Festo: A patent applicant's plague

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Abstract This paper highlights some of the intricacies and complexities associated with patent drafting, particularly in unpredictable sciences such as biotechnology. The paper draws on the new guidelines issued by the Patent Office regarding compliance with the 'utility' and 'written description' requirements of the Patent Statutes to illustrate some of the thorny issues applicants must thoughtfully consider during drafting as well as the pitfalls applicants will encounter when failing to do so. The paper then reviews the recent decision in *Festo Corp. v Shoketsu Kinzoku Kogyo Kabushiki Co, Ltd* to underscore how a lack of forethought can result in the issuance of claims that provide a compromised scope of protection.

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Introduction

Patent drafting is intricate and complex. It requires considerable planning to ensure that an application complies with the Patent Statutes and lays an appropriate foundation to secure a meaningful scope of protection. This is particularly the case in areas of science that are viewed as unpredictable, such as biotechnology. To illustrate this point, this paper reviews the Patent Office's recent guidelines for assessing compliance with the 'utility' and 'written description' requirements of the Patent Statutes.[1] It draws on those guidelines to highlight some of the complex issues applicants must consider when drafting an application as well as the pitfalls they will encounter when failing to do so. The paper then reviews the recent decision in *Festo Corp. v Shoketsu Kinzoku Kogyo Kabushiki Co, Ltd*[2] and highlights how a lack of forethought during application drafting can result in the issuance of amended claims that provide a compromised scope of protection.

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The force and effect of the examination guidelines

The examination guidelines are designed to assist patent examiners in their review of an application's compliance with Sections 101 and 112 of the Patent Statutes. They are based on the Patent Office's interpretation of those two statutes and related case law. These guidelines only govern internal practices within the agency and are not binding on courts.[3] As such, they do not have the force and effect of law. Notwithstanding, they do serve as useful tools for highlighting issues applicants should consider during drafting as well as the obstacles applicants will encounter during prosecution when such forethought has not been given.

The utility examination guidelines

Section 101 of the Patent Statutes requires that an invention have utility as of the date the application was filed.[4] This requirement

ensures that society ultimately obtains access to something useful after the expiration of the patent term.[5] Thus, only inventions having at least one utility that would be recognised as both 'credible' and 'specific and substantial' by one of ordinary skill in the pertinent art, as of an application's filing date, are worthy of protection.[6]

Under the utility guidelines, compliance with this requirement turns on two considerations: (a) whether the claimed invention has a well-established utility as of the application's filing date; and (b) whether a utility is asserted in the specification. Depending on the interplay of these two considerations, the deference that an examiner must extend to an application takes one of three forms. The highest level of deference applies where there is a well-established utility – regardless of whether it is asserted in the application. In such a circumstance, a claim should not be rejected.[7] A lower-level deference, however, applies where no well-established utility exists and an unrecognised utility is asserted in the specification. In this circumstance, the examiner can reject the claim by showing that the asserted utility is not one that a person of ordinary skill in the art would accept as either credible or specific/substantial.[8] Finally, an examiner can readily reject a claim where there is no well-established utility and no utility is asserted in the specification.[9]

In the latter two instances, the onus then falls on the applicant to rebut the rejection. This can be done by any of the standard means available to an applicant, eg submitting argument, a claim amendment, a declaration, a patent or a printed publication, which shows that the requisite utility was known to exist as of filing.[10] In certain factual settings, however, there may be nothing of substance to provide in response. For example, little evidence may be available to substantiate that the requisite utility was appreciated as of the filing date. Similarly, if the utility was purely speculative or prophetic at the time of filing, it may be difficult to prove that such utility does in fact exist. In either circumstance, applicants will be unable to overcome the rejection and secure an allowable claim. In the field of biotechnology, these risks are likely to arise, for example, where applicants have isolated and purified nucleic and amino acid sequences with unknown biological functions, such as expressed sequence tags (ESTs), and filed applications directed to the same before discerning these sequences' biological relevance.[11]

In some instances, a claim amendment may overcome the rejection. Such a scenario could arise where a claim is directed to a genus (eg a class of genes or proteins) whose utility may be more difficult to prove than the utility of a sub-genus or species embraced by the genus. In this situation, applicants may elect to limit their claims to the sub-genus or species for which a showing of utility can be more easily made. However, any amended claim will probably lose a significant range of equivalents it might have otherwise enjoyed had it been presented in the amended form in the application as filed. In this respect, applicants may be better served originally filing narrow claims rather than generic ones. This flows directly from *Festo*, which is discussed below.

Thus, before filing an application, applicants need to consider carefully whether their claims are directed to inventions with a well-established utility. If the claims are not, applicants should consider whether that utility and any proof thereof should be asserted in the application. Including such information in the application may persuade the examiner that the requisite utility exists and prevent a rejection from being made. At a minimum, following such a course will force the examiner to demonstrate why that utility is either not credible or non-specific/insubstantial before issuing a rejection. If such information is omitted, applicants, nevertheless, should ensure that sufficient evidence is available during prosecution, if necessary, to prove that such utility was appreciated at the time of filing and in fact exists. Otherwise, applicants will be unable to overcome the rejection and secure an allowable claim.

The written description guidelines

Section 112 of the Patent Statutes requires that the specification contain a written description of the claimed invention.[12] This requirement has two primary functions: (a) to ensure that an applicant possesses the subject-matter claimed as of the application's filing date; and (b) to allow others to build on the applicant's teachings and advance the art, while, at the same time, not trespassing (ie infringing) on the claimed invention.[13] To comply with this provision, an application must convey with reasonable clarity to those of skill in the pertinent art that, as of its filing date, the applicant was in possession of the subject-matter claimed.[14]

The guidelines reflect that an application can satisfy this requirement in one of three ways, by containing: (1) a description of an actual reduction to practice of the claimed invention; (2) drawings or formulae that detail the features of the invention; or (3) a verbal description that details relevant identifying characteristics of the invention.[15] In the latter two scenarios, every nuance of the invention need not be described; rather, only those features that are essential/critical and new/unconventional must be set forth in detail.[16]

The type of scrutiny a claim receives is dependent upon whether it is: (a) an original claim versus one that was amended or introduced during prosecution; and (b) directed to a single embodiment/species versus a genus. As to the first consideration, a strong presumption exists that there is an adequate written description for original claims – regardless of whether they are directed to a single embodiment or a genus.[17] No such deference, however, is accorded to new or amended claims. Thus, a patent examiner has greater discretion to reject the latter rather than the former.

As to the second consideration, when the claim is directed to a genus, an adequate description of a 'representative number of species' is necessary to support the genus. In other words, an adequate number of species, representative of the diversity found within the genus, must be disclosed.[18] The number of species needed to support the genus is inversely proportional to both the variability within the genus as well as the skill and knowledge in the pertinent art. Thus, when there is little variation within the genus, a single species may suffice. In contrast, when the genus embraces widely variant species in an unpredictable art, additional species must be disclosed.[19]

Reduced to their essentials, the guidelines highlight two main points that applicants should carefully consider when drafting an application. First, where an application does not describe a complete reduction to practice, does it recite all critical/essential and new/unconventional features of the claimed invention? Any deficiency could be fatal – particularly where there is no support for a necessary claim amendment. Second, does the application clearly and consistently identify those features that are critical/essential and those that are not? Any ambiguity will probably result in applicants being forced to amend their claims to incorporate additional features deemed critical/essential by the patent examiner.

The challenge facing applicants becomes even greater when the invention is directed to a genus in an unpredictable art. In these situations, applicants face the added hurdle of ensuring that a 'representative number of species' is properly disclosed. Unfortunately, in highly unpredictable arts, such as biotechnology, both the courts and the Patent Office have shown a reluctance to allow broad claims.[20] As a result, an examiner is likely to be sceptical when reviewing applications in this art, forcing applicants to limit their claims to those species actually disclosed.

Although written description infirmities can be cured by amendment, the discussion that follows reflects that such amendments come at a heavy premium. By narrowing claims during prosecution, applicants will lose a range of equivalents that the claims would have otherwise enjoyed had they been presented in their amended form at filing. In this respect, applicants may be better off initially claiming narrowly

(thereby preserving full access to the doctrine of equivalents), rather than claiming broadly and having to cut-back during prosecution (thereby compromising their access to the doctrine).

At the same time, however, applicants need to appreciate that the allowance of a set claims that are drawn to a narrower invention than the one disclosed in the application may result in a finding that the described-yet-unclaimed subject matter has been dedicated to the public and cannot be recaptured through the doctrine of equivalence.[21] In this respect, claiming narrowly is a double-edged sword, the risks and benefits of which need to be considered carefully.

The doctrine of equivalents and *Festo*

The doctrine of equivalents is a judicial doctrine that prevents an accused infringer from pirating an invention's essential identity by making minor or insubstantial changes that avoid a literal correspondence to the claim.[22] However, the reach of this doctrine is by no means boundless. To ensure that a patent fulfils its notice function, courts created a separate doctrine – the doctrine of prosecution history (file wrapper) estoppel – to prevent patentees from recapturing through equivalents subject-matter surrendered during prosecution – either by way of amendment or argument.[23] This latter doctrine is premised on the theory that the public is on notice of what equivalents were surrendered based on their access to the file wrapper underlying the issued patent.

Courts, including the Federal Circuit, tended to apply 'a flexible bar approach' to assess the nature and extent to which an estoppel precluded a claim from covering a range of equivalents.[24] The difficulty in applying that approach has been that patentees and putative infringers have had divergent views on the estoppel created and the range of equivalents that remain available. In turn, the boundary between infringement (under the doctrine of equivalents) and legitimate improvement and design-around were often blurred. Thus, judicial intervention was required for clarity.[25]

Festo removes this cloud of uncertainty by adopting a 'complete bar' approach to prosecution history estoppel. Under this approach, no range of equivalents will be available to any claim element narrowed 'for a substantial reason related to patentability' during prosecution.[26] Given this holding, an estoppel arises from any amendment that brings a claim into compliance with any of the statutory requirements governing the issuance of patents, including the utility and written description requirements of Sections 101 and 112.

Consequences of *Festo* on patent application drafting

One major consequence flowing from *Festo* is that an even greater premium is placed on application drafting. This is particularly so in emerging and unpredictable arts, such as biotechnology. The utility and written description guidelines highlight some of the thorny and complex issues applicants must consider during drafting as well as the pitfalls applicants may encounter when proper forethought is not given. Great care and restraint must be exercised to craft a conservative set of claims of an unambitious breadth. In crafting claims of that scope, applicants can hope to avoid making amendments during prosecution and preserve their right to resort to the doctrine of equivalents for a finding of infringement, if necessary. Inattention to such details will probably result in applicants having to amend claims, which, in turn, will create estoppels that would-be copiers can freely exploit to pirate the claimed invention without actually infringing it. As a result, the economic promise an application was once thought to possess will never be realised by the corresponding patent that issues.

References

1. Utility Examination Guidelines, 66 Fed. Reg. 1092 (January 5, 2001); Guidelines for Examination of Patent Applications Under 35 USC 112, para. 1, 'Written Description' Requirement, 66 Fed. Reg. 1099 (5th January, 2001).
2. 234 F.3d 558 (Fed. Cir. 2000) (*en banc*).
3. 66 Fed. Reg. 1092; 1099, Supplementary Information.
4. 35 U.S.C. s. 101.
5. *See Brener v Manson,* 383 US 519, 534–35 (1966).
6. 66 Fed. Reg. at 1094, Comment 9.
7. *Id*. at 1097–1099, Section II B.1.(c).
8. *Id*., s. II B.3.(a)–(b).
9. *Id*., s. II B.3.(c).
10. *Id*., s. II B.4.
11. *Id*., at 1094, Comment 8.
12. 35 USC s. 112, para. 1.
13. 3 Donald S. Chisum, Chisum on Patents, s. 7.04, n.1 (2000).
14. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991).
15. 66 Fed. Reg. 1105–07, s. II.A.3.a.–b.
16. *Id*., s. II.A.3.
17. *Id*. at 1104–1105, s. I.A.
18. *Id*. at 1105–1107, s. II.A.3.a.(2).
19. *See generally id.*
20. For example *Regents of University of California v Eli Lilly & Co*., 119 F.3d 1559 (Fed. Cir. 1997) (invalidating claims to DNA encoding a vertebrate form of proinsulin); *Fiddes v Baird*, 30 USPQ2d 1481 (Bd. Pat. App. & Int'f 1993) (rejecting claims to DNA encoding a mammalian fibroblast growth factor).
21. *Moore USA, Inc. v Standard Register Co*., 299 F.3d 1091, 1107 (Fed. Cir. 2000) (petition for cert. filed 26th February, 2001).
22. *Graver Tank & Mfg. Co. v Linde Air Prods. Co*., 339 US 605, 608 (1950).
23. *Festo,* 234 F3d at 564.
24. *Id.* at 572.
25. *See generally id. at* 572–575.
26. *Id.* at 566.