)

To obtain a patent, an applicant must comply with the requirements for patentability as set forth in Title 35 of the *United States Code*. One such hurdle is the enablement requirement of Section 112, which dictates that the description of an invention enable another to make and use the subject of the patent commensurate with the scope of the patent "claims," which legally define an invention's boundaries.

During examination of applications for cross-disciplinary nanotechnology inventions, applying the enablement requirement raises three issues. First, since different PTO examining groups may interpret the enablement requirement differently, applicants may find it difficult to gauge the necessary content of a disclosure. Second, the enablement analysis may be especially complex for devices that rely on communication between biochemical and electrical components, increasing the likelihood that the enablement requirement is improperly applied during examination. And third, an examiner is unlikely to have a working knowledge of each scientific discipline or technology needed for thorough examination of some nanotechnology patent applications.

Issues of inconsistency

The enablement requirement is applied more stringently for inventions in the area of biotechnology than for electrical and mechanical inventions. For illustration, consider how the enablement requirement is applied during a PTO examination of a patent application.

In seeking some scope of patent protection, patent claims are often drafted to define an invention's boundaries in broad terms. Thus, a claim could cover many "embodiments" of the invention, each created by picking and choosing from elements of the device encompassed by the claim language. For example, a claim to a biosensor invention that recites "an enzyme" coupled to a "transducer" covers devices with any enzyme coupled to any transducer. Of course, some combinations of elements may not work for the intended purpose.

However, not every embodiment within the scope of a claim is required to be operable for the claim to satisfy the enablement requirement, but the inoperable embodiments must be predictable. That is, one skilled in the relevant nanotechnology field, in light of the application's description, is able to make and use the invention defined without undue experimentation, including predicting those embodiments that will work for the intended purpose. Ultimately, a patentable claim's scope is inversely proportional to the amount of experimentation required to practice the invention as defined by the claim.

While all patents must satisfy the enablement requirement, enablement is more often an issue for patent applications in technologies branded as "unpredictable," such as biology and chemistry. Conversely, the enablement requirement is often less of an issue for patent applications in "predictable" technologies, such as in the electrical and mechanical arts. Just as the degree of predictability varies between different technologies, so too does the interpretation of the enablement requirement by PTO examining groups.

For example, biotechnology and chemical groups apply a relatively strict standard, allowing very little unpredictability within the scope of the claims. Mechanical and electrical

groups apply a relatively loose standard, allowing a higher degree of unpredictability. The courts, which have the final word on the validity and enforceability of any patent, theoretically, but not always in practice, apply the enablement requirement uniformly across disciplines.

The PTO has yet to establish guidelines for classifying nanotechnology patent applications, which, therefore, may be assigned to any one of several examining groups. Given the inconsistency with which the enablement requirement is applied between examining groups, the enablement requirement itself, as it applies to nanotechnology, is unpredictable. Thus, the necessary disclosure deemed sufficient to enable the desired claims could vary substantially between examining groups.

Complex analysis for biosensors

The multidisciplinary aspect of nanotechnology also renders the enablement analysis more complex when compared with inventions in other technological fields.

Traditionally, biochemical components of an invention are considered unpredictable, where the relevant properties of a given molecule vary unpredictably with subtle changes in chemical structure. On the other hand, electrical and mechanical components are typically deemed predictable, where an appropriate structure can be constructed on the basis of the desired function. Nanotechnology devices, however, often require coordination between traditionally predictable and unpredictable components.

For example, a biosensor for detecting physiological substances (sometimes called the "analyte") may contain biological molecules—such as polynucleotides, antibodies, or enzymes—functionally coupled to a transducer that converts a biological signal into an electrical one. A corresponding patent application may attempt to broadly claim both an unpredictable element, such as an analyte, and a predictable element, such as a transducer. To the extent that an operable structure of an electrical/mechanical component cannot easily be predicted for a given selection of a biochemical component, these so-called predictable elements may be unpredictable in the context of a nanotechnology device.

Therefore, traditional thought regarding predictable and unpredictable technologies may not always be sufficient for proper examination of nanotechnology applications.

Effect on patent quality

While a patent is presumed to be valid, a patent may be invalidated in litigation if a court determines that the patent does not comply with the enablement requirement. Thus, where the enablement requirement is improperly applied, or not applied, during examination of the application, a patent's enforceability is compromised.

As discussed, examination of patent applications for nanotechnology devices may prove to be inconsistent. For instance, if a patent application for a nanotechnological device is assigned to a biotechnology examining group, the application's claims may be initially rejected for failing to comply with the enablement requirement. The applicant may have to expend significant effort during examination to overcome the enablement rejection or, otherwise, narrow the scope of the claims to that subject matter that the examiner believes is enabled. If the same application is assigned to an electrical examining group, however, an examiner may be less likely to raise enablement challenges.

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Furthermore, while an examiner with a biology background may focus examination particularly on the biochemistry elements, this examiner may unintentionally neglect the electrical elements or lack the requisite technical background to carefully examine them. Conversely, an examiner with an electrical background may neglect the biochemical components. That is, individual examiners are likely to follow the normal tendency of concentrating on aspects of the invention they are most familiar with.

Thus, the substance of examination may differ drastically depending on the examining group to which a nanotechnology application is assigned and the technical background of the examiner. Consequently, some nanotechnology applications may be poorly examined, leaving the corresponding patents vulnerable in litigation or otherwise of questionable value and difficult to license.

Mitigating the problems

Because of the inconsistent manner in which the enablement requirement is applied, nanotechnology patent applicants should be particularly careful when drafting a patent application. Generally, all available data and information relevant to an invention should be included in the application. However, given that time and resources for experimentation are limited, applicants should focus on establishing critical features for those aspects that are the most unpredictable and would require the most experimentation for another to practice the invention.

Bearing in mind the limitations of a given examiner's technical background, it would be helpful for patent counsel prosecuting the application to interview the examiner during prosecution. Doing so may help secure the proper claim scope and ensure that the claims are not narrowed during examination to overcome improper enablement rejections.

For example, it would be beneficial to draw the examiner's attention to those elements of the invention that are, and are not, predictable, and point out how the disclosure provides guidance to deal with this unpredictability. Further, examiner interviews may facilitate examination by helping an examiner to fully understand the invention. To this end, applicants should consider referring to literature relevant to the issue of enablement, such as review articles that discuss the state of the related field.

Given the complex nature of many nanotechnology devices, it should be no surprise that the patentability analysis for these devices is equally complex. Appropriate resolution of enablement issues before filing of a patent application will increase the value of the resulting patent.

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