DUTY OF DISCLOSURE IN A PATENT APPLICATION

Quite often patent applicants are hesitant in revealing in their patent application, prior art references that may have an adverse impact on the patentability of their patent application. Further, some of the applicants may reveal such references while filing an application, however, they may ignore informing the patent office any additional relevant references that they may come to know of after filing the patent application but before the patent is issued. Failure to reveal relevant prior art references that the applicant is aware of to the patent office can have an adverse impact on the validity of a patent that was obtained by concealing such information.

The Duty

The US patent law obligates individual associated with the filing and prosecution of a patent application to disclose information material to patentability of the patent application.

> ***37 C.F.R. 1.56 Duty to disclose information material to patentability.***
> *"...Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability..."*

The duty to disclose applies to individuals associated with the filing and prosecution of a patent application, which may include the inventor(s), each attorney or agent, and every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the assignee or anyone to whom there is an obligation to assign the application. Additionally, individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

All information "material to patentability" includes prior art such as patents and publications, information on enablement, possible prior public uses, sales, offers to sell, derived knowledge, prior invention by another, inventorship conflicts and so on. The duty applies only to the one or more claims pending in the application and not the claims that have been cancelled or withdrawn from consideration. The duty to disclose is an ongoing obligation and continues until a patent is issued or abandoned.

Materiality applies to any information that an examiner would be likely to take into account in deciding whether to allow an application to issue as a patent. Any information that may be cumulative to something already being cited or submitted to the USPTO may not qualify as "material to patentability", and hence may not be disclosed.

Dilemma

Sometimes, such individuals may face conflicts in deciding whether a piece of information that he has would be considered material information. Actually what information is considered "material" for an application in question is sometimes difficult to determine. But as the saying goes "better safe than sorry", hence any piece of information that is likely to put the individual under confusion in determining whether the information is "material" may be submitted so as to avoid regretting later, unless the information is cumulative information.

It may be noted that "material information" may include references cited in search reports of foreign patent offices with respect to counterpart applications. Such prior art is material where it has been used in rejecting the same or similar claims in the foreign application or where it has been identified as relevant. Apart from relevant prior art, material information that may be of interest to the patent office can be one or more among co-pending US Patent Applications, information from related litigation, if any, and information relating to claims copied from another patent.

How and when should the information material to patentability be disclosed to the Patent Office?

Any individual associated with the filing or prosecution of a patent application can disclose relevant information to the USPTO by submitting an Information Disclosure Statement (IDS). As mentioned earlier, since the duty to disclose is an ongoing process, multiple Information Disclosure Statements may be filed for a single application, at various stages from the date of filing and

a) within 3 months of the filing date of the national application or before the mailing date of a first Office action, whichever is later.
b) after (a) and before the mailing of a final Office action, a Notice of Allowance.
c) after (b) and before the issue fee is paid.

It may be noted that, other than the provision presented in (a), a fee will have to be paid of the IDS is submitted in accordance with any of the remaining provisions.

The IDS may include a list of relevant US patents, publications and applications, legible copies of each foreign patent, each publication or the portion which caused it to be listed and non-patent literature. A concise explanation of the relevance, as it is understood by the individual most knowledgeable about the content of the information should be included for any information that is not in English language. A copy of the English-language translation of a non-English-language document, or portion thereof must be disclosed.

Consequences

An individual should always act in compliance with the duty of candor and good faith in dealing with the USPTO, failing which the individual may be charged with engaging in inequitable conduct or practicing fraud on the Patent and Trademark Office. No patent is granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. For any patent that was granted but later held for inequitable conduct, all claims of such a patent are held unenforceable.

However, to prove inequitable conduct due to failure to disclose, proper evidence is necessary to establish failure to disclose material prior art with intent to mislead. Where intent to mislead is clear, fraud may be found to exist, otherwise not.

The duty of disclosure also applies to the patent owner during reexamination proceedings. That duty is a continuing obligation on the part of the patent owner throughout the proceedings. However, “fraud,” “inequitable conduct,” or “violation of duty of disclosure” are not considered in the reexamination proceedings.

The consequences and interpretation of the duty of disclosure can be understood from the proceeding of the below listed cases.

Case 1: *Apotex Inc. v. UCB, Inc*

The Federal Circuit affirmed a finding of inequitable conduct and held a patent unenforceable.

Apotex (plaintiff) held a US patent 6,767,556 (’556) which issued on July 27, 2004, from an application that claimed priority to a Canadian application filed on April 5, 2000. Dr. Bernard Charles Sherman, founder and chairman of Apotex was the sole inventor of the ’556 patent. Apotex filed suit on April 20, 2012, accusing UCB (defendant) of infringing the ’556. U.S.

Patent No. 4,743,450 (’450 patent), was a prior art to Dr. Sherman’s patent. Further, interestingly two of Apotex’s products Univasc and Uniretic were produced using the process claimed in ‘556, even before the patent application was filed; however, the instant information was concealed. During prosecution before the USPTO, the ’556 patent received three obviousness rejections. After the final rejection, at the direction of Dr. Sherman, his counsel submitted the expert declaration of Dr. Michael Lipp, who reinforced the representations regarding the prior art (the ’450 patent and the Gu article).

On a three day bench trial, the district court found that Dr. Sherman was aware that Univasc was made according to his claimed process before the’556 patent, but concealed this knowledge from the PTO, and misrepresented the nature of Univasc and the prior art through his counsel’s arguments and Dr. Lipp’s declaration. The district court found that Dr. Sherman made several misrepresentations to the PTO regarding the prior art and lied in the ’556 patent application by including certain examples of experiments that were never conducted, which he later admitted. The district court further concluded that Dr. Lipp was only hired to add legitimacy to Dr. Sherman’s misrepresentations. The district court concluded that Dr. Sherman intentionally violated his duty of candor by making repeated misrepresentations to the PTO during prosecution of the ’556 patent. The district court therefore held the ’556 patent unenforceable due to inequitable conduct. The Federal Circuit found evidence that that Dr. Sherman directly instructed his counsel to bolster their arguments against the PTO through an expert declaration. The federal Circuit affirmed that the district court did not err in finding that Dr. Sherman knew, or at least had a strong suspicion, that he was seeking to patent the very same process used to obtain an already existing and widely available drug. Hence the Federal Circuit affirmed the judgment of the District Court in favor of the defendants.

Case 2: *Santarus, Inc., v. Par Pharmaceutical, Inc*,

Plaintiff, Santarus, Inc. was the exclusive licensee of the patents that were for the inventions of Dr. Jeffrey Phillips, assigned to the University of Missouri. Par Pharmaceutical, the defendants, filed an Abbreviated New Drug Application (ANDA) for FDA approval to sell a generic counterpart of the Santarus products requesting permission to market the same formulations describing Par’s products as bioequivalent to the products marketed by Santarus. Santarus charged Par with infringement for which Par asserted unenforceability and invalidity of all of the

claims of the Phillips' patents. While this case uncovers several grounds for invalidating the claims, in this decision we shall not go into the details of the other grounds, only a brief discussion on the ground of "inequitable conduct", will be presented. Each of the Phillips patents in question was a continuation or continuation-in-part in a chain that originated with Patent No. 5,840,737 (the '737 patent) filed on January 4, 1996. Par argues that the Phillips patents are unenforceable due to inequitable conduct by Dr. Phillips, the University of Missouri, and their attorneys, on the ground that they failed to inform the PTO that Dr. Phillips administered a medication disclosed in the patents to some hospital patients and recorded the test results in hospital records, before the filing date of his first patent application. However, the test information and report had been provided to the PTO only during the prosecution of the continuing application. Dr. Phillips testified that he believed that only sale and public use were required to be disclosed to the PTO and not his experimental administration to patients, and that he had not intentionally withheld information or delayed its disclosure to the PTO. The district court found that the evidence presented was not sufficient to establish that Dr. Phillips acted with an affirmative intent to deceive because the accused infringer could not prove that the patentee acted with the specific intent to deceive the PTO. The decision of the district court was affirmed by the Federal Circuit.

Provision made in the Indian Patent Act

The Patents Act, 1970, of India has a similar provision under Sec 8, which states that an applicant of an Indian patent application shall provide "detailed particulars" about patent applications filed outside India (foreign applications) for the same or substantially same invention. Such "detailed particulars" will have to be submitted as long as those foreign applications are filed by the applicant, or by any person deriving title from him or by any person through whom he derives title. The Controller is empowered to seek such information corresponding to the foreign applications at any time during the prosecution of the Indian patent application. The applicant should file the statement and undertaking within 6 months of filing the Indian patent application or when foreign applications are filed subsequent to filing of the statement and undertaking, then detailed particulars of such applications shall be filed within 6 months of such filing. The Act, however, does not clarify what information falls within "detailed particulars". General practice suggests that "detailed particulars" relate to details corresponding to filing of patent application, grant of patent, issuance of examination report, response to

examination report, amendment of specification and objections to grant of patent, among others. The details of this provision in the Act can be accessed here.

Duty of Disclosure under the European Patent Office

The European Patent Office also has the provision of "duty to disclose" under Article 141, which requires the applicants to disclose results of any official searches/examinations carried out on priority applications. The EPO requires the applicant to provide information on prior art taken into consideration in national or regional patent proceedings and concerning an invention to which the European patent application relates.

Conclusion

The burden to disclose relevant prior art to patent offices varies from one country to another. The US seeks a large spectrum of prior art to be disclosed, as opposed to India or the EPC. However, the negative consequences of not complying with the discussed duty of disclosure can be far reaching in most of the countries. Hence, individuals applying of patents should comply with their duty of disclosure.

InvnTree offers Information Disclosure Statement (IDS) preparation services and patent search services, among other patent services.

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Best regards – Team InvnTree