

19 Decision Standards for Duty of Disclosure

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In U.S. patent practice, applicants are obligated to "disclose all information to the USPTO (United States Patent and Trademark Office) that the applicant knows to be material to the examination, and not to alter or inaccurately convey the facts," that is, they are imposed the duty of candor. Information subject to disclosure is not limited to the prior art as mentioned below, violation of the duty is recognized as inequitable conduct and the relevant right is deemed to be unenforceable. Due to the uncertainty of the U.S. intellectual property precedents, patent applicants in Japan now must worry about the handling of the duty of disclosure system.

The determination of "materiality" and "intent to mislead" under the U.S. duty of disclosure system was considered in view of the decision standards of the court, such as immediate relevance between information that must be disclosed and claims, cumulative prior art, indirect evidence, recognition of information that must be disclosed, errors, and disclosure of non-English language references.

In addition, a comparison was conducted between the U.S. duty of disclosure system and the Japanese system for disclosure of information on prior art documents, which is similar to the U.S. system, and thereby consideration was given to the desirable system in both countries.

I Introduction

The United States adopts an information disclosure system in which applicants have a duty to disclose all the prior art that they know of in relation to the contents of a relevant patent application when filing an application and applicants cannot exercise their rights if they violate this duty. Prior art that applicants have a duty to disclose includes not only that which applicants know of at the time of filing the relevant application but also that which they subsequently come to know of before a patent is granted. Therefore, applicants have a duty to submit prior art cited in search reports and notices of reasons for refusal prepared by foreign patent offices in a timely manner.

Such system is considered to be significant in securing precise examination. However, because the extremely subjective question of whether a person having a duty to disclose knew of prior art will become the focus of dispute on the duty of disclosure violations in litigation, the decision standard of the court is actually ambiguous.

Therefore, this research and study was conducted to understand the details of this system in the United States and the actual judicial precedents thereof.

II Decision Standards for Duty of Disclosure Violations

1 Decision Standards for Materiality

Inequitable conduct, or violations of the duty of disclosure, must be established by clear and

convincing evidence with regard to the decision standards of both the materiality of the prior art that the applicant failed to submit and the applicant's intent to mislead the USPTO examiner, and any person asserting inequitable conduct is charged with the burden of proof. Materiality and intent are questions of fact subject to clear examination error standards. The CAFC upholds local court authority as long as there is no clear and certain conviction that a misjudgment has been issued.

By establishing decision standards for materiality and intent, the court performs comparative deliberations to determine whether the acts of the applicant constitute inequitable conduct.

(1) Evaluation of Immediate Relevance to Claims

For the determination of materiality, the claimed invention becomes a standard. However, with regard to the distance between the prior art in question and the claimed invention, that is, the question of how close the information subject to the duty of disclose should be to the prior art depends on what kinds of references are provided to the examiner, and there is no absolute measure.

In the decision on *Baxter International, Inc v. McGaw, Inc.*,^(*) the CAFC decided that determination of inequitable conduct required a two-step analysis. This meant that it must be first determined whether the undisclosed reference meets a threshold level of materiality, and also whether the evidence shows a threshold level of intent to mislead the PTO. Once the abovementioned determinations have been made, it

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(*) 149 F.3d 1321, 47 USPQ 2d 1225(Fed.Cir.1998).

is necessary to weigh materiality and intent. If there is substantial likelihood that a reasonable examiner would regard it as material when performing the examination for whether to allow a patent for the application in question, a reference is regarded as material.

(2) Decisions on Cumulative Prior Art

It has been decided that there is no need to submit prior art that is merely cumulative.^{(*)2} In other words, it is not material.

In *Rolls-Royce Ltd. v. GTE Valera Corp.*,^{(*)3} it was ruled that "Nothing in law or logic, however, requires an applicant to submit non-material, merely cumulative references for PTO review," and that there was no requirement to submit prior art that had been raised by the examiner, nor prior art of cumulative content.

2 Decision Standards for Intent to Mislead

(1) Determination of Intent

One more necessary element of the duty of disclosure is the determination of whether the applicant deliberately did not reveal information, that is, whether there was "intent to mislead."

To establish "intent to mislead," logically it should be possible to demand presentation of all prior art that was not disclosed by the inventor and all documents in the possession of the inventor that could indicate the motives of the inventor (evidence showing that there was an intention to deceive the PTO) for evidence disclosure procedures. In addition, since it is possible to obtain testimony from the inventor and any agents connected to the prosecution of the patent, it was considered easy to obtain direct evidence of intent. In fact, however, since it is likely that almost all the questions during the testimony will cause the party's lawyer to raise objections, or the lawyers may instruct the inventor and the agents to refuse to answer by citing lawyer-client privilege or professional confidentiality principles, it is extremely difficult to establish direct evidence. For this reason for decisions on intent to mislead, in *J.P. Stevens & Co., Inc. v. LEX TEX Ltd., Inc.*,^{(*)4} the court held that for the establishment of evidence, proof of direct intent was not required, and that indirect intent or gross negligence was sufficient. In *Rohm & Haas Co. v. Crystal Chemical Co.*,^{(*)5} the court held that with regard to the proof of intent to mislead, a certain degree of inference is permissible. This broadened

the decisions of the courts.

The decision of whether having some serious negligence = indirect intent to mislead has been presumed in a variety of cases.

(2) Establishment of Intent to Mislead through Indirect Evidence

As mentioned previously, some boundaries for intent to mislead were established in *J.P. Stevens & Co., Inc. v. LEX TEX Ltd., Inc.*^{(*)6} It is rare for the accused infringer to have direct evidence showing intent. Accordingly, it is necessary to infer imputable intent from actions, etc. that offer some kind of corroboration. As standard for this, the court stated in (*FMC Corporation v. Manitowoc Company*)^{(*)7} that "No single factor or combination of factors can be said always to require an inference of intent to mislead; yet a patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish "subjective good faith" sufficient to prevent the drawing of an inference of intent to mislead." In the same case the court held that "An applicant must be chargeable with knowledge of the materiality of the art or information; yet an applicant who knew of the art or information cannot intentionally avoid learning of its materiality through gross negligence, i.e., it may be found that the applicant "should have known" of that materiality." In other words, if the applicant knew the materiality of the information that was not disclosed, even if it is claimed that there was no intent to cause a wrong determination by the Office, there is a high probability that it will be presumed that there was intent to mislead. It is also suggested that if there is intentional neglect in the investigation of whether information is material, it is likely that it will be presumed that there was gross negligence with regard to the recognition of materiality.

(3) Circumstances of Recognition

It is possible to establish whether a patent holder knew of information that should have been disclosed through indirect evidence. There are the following decisions in specific cases on the determination of the circumstances that could be known.

First, in *FMC Corporation v. Hennessey Industries Inc.*,^{(*)8} the court stated that in instances where there is clear evidence that the applicant was aware of the existence, as well as the materiality, of prior art, there was good justification to presume

(*)2 Rule 1.98 (c) "When the disclosures of two or more patents or publications listed in an information disclosure statement are substantively cumulative, a copy of one of the patents or publications may be submitted without copies of the other patents or publications provided that a statement is made that these other patents or publications are cumulative."

(*)3 800 F.2d 1101, 231 USPQ 185 (Fed. Cir. 1986).

(*)4 747 F.2d 1553, 223 USPQ 1089 (Fed. Cir. 1984).

(*)5 722 F.2d 1556, 220 USPQ 289 (Fed. Cir. 1983).

(*)6 747 F.2d 1553, 223 USPQ 1089 (Fed. Cir. 1984).

(*)7 835 F.2d 1411, 1415, 5 USPQ 1115-1116 (Fed. Cir. 1987).

(*)8 836 F.2d 521, 5 USPQ2d 1271 (Fed. Cir. 1987).

intent, and that convincing evidence of subjective good faith would be necessary to refute this. In this decision, with respect to whether there was an obligation to search prior art, the court refused to make the decision on the existence of a duty to search, and ruled that in this case the broad patent search conducted by FMC Corporation for the attack on the validity of the patent was not an obligation that Hennessey Industries Inc. was required to fulfill. However, the court also decided that the act of intentionally ignoring the possibility that prior art exists, for example, the act of not conducting any kind of prior art search, may be presumed to be intent.

With regard to the recognition of information, the requirement to determine the point at which the information actually becomes known (as in *Nordberg v. Telsmith*,⁽⁹⁾ even if the prior art in question is actually physically present in a bookcase, it cannot be assumed that it was known), can be considered a precedent in judging the boundaries of awareness of information. If there is clear evidence that the applicant actually did not know, it is possible to avoid a breach of the duty of disclosure. However, in cases where there is an intentional refusal to learn, for example, not conducting a prior art search, and submission of an application without accessing past applications for one's own company's patents,⁽¹⁰⁾ there is no clear decision on whether this would be considered intent to mislead.⁽¹¹⁾

(4) Decisions on Errors in the Examination Process

With regard to violations of the duty of disclosure, the court's decisions are divided over the relationship between negligence and intent to mislead. In *Kingsdown Medical Consultants, Ltd v. Hollister Inc.*⁽¹²⁾ a specific answer was given on the question of whether to judge acts of non-disclosure caused by the applicant's error during the patent examination process as intent to mislead.

The CAFC ruled that "a finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive."⁽¹³⁾

However, in *Rohm & Haas Co. v. Crystal Chemical Co.*,⁽¹⁴⁾ as noted by the court, if

inequitable conduct is discovered during the application process, the applicant can rectify or overcome the inequitable conduct by taking action to inform the examiner of the facts. The converse interpretation is that in the event an applicant detects flaws during the examination process, he is required to make diligent efforts to bring it to the attention of the examiner, and that failure to make such effort could be presumed to be intent to mislead.

(5) Decision Standards Involving Non-English Language References

In *Key Pharmaceuticals Inc. v. Hercon Laboratories Corp.*,⁽¹⁵⁾ there was no intent to mislead found, even though there was no proper translation of a foreign language reference that should be disclosed, and no concise statement of relevance; while in *Semiconductor Energy Laboratory Co. Ltd. v. Samsung Electronics Co. Ltd.*,⁽¹⁶⁾ the failure to provide proper translation of foreign references that should be disclosed and the lack of a proper concise statement of relevance led to a ruling of intent to mislead. At first glance these cases appear to involve similar actions related to disclosure by applicants with different decisions.

In other words, even if the material portion of a non-English language reference is not included in the translated portion, the court will not automatically infer that there is intent to mislead. As noted by the district court in *Key Pharmaceuticals Inc. v. Hercon Laboratories Corp.*, "the finding on intent in particular depended heavily on the presentation of evidence and witness testimony at trial. The trial court was able to hear these matters first hand and assess witness credibility," and that if it is not found that the actions of the attorney prosecuting the case "allow a clear inference of a deceitful motive," it will be ruled that there is no intent to mislead, and no existence of inequitable conduct. On the other hand, in *Semiconductor Energy Laboratory Co. Ltd. v. Samsung Electronics Co. Ltd.*, the district court applied the standard that "a requirement in finding intent to deceive should be determined through the evaluation of the objective circumstances as a whole." As a result of a significant loss of credibility before the court by the inventor and patentee of Semiconductor Energy Laboratory Co. Ltd., it was ruled that there was inequitable conduct. The issue

(9) 48 F.3d 1172,33 USPQ2d 1824(Fed.Cir.1995).

(10) For patent applications in which an adequate prior art search has not been conducted, questions arise on the substantive aspects, so such applications cannot be considered practical examples.

(11) In *FMC Corporation v. Manitowoc Company*, the court cautioned that it is not possible to promote ignorance such as ignoring the possibility of the existence of material information or prior art simply for the purpose of avoiding the recognition of the existence of such information (that is material enough to be needed to be disclosed).

(12) 863 F.2d 867, 9 USPQ 1384(Fed.Cir.1988).

(13) 863 F.2d p876.

(14) 722 F.2d 1556, 220 USPQ 289 (Fed.Cir.1983).

(15) 161 F.3d 709, 48 USPQ2d 1911 (Fed.Cir. 1998).

(16) 204 F.3d 1368; 2000 U.S. App. LEXIS 3164; 54 U.S.P.Q.2D (BNA) 1001(Fed.Cir.2000).

of submitting a partial translation is not a question of the illegality of the act itself, rather it is related to the question of deciding on the overall credibility of the applicant.

Incidentally, for documents written in languages other than English, many patent examiners perform the investigations using only the content noted in the concise explanation or within the scope based on the information obtained from the appearance of the document. Although the PTO examiners have the resources and authority to obtain translations of documents written in languages other than English on their own, unless an examiner believes there is an extremely large possibility that the document is material to the examination, it is actually rare for this to occur. Since it also gives rise to extra costs and extends the examination process, examiners are not encouraged to obtain translations on their own. Under these circumstances, the PTO made the requirement of submitting a "concise statement" of relevance for each of the non-English language references cited in the IDS.^(*17) A "complete" translation into English for foreign language materials is not necessarily required, but it is usually better to submit full translations for several points rather than "concise statements" of relevance, excerpts and abstracts.^(*18)

3 Weighing the Balance of Materiality and Intent

If it is proved that the thresholds for materiality and intent are reached, the court must weigh the balance of the standards for these two, and decide whether to conclude that inequitable conduct as a legal issue has occurred.^(*19) When considering the relative balance of these two, it is presumed that the limit levels for both materiality and intent have been met. In other words, if the materiality does not exceed the required minimum level (regardless of how high the degree of intent may be), there is no inequitable conduct.

If there is clear evidence of good faith, the court will not find inequitable conduct. Furthermore, if the degree of materiality is low, gross negligence is insufficient, and a certain higher level of intent is demanded.

4 Conclusions and Observations

In addition to the existence of intent to

mislead, inequitable conduct includes the act of making positive statements of material facts, not-disclosing material information, or making submissions on the pretext that it is material information. The standards for materiality of information are decided based on whether such information would influence a decision by a reasonable examiner about whether to allow a patent. It has not been made clear whether the court's decision standards for materiality are changing to obvious patentability along with the revision of the rules.

The intent to mislead must be inferred from the facts and circumstances of the actions of the applicant. This circumstantial evidence must indicate acts that go beyond mere gross negligence or inappropriate behavior; i.e. actions that do not reach a threshold of serious misrepresentation will not be found to be inequitable conduct. It may be possible to claim that the breadth of the court's decisions is expanding, since a certain degree of inference is permitted for proof of intent to mislead. As mentioned previously, for decisions prior to the 1988 Kingsdown decision,^(*20) there were a variety of cases of strict decisions of defects in the disclosure process against the patent applicants and patentees, for example, cases where intent to mislead was found regardless of the existence of records suggesting that neither the patentee nor his agents considered information material due to the existence of undisclosed prior art discovered independently by the examiner in the examination procedure after interference,^(*21) cases where intent could be inferred if there was evidence of gross negligence,^(*22) and cases where it was held that if there was clear evidence that the applicant was aware that the prior art existed and that it was material, there was good justification to infer intent and clear and convincing evidence of subjective good faith was required to refute such inference.^(*23)

The 1988 Kingsdown decision created a disturbance in this flow. The Kingsdown decision stated that "a finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." This was a clear decision on the point that (gross) negligence does not necessarily equal proof of intent to mislead.

After the Kingsdown decision, court decisions

(*17) M.P.E.P §609A(3).

(*18) M.P.E.P §609A(3) notes that "Submission of an English language abstract of a reference may fulfill the requirement for a concise explanation."

(*19) *American Hoist*, 725 F.2d at 1364, 220 U.S.P.Q. at 774.

(*20) *Kingsdown Medical Consultants, Ltd v. Hollister Inc.*, 863 F.2d 867, 9 USPQ2d 1384 (Fed. Cir. 1988).

(*21) *A.B. Dick Co. v. Burroughs Corp.* 798 F.2d 1392, 230 USPQ 894 (Fed. Cir. 1986).

(*22) *J.P. Stevens & Co., INC v. LEX TEX LTD., INC.* 747 F.2d 1553 223 USPQ 1089 (Fed. Cir. 1984).

(*23) *FMC Corporation v. Hennessy Industries Inc.* 836 F.2d 521, 5 USPQ2d 1271 (Fed. Cir. 1987).

became strict for the person accused of infringement, that is, the side protesting breaches of the duty to disclose. In other words, court decisions restrain the submission of claims from the accused infringers based on unwarranted inequitable conduct.

As this illustrates, although the overall trend is not clear, it can be said that for the proof of intent there is a tendency of a higher degree of difficulty for proof on the side accused of infringement.

The predictability for decision standards depends heavily on the individual cases, and it cannot be claimed that there is necessarily a clear trend in precedents. One reason for this is the necessity to prove intent in order to rule that there is inequitable conduct. Proof of intent is a problem that depends on the relationships of the various facts. Since there are also subjective standards, it can probably be said that it is inherently incompatible with precise tests. A second reason is that different judges have different ideas regarding "how far the court should go to maintain or invalidate a patent." With regard to the determination of inequitable conduct, since it is necessary to make a subjective decision, as mentioned above, decisions in this field may be more likely to reflect the inclinations of the bench with respect to patents in general than other issues for both the original trial and the appeals.

With regard to the issue of information disclosure, although it is an issue of a duty of candor, it is thought to be possible to construct ways to benefit applicants, the patent office and third parties through technological methods. In particular, for prior art cited in the reasons for rejection of corresponding foreign applications, the construction of a database that can be mutually searched by the U.S. patent office and the country in question would greatly decrease the burden on an applicant. This is expected to be addressed in the future between patent offices.

III Comparison with the Japanese System for Disclosure of Prior Art Documents

The basis of the U.S. system for disclosure of information is compliance with the duty of candor. The U.S. system is a unique system in comparison to other countries' systems. Even in the United Kingdom which also uses common law as a base, inequitable conduct will not lead to the invalidation of a patent or the impossibility of exercise of the right.^(*24)

However, looking at this U.S. system not only

from a mere ethical aspect of the duty of candor but also from the aspect as a safety valve in the process of determining the validity of a patent, the system can be interpreted as a rational system that matches the U.S. system architecture for determination of patentability.

In the United States, the procedures for invalidation of a patent after the issuance thereof are as follows, but when demanding the invalidation of a patent in a suit (infringement suit/declaratory judgment suit), invalidity must be proven by "clear and convincing evidence," and this requires the proof of fact with a higher level of certainty than general proof. In other words, this means that once a patent is established as a right, the hurdle of a decision to invalidate the patent becomes higher than that in the examination by the PTO. If the duty of disclosure system does not exist, the applicant can hide information that will have a material influence on patentability at least until the issuance of a patent by the PTO in order to reduce the possibility that the patent will be invalidated in comparison to the possibility in the case where the relevant information is examined by the PTO at the examination stage, even if a suspected infringer has found the relevant information and makes an argument for the invalidity of the patent in an infringement suit. In short, in some cases, even if a prior art is sufficient to block the grant of a patent in the examination by the PTO, it cannot invalidate, once a patent is established, the relevant patent in a suit.

This situation is "advantageous to those who hide" seen from the viewpoint of applicants. The fact that a defective patent that is originally supposed to be judged invalid at the examination stage exists by accident as an effective right due to variations of search capability of the Patent Office causes an undeniable sense of inequity.^(*25) It must not be permitted that a strong right that is exercised as an exclusive right for 20 years remains effective due to the misfortune (fortune) of prior art having not been found at the examination stage.

As a methodology for correcting such inconvenience, it is also considered extremely rational from the viewpoint of stable and precise patent rights to change the basic idea of the system for disclosure of information from "advantageous to those who hide" to "disadvantageous to those who hide" by setting severe sanctions.

On the other hand, in Japan, the procedure for invalidation after the establishment of a patent right is conducted based on the system of trial for invalidation. On this occasion, decision standards for the validity of a patent are the same as the

(*24) In the U.K. Patents Act 1949, a false suggestion and representation were reasons for revocation (Section 32).

(*25) Such information can be obtained if the Patent Office has the high search capability and well-developed system to collect information from wide general public, such as the opposition system, but it is in practice never possible to obtain information evenly.

standards for examination and those for appeals and trials at the Patent Office. Thus, in Japan, the situation "advantageous to those who hide" will never arise even after the establishment of a patent, because the decision standards for patentability do not change.

Taking the above into consideration, the introduction of the duty of disclosure system mainly for the duty of candor is unlikely to fit in with Japan simply. Therefore, in Japan, the system should be matured from a viewpoint completely different from the United States, i.e. the system for disclosure of prior art to increase the efficiency of development.

However, the duty of disclosure system to actively motivate applicants to assist in the achievement of precise and prompt examination as well as the increase of the efficiency of development is probably necessary for the future when the value of patent rights as exclusive rights is going to relatively increase.

