Some practitioners in the mechanical arts may prosecute patents their entire careers without ever wrestling with a written description or enablement rejection. These days, those in the area of biotechnology and pharmaceutical patent prosecution rarely see an office action without such a rejection. Patent attorneys in the mechanical arts spend most of their time addressing anticipation and obviousness rejections. In the biotechnology (biotech) and pharmaceutical fields (pharma), obviousness rejections are becoming less and less common. Perhaps the basis for this dichotomy at the United States Patent and Trademark Office (USPTO) is that, despite the high level of skill in the biotech and pharma fields, little is obvious in the life sciences because of the unpredictability associated with these fields.

Prosecutors of patent applications relating to biotech and pharma technology often see fifteen- and twenty-page office actions relating almost entirely to rejections based on 35 USC §112, first paragraph. This section has three distinct elements. The first is the written description requirement, which somehow has morphed from simply requiring that the claimed subject matter be described in writing to requiring a “possession” of the invention, according to recent Federal Circuit cases. This standard arguably requires an applicant to reduce the invention to practice and has been labeled a “super enablement” requirement for biotech and pharma applications. The second is the requirement for enablement, which refers to whether the application describes the claimed subject matter in such a way as to enable one of ordinary skill in the art to use and make the invention – usually based on whether “undue experimentation” is required to make and use the claimed subject matter of the invention. The third is the requirement to set forth the best mode for the claimed invention, but as this requirement is rarely, if ever, a factor during prosecution, it will not be discussed here.

On November 20, 2003 the Boston Patent Law Association hosted a “Road Show” with representatives from Technology Center 1600 of the United States Patent and Trademark Office (USPTO) to discuss “hot topics” in prosecution practice. The half-day workshop involved top supervisors from the USPTO who presented on various topics and explained a complete overhaul, or retraining of Examiners, being done at the USPTO regarding prosecution of biotech and pharma patents. More than two-thirds of the subject matter covered in detail by the USPTO focused on enablement and written description, with practice claims and examples from hypothetical applications used by the USPTO to detail the increasing emphasis on enablement/ written description in patent prosecution in the biotech and pharma fields. This new emphasis in biotech/pharma prosecution at the USPTO stemmed in part from a Trilateral Study undertaken by the USPTO, European Patent Office, and Japanese Patent Office in efforts to develop similar standards for prosecution in all three patent offices.

The USPTO speakers at the Road Show also outlined an increased emphasis on utility, as it arose under §112, first paragraph, and explained with hypothetical claims and disclosures taken from the Trilateral Study that it is not enough just to satisfy the utility requirement of §101, one must also satisfy the requirement to set forth how to make and use the claimed invention. Thus, a claimed invention may be useful, and the specification may enable someone of ordinary skill in the art to make the claimed invention, but if the specification does not enable that same someone to also use the invention, then the claims are rejected for failing to meet the “use” requirement of §112, first paragraph (and may also be rejected for lack of utility under §101, depending on the context).

Shaking my head after the road show, I now counted four distinct requirements for biotech and pharma patents under §112, first paragraph – (i) best mode; (ii) possession of the invention (written description); (iii) enablement generally (how to make); and (iv) enablement utility (how to use). Which prompted me to ask “What happened to rejections based on prior art?”

Two recent federal circuit cases highlight the greater emphasis on utility in biotech and pharma applications, both under §101 and §112, first paragraph. The first is In re Fisher, 421 F.3d 1365 (Fed.Cir. 2005), a case about lack of utility, or more to the point, lack of a utility that the US Patent Office and the Federal Circuit deem sufficient to earn the right to patent protection. In this case, Fisher appealed from the decision of the USPTO Board of Patent Appeals and Interferences (the “Board”) against a final rejection based on lack of utility. The Fisher application cited seven uses for the claimed technology, and both the USPTO and the Federal Circuit acknowledged (at least some of) these uses. But the USPTO and the Court held that these uses did not meet the §101 requirement that the claimed invention have “specific and substantial utility.” Because the uses cited by Fisher did not yield an immediate benefit to the public, and because the cited uses were not distinct to the claimed invention – in other words, any compositions in this field of research would do the same thing – the USPTO, and the Court on appeal, held that the uses were not specific or substantial to the particular compositions claimed. Thus, the utility requirement under 35 USC §101 became a complete bar to patentability for the pending patent application. Prior art was not an obstacle. But as noted by Judge Rader in his dissent in In re Fisher, utility was the wrong section of the statute to deny patentability to this application, if it should have been denied at all. According to Rader, this application had utility, and both the Board and the Federal Circuit made a value judgment that the cited utility was not sufficient. Rader believes such a value judgment completely ignores prior (Continued on page 9)
case law, wherein—unless there is evidence provided by the Examiner that the cited utility is not credible to those skilled in the art—the utility cited by the applicant in the application is sufficient to meet the utility requirement under § 101. According to Rader, the better section of the Patent Act for rejecting this application would have been obviousness under § 103, but Rader argues that after In re Deuel (51 F.3d 1552 (Fed. Cir. 1995)), the obviousness rejection for biotech patents became so dissipated as to be essentially useless. Interestingly, there were eight amicus briefs filed in the In re Fisher case siding with the Board, seeking to persuade the Court that the claims pending in the Fisher application should not be allowed because of lack of utility. If the invention is so useless, why not let the patent issue? Of course, the claimed invention was useful—or at least potentially useful. The USPTO and the Federal Circuit, however, are requiring the applicant to have set forth in the application, as filed, a sufficiently specific use, different from the uses of prior art compounds, and perhaps even requiring a unique use.

In other cases, the USPTO seems to be rejecting claims for lack of utility under § 101 on the basis that the claimed invention does not perform well enough. For example, I have seen one instance involving an application with claims to novel molecules which are expressed in certain cells in humans, and methods of using these molecules. The application also discloses that proliferation of these particular cells in humans is linked to specific real-world diseases. However, the USPTO rejected all the claims citing a lack of utility, alleging that because these molecules are not expressed only in the proliferating cells linked to the disease that the molecules and methods of using them have no specific and substantial utility. As in the Fisher case, the USPTO has made a value judgment that the utility cited is not sufficient to meet the standards for § 101. In my view, there is no statutory basis for rejecting claims for an invention that provides the equivalent of false positives, or for an invention that does not perform perfectly well.

The other recent Federal Circuit case is Rasmusson v. Smithkline (413 F.3d 1318 (Fed. Cir. 2005)) an interference case that describes two distinct standards for enablement, one for whether a specification’s written description is sufficiently enabling to support the claims; and one for whether prior art is sufficiently enabling to anticipate a claimed invention.

How does the Federal Circuit arrive at this dual standard for enablement? After arguing that these different standards are not new, the Court argues that §112 requires that the invention be described to enable one of ordinary skill in the art to make and use the claimed invention. However, unlike §112, §102 contains no such “use” requirement. Thus, in the Rasmusson case, a pending application for Rasmusson which relies on a string of eight prior filings was denied a priority date until the date of filing of the final application because of lack of enablement in the priority documents. According to the Court, there was no enablement to use the claimed invention in the earlier filings.

Conversely, the Smithkline reissue applications involved in the interference procedures were held to be invalid based on a published European application of Rasmusson corresponding to the earliest priority document cited in the Rasmusson application at issue. Now the first-filed Rasmusson application was enabling as prior art to the Smithkline patents because §102 does not require that the disclosure in the cited reference be enabled for how to use, only for how to make. Thus, for Rasmusson the priority document was not enabling for obtaining an early filing date; for Smithkline, the cited Rasmusson European published application was enabling as anticipatory art. Is this an attempt by the Court to add more punch to prior art rejections? Certainly the argument that a cited §102 reference is not enabling looks less likely to be successful, for overcoming that prior art, now that the Rasmusson case has been decided.

Increasingly it appears that the only useful rejections left to the Patent Office for narrowing claim scope in biotech/pharma patent applications, and in some cases completing barring patentability, are non-prior art rejections namely, §§101 and 112 rejections dealing with utility and enablement/written description, particularly since one can usually overcome an anticipation rejection under §102 by amending the claim. Time will tell whether utility and enablement rejections continue to define the limits of patentability for biotech and pharma patents, or whether the importance of prior art will enjoy a resurgence. For the moment, it appears that inventors and patent attorneys are caught in something of a Catch-22 situation. The unpredictability in the biotech and pharma fields provides a powerful tool in arguing against obviousness. But at the same time, this very unpredictability is used by the USPTO and the Federal Circuit to narrow and sometimes bar patent protection in the biotech and pharma fields.

The challenge is for the applicant to get an application on file quickly to obtain an early date, yet still have enough support in the application to meet the increasingly stringent requirements for enablement and written description, and at the same time, provide evidence of substantial and specific utility. Unfortunately, there appears to be a de facto requirement developing to reduce the invention to practice to meet these requirements in the biotech and pharma fields. It appears that patent law in the biotech and pharma fields is developing an even more distinct nature from patent law in the mechanical and electrical arts simply because of the nature of the technology—unless the USPTO tries to be more consistent across the fields and starts raising some of these utility, written description and enablement issues in the mechanical and electrical arts.

University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916 (Fed. Cir. 2004); Noele v. Lederman, 355 F.3d 1343 (Fed.Cir. 2004); Enzo Biochem v. Gen-Probe Inc, 323 F.3d 956 (Fed.Cir. 2002); Regents of the University of California v. Eli Lilly, 119 F.3d 1559 (Fed. Cir.1997);

*Enzo Biochem v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002) at 981-82; and Reister, Andrea G. in “Enablement & Written Description: Friend or Foe in Litigation?”, Practising Law Institute, 804 PLI/Pat 607 (October - November, 2004).

*In re Wright*, 999 F.2d 1557, 1561 [27 USPQ2d 1510] (Fed. Cir. 1993)

The best mode requirement is more commonly brought up during patent infringement litigation.


*Brenner v Manson* (383 US 519 (1966)).

The Court in *Fisher* held that specific utility requires a “well-defined and particular benefit to the public” (see Fisher at 1371).

The Court in *Fisher* held that substantial utility provides “some immediate benefit to the public” or “a significant and presently available benefit to the public” (see Fisher at 1371), building on *Nelson v. Bowler* (626 F.2d 853 (CCPA 1980)) which held that substantial utility requires “practical” utility and “real world” utility (see *Nelson* at 856). See *Fisher* at 1380.

Id. at 1381 (“Rather than fault Fisher for not presenting evidence it was prevented from offering, this court should instead observe that the Board did not satisfy its burden of challenging Fisher’s presumptively correct assertion that the ESTs were capable of performing those functions. See MPEP § 2107.02(IV) at 2100-40 (noting that the initial burden is on the office to establish a prima facie case as to lack of utility and to provide evidentiary support thereof); *In re Brana*, 51 F.3d 1560, 1566 (Fed.Cir.1995) (where an applicant has asserted utility in the disclosure, the Patent Office has the initial burden of challenging this presumptively correct assertion of utility.)”).

Id. at 1382 (“The proper tool for assessing sufficient contribution to the useful arts is the obviousness requirement of 35 U.S.C. § 103. Unfortunately this court has deprived the Patent Office of the obviousness requirement for genomic inventions.”).

See *Rasmusson* at 1325 (“The standard for what constitutes proper enablement of a prior art reference for purposes of anticipation under section 102, however, differs from the enablement standard under section 112. In *In re Hafner*, 56 C.C.P.A. 1424, 410 F.2d 1403 (Cust. & Pat.App. 1969), the court stated that "a disclosure lacking a teaching of how to use a fully disclosed compound for a specific, substantial utility or of how to use for such purpose a compound produced by a fully disclosed process is, under the present state of the law, entirely adequate to anticipate a claim to either the product or the process and, at the same time, entirely inadequate to support the allowance of such a claim."

Id. at 1405; see *Schoenwald*, 964 F.2d at 1124; *In re Samour*, 571 F.2d 559, 563-64 (Cust. & Pat.App. 1978).

Id. (“The reason is that section 112 "provides that the specification must enable one skilled in the art to 'use' the invention whereas [section] 102 makes no such requirement as to an anticipatory disclosure." *Hafner*, 410 F.2d at 1405; see 1 Donald S. Chisum, *Chisum on Patents* § 3.04[1][c] (2002); see also *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349-52 (Fed.Cir.2002) (finding anticipation where applicant sought a patent based on a new use for a previously disclosed method).”)