III. How to achieve freedom to operate (FTO)

A. Overviews of FTO analysis preparations

We have already found how unique the key features of innovation in the pharmaceutical industry are, and accordingly how significant patents are for pharmaceutical companies to recoup their investments. Therefore, pharmaceutical companies are much more desperate to monopolize the market compared with companies in other industries. In case of finding the patent infringing activities by third parties, a pharmaceutical company would take all possible measures to exclude them from the market. This means when a pharmaceutical company would like to start researching and marketing its new drug, the pharmaceutical company must make sure that it would not infringe other pharmaceutical companies' patents. Discontinuance of the project for developing a new drug due to patent infringement of third parties must be avoided by any means possible because it could be almost amount to the failure of the project. Therefore, examining third parties' patents and making sure that the new drug is totally free from patent infringement is very important.

The procedure for assessing whether the product/process is free to sell or not is called an FTO analysis.[21] As much of the money and time is invested in one project in the pharmaceutical industry, it is absolutely indispensable for a pharmaceutical company to carry out intensive research on the FTO analysis from the very early stage of its R&D.

B. Building up the multidisciplinary FTO team

Ideally, an FTO team leader should have special expertise of pharmaceutical product and process because comprehensive and sophisticated understanding of its own product and process is essential for the team leader to

21 Stanley P. Kowalski, *Freedom to Operate: The Preparations,* ipHandbook of Best Practices, at 1329 (last visited September 5, 2016), http://www.iphandbook.org/handbook/ch14/p02/

accomplish intensive FTO analysis.[22] Additionally, the FTO team leader must have considerable expertise in IP-related issues, such as a technology transfer professional officer, intellectual property practitioner like a patent agent, a scientist who has participated in various IP rights and technology transfer courses, workshops, or seminars.[23] In this way, the FTO team leader must be capable in two different professional fields since an FTO analysis is conducted in the domain where science and law overlap.

Other than the team leader, the FTO members should include scientists who had supervised the project, technology transfer personnel, and technicians/support staff.[24] A participation of technicians/support staff is very important because they know what exactly happened during the product research, development, and commercialization. It is also helpful to include business personnel (depending on the stage of commercialization) and possibly administrative staff to the FTO team. They might have information on relevant communications, documents, and agreements.[25]

One important thing when building up the FTO team is to make constituent team stuffs multidisciplinary. Opinions from several points of view and discussions would make their FTO analysis more precise and in-depth.

C. The FTO search

The FTO search is normally conducted by a competent professional searcher[26]. The searcher will normally use the patent clasification codes and keywords in order to narrow the scope of the third parties' relevant patents and patent application. This FTO search is extremely important and must be conducted in the most deliberate manner. The FTO team will examine and pick up most relevant patents and patent application among the search result. If the searcher fails in picking up even one relevant third parties' patent, the FTO team will not able to find it in later procedure no matter how intensively the FTO team conducts FTO analysis. It should be noted that just one patent could kill whole one pharmaceutical project.

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22 *Id.* at 1331.
23 *Id.* at 1331.
24 *Id.* at 1332.
25 *Id.* at 1332.
26 H. Jackson Knight, Patent Strategy 158 (3rd ed. Wiley 2013).

One should carefully bear in mind that the FTO search is totally different from a patentability search.[27] The purpose of a patentability seach is to find relevant prior arts which could destroy the subject patent or patent application. These prior arts basically need to disclose concrete example in order to destroy the broad claim of the subject patent or patent application. This is as we call "Species/Genus anticipation rule", which means that species anticipates genus, but genus does not necessarily anticipate species.[28] On the other hand, the purpose of the FTO search is to look for patents and patent applications which might have a great impact on the legal practice of the invention. Therefore, the searcher must look for patents and patent applications that have broad claim that might cover the product/process a pharmaceutical company is going to market, even though the invention is not specifically mentioned.[29] There are many patents and patent applications that look irrelevant to the product/process at first sight, but nevertheless it is likely that the claims of which are described broadly enough to cover them. In other words, it is quite common that the claims of relevant patents and patent applications don't contain keywords to specify the product/process at all. For example, when you would like to conduct the FTO search for your newly developing drug with a new chemical entity X, the typical keywords for finding relevant patents and patent applications could be chemical structure of X, molecular name of X and characteristic functioning group of X. However, you have to pay attention to numeric value patents, functional patents and product by process claim patents, all of which might not contain typical keywords for X but still cover X within the scope of the claims. This makes the FTO search very difficult to conduct accurately. The searcher must accurately predict what kind of wordings are used in the claim of possible relevant patents and patent applications.

D. Pharmaceutical Technical Considerations

The FTO team should consider pharma-product/process-specific components.[30] First, the FTO team has to take into account the compounds them-

27 Id.
28 Janice M. Mueller, Patent Law 176-177 (4th ed. Wolters Kluwer 2013).
29 Knight, *supra* note 26.
30 Kowalski, *supra* note 22, at 1335.

selves including the form of the compounds (ex. crystalline form, amorphous form), the steric structure of the compounds (ex. enantiomers), and the components which will be produced by metabolic process in human body (ex. metabolites, prodrugs). Second, the type of pharmaceutical compositions (ex. delivery system, vehicles and adjuvants) must also be considered. Third, the methods, steps, and components involved in the product synthesis are also critical. Drug synthesis normally consists of many steps. In each step, the reagents, the intermediates, purification techniques, and handling techniques of the third parties' patented invention might be involved. Fourth, downstream considerations (ex. method of use, modes of treatment, dosimetry, and limiting side effects) are also important to keep in mind.

In case of vaccines, there are additional FTO analytical considerations specific for vaccine research, development, manufacture and deployment, including expression systems, fusion partners, immunostimulators, adjuvant systems, excipients, and delivery devices.[31]

These pharma-product/process-specific considerations are very complicated. But an interview with technicians/support staff would greatly help the FTO search because they are the PHOSITA (Person Having Ordinary Skill In The Art) who might have information on "dangerous or safe" technique for patent infringement.

E. Pharmaceutical Patent Information

In addition to the standard patent search tools and resources, pharmaceutical patent search needs to check specific patent resource materials. The Orange book, the Merck Index and the actual file wrapper search are typical examples.[32]

The FDA[33] publishes a list of all drugs approved for marketing in the US under the title "Approved Drug Products with Therapeutic Equivalence Evaluations", which is also called "Orange Book". Orange Book is

31 Kowalski, *supra* note 21, at 1336.
32 Kowalski, *supra* note 21, at 1340.
33 U.S. Department of Health and Human Services, Food and Drug Administration

daily updated and can be readily accessed via the Internet.[34], [35] The FTO team can obtain information about approved drug products with therapeutic equivalence, as well as the expiration dates of patents on therapeutic small molecules and on approved indications and compositions[36].

The Merck Index is a one volume encyclopedia of chemical, drugs and biologicals that contains more than 10,000 monographs, which lists patents and publications on older drugs and reagents.[37] The Merck Index is available as a printed edition or online.[38] One of the advantages of the Merck Index Online is its accurate search ability by the chemical formula. It is risky to rely on only keyword patent searching because in pharmaceutical patents, a claim often contains a chemical formula to define the scope of the claim. And this chemical formula cannot normally be found only by keyword patent searching. The FTO team can easily and accurately search the patents by the chemical formula of the product.

It is prudent that the FTO team actually goes to the patent office to examine the boxes containing patent prior arts.[39] This is sometimes necessary to know the differences in nomenclature used by various patent drafters since some of differences might not be readily identified and sorted out in electronic searching.[40] As described above, there is the possibility that relevant patents and patent applications use a different nomenclature in the claims from the ones the FTO team grasps and include as the keywords. One of the purposes of examining patent prior arts filled in the patent office is to obtain the information on other possible nomenclatures. There are many ways to describe only one chemical entity. For example, an alcohol, which is contained in beer and has simple chemical structure, could be described either as “alcohol”, “drinking alcohol”, “ethanol”, “ethyl alcohol”, “1-ethylalcohol”, ”C_2H_6O”, “C_2H_5OH”, “CH_3CH_2OH”,

34 Orange Book, *Approved Drug Products with Therapeutic Equivalence Evaluations* (last visited September 6, 2016), http://www.accessdata.fda.gov/scripts/cder/ob/.
35 John R. Thomas, Pharmaceutical Patent Law, 418 (Bna Books 2005).
36 Kowalski, *supra* note 21, at 1340.
37 Kowalski, *supra* note 21, at 1340.
38 The Merck Index Online (last visited September 6, 2016), https://www.rsc.org/merck-index?e=1.
39 This is the case in the US. In other countries like Japan, the patent office provides this type of information online for free of charge (Japan Patent Office (last visited September 6, 2016), https://www.jpo.go.jp/).
40 Kowalski, *supra* note 21, at 1340.

"Et-OH", and "^OH"[41]. Normally, the structure of a new drug component is much more complicated, and therefore the nomenclature of which is fairly diverse.

F. Period of silence

The FTO team must recognize that patent applications are not available until they are published. In Europe and Japan, this period of silence is 18 months[42] after the earliest effective filling date. This means that there may be pending patent applications still below the surface, but nonetheless relevant to the FTO analysis.[43] This is called "period of silence". The FTO team has to keep searching for this secret patent application for at least 18 months to secure that there is no relevant patent applications. In US, historically, all pending patent applications were maintained in secrecy unless and until they are issued as patents. But after the American Inventors Protection Act of 1999, the default rule is that a regular U.S. utility patent application will be automatically published 18 months after its effective filling date.[44] It is worth noted that even under the current law a purely domestic patent application can avoid 18-months publication.[45] But with regard to pharmaceutical patent search, the FTO team can practically ignore this secret US patent application because there is substantially no pharmaceutical company that files patent application only in US.

G. Interpreting potentially adverse patents

When the search ends with relevant patents or patent applications which might have potential impact on the legal practice of the invention, the analysis then should be conducted as a next step. This analysis should be conducted by or with the help of an intellectual property professional[46] like qualified patent counsel because the claim will be often stated in an am-

41 "^OH" is the expression representing only carbon skeleton and functioning group.
42 In Europe: EPC Article 93(1)(a), and in Japan: JPA Article 64.
43 Kowalski, *supra* note 21, at 1341.
44 Mueller, *supra* note 28, at 65.
45 35 U.S.C. § 122(b)(2)(A)(ii), (iv)
46 Knight, *supra* note 26, at 159.

biguous manner, and interpretation of patents needs the help of specialized expertise with experience. The analysis is done by carefully and objectively reviewing the claim of the patents or the claim and description of the patent application.

1. Difference of analysis between patent and patent application

It should be noted that the FTO team has to clearly differentiate the way of reviewing between patents and patent applications. The biggest difference between them is whether patents are finally granted or not. Patent applications are the pending state before patents are granted. Accordingly, patent applications have chances of claim amendment in the future.

a) The scope of possible amendment

In case of patents, the scope is determined by the claim, and the description and drawings is used to interpret the claim.[47] The claim may not be amended in such a way that the claim is extend from the original claim.[48] Accordingly, the FTO team basically can review the claim as the maximum scope of the invention. On the other hand, in case of patent applications, applicants can amend the claim unless the amendment contains new subject-matter which is not included in the content of the application.[49] This means that until the patent application is granted, it is possible that the scope of the claim can be freely extended within the disclosure of the patent application, which is known as "claim up amendment". This is called so because applicants can claim the inventions that are stated only in the description. Accordingly, the FTO team should take into account not only the current claims but also possible future claims that could appear from the invention disclosed only in the description.

47 In Europe: Article 69 EPC, in Japan Article 70(1)(2) JPA.
48 In Europe: Article 123(3) EPC, in Japan Article 126(6) JPA.
49 Article 123(2) EPC, in Japan Article 17bis(3) JPA.

b) Patentability

In case of patents, they normally meet the requirements of patentability since they survived the review of patentability by an examiner at the patent office although the validity of patents is sometimes challenged and some of patents disputed are actually revoked. Therefore, the FTO team should examine the claims of patents on the condition that they are valid. On the other hand, in case of patent applications, since they are not yet reviewed and patents are not granted, the FTO team should first of all review validity of the claim. In practice, patent drafters tend to draft claims in a very broad manner which might even lack inventive step from prior art with the purpose of obtaining as broad claim as possible. If the applicant received an office action from the patent office, then he is able to amend the claims to the minimum extent which is necessary to circumvent the cited prior art. With this drafter's IP strategies in mind, the FTO team should predict how the claims would be amended to meet patentability requirement under prior arts that are considered to be cited by the patent office in the future. In this way, this process requires deep insight and experience in IP field.

2. File wrapper

It is also important to consider the information provided by the applicant to the patent office, which is called "prosecution history" of the patent.[50] An applicant, in an effort to obtain the patent, usually tries to differentiate the claimed invention from prior art found by an examiner. For this purpose, the applicant amends the claim and/or submits statements on interpretation of the claim. In many jurisdictions, it is prohibited to adopt patentee's assertion in the patent infringement case which contradicts the assertion made in the prosecution history (prosecution history estoppel). Therefore, in case of an interpretation of the claim, the FTO team should examine this prosecution history to check relevant amendment and/or statement which might narrow the scope of the claim. Ideally, the file wrapper should be searched and analyzed only by qualified patent counsel because searching file wrapper is part of claim interpretation. A patent

50 Knight, *supra* note 26, at 159-160.

counsel will use the contents of the file wrapper (claim amendments or disclaimers etc.) in order to interpret the precise meaning and scope of the claim wordings.[51] If the patents or patent applications are filed globally, it might help the FTO team to examine file wrapper in another countries because file wrapper could be helpful on worldwide-base.

It should be noted that in some countries such as Germany and UK prosecution history is not taken into account or not so directly relevant when the court examines the scope of the claim. In these countries, the FTO team can simply skip or spend less time to examine file wrapper.

3. Doctrine of equivalents

Even if it is clear that the product/process does not literally fall within the scope of the claim, the FTO team should not easily eliminate that patent from the watching list because the product/process still carries significant risk of infringing that patent under the doctrine of equivalents. The Doctrine of equivalents is a judge-made law that extends the scope of the claim beyond literal wording of the claim. Each country has developed its own requirement for the doctrine of equivalents, and the extent to which the scope of the claim extends differs in each jurisdiction. Accordingly, when the FTO team conducts patent searching in one country, the FTO team staff should familiarize themselves well enough with the infringement under the doctrine of equivalents there. This examination for the doctrine of equivalents is as difficult as that of literal infringement, and even more difficult in many cases. Therefore, final examination should be conducted by IP professionals.

4. Status searches

Once relevant patents and/or patent applications are found, the FTO team should keep an eye on their latest status because the published documents only show the information at the date of publication. It is normal that they will change their status later on. As for patents, the FTO team might find that one patent is not in force anymore because the patentee did not pay

51 Kowalski, *supra* note 21, at 1340.

maintenance fee,[52] or that the claim of another patent is amended[53] in a manner which excludes the subject product/process from the scope of the claim. As for patent applications, the FTO team might find that one patent application is deemed to be withdrawn without being requested to examine.[54]

5. Patent term extension

One unique feature for patents in the pharmaceutical industry is the patent term extension system. The FTO team should be aware of this system in each jurisdiction in terms of the term extension and the scope of the extended patent.

a) Term extension

The period of patent extension shows clear difference between Europe and other major jurisdictions (US and Japan). By paying attention to this difference, the FTO team can anticipate when exactly the relevant patent will expire, and accordingly its pharmaceutical company can be free to operate the invention.

In Europe, Council Regulation of 1992 concerning the creation of a Supplementary Protection Certificate (hereinafter referred as "SPC") was approved and came into effect in 1993, which provides different protection from patent law.[55] The European SPC aims to improve the protection of innovation in the pharmaceutical industry, and it intends to provide a uniform solution at the European Community level. As is set out in the Recitals (1) to (5) of the European Regulation, the purpose is to give sufficient incentive for the pharmaceutical industry to carry out the long and costly research necessary to bring new medicinal products to the market.

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52 Knight, *supra* note 26, at 160.

53 Philip W. Grubb, Peter R. Thomsen, Patents for chemicals, pharmaceuticals and Biotechnology: Fundamentals of Global law, Practice and Strategy 371 (Oxford University 5th ed. 2010)

54 In Europe: Article 94(1)(2) EPC, in Japan Article 48ter(4) JPA.

55 Ryoko Iseki, *Patent term extension in Japan: an academic and comparative perspective*, *in* Pharmaceutical innovation, Competition and Patent law 188 (Josef Drexl & Nari Lee eds., Edward Elgar Pub 2013).

The period of patent term extension by the SPC ranges from the date on which the application for a "basic patent" was lodged to the date of the first authorization to place the product on the market in the Community, reduced by a period of five years.[56], [57] This period is quite unique to Europe and different from the ones in US and Japan. Here, the time when the patent right is registered is not an issue. Even if the patent right registration comes after the date of marketing approval, it is still possible to add the period from the date on which the application is filed to the date of marketing approval.[58]

In US and Japan, the purpose of the system is to restore the effective period of the patent right that was lost due to the waiting period. According to the provision under US Patent Act, the extension term shall be the same with the time equal to the regulatory review period for the approved product for the period that occurs after the date on which the patent is issued.[59] Thus, in case that the regulatory review period occurred before the issue date, the extension term would become zero in the US. This is the same in Japan.

b) The scope of the extended patent

The extent of protection of the patent is normally determined by the claims.[60] However, when the FTO team examines the scope of the extended patent, it should be aware that the extent of it is determined in the different manner. In order to acquire patent extension, a pharmaceutical company must obtain a certificate that proves the period for which the pharmaceutical company can't place the drug on the market because of waiting the authorization. The scope of the extended patent shall not cover the

56 Article 13,1 of the Council Regulation (EEC) No. 1768/92 of 18 June 1992.

57 Iseki, *supra* note 55, at 192.

58 Matsui, S. and T. Aoki, *"Tokkyoseido no kokusaiteki seigouka to iyakuhinbunya no tokkyoken kikan enchoseido ni mirareru hiseigou (International Harmonization of the Patent System and Disconformities in the Patent Right Term Extension System in the Drug Field)"*, AIPPI, 2008, 53(6), 2 and 14.

59 35 U.S.C. § 156(c).

60 § 69(1) European Patent Convention in EU and § 70 Japan Patent Act in Japan. In US there is a case law with regard to the extent of the protection and it is the claim that basically determines it.

whole claims, but shall cover only the drug[61]. But, this interpretation is really difficult because it is totally different from the interpretation of normal claims and there are not so many cases in the past that can show the criterion for that. Therefore, the FTO team has to understand the uncertainty of this type of scope interpretation.

H. Dealing with Adverse Patents

If the intense review of potentially adverse patents by an IP professional unfortunately brings the FTO team the conclusion that the proceeding with making, using, or selling an invention constitutes an infringement of the patent, there are several options to be considered.

1. Legal / IP management strategies

a) License-in / Cross-license

One of the options is obviously to obtain a patent license from the patent owner, that is, the permission to use the patented invention in exchange for royalty payment. Although a licensee will become harder to make a profit from selling its licensed product due to royalty payment to a licensor, it is nevertheless advantageous to obtain a patent license because the licensee can completely eliminate the risk for injunction of its product in the market and troublesome patent infringement in the future.

However, the patent owner is generally not obliged to give a patent license. Even if the patent owner accepts to give a patent license, the licensing terms would probably involve a very large sum of money.[62] In the pharmaceutical industry, it is rarely seen to obtain a reasonable patent license under normal circumstances because the patent owner is also desperate to recoup the investment, and monopolizing the market with no licensee is the best way to achieve it.

The FTO team should then think of several IP strategies to make the patent license negotiation advantageous for its pharmaceutical company. One of the IP strategies is to create the circumstance under which the

61 § 4 SPC in EU, and § 68 bis Japan Patent Act.
62 Knight, *supra* note 26, at 160-161.

patent owner can't refuse the offer for licensing. That is to find the patent owner's weak points and attack them.[63] The key is the patents of the FTO team's pharmaceutical company.

It is highly recommended that the FTO team's pharmaceutical company owns various types of patents prior to license negotiation in order to obtain better license condition. These patents are roughly classified into two categories; "aggressive patent" and "defensive patent". "Aggressive patent" is the one that is used to overcome the weak point of the FTO team's pharmaceutical company. The FTO team can use this "aggressive patent" to conduct a patent license negotiation advantageously. "Aggressive patent" does not necessarily have to do with the technologies that the FTO team's pharmaceutical company is developing and marketing. Rather, "aggressive patent" should be aimed to attack the negotiating partner, whose patent is covering the technologies that the FTO team's pharmaceutical company. "Aggressive patent" is designed to cover the technologies that the competitors (therefore, future negotiating partner) would use now or in the future, rather than the FTO team's pharmaceutical company itself. As described above, it is the patent aimed to conduct the patent license negotiation advantageously.[64] Filling and obtaining "aggressive patent" is one of the IP strategies. It's not something the FTO team can prepare just before a patent license negotiation, but the pharmaceutical company always has to bear that in mind and continue filling patent applications to obtain in the future. On the other hand, "defensive patent" is the one that is used to protect the business and most important right for technology-based companies. The company should not allow the third party to infringe this "defensive patent" right and should not license out "defensive patent" to the third party. If "defensive patent" is infringed, the company should enforce the right and let the third party stop it by all means.[65]

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63 Giichi Maruyama, Chitekizaisan Sennryaku, gijyutu de jigyou wo tsuyokusurutame ni (The IP Strategy: Strengthening the Business by means of the Technology) 123 (Diamond sya 2012). The author has 40 years' of experience at IP department in Cannon Inc., Japanese Electronics Company selling camera, video, printer, photocopying machine and so on. He is well known in Japanese IP industry as one of the successful IP managers who performs skillful IP strategies. Some say that one of the reasons Cannon Inc. survived very competitive electronics industry was his ingenious IP strategies.

64 *Id.* at 123.

65 *Id.* at 113.

In case of the pharmaceutical company that carefully considers this IP strategy for "aggressive patent", the first thing that the FTO team should examine would be whether or not the negotiating partner is infringing one of "aggressive patents". If the FTO team is lucky enough to find that the negotiating partner is likely to infringe one of its "aggressive patents", then the negotiating partner would be substantially obliged to license out the patent at issue in the patent license negotiation since the negotiating partner would otherwise be accused of the infringement of "aggressive patent". The content of this "aggressive patent" could be anything as long as it covers the negotiating partner's act. It is not limited only to the one about drugs. If the negotiating partner develops other business, for example apparatuses for medical operation and chemical products, and the FTO team's pharmaceutical company also develops the business and hold patents, it is worth while checking the possibility that the negotiating partner's infringement in those products because even such the patent can work as "aggressive patent" in a patent licensing negotiation for a drug. In this way, "aggressive patent" would give the FTO team a great chance to successfully conclude advantageous patent license agreements.

In addition to the above, there is the further advantage of having "aggressive patent".[66] For example, imagine the circumstance where the FTO team's pharmaceutical company (X) has the risk of infringing patents B_1 and B_2 (hereinafter referred as "problematic patents") of the third party negotiating partner (Y) according to the FTO survey. But, at the same time, X finds that some of Y's activities also have the risk of infringing X's patents, A_2 ("aggressive patent"). Here, the patents A_1 and B_1 are the core technologies for X and Y respectively. Thus both X and Y don't want to license out these technologies unless they are obliged to do so. The patents A_2 and B_2 are non-core technology, which can be licensed out depending on the condition of the licensing agreement (See Table 1). Here, we assume that X's product has not been put on the market yet because it is still at the early stage of the development. Accordingly, Y does not know it. Y is not infringing X's patent A_1 but Y will probably assess it as very attractive technology that should be included in Y's product if Y could somehow succeed in licensing it in.

66 *Id.* at 127-128.

[Table 1]

		Patents	License
X	Core technology	A_1	X does not wish to license out.
	Non-core technology	A_2 = ”aggressive patent”	X can license out with good condition.
Y	Core technology	B_1 = problematic patent	Y does not wish to license out.
	Non-core technology	B_2 = problematic patent	Y can license out with good condition.

Under this circumstance, X sends a warning letter to Y, making the case that Y's product is infringing X's patent A_2 (“aggressive patent”) and X is prepared to license it out to Y in return for concluding cross license agreement in which Y will license out Y's patents B_1 and B_2. Y has no choice but to accept X's offer for cross license in order to continue Y's business. Good thing for X is that X does not have to license out patent A_1 on X's core technology (Table 2).

[Table 2]

	Patents relevant to their activity.	Patents they wish to license in	Actual cross license
X	A_1, A_2, B_1, B_2	B_1, B_2	License in: B_1, B_2 License out: A_2
Y	A_2, B_1, B_2 Y does not use A_1 but wishes to use it if possible.	A_1, A_2	License in: A_2 License out: B_1, B_2

However, if the X's product has already been put on the market, the patent license negotiation could have been totally different. In this case, Y knows X's weak point, that is, X can't continue its business on X's product unless X obtains the license for Y's patents B_1 and B_2. Therefore, Y can strongly insist that X should license out not only patent A_2 but also patent A_1 on X's core technology in cross license agreement. X has no choice but to accept Y's offer in order to continue its business. In this way, the license negotiation with “aggressive patent” before X puts its product on the market is really advantageous for X. Therefore, the FTO team should be

aware of the importance of obtaining as many "aggressive patents" as possible in advance and using them for the license negotiation before the FTO team's pharmaceutical company puts its product on the market.

b) Oppose / invalidate third-party patents

Since granted patents survived the review by examiners with regard to patentability, they are basically valid. But patents can be challenged even after they are issued. A successful challenge will invalidate a patent claim, and sometimes the entire patent.[67] One drawback of these procedures is the cost. But if a pharmaceutical company ignores the patent in question and continues to sell its product, it is likely to end up with patent infringement law suit that cost is much more expensive than the one for opposition or invalidation procedures. Another drawback is that this procedure might trigger and accelerate patent holder's actions for finding a possible infringer and filing a law suit.

c) Seek compulsory license

Article 31 of TRIPS (the Agreement on Trade-Related Aspects of Intellectual Property Rights) provides the issuing of compulsory licenses to national producers in national emergencies. This provision has been adopted by most countries, and is mainly aimed to the pharmaceutical industry. Although the applicable case is very limited, it is worthwhile examining this compulsory license.

67 Anatole Krattiger, *Freedom to Operate, Public Sector Research, and Product-Development Partnerships: Strategues and Risk-Management Options*, ipHandbook of Best Practices 1323 (last visited September 6, 2016), http://www.iphandbook.org/handbook/ch14/p01/

2. R&D strategies

a) Modify product

An alternative to patent license is to change the product specifications. This is possible only if (1) the FTO analysis is performed at the early stage of the development and (2) there is an alternative technology for modification in the public domain that would work at least as well as the prior product. Otherwise this strategy is not a good idea because many years' of works and a lot of investment would be lost, and a license negotiation might be a better solution.[68]

b) Invent around

Invent around is the option in which the pharmaceutical company seeks alternative ways to develop the product. This would delay product development, but could lead to significant benefits in terms of new patents for cross license, and perhaps even better products.[69] As described above, "aggressive patents" can work as a strong weapon for advantageous cross license. The drawback would be very high costs.

3. Business Strategies

a) Wait-and-see

With regard to business strategies, the simplest option for the pharmaceutical company is to commercialize the product in question and wait to see if the patent holder contacts you for a license.[70] It would be still possible to come to a licensing agreement. However, the pharmaceutical company should understand that it is very dangerous option because the company would be sued as a patent infringement once the patent holder refuses the licensing-out, causing the pharmaceutical company to give up its business. What's worse is, in US, if it can be proven that the infringer willfully in-

68 *Id.* at 1324-1325.
69 *Id.* at 1325.
70 *Id.* at 1325.

fringed the particular patent of the third party, then a court may assess damages three times higher than the patent holder's actual lost revenue.[71] For the pharmaceutical company that has to minimize the risk of business failure, this option is not recommended at all.

b) Merge and/or acquire (M&A)

Instead of the option for licensing-in, the pharmaceutical company can acquire, through mergers and acquisitions, the company that owns relevant patent in order to enable the pharmaceutical company to operate patented invention.[72] Contrary to the licensing option which is to "borrow" the technology, this option is substantially to "buy" the technology. But there are some downsides of M&A. First, in the M&A procedure, both a buyer and a seller usually require the resolution of general meeting of stockholders regarding this M&A transaction. This is not easy as you may imagine. Second, buying a company means accepting the all legal liability that a seller might have in the future. Proper due diligence is indispensable prior to M&A.

71 *Id.* at 1325.
72 *Id.* at 1325.