

## Basics of Writing Patent Non-Infringement and Freedom-to-Operate Opinions

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Non-infringement and freedom-to-operate (FTO) opinions are legal advice given by a patent attorney with an objective to avoid infringement of other's patent(s) by his client. These opinions set forth the attorney's viewpoint on the non-infringing position of the client's proposed product/process/technology. The basics of writing both the opinions are same except that rendering a FTO opinion requires comprehensive searching of existing relevant patents by the attorney, whereas a non-infringement opinion is rendered on one or more relevant patents already identified by the client. In a competent non-infringement or FTO opinion, the patent attorney analyses each claim of every identified relevant patent in a step-by-step manner through a process called as infringement analysis. The infringement analysis is based upon certain legal principles, which help the attorney in determining non-infringing position of the client's proposed product/process/technology. Nowadays non-infringement or FTO opinions are frequently used as important business strategic tools by companies since these opinions assist greatly in critical decision areas like launching of a new product, acquisitions and mergers, contract manufacturing and designing of R&D strategy.

**Keywords:** Patent, infringement, freedom-to-operate, patent practice, clearance search, prior art, infringement analysis, claim construction, claim comparison, prosecution history estoppel

A patent is the right to exclude others from making, using, offering for sale, selling, or importing the patented invention for a limited period of time. Infringement of patent means violation of any of the monopoly rights conferred on the patentee. In other words, any act of trespassing upon the area or domain belonging to a patent owner that is described by the claims of the patent, during the patent term is called infringement.<sup>1</sup> Patent opinions like non-infringement and FTO opinions are legal advice rendered by a patent attorney to his client of activities that would avoid infringement of an unexpired, valid, and enforceable patent. This article describes reasons for getting a non-infringement or FTO opinion, and sets forth the process a patent attorney follows in generating a competent opinion. Since, the subject matter of this article pertains to the field of patent practice and not to the patent law itself, this article presents various patent practitioner's information sourced from Internet based resources.

Although, the law and cases cited in the article pertain to US but the basic principles and methodology of writing patent non-infringement and FTO opinions discussed in the article also hold good

for other countries like Canada, China, Switzerland, Germany and Singapore wherein the practice of using FTO and non-infringement opinions is common. In these countries, patent opinions such as FTO and non-infringement opinions are frequently employed in the fields of pharmaceuticals, medical devices, mechanical engineering, etc.

### **Purpose of a Non-Infringement or FTO Opinion**

These opinions are two different yet related types of opinions. A non-infringement opinion is typically directed to a specific patent or patents of which the client has become aware. Through a non-infringement opinion a client gets some assurance that a proposed product/process/technology will not infringe the specific patent or patents. In contrast, a FTO opinion is broader in scope and addresses the potential for infringement by any patent, whether known or unknown to the client.

Non-infringement opinion is recommended anytime a company is contemplating introducing a new product that is similar to an existing patented product, whereas a FTO opinion is generally sought at the beginning of technology development when the client is considering the costs and benefits of the project. Ideally, the FTO opinion will conclude that

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there are no relevant patents that would impact the technology development, and therefore, the client is 'free to operate' without risk of patent infringement. A non-infringement opinion on the other hand distinguishes a product or service from close claims of an identified patent. It can be prepared for a variety of other reasons also, e.g. as a measure of diligence before acquisition of a business entity, as a preface to negotiation of a license, or as a possible exculpatory defense to allegations of willful infringement in case of any infringement law suit.<sup>2</sup> In any case the basic purpose of a non-infringement or FTO opinion is to evade chances of being sued for infringing other's patent(s).

#### **Preparation a Non-Infringement or FTO Opinion**

The patent attorney generally performs the following four steps in the process of rendering a FTO:<sup>3</sup>

- (i) Understanding client's technology
- (ii) Conducting clearance search
- (iii) Screening patents identified in search for applicability to the technology; and
- (iv) Drafting non-infringement opinion
- (v) For preparing a non-infringement opinion, second and third steps, i.e. conducting of clearance search and screening of identified patents are not required, since in such case the relevant patent(s) is/are already identified by the client.

#### **Understanding the Client's Technology**

A critical step in the process of preparing a non-infringement or FTO opinion is to thoroughly understand the technology. If the technology is not completely understood, subsequent patent search and analysis may be seriously flawed and significant patents may be missed. Generally, details of the technology are learnt through interactions with the client. These interactions may include face-to-face or telephonic meetings with the client, review of documentation prepared by the client that describes the technology, and/or evaluation of a sample or model of the technology.

#### **Conducting Clearance Search**

Once the technology is understood and the field of search defined, the next step is to conduct clearance search. There are many different ways to conduct clearance search; choice between them will depend on the field of technology and the amount of money that the client is willing to spend on the search. A

clearance search is necessary only when conducting a FTO investigation and is not required if the client asks the attorney to opine on the applicability of a particular patent to the technology i.e. to prepare a non-infringement opinion.<sup>4</sup> The most common search methodology is to employ a professional searching agent. They perform searches in the public search room of the patent office or in patent collections found in various depository libraries. Patent search can also be done on many electronic databases available on Internet. Some of the most reliable electronic databases are at websites of USPTO ([www.uspto.gov](http://www.uspto.gov)), Espacenet website of the European Patent Office ([www.ep.esp@cenet.com](http://www.ep.esp@cenet.com)) and WIPO ([www.wipo.int/patentscope/en](http://www.wipo.int/patentscope/en)).

USPTO provides access to 'full text and image database' and 'patent application information retrieval system (PAIR) database' through its website. The 'full text and image database' provides access to both issued patents and published applications. PAIR database displays information regarding patent application status. There is both a public and private side to PAIR. 'Public PAIR' only displays issued or published application status. 'Private PAIR' is the patent application information retrieval system developed to provide secure access for customers. Private PAIR provides real-time status information for all action taken by USPTO for a given application. Private PAIR allows the customer to have access to USPTO's internal database (PALM); therefore, the customer can view the information as soon as it is posted. To access private PAIR, one must be (i) a registered patent attorney/agent, an independent inventor, or a person granted limited recognition (ii) have a customer number, and (iii) have a digital PKI certificate to secure the transmission of the application to the USPTO.

The Espacenet website provides access to collections of patent documents held at patent offices throughout the world. The search page for the worldwide collection permits searching in text fields and numerical fields. The searchable text fields include applicant name, inventor name, title and abstract. The WIPO database provides access to copies of international Patent Co-operation Treaty (PCT) applications.

#### **Patent Search Strategy**

Before actually conducting searches on the patent databases e.g. electronic databases mentioned above, a suitable search strategy is prepared. The search

strategy is a plan to carry out patent searches in such a manner that it saves valuable resources like time, effort and money and avoids the chances of missing out important patents during the search. Search on the electronic databases can be conducted by using suitable key terms under the fields available on database e.g. title, abstract, specification, claims, assignee name etc. or by using patent classification codes. Preparation of a patent search strategy comprises of selecting appropriate database(s) to carryout the search. It also includes determination of specific key terms and patent classification codes to retrieve patents that are relevant to the client's product, process or technology under consideration.

#### **Screening Patents Identified in Search for Applicability to the Technology**

The patents identified in the search are screened in accordance with a two-stage process. In the first stage, each patent identified in the search is evaluated to determine whether it can reasonably be eliminated from further consideration. Patents identified in the search can be eliminated from further consideration only if a reasonable infringement argument could not be made i.e., the specification clearly covers subject matter distinct from the client's technology and all claims include definite limitations that could not possibly be met by the technology under any reasonable construction. In the second stage, the patents that cannot be eliminated in the first stage are evaluated in further detail, including an infringement analysis of the claims in the light of their file history and cited prior art.

#### **Drafting the Non-Infringement or FTO Opinion**

After the search results have been obtained, the patent attorney typically drafts a report to the client.

### **Sections of a Non-Infringement or FTO Opinion**

#### **Description of the Technology**

The non-infringement or FTO opinion includes a description of the client's technology. The search results may be of little or no value if the invention is not properly understood by the patent attorney and searching agent. Similarly, an infringement analysis will also be of little or no value if based on obsolete facts. Therefore, by including a description of the technology in the opinion, the attorney makes clear the basis for the search and subsequent opinion. It is always helpful to include drawings or photographs of the technology in conjunction with the opinion text.

#### **Search Methodologies and Findings**

The opinion describes the search methodology that was used. If the patent attorney retained a professional searching agent, the opinion explains that the search was conducted by an agent and it also explains the specific classes and subclasses identified by him. Likewise, if the patent attorney performed an electronic database search, opinion identifies which databases were searched and the queries that were used. It is also helpful to include a chart identifying all of the patents found in the search. The chart may include columns for patent number, title, inventor name, and assignee name. Out of all identified patents those patents, which are found to be relevant to the client's technology are short listed.

#### **Relevant Laws**

The non-infringement or FTO opinion includes a discussion of the relevant laws i.e., legal standards of infringement and legal principles for infringement analysis.

#### **Legal Standards of Infringement**

The US patent law is codified in Title 35, United States Code (35 U.S.C.). The definition of 'patent infringement' can be found in 35 U.S.C. § 271(a), which defines direct infringement as making, using or selling of a patented invention in the US without authority from the patent owner.<sup>5</sup> 35 U.S.C. § 271(b) extends liability for infringement to those who 'actively induce' another to infringe a patent. Induced infringement can only be alleged where there is some positive act of inducement to carry out a direct infringement. 35 U.S.C. § 271(c) defines contributory infringement. Contributory infringement is an act of offering to sale/selling/importing into the United States a component of the patented article or material/apparatus for use in a patented process if:

- The component or material/apparatus constitutes a material part of the invention and
- The person supplying it knows that it is especially made/adapted to be used in an infringement of such patent.

35 U.S.C. § 271(e)(2) defines infringement due to filing of Abbreviated New Drug Application (ANDA) as follows:

'It shall be an act of infringement to submit an application under Section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in

Section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent.’

As per 35 U.S.C. § 271(g) without authority import, offer to sell, sell, or use in the US, a product which was made outside US by a process patented in the US is an act of infringement. But there will be no infringement if the product is materially changed by subsequent processes or it becomes a trivial and nonessential component of another product.

#### *Legal Principles for Infringement Analysis*

A patent infringement analysis includes two steps viz., (i) claim construction and (ii) claim comparison. The first step is to construe the patent claims by determining the meaning and scope of each claim. The second step is to compare properly construed claims to the allegedly infringing device. For the second step, infringement may be either literal or, under the doctrine of equivalents.

#### *Claim Construction*

Claim construction or claim interpretation means defining meaning of claim terms to determine the scope of patent. It is a way of elaborating the normally abrupt or concise claim language in order to understand and explain, but not to change, the scope of the claims.<sup>6</sup> To construe a patent claim both intrinsic and extrinsic evidences can be analysed. Claims, specifications and prosecution history are intrinsic evidences. Extrinsic evidences like expert opinion, testimony, unrelated applications/patents, dictionary or treaties, may be obtained when intrinsic evidence ambiguously describes the scope of a patented invention. Claim interpretation begins with the claim language. The general rule is that terms in the claim are to be given their ordinary and accustomed meaning.<sup>7</sup> Courts often turn to dictionaries, encyclopedias, and technical treatises to determine the ordinary meanings attributed to disputed terms.<sup>8</sup> Patent's specification must provide a written description of the invention that enables one of ordinary skill in the art to make and use the invention.<sup>9</sup> The Federal Circuit described the importance of the specification in interpreting claims, as follows:

‘Claims must be read in view of the specification, of which they are a part. . . For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims. . . As we have

often stated, a patentee is free to be his own lexicographer. . . The limitation is that any special definition given to a word must be clearly defined in the specification. . . The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims’.<sup>10</sup>

Under 35 U.S.C. §112, sixth paragraph, claim language can be expressed in ‘means-plus-function’ form. It provides ‘An element in a claim for a combination may be expressed as a means or step for performing a specified function without recital of structure, material, or acts in support thereof, and such claim shall be construed to cover corresponding structure, material, or acts described in the specification and equivalents thereof.’ Therefore, 35 U.S.C. §112, sixth paragraph permits an element in a claim to be expressed as a means or step for performing a specified function. However, scope of such a claim is confined to structures expressly disclosed in the specification and corresponding equivalents. Thus such a means-plus-function or step-plus-function element must be interpreted in view of the corresponding structure, materials, or acts, and equivalents thereof, described in the specification.<sup>11</sup> Therefore, statutory provision prevents an overly broad claim construction by requiring reference to the specification, and at the same time precludes an overly narrow construction that would restrict coverage solely to those means expressly disclosed in the specification. The prosecution history is a necessary tool in claim interpretation, and a necessary component assessing infringement under the doctrine of equivalents.<sup>12</sup>

#### *Claim Comparison*

Under claim comparison, the claims are tested to see whether they describe the product/process under consideration. A claim may be infringed either literally or under the doctrine of equivalents.

#### *Literal Infringement*

The claims must ‘read on’ the product/process to establish an act of literal infringement. Claims are generally comprised of one or more elements or limitations. The term ‘literal infringement’ means that each and every element recited in a claim has identical correspondence in the alleged infringing device or process. This is called as ‘All Elements Rule’. Missing of even a single element from the product/process makes it literally not infringing to

that claim.<sup>13</sup> If the claim contains a means-plus-function element, an accused device will infringe only if it performs the identical function specified in the element and includes the corresponding structures disclosed in the specification or substantial equivalents thereof.<sup>14</sup> Similarly, if a claim contains a step-plus-function element, an accused device will infringe only if it performs the identical function specified in the element and includes the corresponding acts disclosed in the specification, or substantial equivalents thereof, for performing the recited function. However, even if there is no literal infringement, a claim may be infringed under the doctrine of equivalents.

#### Infringement under the Doctrine of Equivalents (DOE)

Where literal infringement is not found, it is appropriate to consider infringement under the doctrine of equivalents. The DOE recognizes the deficiencies of words and effectively expands the scope of the claims beyond their literal language to the true scope of the inventor's contribution to the art. The doctrine of equivalents allows the patentee 'to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes' to the literal scope of the claims.<sup>15</sup> The function-way-result test can be used to check DOE. A product may conceivably infringe under the doctrine of equivalents, even though it does not literally infringe, if it 'performs substantially the same overall function or work, in substantially the same way, to produce substantially the same overall result as the claimed invention.'<sup>16</sup> In applying this test, each element of the claim must also be compared with the accused device or process to determine whether the accused device or process contains each element of the claim or its substantial equivalent. '[T]he doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole.'<sup>17</sup>

Under another consideration of the doctrine of equivalents, a 'substantial equivalent' may be found if a person of ordinary skill in the art would have considered the differences between the claim element and the accused device to be 'insubstantial' at the time of infringement (The Insubstantial Differences test).<sup>18</sup> An element in the accused product is equivalent to a claim limitation if the differences between the two are □insubstantial□ to one of ordinary skill in the art.

#### *Limitations to the Claim Construction under the Doctrine of Equivalents (DOE)*

There are limitations to the doctrine of equivalents, which limits on the scope of equivalents to which the patent owner is entitled and, in particular, the scope of equivalency that may be permitted to support a claim of infringement. There are at least three ways in which the scope of equivalence claimed by a patentee may be limited:

- (i) Under the Doctrine of Prosecution History Estoppel;
- (ii) by the prior art; and
- (iii) by surrender or dedication to the public

#### *Prosecution History Estoppel*

Prosecution History Estoppel applies most frequently when a patent applicant amends or cancels claims rejected by the patent office as unpatentable based upon prior art. When a patentee responds to a rejection from the USPTO by narrowing the claims of a pending patent application, the doctrine of prosecution history estoppel prevents the patentee from later arguing that the subject matter covered by the original, broader claim is an equivalent under the doctrine of equivalents.<sup>19</sup> Thus the essence of prosecution history estoppel is that a patentee should not be able to obtain, through the doctrine of equivalents, coverage of subject matter that was given up during prosecution to procure issuance of the patent. Competitors may rely on estoppel to ensure that their devices do not infringe by equivalence.

The extent to which a claim amendment creates prosecution history estoppel and affects the doctrine of equivalents was clarified in *Festo Corp v Shoketsu Kinzoku Kogyo Kabushiki Co* (The Rule of *Festo*).<sup>20</sup> In *Festo*, the Supreme Court commented that estoppel is a 'rule of patent construction' that ensures that claims are interpreted by reference to those 'that have been cancelled or rejected.' During claim construction, courts often go beyond deciding what a claim covers and address what the claim cannot cover. Therefore, courts apply estoppel concepts as part of a claim construction analysis.

#### *Effect of Prior Art*

A second limitation of the application of the doctrine of equivalents is the scope and content of the prior art. It is well established that the range of equivalents permitted under the doctrine of equivalents must not ensnare the prior art. The

fundamental purpose of all such evaluations must be to prevent the patentee from obtaining, under the doctrine of equivalents, coverage which the patentee could not have obtained from the patent office by literal claims. Thus, for example, if an interpretation of the equivalents of the claims is broad enough to also ensnare or cover the prior art, there is no infringement.

#### *Surrender or Dedication to the Public*

Where an applicant abandons a claim in its patent application because of a rejection based upon the prior art, the applicant is not allowed to recapture the claim under the doctrine of equivalents and the subject matter of the claim is surrendered to the public.

#### **Analysis of the Relevant Patents**

Analysis of the relevant patents is the most critical aspect of the opinion. For a FTO opinion this section will first describe the criteria used to eliminate clearly inapplicable patents from further consideration, and will next provide a detailed infringement analysis of the patents that could not be eliminated from consideration in the first stage. For a non-infringement opinion in which the client already identified particular patents for study, only the second of the two stages needs to be included.

To present the criteria for eliminating clearly inapplicable patents, it is helpful to include a chart that lists the patents of each category and the representative claim limitations that distinguish them from the client's technology. The patents that cannot be eliminated from consideration are then subjected to a thorough infringement analysis. For each patent, the opinion includes a description of the patent, a review of the prosecution history, and an analysis of the claims. Infringement analysis addresses claim construction, literal infringement, and infringement under the doctrine of equivalents.

#### **Conclusions**

The opinion should be reasonably definite in the conclusions that are reached, and should not be ambiguous on issues of claim construction or infringement.

#### **Disclaimers**

Like other kinds of legal opinions, the non-infringement and FTO opinions include appropriate disclaimers that set forth any limitations of the opinion. Specifically, the disclaimers address inherent

limitations and potential deficiencies of the clearance search that may have caused relevant patents to be missed. It should also be specifically mentioned that the opinion presents only the attorney's view point on the issue and it does not have any legal binding attached to it.

#### **Steps after Taking the Opinion**

A non-infringement or FTO opinion typically concludes that the client's proposed product, process or technology is non-infringing to any or all of the identified patents. But, unfortunately in future course of time it may happen that an infringement issue is raised and subsequently the client's product, process or technology is proved to be infringing to one or more patents in the court. In such a case the client would be required to either abandon or redesign his project, or else he may assess whether the problem patent could be invalidated.

#### **Conclusion**

A competent non-infringement or FTO opinion provides a reasonable basis for determining whether a proposed product, process or technology will infringe a third party's patent or not. But at the same time it has to be noted that these opinions are merely a form of precautionary practice for the companies or clients seeking such opinions. Non-infringement and FTO opinions do not have any binding value on actual patent laws or future infringement other than reflecting the mere fact that the company or client has taken possible steps on good faith. While determining the value of a non-infringement or FTO opinion, it is extremely critical to assess the qualification and expertise of the person who has issued the opinion. A patent opinion is considered to be competent only if it is issued by a person who possesses sufficient qualification and expertise both in patent law and the concerned technology. Although, the practice of using non-infringement and FTO opinions has yet to be accepted and recognized in jurisdictions like India but in today's context a patent opinion written with due diligence can be proven to be a very important business strategic tool.

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- 9 35 U.S.C. § 112.
- 10 *Markman v Westview Instruments Inc*, 52 F 3d 967, 979 (Fed Cir 1995), *aff'd*, 517 US 370 (1996); *Vitronics Corp v Conception Inc*, 90 F 3d 1582 ('[I]t is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning').
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