

## SUFFICIENCY OF DISCLOSURE (ENABLING DISCLOSURE, DISCLOSURE OF PRIOR ART, BEST MODE)

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### **What is the purpose of the description in a patent specification?**

We grant exclusive rights for an invention when we believe that the applicant has invented something new and useful. Part of the reason for doing so is that we think the applicant has something worthwhile to teach us, which we might not otherwise learn. The disclosure of the patent specification is the teaching.

It teaches the public how to operate the invention. This is an important part of the consideration the applicant gives for 20 years of exclusive rights. Even before the patent expires, the public has use of the information: for private purposes, for experiment (in some degree), and in any way that falls outside the scope of the patent claims.

The disclosure also helps us to decide what rights we should grant the inventor.

### **Teaching the invention**

Who is to be taught to operate the invention? Most inventions are improvements<sup>1</sup> (sometimes apparently quite small improvements) on what is already known. There is no need to start all over again from first principles.

The obligation to disclose is stated in patent laws in various ways. For example, in the European Patent Convention:

*Article 83*

*Disclosure of the invention*

*The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.*

In USA, 35USC 112 provides, in part:

*"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same,..."*

From Section 112 comes the term 'enabling disclosure'. The person, then, to whom the invention must be taught is a notional 'person skilled in the art'. Such a person is competent, and already well-instructed in the common practices of the art. Exactly what such a person knows is a question of fact, to be determined, where necessary, by evidence in each particular case. It will vary according to the art, and naturally according to the date of the invention. An inventor is not entitled to rely on what

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<sup>1</sup> "The claim may be that the whole thing is a novelty. It is difficult to suppose such patents at the present day..." (per Grove J. in *Young and Neilson v. Rosenthal & Co*, 1 RPC p29, at p.33 – reported in 1884).

subsequently became known in the art: he may not later fill in gaps in his original disclosure, or add essential details necessary to make his invention work. But it is not the job of the inventor to tell the public what they can reasonably be expected to know already. Patent specifications are long enough as it is.

Now, it is rarely completely clear, in any art at any date, exactly what the skilled person knows, and what not. A sensible patent applicant, therefore, will err on the side of caution, and disclose the invention in full and careful detail, so as minimise the risk of subsequent argument. If in doubt, one may refer to published text-books for evidence of 'the common general knowledge'. The 'person of ordinary skill in the art' has been criticised as an awkward and artificial abstraction, and there have been moves to replace him, or her. But the abstraction has other uses: it is a similar 'person of ordinary skill' who is the yardstick for whether an invention is obvious.

### **Biological Deposits**

It is sometimes difficult, or even quite impractical, to describe inventions in a way which allows them to be repeated from written instructions alone. This particularly applies to inventions based on biological materials, which frequently depend on having access to the right starting material. In consequence, descriptions of such inventions generally contain details about the source of the starting material. If this material is not readily available, a patent using it could be invalid because its disclosure was not repeatable. This difficulty has been partially overcome by the practice of depositing biological materials. For micro-organisms, this is regulated by the Budapest Treaty 1977<sup>2</sup>. This allows applicants to deposit samples of biological material in recognised depositories, so that they become available to persons wishing to repeat the disclosure of the patent application. Rule 28.1b EPC requires disclosure in the specification of "such relevant information as is available to the applicant on the characteristics of the biological material"<sup>3</sup>. This practice of deposit has been extended to other materials either arguably not, or clearly not, micro-organisms: for example, genes or other DNA sequences in vectors, and plant seeds. The practice is to limit distribution of the materials until the patent is granted or refused, following which the materials become freely available.

### **Fair basis**

In general, the applicant needs only to describe in detail one method of carrying out the invention, from manufacture from available materials through to practical use. Often the applicant will show variants and alternatives falling within the scope of his claims. The importance of these depends on the nature of the invention. Some arts (for example the mechanical arts) are more predictable than others. "There is no prevision in chemistry", it used to be said<sup>4</sup>. This overstates the position: but it remains true that chemistry and related sciences (notably biotechnology) are by no means completely predictable. Many or most inventions in such arts are based on discoveries<sup>5</sup> of something unexpected: a class of chemical compounds is found to have previously unsuspected biological activity. The question then is, how large is this class? Thus, in the chemical field, an applicant claiming a new class of bioactive

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<sup>2</sup> [http://www.wipo.int/treaties/en/registration/budapest/trtdocs\\_wo002.html](http://www.wipo.int/treaties/en/registration/budapest/trtdocs_wo002.html)

<sup>3</sup> Which would appear to include information about the natural habitat of the micro-organism.

<sup>4</sup> For example, in the Canadian case *Chipman Chemicals Ltd. v. Fairview Chemical Co. Ltd.* [1932] Ex. C.R. 107 at 115.

<sup>5</sup> In arts like these, there is often a close link between 'discoveries' and 'inventions'. The distinction between them drawn in some patent laws often misleads. The important distinction is between what is old and what is new.

compounds will normally be required to show a range of examples to confirm that they share this activity: if only one compound is disclosed, the claim may have to be limited to it. To support a broad claim, a wide range of examples is desirable: the more examples, the easier to negotiate with the Examiner a broad claim scope. As always, there is a balance. The Examiner must make a judgement. If he is too severe, the applicant may be deprived of the benefit of his invention by a competitor making something very similar. If he is too lax, the applicant may receive a broad patent covering a largely uninvestigated area generally lacking the advantages claimed, thereby inhibiting research and development for no benefit. Practice varies, not only from Examiner to Examiner, but from art to art. In chemistry, it is relatively strict, having been developed over several decades. In biotechnology, it tends to be more generous to the applicant<sup>6</sup>, though it is doubtful if biotechnology is much more predictable than chemistry. Very significant questions arise as to the scope of claims to broad new concepts proven only over a narrow area. For example, is the patentee entitled to define his claim by what works? 'Support for the claims' is a fundamental question, and it is a defect of the European Patent Convention that it is finally settled in the examination phase, so that the 'fair basis' for claims cannot thereafter be challenged either in opposition or in the courts.

Meanwhile, the best advice for applicants in cases of this kind is to provide as many examples as they can.

### **'Best mode'**

It is sometimes said that patent disclosures are deliberately skimmed, in an effort to gain exclusivity without paying the proper price for it. If this practice happens at all, it is certainly not widespread. Any patent attorney knows the importance of including the fullest details in the specification - how often it turns out that some procedure originally thought optional is in fact essential. This may be because the invention proves not to work properly (or even at all) without it: or because the procedure without the preferred detail is found to be known, so that the previously preferred but optional feature becomes essential to provide novelty.

But some countries have gone further than this, and put a duty on the applicant to disclose the best method he knows of performing the invention. This was the law in UK under the Patents Act 1949<sup>7</sup>, until superseded in 1978 by the law of the European Patent Convention. It is still the law in USA - where 35 USC 112, quoted in part above, continues : "... and shall set forth the best mode contemplated by the inventor of carrying out his invention." It is also the law in Australia: Australia Section 40(2)(a) - "*A complete specification must describe the invention fully, including the best method known to the applicant*".

One of the functions of the patent system is to encourage the publication of new technology. It is in the interest of the public to have the best information available. There is thus a public interest in the disclosure of the best mode. However, 'the best is the enemy of the good': too stringent disclosure requirements can hinder rather than promote this. All patent attorneys have clients who balance the likelihood of getting

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<sup>6</sup> But see *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997), which held that a disclosure of rat insulin cDNA was not enough to support a claim to all 'mammalian insulin cDNA'.

<sup>7</sup> Section 32 (h) (Patent may be revoked if it) "... does not disclose the best method of performing it which was known to the applicant for the patent and for which he was entitled to claim protection"

a patent against the value of the knowhow to be disclosed - and decide in each case whether to file or maintain secrecy. Disclosure standards must be realistic.

Even if only in force in one or two countries, the best mode requirement has an important influence: if an inventor has to disclose it in one country, he may as well disclose it in all. There are limitations: the USA, for example, requires only the best mode 'contemplated by the applicant', i.e., the inventor. Sometimes the applicant's employer, who owns the invention, may know more. No country requires the best mode to be *identified*: thus, it can (at least in theory) be buried in Example 57 of a 200-page specification, with nothing to distinguish it from eighty-three other methods of carrying out the invention. There are proposals to remove the obligation from US law, on the theory that the requirement is subjective and difficult to judge, and that its main effect is to increase the cost of litigation.<sup>8</sup>

### **Disclosure of Prior Art**

As most inventions are improvements, most patent specifications refer, either generally or specifically, to what has been done before. Although in most countries there is no absolute compulsion to do so, it is nevertheless commonly done. In the European Patent Office, for example, Rule 26 requires the applicant to:

*"..indicate the background art which, as far as known to the applicant, can be regarded as useful for understanding the invention, for drawing up the European search report and for the examination, and, preferably, cite the documents reflecting such art".*

This falls short of compelling the disclosure of relevant prior art to the Office. Clearly, though, it is in the applicant's interest to do so if he wishes to obtain a valid patent. Equally, it is in the public interest to have all relevant prior art considered during the patent examination.

Other Offices (UK, Australia, for example) do not specifically require disclosure of relevant art, but do require to be informed of citations made in parallel applications prosecuted in other countries.

The USA takes a more stringent view. The applicant is obliged to disclose to the Patent Office the relevant art of which he is aware. Such an obligation, appropriately policed, must surely produce patents of higher quality, patents which are more likely to withstand scrutiny? The sanction, in US practice, for failure to disclose relevant prior art of which the applicant is aware, is severe. It is held to amount to 'inequitable conduct', also termed 'fraud on the Patent Office'. Not merely does this render the patent unenforceable, but a patent so obtained is considered as an illegal monopoly and attempts to enforce it may lead to triple damages under the anti-trust laws. Note that the art to be disclosed need not necessarily be such as to invalidate the granted claims: it is sufficient if it is so relevant that the Examiner might have taken it into account. How relevant that is will not be too easy to determine. It follows that the applicant and his advisors are obliged to take a conservative view: if in doubt, disclose. That can lead to long lists of citations of marginal relevance. The need to plough through these can make the Examiner's job more difficult. The practice also adds to the expense of US litigation, in which a patentee will be required to discover all the prior art he had access to and challenged to produce reasons for not disclosing

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<sup>8</sup> See "A Patent System for the 21<sup>st</sup> Century", Summary of a Science, Technology and Economic Policy Board report at [http://www7.nationalacademies.org/step/Patent\\_Summary\\_Research.pdf](http://www7.nationalacademies.org/step/Patent_Summary_Research.pdf). This is one of a number of proposals in a draft bill currently before the US legislature (H.R. 2795).

anything that can be argued to be relevant. Again, changes are under consideration<sup>9</sup>. It will still remain in the strong interest of the applicant to disclose relevant art, because of the 'presumption of validity' - if the Patent Office has considered a citation already, it is hard to get a US Court to revoke because of it.

## Conclusions

The requirements for disclosure of the invention are, for the most part, not laid down in specific detail. This allows flexibility in providing a disclosure adapted to the needs of the technical field and the nature of the invention. The applicant has to work out in each case what is appropriate, and the patent examiner needs to check it. Formal requirements should not be multiplied unnecessarily. PCT Rule 5(1)<sup>10</sup> is a good example: it is admirably permissive (see in particular 5(1)b).

It is highly desirable that the principles governing disclosure should be uniform for all Patent Offices. If they vary, different specifications must be written for different jurisdictions. That adds greatly to the expense of international filings, and increases the relative advantage of those with the deepest pockets.

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<sup>9</sup> See Note 8 above.

<sup>10</sup> *PCT RULE 5.1.Manner of the Description*

(a) The description shall first state the title of the invention as appearing in the request and shall:

(i) specify the technical field to which the invention relates;

(ii) indicate the background art which, as far as known to the applicant, can be regarded as useful for the understanding, searching and examination of the invention, and, preferably, cite the documents reflecting such art;

(iii) disclose the invention, as claimed, in such terms that the technical problem (even if not expressly stated as such) and its solution can be understood, and state the advantageous effects, if any, of the invention with reference to the background art;

(iv) briefly describe the figures in the drawings, if any;

(v) set forth at least the best mode contemplated by the applicant for carrying out the invention claimed; this shall be done in terms of examples, where appropriate, and with reference to the drawings, if any; where the national law of the designated State does not require the description of the best mode but is satisfied with the description of any mode (whether it is the best contemplated or not), failure to describe the best mode contemplated shall have no effect in that State;

(vi) indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry and the way in which it can be made and used, or, if it can only be used, the way in which it can be used; the term "industry" is to be understood in its broadest sense as in the Paris Convention for the Protection of Industrial Property.

(b) The manner and order specified in paragraph (a) shall be followed except when, because of the nature of the invention, a different manner or a different order would result in a better understanding and a more economic presentation.

(c) Subject to the provisions of paragraph (b), each of the parts referred to in paragraph (a) shall preferably be preceded by an appropriate heading as suggested in the Administrative Instructions.