

FREEDOM TO OPERATE

MANUAL



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ABOUT THE COVER

The cover illustrates the Freedom to Operate process including its scope and coverage. The magnifying glass elucidates the verification process that will be undertaken to determine whether a particular invention as represented by the light bulb has a blocking patent that will limit its commercialization activities. The map of the Philippines signifies the scope and coverage of the territorial search to be conducted.

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MESSAGE

Congratulations to the Technology Application and Promotion Institute (TAPI) for their dedication in the development and publication of the Freedom to Operate (FTO) Manual.

The FTO assessment in our country is still undergoing development, which is undoubtedly imposing major challenges for some government funding agencies and research and development institutes. Since commercialization is the ultimate test for the home-grown technologies that the Department of Science and Technology (DOST) is continuously developing, a standard FTO strategy would be a quick and practical approach for technology transfer.

With these in mind, TAPI developed this manual to set a benchmark in the science and technology (S&T) landscape in aiding challenges in transferring technologies. Moreover, this will certainly serve as a reference material that comprises a digest of vital information for all the researchers, government agencies, stakeholders, and the DOST community. It is also worth mentioning that this manual is a breakthrough as it is the first to be issued in the country.

It is hoped that this handbook will equip our licensing and negotiations teams in all our technology transfer-related endeavors and in the long run, benefit and be of service to the Filipino people.



FORTUNATO T. DE LA PEÑA

Secretary

MESSAGE

I wish to commend the Technology Application and Promotion Institute (DOST-TAPI) for taking the initiative to prepare this Freedom-to-Operate (FTO) Manual. It is a timely solution to the pressing problem in FTO assessment that plays an essential role in technology transfer.

The Department of Science and Technology (DOST) spearheads various Research and Development (R&D) programs that produce new technologies, products, processes and services. FTO is invariably a critical part in the R&D process.

Science and Technology development stakeholders such as research and development institutions, government agencies, the private sector and the science community are working together to accelerate the FTO process.

This manual will contribute to the on-going harmonization in the FTO process to address the need to maximize the use of science, technology and innovation (STI), which will eventually impact the society and the economy.

In writing this manual, TAPI is enabling technology transfer in the country through the FTO mechanism. I am certain that this publication will expand the translation of research and development outputs for the benefit of society.



ROWENA CRISTINA L. GUEVARA, PhD

Undersecretary for Research and Development
Department of Science and Technology

FOREWORD

In 2017 , the very first training on Freedom-to-Operate (FTO) in the Philippines was conducted through the efforts of our agency, the Technology Application and Promotion Institute of the Department of Science and Technology (DOST-TAPI) and the Philippine Council for Agriculture, and Natural Resources and Development (PCAARRD), in order to address long-standing clamor for such capacity building. TAPI and PCAARRD have long been innovation partners that resulted in spearheading the implementation of various projects in technology transfer, intellectual property rights, fairness opinion report, valuation, and FTO.

For a specific technology to legally commercialize, a series of processes and evaluations is ideally conducted and FTO is one of the crucial tools that need to be prepared. FTO analysis is vital if there is already an existing patent, trademark or other intellectual property rights that would effectively block the success of a certain technology. By initiating FTO, technologies, inventions and researches can avoid potential infringement of IP-protected commercial products in the market and the analysis can also be useful in developing other strategies to ensure technology transfer success.

For years, DOST-TAPI has been focused to improve and scale up the FTO mechanism in a precise and systematic manner that can fuel the thrust towards the success of a technology.

With this, I am immensely pleased that through the relentless efforts, commitment and single-minded devotion of TAPI specialists, this manual is prepared to synthesize and reframe the FTO practice for all researchers, technologists, and actors in technology transfer and commercialization. This shall also support and nurture the process and thereby contribute to more effective and efficient technology transfer-related programs.


EDGAR I. GARCIA
Director

Technology Application and Promotion institute
Department of Science and Technology

TABLE OF CONTENTS

Foreword

Messages

Preface

Chapter I: Introduction 1

- A. What is "Freedom to Operate" 2
- B. FTO Search Distinguished From Patentability Search 2
- C. Conducting an FTO Search 4
- D. Where to Search 5
- E. Who should Conduct The FTO Search 7

Chapter II: Conducting an FTO Search 9

- A. Step 1: Determining the Scope of the Search 9
- B. Step 2: Preparing for the Search 11
- C. Step 3: Conducting the Search 15

Chapter III: Methods And Strategies 23

- A. Basic Considerations 24
- B. Novelty Analysis 27
- C. Validity Analysis 37
- D. Claim Analysis 39
- E. Analyzing the Degree of Freedom 45

Chapter IV: Writing FTO Search 65

- A. Contents of the FTO Report 65
- B. Template of FTO Search Report 67

Annexes 69

About TAPI 86

Authors 89

PREFACE

This Manual is an attempt to teach the basic concepts of and provide simplified explanations on Freedom to Operate (FTO), an activity that aims to determine if a technology can be freely commercialized in the Philippines and to avoid the risk of infringing third-party intellectual property rights (IPR). Prepared by selected specialists of the Technology Application and Promotion Institute (TAPI), an agency under the Department of Science and Technology (DOST), who are composed of intellectual property (IP) lawyers, patent agents, and other IP or technology transfer specialists, this Manual offers a valuable resource that will serve as a basic guide in the conduct of an FTO search and the preparation of an FTO search report.

Republic Act No. 10055 (RA 10055), otherwise known as the "Philippine Technology Transfer Act of 2009", requires the DOST system to transfer the technologies, generated from R&D funded by its Councils, to possible adopters for commercialization purposes, so as to maximize the benefits from the use of the taxpayers' money. However, a challenge that regularly faces any government funding agency (GFA) or research & development institution (RDI) is how to perform due diligence for technology commercialization. For instance, while the DOST Secretary is mandated to issue a Fairness Opinion Report (FOR) in the transfer of government-funded projects, to determine whether or not a proposed arrangement or agreement is fair to the government, both of the funding and R&D-implementing agencies of the DOST are always challenged in complying with the requirements of the law. The FOR is prepared by the Fairness Opinion Board (FOB), a three-member experts' group that is convened to assess whether a proposed transaction is fair to the government. To appropriately draft the FOR, it is ideal that a due diligence of the subject technology is made by the Requesting Party, whether the GFA or the RDI,

which would include assessing the strength of the technology in terms of its IP protection.

The assessment of the strength of a technology's IP protection requires the expertise of an IP specialist. An important question to address is whether the subject technology can be produced or sold in the Philippines, without infringing the existing IPR of third parties. As the TAPI gets more and more engaged in the technology transfer activities of the DOST, there is a realization that technology managers and negotiators are inexperienced in determining if the technologies offered, even though covered with patent protection, can take off smoothly without the risk of infringement.

An FTO assessment is a precautionary measure in the business realm to determine and avoid possible IP infringement. It identifies valid patent claims that can potentially block technology commercialization. This activity addresses the risks associated with the possible infringement of the government-funded technologies by obtaining FTO reports prior to commercialization.

The TAPI's goal in the publication of this Manual is to provide researchers with basic information and guide in conducting an FTO search and preparing an FTO report. This Manual is the result of TAPI's experience in FTO assessment, which we hope will benefit the DOST community, other government agencies, and researchers in the commercialization of government-funded technologies in the Philippines.

CHAPTER I INTRODUCTION

Intellectual property (IP) can be the most important asset of an organization, the value of which can even surpass fixed and other capital assets of the company. However, unlike the ownership of real property, the ownership of IP does not always mean that the owner can exploit the same without fear of encroaching upon another IP owner's rights. In the sale of a parcel of land, for instance, the buyer only needs to ensure that the title is in the name of the seller and that there is no encumbrance to the property. As such when the sale is consummated, the buyer is given the absolute right to enjoy, use or dispose of the property in any manner during his or her lifetime. On the other hand, the sale of IPR to an invention requires more than ensuring that the registration is in the name of the inventor or the patent holder. It is important, for example, to verify whether or not the patent is active. An invention covered by a lapsed or expired patent becomes part of the public domain. The buyer, as well as other interested parties, can use the technology freely as the exclusivity afforded by patent protection is lost.

Technology commercialization, therefore, requires the conduct of due diligence by both parties to the transaction. The Licensee (buyer) would want to know if the price they are paying is worth the return they will receive. They would also like to understand the risks involved, if any. Otherwise, they will have to rely merely on the Licensor's contractual warranties, subject to the

*IP can be the **most important** asset of an organization.*

*It is **important to verify whether or not the patent is active!***

principle of "caveat emptor" or "buyers beware". Normally the Licensee conducts due diligence once negotiations for licensing has started or is imminent.

On the other hand, a Licensor may want to verify the status of its IPR protection even before the invention is offered for sale, license or investment. The Licensor has to check the metes and bounds of its IPR and whether there are "skeletons in the closet" that have to be disclosed and discussed during the negotiation process, in order that the Licensee will be prepared to assume the risks involved in commercialization. Patent litigation can be a very expensive, uncertain, tedious and risky undertaking. Oftentimes, the Licensor will secure an FTO to determine if it can proceed with commercialization with minimal risk of infringing the IPR of others. In doing so, the Licensor will be able to justify the valuation and price of its IP to the other party.

A. WHAT IS "FREEDOM TO OPERATE"

"Freedom to Operate" or FTO is a due diligence process undertaken by IP rights owner to determine potential risks of infringing activity or patent barriers in commercialization. This procedure includes the careful examination by the IP rights owner of the patent claims of the third party, in force patents as against his claims to weight and possibly calculate the extent of infringement.¹

B. FTO SEARCH DISTINGUISHED FROM PATENTABILITY SEARCH

While both processes involve a search for relevant patents, FTO and patentability search differ in the following aspects:

¹ Kowalski, Preiss, Chiluwal, & Cavicchi, J. (February 17, 2011). *Freedom to Operat, Product Deconstruction and Patent Mining*. New Hampshire. Retrieved from https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_wk_ge_11/wipo_ip_wk_ge_11_ref_3_kowalski.pdf

Area	Patentability Search	Freedom to Operate
1. Objective	To find out whether claims to inventions would be novel and non-obvious in view of everything that has been published.	To find out whether a certain product or process would infringe patent claims granted to others.
2. Purpose	For registration	For commercialization
3. Coverage	Published information which may or may not be covered by an IP registration	Patented/registered inventions/rights
4. Use	To determine novelty and inventiveness for registration purposes	To determine the risk of infringing IP rights of others
5. When conducted	Before the conduct of research and development	Before offering the technology for license, sale and/or investment
6. Person of interest	Researcher, inventor, funding agency	Parties to the negotiation (e.g. licensor, licensee)
7. Area	Worldwide, wherein novelty tests, for instance, are conducted from patent and non-patent databases from around the world. In this case, novelty must be tested worldwide.	Jurisdiction-specific, wherein test is done in the country of interest (i.e., where commercialization shall take place). For the purpose of this Manual, area will be limited to the Philippine jurisdiction.

C. CONDUCTING AN FTO SEARCH

RA 10055 aims to promote and facilitate the transfer, dissemination, effective use, management and commercialization of the IPR, technology, and knowledge resulting from the R&D funded by the government, for the benefit of the national economy and taxpayers. It is essential in the technology transfer activity to conduct an FTO search to avoid or minimize the risks of infringing third party IPR.

*...conduct an
FTO search
to avoid or
minimize the
**risks of
infringing**
third party
IPR*

1. Why an FTO Search is Necessary

The FTO search report is one of the requirements for the preparation and issuance of a Fairness Opinion Report (FOR) in the transfer of government-funded projects. FOR is necessary to determine whether or not a proposed transaction, such as a licensing agreement, is fair to the government. The conduct of an FTO search plays a fundamental role in the determination of whether or not it is beneficial to proceed with the proposed technology transfer as well as the terms thereof.

2. Purposes and Benefits of an FTO Search

The following are some of the reasons for, and the benefits of, conducting an FTO Search:

- a. Assess infringement risks - A patent grants the patent holder the right to exclude unauthorized third parties from making, using,

selling and commercially dealing in the patented invention for a limited period of time. Infringement of a patent means the violation of any of the monopoly rights granted to the patentee. The assessment of infringement risks through the conduct of an FTO helps to identify existing third-party IPR within the jurisdiction and further avoids the litigation cost that may be incurred due to unintentional infringement.

b. Uncover licensing requirements and commercial opportunities – There are instances where an FTO search will uncover essential IPRs held by a third party or competitor, which may become roadblocks to the successful commercialization of a technology. An FTO search provides a good opportunity, prior to commercialization, to explore possible licensing or other commercial agreements with the IPR holder, which will not only avoid possible infringement but which may be commercially lucrative for all parties involved. An FTO search is also a useful method for tracking the expiration of third party IPR, to effectively plan the proper timing of a technology's entry into the market.

***FTO search
helps to
effectively
plan the
proper
timing of a
technology's
entry into
the market.***

c. Provide direction to R&D activities – Conducting an FTO search also provides an opportunity to identify essential technologies that can be modified or tweaked, without infringing relevant IPR. R&D activities may be directed to develop products and processes that would not anticipate any infringement.

D. WHERE TO SEARCH

Considering the territorial nature of patents, these are only enforceable in the country or region in which they are granted. For example, if a patent for a certain technology was granted in the Philippines but not in Country X, the use and practice of said technology in Country X do not infringe the patentee's exclusive rights simply because it has no patent in Country X. Thus, for purposes of assessing infringement risks, an FTO search should be conducted with regard to valid patents in the territory where commercialization will be undertaken.

For commercialization activities in the Philippines, an FTO search of all valid patents granted in the Philippines should be made. The search can be done using the patent database of the Intellectual Property Office of the Philippines (IPOPHL), which is accessible at www.ipophil.gov.ph. Below is the interface of the IPOPPhil's search platform:

The screenshot displays the IPOPHL Patent Search interface. At the top, there is a blue header with the IPOPHL logo and the text 'IPOPHL Patent Search (WIPO Publish)'. On the right side of the header, there are tabs for 'Designs' and 'Patents'. Below the header, there is a search bar with the text 'Enter Keyword' and a 'Search' button. The main content area shows search results for 'FOOTWEAR REGISTRATION POLYMERIZATION PROCESSES'. The results are displayed in a table format with columns for Status, Title, Applicant, Filing Date, Pub. Date, and Inventor. The first result is for 'FOOTWEAR REGISTRATION POLYMERIZATION PROCESSES' with a filing date of 2016-07-14 and a publication date of 2016-02-10. The second result is for 'FOOTWEAR REGISTRATION POLYMERIZATION PROCESSES' with a filing date of 2016-07-14 and a publication date of 2016-02-10. The interface also includes a navigation bar with 'SEARCH' and 'ADVANCED SEARCH' options, and a 'Results' button.

Status	Title	Applicant	Filing Date	Pub. Date	Inventor
Available	FOOTWEAR REGISTRATION POLYMERIZATION PROCESSES	IPPHIL	2016-07-14	2016-02-10	IPPHIL
Available	FOOTWEAR REGISTRATION POLYMERIZATION PROCESSES	IPPHIL	2016-07-14	2016-02-10	IPPHIL

All active and enforceable patents, or patents that are not yet expired or lapsed/forfeited, can be cited as prior art to be considered in the search. Expired patents under Republic Act 165 (with validity of 17 years from the date of grant) and under Republic Act 8293 (with validity of 20 years from application date) and lapsed/forfeited patents (for failure to pay maintenance fees or annual fees) will not be considered since these already belong to the public domain. Anyone can use, manufacture or sell the technologies covered by expired or lapsed patents.

The methods of conducting an FTO search, using publicly available patent databases, are illustrated in the next chapter.

E. WHO SHOULD CONDUCT THE FTO SEARCH

The inventor or the technology owner may conduct an FTO search even in the early stages of the product or process development. While it is understood that an FTO search is not usually done by the researchers themselves due to the complexity and nuances that comes with it, it would be a good practice for researchers to know how to perform an FTO search. This would give the researchers a timely caution with regard to possible infringement. An FTO search also plays an important part in establishing the areas to which R&D and commercialization activities should be directed.

*FTO search plays an important part in establishing the areas to which **R&D** and **commercialization** activities should be directed*

An FTO search and analysis usually accompanies a clearance opinion prepared by the patent counsel, which forecasts the potential for the autonomy of a pending patent application or an issued patent's claim/s.² A patent counsel in the Philippines refers to a lawyer who specializes in IP and is one who is licensed to practice law by the Supreme Court. A clearance opinion, in this case, would refer to a legal opinion on the FTO of a particular subject technology.

The forecast in the FTO analysis will be used as critical information not only by the technology owner or the funding agency but also by the potential parties to the negotiation. The potential sale, spin-off or license agreement that revolves around the technology would be relying on the forecast and analysis resulting from the FTO search.

²Hunt, D., Nguyen, L., & Rogers, M. (2007). *Patent Searching Tools & Techniques*. New Jersey: John Wiley & Sons, Inc.

CHAPTER II

CONDUCTING AN FTO SEARCH

A good FTO report depends on the quality of the information that the FTO analyst obtained and assessed. There is no other way but to perform an FTO search that is directed to identifying all potentially blocking patents. For a new practitioner, FTO search can be merely viewed as a prior art search, with all the intricacies and specialized techniques that must be done. The tools and techniques are similar, however, prior art search looks into worldwide documents while FTO is focused on the patent database in a country of interest.

FTO search that is directed to identifying all potentially blocking patents.

In a prior art search, the results are expected to identify novelty-destroying information or documents that were disclosed anywhere in the world prior to the subject technology. In an FTO search, on the other hand, the results are expected to yield existing patent rights for a product or process in a particular jurisdiction.

The following is a set of simple steps to conduct FTO search:

Step 1. Determining the Scope of the Search

The FTO analyst is encouraged to get ready with basic information on the subject matter as this would be used as input to the search and assessment. The scope will allow the FTO analyst to search for patents filed in the country of interest, such as the Philippines, where the technology is

intended to be marketed. The same input will also allow the FTO analyst to decide whether both expired and unexpired and all available non-patent literature shall be needed.³

i. Granted Patents

These may include (a) granted and active (in-force) patents with the renewal fee having paid, (b) lapsed patents due to non-payment of renewal of fees, with the option of being reinstated, thus, these patents should be tracked until the time reinstated date has lapsed, (c) lapsed patents due to non-payment of renewal of fees, without the option of being reinstated. As to Items (a) and (b), these patents pose risk in the commercialization of the proposed technology thus, caution should be exercised. However, as to Item (c), these patents present no risk at all for infringement and are a good target for acquisition or may be free to use upon confirmation of their status.

ii. Patent Applications

These patents pose potential future risks and may eventually impact the FTO of the proposed technology especially (a) patents awaiting examination and (b) patent applications undergoing prosecution. As to abandoned patent applications, these may not pose risk at all provided the confirmation that there is no pending family application.

iii. PCT Applications

Foreign patents entering the (Philippine) national phase should also be considered as they may also pose impact in the FTO of the proposed technology which is also intended to be commercialized in the Philippines.

³Hunt, D., Nguyen, L., & Rogers, M. (2007). *Patent Searching Tools & Techniques*. New Jersey: John Wiley & Sons, Inc.

iv. Non-Patent Literature (NPL)

Although NPL may not be significantly relevant in the clearance search as they do not pose potential threats to the release of the proposed technology, they are useful in identifying possible competitors in the market and in determining if there are ways to work around the technology.

Step 2. Preparing for the Search

i. Properly scoping the subject matter

Scoping the subject matter is important to determine the key features of the invention and answer the following questions: (a) What is the invention?; (b) What problem does the invention solve?; and (c) What does the invention do?

Let's consider the example below of an actual technology assisted by TAPI through the PCAARRD-FTO Project:

An extender formulation for artificial insemination packed in sachet form comprising: a soybean lecithin as non-penetrating cryoprotectant; a formulated buffer solution consisting of Tris (hydroxylamino) methane of 3.028g; citric acid of 1.675g and fructose of 1.25g diluted in 100mL of distilled water; and a formulation of the semen extender consisting of 73% buffer solution, 20% non-penetrating cryoprotectant, and 7% penetrating cryoprotectant. The semen extender has a pH range of 6.2-7 and improves the post-thaw motility of the spermatozoa from 30%-50%. It also improves the viability of spermatozoa stored

*Scoping the subject matter is important to determine the **key features** of the invention.*

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