Chapter 1

Introductory Chapter: Intellectual Property Rights

Sakthivel Lakshmana Prabu,
Timmadonu Narasimman Kuppusami Suriyaprakash and
Rathinasabapathy Thirumurugan

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1. Introduction

Intellectual Property Rights are rights given to any particular person/organization for their new creations based on their minds for a certain period of time with an exclusive right over the use of their creation [1].

1.1. International Intellectual Property Regime

In the nineteenth century, foundation for the International Intellectual Property Protection was created at various assemblies held in Vienna and Europe. In Paris Convention in the year 1883, Industrial Property Protection was created. Under the Industrial Property Protection, patents, trademarks and industrial designs are protected. Various countries became members of Paris Convention, subsequently special unions and arrangements were created which made the beginning of protection of international trademarks as well-known marks internationally. Special unions and arrangements are created for the countries who are the members of Paris Convention. Madrid agreement is an agreement represented in Paris Convention with vital principles for the regulation of the trademarks. In Berne Convention in the year 1886, International Copyright Act was passed. Under International Copyright Act, literary and artistic works are protected.

In United Nations (UN) Conference, General Agreement on Tariffs and Trade (GATT) was conveyed on Trade and Employment. Due to failure, Governments created the International Trade Organization (ITO). GATT was formed in the year 1949 and lasted until 1993; subsequently, it was replaced by the World Trade Organization in the year 1995 [2].

World Intellectual Property Organization (WIPO) was started in the year 1960 based on the rules and regulations of Paris Convention and Berne Convention. Later, World Intellectual

Property Organization (WIPO) was established in the year 1967 based on these conventions. World Trade Organization (WTO) was made in the year 1977. This organization becomes an important international organization for development and understanding of Intellectual Property Rights (IPR) [1].

The great discrepancy between the developed and developing countries related to international market and multinational corporations, United Nations Conference on Trade and Development, was made. Later, in the year 1964, United Nations Conference on Trade and Development was established to make available an opportunity to discuss their problems related to economic development in the developing countries. Trading, investment and developing the opportunities are the main aim of this organization in the developing countries and also support for their efforts towards the world economy as an equitable basis [3].

In the year 1960, world trade was initiated to expand dramatically. This dramatic expansion made the realization by various national governments to set rules/regulations and standards to harmonize the national and regional regulations. In the year 1966, United Nations General Assembly established the United Nations Commission on International Trade Law (UNCITRAL). The main aim of the law is to promote the liberal harmonization and association of international trade law [4].

Generally, in various industries, IPR is made a part of their intentional preferences in the regular activities. Various corporations, in order to ensure their sustained growth, enhanced profits and leadership in the market they intended their project management system based on:

- Optimized use of inter/intra knowledge base
- Strategic management of IPR
- External channels for knowledge and inventions as inputs
- Internal expertise to manage research and collaborations
- Clarity on knowledge ownership issues through mutually beneficial licenses
- Pooling of IPR as in the case of several companies who have formed patent pools of their DVD patents for mutual benefits [5]

1.2. New dimensions and issues for resolution

Recent exploration in the technology towards new dimension and path, IPR system helps to ensure and encourage new innovation and sharing the acquired knowledge during the innovation globally. Various IPR issues are:

- Domain names and trademarks: Copyright in cyberspace
- Rights on traditional knowledge, prior art, material transfer agreement and bio-prospecting
- Software and patents
- Biotechnological inventions and moral issues and patents

- Compulsory licensing options, border measures and parallel imports and exhaustion of IPR
- Government control on export of technology [6]

1.3. IPR in developing countries

IPR in developing countries is based on the potential significance and its intensity of the technological activity. Most of the developing countries followed TRIPS agreement for agricultural and cloth markets considering they can get the additional access in rich nation related to various technology transfers and innovations. The growth effects of IPR in different parts of the world in different time durations vary significantly, which affect the poor countries in the long term.

1.4. Impact of stronger IPR in developing countries

When granting the monopoly rights for an innovation, organization can gain the following paybacks, they are:

- The primary social benefits of IPR are the motivation for inventions
- The enhancement of productive activity is based on the use of new knowledge
- The enhanced dissemination of acquired knowledge to other agents
- The motivation for innovations by other enterprises [7–10]

1.4.1. Category of intellectual property

Based on the TRIPIS agreement, intellectual property is categorized into the following areas. They are:

- Patents
- Copyrights and related rights
- Trademarks
- Geographical indications
- Industrial designs
- Layout designs of integrated circuits
- Protection of undisclosed information (Trade Secrets)
- Plant varieties

Intellectual Property Rights are allocated into two main areas:

1. Copyright and rights-related copyright
2. Industrial property

1.4.1.1. Copyright and rights-related copyright

Copyright and rights-related copyrights are the rights of authors for their artistic and literary work, which include books and other writings, musical compositions, paintings, sculpture, computer programs and films protected for a period of 50 years after the death of the author under this copyright.

Rights related to copyright is referred as neighbouring rights, which includes the rights of performers such as actors, musicians, singers, phonograms and broadcasting. Copyright and rights-related copyright can encourage and reward for their creative work.

1.4.1.2. Industrial property

Industrial property is categorized into two main areas:

1. Protection of distinctive signs

The main aim of the protection of distinctive signs is to ensure the fair completion and protect consumers for various goods and services by making knowledgeable adoptions of its distinctive signs.

Protection of distinctive signs includes:

(i) Trademarks—distinguish the goods or services from other goods or services

(ii) Geographical indications—It is an identity for a goods or product having an essential characteristic attributable one originating from a geographical place of origin

2. Motivate innovation, design and the creation of new technology

The main aim of this category is to protect their investment related to development of new techniques; its results subsequently provide incentives by means of finance research and activities related to development. The duration of the protection period is given for a fixed term; during the term, the inventor can facilitate the foreign investment directly in the form of technology, licensing and joint venture for the new innovation or creation or new technology development. Patents, industrial designs and trade secrets are protected under this category.

1.5. Categories of intellectual property

1.5.1. Patents

Patents are rights under Intellectual Property Rights related to an invention for which patent has been given by the Government/statute to the patentee in exchange of full disclosure of their invention either an individual or a company/organization. Patent has been given as exclusive right for a limited period to exclude others, from making, using, selling and importing the patented product or process producing that product. The patent rights are enjoyable without any insight to the invention place, field of technology and the products either imported or produced locally.

The main aim in IPR system other than encouraging the inventions is the application and promotion so as to develop the industries, subsequently that contributes to technological innovation, distribution and transfer of technology.

1.5.2. Copyright

Copyrights are rights under Intellectual Property Rights related to computer programs protected under Berne Convention, which outline the literary works and databases protected for a period of not less than 50 years. This copyright covers rental rights and expands internationally. In public, the authors have the right to prohibit the commercial rental of their copyright works like computer programme and sound recording procedures. Films also have this copyright as an exclusive right, where commercial rental has managed to be widespread. Under this copyright protection, reproduction of recording and broadcast of live performance are protected for performers.

1.5.3. Trademark

Trademarks are rights under Intellectual Property Rights related to sign or any combination of sign for any goods or services to make a distinguishing mark. Any distinguishing mark can be made registration and the registered trade mark get protection for 10 years and it can be renewed every 10 years indefinitely. Under this trademark, compulsory license provision is not permitted.

1.5.4. Geographical indications

Geographical indications are rights in the aspect of industrial property under Intellectual Property Rights related to geographical indication situated being the country or place or the origin of that product. The geographical indication products are originated from a specific geographical location, which has definite qualities and reputation for its quality due to its place of origin. Under this category, place name generally indicates where the product has been made as product identification. Consumers can be misled and make unfair completion by using the place name for the product, which has been made elsewhere or does not meet the specific quality or character for those particular products.

1.5.5. Industrial design

Industrial designs are rights under Intellectual Property Rights related to any ornamental or aesthetic which have any three-dimensional features such as the shape or surface of the article or any two-dimensional features such as patterns, lines or colour.

Industrial design are rights that can be applied to a wide variety of products made from industry or handicraft which include watches, jewellery, fashion, other luxury items, house ware, furniture, electrical appliances, architectural structures, practical goods, textile designs to leisure items, such as toys and pet accessories.

1.5.6. Layout designs of integrated circuits

Layout designs of integrated circuits are rights under Intellectual Property Rights related to interconnections of an integrated circuit or three-dimensional disposition prepared for an integrated circuit intended for manufacture. Under this layout designs of integrated circuits right of reproduction, right of importation, sale and other distribution for commercial purposes are prevented.

1.5.7. Protection of undisclosed information

Protection of undisclosed information is rights under Intellectual Property Right related to protection of information that is applied as trade secret, which has commercial value. The protection of undisclosed information cannot be considered or treated as a form of intellectual property. Protection of undisclosed information requires, that the information must have prevention to disclose, learnt or using the same by others without his or her permission/consent for commercial purpose.

1.5.8. Plant varieties

Plant varieties are rights under Intellectual Property Rights related to the protection of new plant varieties. Plant variety protection is given to the breeders as an exclusive right for a limited period to the breeders to acknowledge the achievements of new plant varieties with the satisfaction of specific criteria. New plant variety is defined as a plant grouping within a single botanical taxon of the lowest known rank provided that the plant/herb should be new or novel, distinct, uniform, stable and have a satisfactory denomination [11–15].

1.6. Patents

Patents are rights under Intellectual Property Rights related to an invention for which patent has been given by the Government/statute to the patentee in exchange of full disclosure of their invention either an individual or a company/organization. Patent has been given as exclusive right for a limited period to exclude others from making, using, selling and importing the patented product or process producing that product. The patent rights are enjoyable without any insight to the invention place, field of technology and the products either imported or produced locally. Compulsory licensing is a condition made fairly liberal based on the concept of 'license of right' for patents related to drugs, pharmaceuticals and foods [12–20].

1.6.1. Categories of patents

Patents are categorized into following types:

1. Ordinary patents
2. Patents of addition

3. Convention applications with priority date, claiming on the basis of filing in convention countries
4. National phase applications under PCT

1.7. Patentable invention

An invention means 'a new product or process which involves an inventive step and able to be used in the industry' can be patentable under the Patent Act. In short, patentable invention should have technical nature and meet the basic common features:

1. Novelty
2. Utility
3. Inventive step/non-obviousness [12, 13]

1.8. Novelty

Under this basic feature, the patentable invention must be new by the original inventor at the time of invention, and it should not be known to the public or public domain or any part of the existing state of the art. Novelty of an invention is justified based on the comparison between his/her embodiment and the materials available in the public domain.

1.9. Utility

The next basic feature of the patentable invention is utility. Under utility, the invention must be capable of having an industrial application to provide positive benefit to society. The industrial application under utility, need not to have any superior to existing products or processes, but it must secure the intended result even small degree of utility is sufficient.

1.10. Inventive step/non-obviousness

The next basic feature of the patentable invention is inventive step/non-obviousness.

An invention can be patented until it satisfies the non-obviousness criteria, even an invention has novelty and utility. The non-obvious clause is applicable to those who are skilled in that art [12, 13].

1.11. Not-patentable inventions

The following are non-patentable inventions within the meaning of the Patent Act:

- Any invention that is against the established natural law
- Any invention that leads to commercial exploitation or harms any life, whether animal, plant or human, or the environment
- Any discovery that already exists or scientific principle

- The mere discovery of any new use for a known substance or any unexpected property or just use of a known process, machine or apparatus unless such known process leads to a new product or employs at least one new reactant
- Any product obtained in just mixing any two substances
- A method of agriculture or horticulture
- Treatment to patients for medicinal, surgical, curative, prophylactic purpose to render them free of disease
- Plants, animals in whole or any part thereof other than microorganisms
- A mathematical or business method or a computer programme per se or algorithms
- A literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions
- A divulging of information
- Topography of integrated circuits
- An invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components
- Atomic energy and prejudicial to the defence of India [12, 15]

1.12. Inventions and discoveries

The terms inventions and discoveries are two different applications. The term invention is new and useful solution, which is invented through practical analysis for some technical problems; whereas the term discovery is not the result of creation.

1.13. Patent application

To get patent protection for an invention, the inventor has to provide the specification in the patent application.

1. A patent application can be made by any of the following persons.

(a) Any person claiming to be the true and first inventor of the invention

(b) Any person being the assignee of the person claiming to be the true and first inventor in respect of the right to make such an application

(c) The legal representative of any deceased person who immediately before his death can be entitled to make such an application

2. An application under subsection can be made by any of the persons referred to therein either alone or jointly with any other person [12, 15, 21].

1.14. Form of application

1. Every patent application is made in the prescribed form for only one invention and filed in the patent office.
2. Applying for the patentable invention, the applicant should furnish the details within specified period and submit the proof of the right to make the application is valuable.
3. Application should state that the applicant's name will be claiming to be the true and first inventor; if the person is not the applicant or one of the applicant of the claiming, a declaration might be obtained from the applicant stating that the applicant believes the person so named to be the true and first inventor.
4. Each application should be accompanied by a provisional or a complete specification [12, 15, 21].

1.15. Types of patent specification

The specification of the patent application should meet the three fundamental principles:

1. Written description
2. Enablement
3. Best mode

1.15.1. Provisional specification

Provisional application describes the nature of the invention or the process involved in the invention. Provisional application provides a fair indication of the art or the subject to which the invention relates if required with drawing and not necessary to include any claim of the inventions.

1.15.2. Complete specification

The complete specification is an important document subsequently filed after the provisional specification in the patent application procedure. The complete specification should be written in detail with clarity if any drawing is required and disclosing the claim/claims in a best mode to protect their invention. The complete specification should be written in detail such a way that any person in the relevant field with the ordinary skill can be understand the invention and its invention pertains [12, 13].

1.15.3. Components of specification

Components of the provisional and complete specifications are different. The components of the specification are given in **Table 1** [12, 15, 21].

Provisional specification	Complete specification
1. To get the priority date at the earliest and need not contain any claims.	1. This establishes the date of patent, if sealed.
2. When the invention is at the intangible stage, a lot of fine tuning has to be done in the subsequent application.	2. When the invention is ready to utilize in the market or invention information is known.
3. The nature of invention is disclosed at the core of it.	3. The invention is disclosed in best manner, that is, if the invention has been given to a person skilled in the art can be able to perform without further clarification of the invention
4. It need not have detail related to the invention.	4. It needs to have detail related to the invention.
5. The format in the provisional specification: **a.** Area of invention **b.** Status of PRIOR ART, that is, what is already known to the industry **c.** Problems with the prior art **d.** How this invention solves the problems **e.** Description of the drawing (optional, if required)	5. Format as in provisional, but it also includes: **a.** Statement of invention **b.** Claims **c.** Drawings

Table 1. Components of provisional and complete specification.

1.16. Contents of specification

1. Specifications, either provisional or complete, should sufficiently indicate the subject matter of the invention-related information in title.
2. If any subject matter in the form of drawing is made under the Patent Act, it should be submitted along with specification either provisional or complete wherever necessary.
3. In any circumstance, if any model or sample exemplify the invention, it should be submitted in the part of the specification.
4. If, in any particular case, the controller considers that an application should be further supplemented by a model or sample of anything illustrating the invention or alleged to constitute an invention, such model or sample as he may require shall be furnished, but such model or sample shall not be deemed to form part of the specification.

Each complete specification must contain:

- Depict the invention, operation and its procedure in full detail
- Express the performance of the invention and the claim protection in the best method
- Explaining the scope of the invention for which the protection is claimed
- Provide the technical information about the invention in the abstract

5. In complete specification, the claim or claims should be clear and concise to relate a single invention or a group of inventions linked so as to form a single inventive concept.

6. Inventorship of the invention should be furnished in the prescribed form along with the complete specification.
7. Complete specification can include in the claims any developments or additions to the invention which were not mentioned in the provisional specification [12, 21].

1.17. Procedure for obtaining patents

1.17.1. Publication and examination of patent applications

1.17.1.1. Publication

Publication of the patent applications is the first process in the procedure for obtaining patents. The publication of the patents includes date of application number, name and address of the applicant along with the abstract. Patent application will not be opened for public inspection before publication. After the date of publication of the patent application, the applicant must give a written request in the prescribed format to the concerned authority to inspect the complete specification along with provisional and drawing (if any) and abstract.

1.17.1.2. Request for examination

Patent application will not be examined until the request is made by the applicant in the prescribed format along with the prescribed fee within a specific time duration. If any applicant has not requested against the patent application within the prescribed time period, the abovementioned application will be treated as withdrawn and hereinafter the application cannot be revived.

1.17.1.3. Examination

When a request is made by the applicant within the prescribed time, the application will be examined strictly based on the serial number of the request received in the prescribed format. After examination of the patent application, the objections/requirements are communicated to the applicant as First Examination Report (FER). Based on the objections/requirements of the patent application, applicant shall submit the reply within the specified period of time. No further extension will be given if the application for amendment is not received within a period of specified time. If any application meets the acceptance criteria, it will be notified to the concerned authority.

1.17.1.4. Search for anticipation by previous publication and by prior claim

When a patent application is examined by an examiner (whom the patent application is referred to), he/she will be responsible to investigate whether the invention, as far as claimed in any claim of the complete specification, has been anticipated by any publication before the date of filling of the complete specification by the applicant.

1.17.1.5. Opposition proceedings to grant of patents

1. During publication of the patent application but before granting of patent, any interested person can oppose in writing against the grant of patent to the concerned authority.
2. At any time of patent grant, but before the expiry of a period, any interested person can represent and give notice of opposition against the grant of patent to the concerned authority in the prescribed format.
3. If any notice of opposition is received by the concerned authority, they will notify the same to the patentee. The concerned authority will constitute a board namely Opposition Board having such officers. The notice of opposition along with the documents will be submitted to the Board for examination. Once examination is complete, the opposition board submits their comments (recommendation) to the concerned authority for further process.
4. On receipt of the recommendation from Opposition Board and from patentee, an opportunity will be given to the opponent to propose his/her opposition being heard. Based on the results, the concerned authority shall order either to maintain or to revise or to cancel the patent.

1.17.1.6. Grant of patents

1. When the patent application is found to be in order, patent will be granted.
2. The concerned authority of patents shall publish the fact that the patent has been granted and thereupon the application, specification and other documents related thereto shall be open for public inspection on the grant of patent.

1.17.1.7. Grant of patents to be subjected to certain conditions

The grants of patent to be subjected in certain conditions under the Patent Act are:

1. Any article, machine or apparatus in respect of which the patent is granted may be imported or made by on behalf of the Government for the purpose merely of its own use.
2. For Government use in respect of which the patent is granted.
3. Any article, machine or apparatus in respect of which the patent is granted may be used by any person, for academic/education purpose.
4. Import of drugs by Government for hospital purpose or for distribution in any dispensary.

1.17.2. Rights of patentee

1. When a patent is granted for a product, an exclusive right to prevent third parties for making, using, offering for sale, selling or importing for those purpose that product.
2. When a patent is granted for a process, an exclusive right to prevent third parties for using, offering for sale, selling or importing for those purposes the product obtained directly by that process.

1.17.3. Register of patents

Particular of the patent will be entered in the register of patent; it includes the names, addresses of grantees of patents, notifications of assignments, transmissions of patents, licenses under patents, amendments, extension and revocations of patents.

1.17.4. Renewal fee

In order to keep the patent in force, every year renewal fee is needed to be paid. Within the specific time period, if the patent has not been issued, the renewal fees will be accumulated and paid immediately after the patent is sealed or within specific time period of its record in register of patents. The patent will end and have no effect if the renewal is not paid within the prescribed time.

1.17.5. Restoration

An application is to be filed to the appropriate office according to the jurisdiction within the specific time period for restoration of a patent that lapses due to non-payment of renewal fees [12, 15, 21, 22].

1.17.6. Drafting of patent specification in patent application

The principles of construction of details summarized as follows[6]:

The general rules of construction of details in the patent specification are:

- The complete specification must have all the related details towards the invention without favour to subsequent infringement or conduct of the patentee. In some cases, the priority date is preferred.
- The claimed part is mostly legal with what is not claimed is disclaimed. After patented, it is not permissible to change any references mentioned in the claim.
- The specification should be constructed, that is, it should not be obvious to the person skilled in the art of the invention. The specification should not construe the claims by reference to the subjective thoughts, intentions, purposes and opinions of the patentee.
- The specification content should not be a literal one, and it should be a purposive construction.
- Documents subsequent to the complete specification are prohibited.
- The claim in patent must be constructed keeping in mind the infringement and invalidation purpose also.

1.17.7. Parts of the complete specification

Each specification should have the following parts.

- Title of the invention
- Opening description of the invention

- Prior art description
- Objects of the invention
- Statement of invention (optional)
- Detailed description of the invention
- Claims

1.17.7.1. Title

In drafting the complete specification, the first step is to define the scope of the invention or forming a mental picture of what is to be claimed. Converting the mental picture into suitable words is the second step. While framing the title, attention has been taken to incorporate the entire scenario about the invention.

1.17.7.2. Opening description of the invention

The opening description of the complete specification provides more details about the invention. Some of the applicant may prefer to draft the full set of claims first; in general, the main claim will be derived from the title of the invention, then the rest of the specification will be drafted followed by claims of the invention. Procedure for the invention to be carried out can be described in the opening description of the specification.

1.17.7.3. Prior art references

Relevant prior art references of the invention are provided subsequent to the opening description. The prior art references provide the disclosed or known details of their invention. To increase the credibility of the invention; discuss the prior art reference/invention, its drawbacks individually and mention the advantages of invention related to the prior art invention.

1.17.7.4. Objects of the invention

The objects of the invention should be briefly stated. In general, the main object or essential object is mentioned in the invention, followed by additional objects of the invention either separately or subsequent to the essential object.

1.17.7.5. Statement of invention

If the application contains one or more collective claims, the applicant should provide supporting statement of the invention. The applicant is not incorporating any collective claims; then the applicant need not provide any statements of the invention.

1.17.7.6. Detailed description of the invention

In this section, the applicant should describe in detail about the information related to invention. The applicant should keep it in mind that the specification of the invention is not

addressed to any general public or a layman but to a skilled person in the art. The patent will be invalid, if the description of the invention in the specification is not sufficient to allow a person having average skill in, and average knowledge of, the art to which the invention relates, to work the invention.

Description of the invention is assessed based on the two criteria:

1. A detailed specification must describe the embodiment of the invention specified in each and every claim.
2. Description of the invention must be fair.

The written description requirement is essentially a requirement that each claim should be fairly based on the disclosure.

1.17.7.6.1. How to make the specification

The specification detail of the invention must facilitate the skilled person in the art to read, understand and to make the invention which is claimed in the specification.

1.17.7.6.2. How to use

The invention should have the utility and meet the scope of the invention claimed. In some field, there is no need to disclose specifically about the utility of a claimed product. If the invention claims other than pharmaceutical, there is no need to provide prior art compounds' comparative data.

1.17.7.6.3. Best mode

The applicant should disclose the invention in best possible method in the specification. In short, three expressions are needed to be kept in mind by the applicant during the preparation of patent specification in the patent office. The three expressions are:

1. Sufficiently and fairly describe the invention
2. Sufficiently and clearly describe the invention
3. Fully and particularly describe the invention

The procedure for carrying out the invention is best known by the inventor, it should be given in each description of the invention in the patent specification.

If any illustration or drawing directed to machines, articles of manufacture and certain processes are part of the invention, it should be included in the application. Dimensions or spatial relationships are needed to be included in the invention. Addition of tables, graphs and charts are advisable for disclosing the patent invention in the application. If any tables, graphs, charts, figures and drawing are included in the application, it should be arranged serially. If any description is included in the specification, it should support each and every claim of the invention.

If the invention is related to mechanical device/apparatus, its connections or interconnections between the parts of the mechanical device and its function, the invention details need to be described clearly in the specification.

If the invention related to chemical process, the process details like starting materials, key process steps, its parameters, and the description of the end product details are need to be described clearly in the specification.

1.17.7.7. Claims

The patent invention for which the patentee expect the exclusive right are should be clearly described in the claim or claims of the complete specification.

1.17.7.7.1. General philosophies in the interpretation of claims

- Claims are always a question of law and it should be mentioned unambiguously.
- Whatever unclaimed in an invention may be interpreted as a matter of law not owned by the inventor!
- Extrinsic evidence by means of expert testimony may be adduced, if the meaning of a term of art in the claims is disputed, but the decision in a question of law is to be made by the court.
- Factors, if any, in the claims should be considered.

1.17.7.7.2. Function of claims

The patent invention should be clearly defined in the claim. The main purpose of the claim is to define the scope of the subject matter that is to be protected under the patent. The claim of the patent should be drafted in such way that any competitor does not infringe the patent and the claim should be interpreted literally. The patent claims are not interpreted alone, instead it should be written in clear and concise manner in the description of the specification itself. Thus, the description of the specification not only provides the basis of the claim but also the claims are restricted with respect to the prior art.

1.17.7.7.3. Categories of claim

In patent, the claims are broadly classified in two categories:

1. Product patent which includes any mechanical device, a machine, an electronic circuit, any chemical compound and chemical formulation.
2. Process patent which includes any method of making, using or testing procedures.

The patent invention related to chemical product, the claims can include chemical substance itself may be useful or itself may be used as intermediates for the production of other substances/compounds. If the invention related to chemical process, the claims can include

process of synthesis, isolation, purification and extraction of chemical substances, testing and assay methods, subsequently its medicinal use. In general, different types of claims can be included in the specification of the patent application, but it should provide the useful protection for the main claim.

1.17.7.7.4. Independent and dependent claims

Independent and dependent claims are two types of claims. Either independent/dependent claim or both can be included in the specification of the patent application. Claim can be included as independent claim in the specification; it is just a form of shorthand to avoid writing out an entire definition many times over. If the claim can be included as true dependent claim in the specification, all the limitations need to be considered.

1.17.7.7.5. Number of claims

Number of claims depends upon the invention. Normally in the patent specification, the main claim corresponds to the patent invention. If any specification of the patent application contains large number of claims, it will be discouraged in several patent offices. Additional fees are to be paid for the claims in excess of a particular number.

1.17.7.7.6. Form of claims

The meaning of claims in the specification must be definite, precise, clear and understandable by any skilled reader. Wording such as 'preferably' or 'for example' should not be included in part of the claims. In describing the claims, avoid internal codes or names, or trademarks without a generic description. Consistent language and vocabulary are to be used throughout the specification and in the description of claims. General abbreviation terms can be used in the specification of the patent application. If the invention utilizes different components, precautions need to be taken while describing the claims and specifying the essential components related to the invention.

1.17.7.7.7. The scope of the claims

Every patent practitioner has responsibility to protect his/her client and to provide best possible protection for their inventions. In general, claims of the invention should be too broad rather than too narrow. Taking into consideration the known prior art references, technical feasibility and its limitations, the claims of the invention should be broadly written in the specification. Therefore, statements of claims are the serious active part of the specification of any patent application, and it should be expressed in legal term about the invention that is to be protected.

The statements of the claims are not necessary to be limited to a claim. Based on the common idea, more than one can be included in the specification of the patent application. The specification may contain any number of claims, but the entire claim must focus towards only one invention that is to be protected. In an invention claiming various features independent of one another, applicant may file different patent application for each feature separately.

1.18. Length of text

Length of the patent specification should be kept as short as possible with sufficient disclosed information about the invention that is to be protected. The reason to keep the specification text content as short as possible is the cost to be paid towards the length of the text of the specification content. In general, if the specification is written very clearly in concise aspects, it is likely to give an enforceable patent to the invention [12, 15, 21–28].

2. Conclusion

To achieve economic, social and technological advancement, IPR is the only key element to protect the ideas, stimulate the innovation, design and help the creation of technology. Various types are IPR are designed to provide benefit in the aspects of sharing the developed knowledge as a new invention leads to give a wealth creation. This IPR can facilitate the transfer the invention as technology transfer in the form of licensing through any joint ventures. The main purpose of IPR is to give protection for their investment as incentives and also to encourage further developments in their research. Among the various IPR system, patent are rights related to an invention given by the Government/statute in exchange of full disclosure of their invention by the patentee. Invention for which the patentee expect exclusive right, it should be clearly described in the patent application as specification. Specification is a statement constructed based on the knowledge acquired during the invention and the prior art information with the drawbacks, it should clearly define the invention as claim or claims in best possible method by applicant to get exclusive rights. The claims in the specification must be expressed legally; the invention as definite, precise, clear and understandable by any skilled reader and any competitor does not infringe the invention. The main purpose of the claim is to protect the subject matter that is to be protected under the patent. Number of claims depends upon the invention, and the length of the specification should be kept as short as possible to reduce the processing charge of the patent application.

Author details

Sakthivel Lakshmana Prabu[1]*, Timmadonu Narasimman Kuppusami Suriyaprakash[2] and Rathinasabapathy Thirumurugan[3]

*Address all correspondence to: slaxmanvel@gmail.com

1 Department of Pharmaceutical Technology, Bharathidasan Institute of Technology, Anna University, Tiruchirappalli, India

2 Department of Pharmaceutics, Al Shifa College of Pharmacy, Perinthalmanna, Kerala, India

3 College of Agriculture and Life Sciences, Kannapolis, NC, USA

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Chapter 2

Patenting in the Pharmaceutical Industry

Risa Kumazawa

Additional information is available at the end of the chapter

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Abstract

The chapter investigates the returns to R&D expenditures on patenting in the pharmaceutical industry, using a panel data of 32 countries. Due to the unique situation in the industry that come from the patent being the new drug and additional clinical trials which must be conducted for safety and efficacy, the pharmaceutical industry is analyzed alone. The results indicated that for pharmaceutical patent applications with the United States Patent and Trademark Office (USPTO), the European Patent Office (EPO) and the triadic family consisting of USPTO, EPO and the Japan Patent Office (JPO), pharmaceutical R&D expenditures had no impact coming from European countries. However, for the six non-European countries in the dataset (Australia, South Korea, Mexico, Romania, Singapore and Taiwan), the R&D always had statistically significant effects on all three patent applications in the industry. The results were more pronounced when the United States and Japan were also included. While China, Brazil and India were excluded due to missing pharmaceutical R&D data, it is hypothesized that the effect of these countries would have made the results stronger.

Keywords: pharmaceutical patents, pharmaceutical R&D, innovation

1. Introduction

Innovation has played a crucial role in channeling the economic growth of countries. Economists have long established a positive link between research and development (R&D) expenditures and innovation, as measured by patenting activity [1]. This has been done at the micro level, across firms [2] and at the macro level, across developed and developing countries with different levels of patent protection and legal systems [3–6] and domestic and foreign flows due to foreign direct investment and the presence of foreign affiliates [7–10]. One of the shortcomings of macro studies is that all industries were lumped together despite the heterogeneous nature of patenting and R&D expenditures across industries. With industry-specific

data available across countries over time, it is possible to study just one industry—namely the pharmaceutical industry which has been considered to be the most successful in attracting private R&D for innovation [11, 12].

A patent gives "exclusive right for a product or process that provides a new way of doing something, or that offers a new technical solution to a problem" [13]. However, patenting in the pharmaceutical industry is quite unlike other industries because the patent is the product itself (a new drug) which is the result of costly R&D and extensive clinical testing [14].[1] For such expensive endeavors, it is not surprising that this is a market that continues to serve primarily Organization for Economic Co-Operation and Development (OECD) countries, in particular, the United States. In 2015, 48.7% of the world pharmaceutical sales occurred in the US market, whereas 22.2% and 8.1% occurred in European and Japanese markets, respectively [16].

Tables 1 and **2** shows time-averaged pharmaceutical patent applications from OECD and non-OECD countries, using OECD's Patent Database. The columns represent the filing office (United States Patent and Trademark Office (USPTO), European Patent Office (EPO) and the triadic families, which include one or more shared applications with Japan Patent Office (JPO), USPTO and EPO. The numbers highlight the vast differences across OECD and non-OECD countries. For almost every country, USPTO filings outnumber the other two filing types. The United States is the unambiguous leader in pharmaceutical patenting, followed by Japan and Germany.

Despite the smaller numbers for non-OECD countries, **Figure 1a–c** show the relative importance of pharmaceutical patents over time. Each data point represents the average ratio of pharmaceutical patents to total patents in each year across OECD countries and non-OECD countries. They range from 5 to 25%, for USPTO, EPO and triadic families. While the ratio is always higher for OECD countries for triadic family patent applications, the ratios for both EPO and USPTO applications are higher for non-OECD countries from the mid-2000s, indicating the growing relative importance of pharmaceutical patents of non-OECD countries.

For ensuring efficacy of the drugs and safety of consumers, government regulations make expensive clinical trials necessary in this industry as the drugs cannot be marketed without approval. In the United States, the Food and Drug Administration (FDA) enforces these regulations. Clinical trials effectively shorten the lives of the patents by several years. To demonstrate efficacy, the clinical trial durations must match the expected survival duration of patients [22]. Patents, on average, delay competition from the entry of generic drugs for approximately 10–14 years in the United States [11]. However, the drug can easily be replicated after patent expiration when generic drugs can be manufactured cheaply without additional investments in R&D or costs associated with clinical trials [11, 14]. This floods the market with competitors. For this reason, proponents of pharmaceutical patents argue that exclusivity through patent protection is crucial to recovering the enormous costs and making profits from the invention of new drugs.

[1]In fact, it was estimated that the out-of-pocket cost per drug was $1395 million, and the capitalized R&D cost per drug was $2558 million in 2013 dollars [15].

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Country	Triadic patents (1999–2012)	EPO patents (1999–2012)	USPTO patents (1999–2011)
Australia	76.91	126.80	192.17
Austria	43.60	78.03	83.03
Belgium	70.83	125.16	152.43
Canada	136.72	252.83	491.59
Chile	2.01	4.74	6.91
Czech Republic	5.47	13.18	12.28
Denmark	91.36	149.50	197.55
Estonia	0.93	1.75	2.42
Finland	21.63	33.19	43.94
France	339.76	500.52	568.82
Germany	605.73	970.46	1,029.34
Greece	2.46	9.79	9.70
Hungary	16.83	26.62	30.21
Iceland	1.92	3.72	5.82
Ireland	12.79	24.48	35.99
Israel	78.51	159.62	289.96
Italy	152.38	277.99	299.40
Japan	621.13	834.87	1,122.74
South Korea	114.59	126.58	242.93
Latvia	2.52	4.80	3.90
Luxembourg	0.72	1.56	2.23
Mexico	3.91	11.28	14.86
Netherlands	79.93	170.33	180.64
New Zealand	13.77	24.09	38.17
Norway	22.06	34.77	44.12
Poland	4.62	12.94	11.21
Portugal	5.71	9.98	10.06
Slovak Republic	1.21	2.34	2.66
Slovenia	4.80	26.63	13.09
Spain	73.59	149.65	134.34
Sweden	104.21	146.58	201.76
Switzerland	171.32	257.35	284.90
Turkey	1.55	22.84	6.55
United Kingdom	409.74	577.86	749.34
United States	2,581.06	3,925.56	9,435.44
OECD total	5,876.29	9098.39	15,950.48
World total	6,119.63	9,570.56	16,740.65

Table 1. Average pharmaceutical patent applications in OECD countries by filing office.

Country	Triadic patents (1999–2012)	EPO patents (1999–2012)	USPTO patents (1999–2011)[2]
Algeria	0.04	0.20	0.14
Andorra	0.01	0.08	0.01
Argentina	2.89	8.55	15.57
Armenia	0.02	0.21	0.33
Belarus	0.11	0.38	0.40
Bermuda	0.12	0.11	0.34
Bosnia & Herzegovina	0.02	0.18	0.13
Brazil	7.75	18.73	26.81
Bulgaria	0.22	1.54	1.10
Cayman Islands	0.04	0.11	0.23
China	84.53	122.24	180.99
Colombia	0.68	1.06	2.67
Costa Rica	0.02	0.35	0.21
Croatia	5.31	8.56	9.79
Cuba	5.72	8.41	9.73
Cyprus	0.37	1.01	0.90
Djibouti	0.00	0.00	0.04
Ecuador	0.02	0.53	0.48
Egypt	0.35	1.17	2.47
El Salvador	0.00	0.00	0.08
Georgia	0.44	0.72	0.86
Guatemala	0.05	0.00	0.03
Hong Kong (China)	2.84	11.33	19.03
India	70.55	160.64	241.89
Indonesia	0.43	0.82	0.90
Iran	0.27	0.57	2.12
Jamaica	0.02	0.02	0.69
Jordan	0.51	3.11	1.85
Kazakhstan	0.18	0.37	0.21
Kenya	0.12	0.45	1.14
Democratic People's Republic of Korea	0.02	0.10	0.07
Kuwait	0.02	0.08	1.33
Lebanon	0.16	0.34	0.72
Liechtenstein	2.83	4.27	3.13
Lithuania	0.14	0.75	0.67

Country	Triadic patents (1999–2012)	EPO patents (1999–2012)	USPTO patents (1999–2011)[2]
Former Yugoslav Republic of Macedonia	0.00	0.09	0.00
Malaysia	2.22	4.41	7.81
Malta	0.05	0.05	0.19
Moldova	0.00	0.11	0.26
Monaco	0.40	0.52	0.74
Mongolia	0.00	0.01	0.03
Morocco	0.41	0.96	0.65
Nigeria	0.00	0.00	0.32
Pakistan	0.01	0.09	1.12
Panama	0.08	0.14	0.20
Peru	0.09	0.29	0.64
Philippines	0.24	0.56	1.17
Puerto Rico	0.00	0.60	0.00
Romania	0.40	1.31	1.44
Russia	13.16	34.29	38.34
Saudi Arabia	0.21	2.66	2.56
Seychelles	0.04	0.18	0.23
Singapore	12.09	20.15	35.05
South Africa	4.06	8.68	13.42
Sri Lanka	0.04	0.16	0.50
Taiwan	20.52	33.25	147.05
Thailand	0.82	1.89	3.79
Trinidad & Tobago	0.07	0.07	0.15
Tunisia	0.40	0.85	1.14
Ukraine	0.59	1.85	2.43
United Arab Emirates	0.26	0.61	1.07
Uruguay	0.27	0.86	1.15
Uzbekistan	0.00	0.02	0.05
Venezuela	0.13	0.41	1.55
Zimbabwe	0.00	0.01	0.08
Non-OECD total	**243.35**	**472.08**	**790.16**
World total	**6,119.63**	**9,570.56**	**16,740.65**

Table 2. Average pharmaceutical patent applications in non-OECD countries by filing office.

[2]There was one less year of available data for patent applications to USPTO.

Figure 1. (a) Pharmaceutical patents/total patents to triadic families (USPTO, EPO and JPO). (b) Pharmaceutical patents/total patents to USPTO. (c) Pharmaceutical patents/total patents to EPO.

In this book chapter, I investigate the relationship between R&D expenditures and patents in the pharmaceutical industry alone using panel data estimations. The differences between patent applications to the EPO, USPTO and triadic families (EPO, USPTO and JPO) are compared for groups of countries. This research makes a contribution to the literature that explores R&D

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expenditures with patenting at the macrolevel but separating out the pharmaceutical industry which is quite different from other industries. The chapter continues as follows. After a cross-disciplinary literature review in various areas, I provide the economic model to be estimated. The chapter concludes after a discussion of the empirical results and conclusions.

2. Literature review

Below, a review of the literature is provided in three key areas: (1) the international patenting system; (2) how pharmaceutical patenting and R&D differ from those of other industries; and (3) results from previous studies on innovation relating R&D to patents.

2.1. International patenting system

The Paris Convention of 1883 established the International Union for the Protection of Industrial Property in 1884. This was an important development in international patenting that ensured equal treatment of inventors, regardless of Convention country of origin [10, 12]. Furthermore, the Convention "priority date" entitles the patent applicant the right to claim the filing date of the first application as an effective filing date for corresponding applicants in other Convention countries within a given time frame, which for patents is a year.

The establishment of the European Patent Convention (EPC)[3] in 1977 allowed a single patent application to be filed for European countries, at the newly created European Patent Office (EPO). The approved applications were validated by other member countries which meant that this was essentially a system of filing a "bundle" of national patents. The Patent Cooperation Treaty (PCT) was soon established in 1985. This treaty allowed nationals or residents of 145 contracting signatory countries to file a single international application at their local patent office [10]. A standardized application (one language and one fee) and a single search by an International Search Authority (ISA) reduced costs for filing. In fact, 87% of PCT applications go to one of the patent offices in the United States (USPTO), Europe (EPO) or Japan (JPO) [12].

2.2. Pharmaceutical R&D expenditures and patents

As mentioned earlier, the pharmaceutical industry has been and still is an industry that largely serves developed countries. The disproportionate location of R&D activity has been noted in the literature. In 2002, an overwhelming 82% of the world's R&D expenditures by global pharmaceutical companies occurred in the United States alone due the lack of price controls that enabled them to exploit market power [14] which was more difficult to do elsewhere, including Europe. By 2010, this figure was down to 57% [18] due to growing cross-country

[3]As of June 2012, there are 38 contracting states to the EPC, also known as the members of the EPO. They are Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Monaco, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom).Bosnia and Herzegovina, and Montenegro are extension states to the EPC.

subsidiary-headquarter relationships of these global companies that impacted the innovation and manufacturing locations. The U.S. dominance in R&D investments lasted for about a decade from 1995 until 2005 [16]. In recent years, in light of fiscal austerity, European countries have faced increasing competition from emerging economies, such as Brazil, China and India [14, 16], who have proven to be important and a growing non-OECD research base for the pharmaceutical industry.

R&D expenditures, in general, only represent tiny fractions of the Gross Domestic Product for most countries. While the average R&D expenditures-to-Gross Domestic Product ratio of OECD countries reported in the World Bank's World Development Indicators (WDI) in 2013 is seemingly low at 2.4%, its "R&D intensity" as measured by R&D expenditures over total sales is the highest across 41 industries at 14.4% [16].

Pharmaceutical patents differ from other technology-based industrial patents as the formula is disclosed publicly in exchange for patent protection (Lehman, 2003). In other words, a new drug cannot be kept a secret until right before marketing of the product. Furthermore, because the patent equals the new product, which is relatively cheap to manufacture, patent protection becomes the only way to receive exclusivity on the market to reap the returns from R&D. In the United States, to obtain approval by the FDA for a new drug, the pharmaceutical company has to file a New Drug Application (NDA) to demonstrate safety and efficacy data from clinical trials [17]. On the other hand, to obtain approval for a generic drug, an Abbreviated New Drug Application (ANDA) is filed, which does not require clinical testing. Instead, the data from the NDA can be used. This additional layer of regulation makes it almost unlikely that a new drug can be developed without patents. No other industry operates in quite the same manner.

Furthermore, it has been argued that not all drugs being developed reach the patent phase as pharmaceutical companies periodically discard ones that are considered to be unpatentable [11]. Legally speaking, the "novelty and non-obvious" requirements of patenting challenge especially inventions in the pharmaceutical industry because patents are not granted if the ideas for the inventions are not new.

2.3. Previous research on the relationship between patents and R&D

Economists have studied whether or not patents are successful in encouraging innovation in both theoretical and empirical research [12]. Among the empirical studies, both micro and macro approaches were taken. At the micro level, the relationship between R&D expenditures and patents was investigated for a cross section of firms. It t was found that the two were almost proportional across firm above a threshold size [2].

At the macro level, strong intellectual property rights positively impacted economic growth through R&D and physical capital accumulation [5] and R&D intensity [6] for a cross section of countries over time. While legal differences were found to be insignificant determinants of patenting to and from the UK [3], strong patent protection positively impacted patenting for a sample of OECD countries [4]. In a later analysis, stronger patent protection was found to attract foreign technology which led to further domestic innovation [7].

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The role of international flows of R&D was recognized in more recent studies. Between 2002 and 2005, North America was the source of fifty percent of R&D Foreign Direct Investment (FDI), with destination R&D affiliates in developing countries such as China and India [9]. Among Japanese multinational firms, there was a high degree of substitutability of domestic and foreign R&D [19]. The sources of R&D expenditures (foreign or domestic) had differential impacts for domestic and foreign patenting [10].

3. Empirical estimation and data

The relationship between patents and R&D with persistence, shown in Eq. (1), was introduced in the literature [20]:

$$P_{ijt} = k\left[R_{ijt} + (1-\delta)\, R^{\beta}_{ijt-1} + \ldots \mu_{ij}\right] + \varepsilon_{ijt} \tag{1}$$

where P_{ijt} denotes patents and R_{ijt} denotes R&D expenditures, both, of j residents in location i at time t. μ_{ij} denotes the time-invariant heterogeneity (fixed-effect or random-effect). It is the country-specific propensity of resident j to patent in location i which takes into account differences in institutions, patent laws, geography and other characteristics which do not change over time. ε_{ijt} is the idiosyncratic error term. R&D depreciates exponentially at the rate of β.

The empirical equation can be derived as a dynamic panel model shown in Eq. (2) as demonstrated elsewhere [10].

$$P_{ijt} = \theta_t \tau_t + \beta \ln R_{ijt} + \gamma P_{ijt-1} + \mu_{ij} + \upsilon_{ijt} \tag{2}$$

The term τ_t denotes the time effects and ν_{ijt} denotes the new idiosyncratic error term. The lagged dependent variable, P_{ijt-1}, on the right side of the equation violates one of the assumptions of the traditional panel model. Equation (2) is best estimated using the Arellano-Bond general method of moments (GMM) model [21]. First differencing of variables will sweep out the heterogeneity, μ_{ij}, and the model uses first-differenced time effects and lagged patents as instruments. The choice of one lag is to simply reduce the number of potential instruments.

Pharmaceutical patent application data to EPO, USPTO and triadic families were collected for 100 countries of inventors' residence for every year (the priority date) from 1997 to 2012 using OECD's Patent Database. The data consisted of most developed countries and about half of non-OECD countries. These seemed to correspond to countries that had positive patents in at least 1 year, as shown in the time-averaged **Tables 1** and **2**. This did not pose potential issues as the pharmaceutical industry primarily deals with OECD countries. Furthermore, the non-OECD countries of growing importance, China, Brazil and India, were included.

However, there were significant problems finding corresponding R&D data especially for the pharmaceutical industry for the same time period. this issue was documented for a previous study on all industries aggregated at the national level [10]. OECD's Patent Database

reported business enterprise R&D expenditure data[4] by industry (ISIC rev.3.1 classification). It was more common to find aggregated R&D (all industries combined or for broader industry groups) than to find data on just the pharmaceutical industry. While these particular pharmaceutical R&D data were potentially available for a longer period spanning 1987–2014, almost every country had missing data in numerous years which were often consecutive. The average years of data for each country were too short to estimate a dynamic panel model with reliable instruments. Hence, I estimated a non-dynamic panel equation without the lagged patent variable, as shown in Eq. (3).

$$P_{ijt} = \theta_t \tau_t + \beta \ln R_{ijt} + \mu_{ij} + \upsilon_{ijt} \quad (3)$$

The assumption of $\gamma = 0$ from Eq. (2) implies that a past patent application does not impact a current patent application. This does not seem to be an unreasonable assumption in the pharmaceutical industry because generic drugs do not require patents. However, the larger problem of R&D data had to do with the fact that non-OECD countries were reduced to 3 countries even though OECD countries were reduced to 29 countries. In addition, these three countries were Singapore, Taiwan and Romania, not China, Brazil and India, which were all dropped due to missing pharmaceutical R&D data. While these would potentially impact the non-OECD country estimates, I proceeded anyway because they would represent the lower bound of the estimates for non-OECD because the three omitted countries would have had larger effects than the three included.

Both patent and R&D data are divided by the population size (in millions) to control for country size and to state them in per capita terms [10]. Total population data from the World Development Indicators (WDI) were collected for all countries in all years, with the exception of Taiwan. Taiwan's population data for all years were compiled from Penn World Tables. I estimated Eq. (3) for EPO patent applications, USPTO patent applications as well as the triad family applications (EPO, USPTO and JPO). Results are presented in the next section.

4. Results

The results of EPO patent applications are presented for various groupings of the countries in **Table 3**. It should be noted that columns (3), (5) and (7) may be potentially larger if the three non-OECD countries of growing importance, China, Brazil and India, were to be included. Fixed-effect models are reported with the Hausman specification tests for rejecting the random-effect models. The results do not show the expected "home advantage" of EPC countries,[5] that the impact of R&D is the highest on EPO patent applications for this group of countries. Rather, the result is a surprising advantage of the non-EPC countries that filed patent applications to EPO. Because a panel regression cannot be run on just

[4]The total reported was supplemented with other government and national funds as well as funds from abroad. The funds from abroad were included to reflect the fact that R&D of foreign affiliates have become important in the multinational firms represented in the pharmaceutical industry.

[5]As mentioned earlier, all EPC and EPO memberships are the same

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	(1) All countries[6]	(2) OECD countries	(3) Non-OECD countries	(4) EPC countries, US and Japan	(5) Non-EPC countries, US and Japan	(6) EPC countries	(7) Non-EPC countries
ln(R&D)	1.34** (0.68)	1.69* (0.93)	0.20 (0.62)	1.44 (9.97)	1.61* (0.85)	1.46 (0.99)	1.93*** (0.75)
Constant	−16.82 (12.01)	−22.48 (16.10)	−0.53 (10.27)	−18.23 (16.74)	−20.13 (13.26)	−17.03 (17.25)	25.15 (12.16)
Number observations	215	184	31	155	60	143	72
Number of countries	32	29	3	26	6	24	8
Average number of years	6.7	6.3	10.3	6.0	10.0	6.0	9.0
Year controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Overall R^2	0.45	0.46	0.22	0.45	0.42	0.44	0.38
Hausman specification test (χ^2)	19.47*	13.28	8.58***	54.49***	6.66	103.77***	4.49

Notes: (1) Standard errors in parentheses below coefficients.
(2) Statistical significance at 1% (***), 5% (**) and 10% (*).

Table 3. Regression results for EPO patent applications.

the United States, the differences between columns (4) and (6) and between columns (5) and (7) are used to demonstrate the effect of including/excluding United States and Japan. Since there are only three non-OECD countries in column (3), it is difficult to discern if the non-significance of the slope is simply due to a small cross section of countries represented or not.

The results of USPTO patent applications for the same grouping of countries are presented in **Table 4**. The results in columns (5) and (7) show a "home country advantage," this time, for the United States. Compared to the same columns in the previous table, the returns to R&D for USPTO patent applications are more than double those for EPO applications. Interestingly, the even columns, which present more robust results from having most OECD countries, are the columns that show no effect of R&D on patenting with USPTO.

The results of triadic family patent applications are presented for the same grouping of countries in **Table 5**. As suggested by the smaller number of this type of application for every country in **Tables 1** and **2**, the effects are statistically insignificant, except for columns (5) and (7). The results

[6]Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Republic of Korea, Mexico, Netherlands, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom, United States, Romania, Singapore, Taiwan.

	(1) All countries	(2) OECD countries	(3) Non-OECD countries	(4) EPC countries, US and Japan	(5) Non-EPC countries, US and Japan	(6) EPC countries	(7) Non-EPC countries
ln(R&D)	1.92** (0.97)	1.93 (1.26)	0.67 (0.62)	1.08 (1.22)	3.86** (1.97)	1.11 (1.26)	4.11** (1.79)
Constant	−25.49 (16.72)	−26.80 (21.64)	−7.57 (9.21)	−12.05 (21.04)	−57.08 (33.09)	−11.56 (21.62)	−62.89 (30.32)
Number of observations	210	180	30	152	58	141	69
Number of countries	32	29	3	26	6	24	8
Average number of years	6.6	6.2	10.0	5.8	9.7	5.9	8.6
Year controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Overall R^2	0.35	0.35	0.53	0.28	0.46	0.28	0.34
Hausman specification test (χ^2)	10.35	7.18	2.04	13.13	2.89	20.52**	7.80

Notes: (1) Standard errors in parentheses below coefficients.
(2) Statistical significance at 1% (***), 5% (**) and 10% (*).

Table 4. Regression results for USPTO patent applications.

	All countries	OECD countries	Non-OECD countries	EPC countries, US and Japan	Non-EPC countries, US and Japan	EPC countries	Non-EPC countries
ln(R&D)	0.44 (0.33)	0.25 (0.44)	0.45 (0.50)	0.01 (0.44)	1.41*** (0.53)	0.07 (0.45)	1.65*** (0.49)
Constant	−4.02 (5.72)	−0.65 (7.85)	−6.36 (8.33)	3.02 (7.68)	−18.73 (8.18)	3.52 (7.84)	−22.67 (7.76)
Number observations	215	184	31	155	60	143	72
Number of countries	32	29	3	26	6	24	8
Average number of years	6.7	6.3	10.3	6.0	10.0	6.0	9.0
Year controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Overall R^2	0.31	0.20	0.45	0.03	0.49	0.02	0.46
Hausman specification test (χ^2)	5.72	7.89	6.11**	0.11	0.20	4.10	3.31*

Notes: (1) Standard errors in parentheses below coefficients.
(2) Statistical significance at 1% (***), 5% (**) and 10% (*).

Table 5. Regression results for triadic family patent applications.

are comparable to those in **Table 4** pointing to the importance of countries other than the United States, Japan and European countries.

While not reported, to demonstrate robustness of the results in the pharmaceutical industry, I ran comparable regressions for the aggregate of all industries. The effects of total R&D on total patents followed the same pattern as the results in **Tables 3** to **5** except the effects were almost always larger. This suggests that the returns to pharmaceutical R&D on pharmaceutical patents are not as lucrative as the returns to R&D in all other industries. This may stem from having additional hurdles in the form of clinical trials or from having companies drop potentially unpatentable drugs during the development phase.

5. Conclusions

This chapter investigated the returns to R&D for patenting applications to EPO, USPTO and the triadic family (EPO, USPTO and JPO) in the pharmaceutical industry. The lack of industry-specific R&D data hampered the results of this study in the form of having inadequate number of non-OECD countries. However, it is noteworthy that pharmaceutical R&D has no impact on USPTO, EPO and triadic family applications, coming from European (EPC) countries. The 6 non-European countries (Australia, South Korea, Mexico, Romania, Singapore and Taiwan) always showed positive and statistically significant results. This was unexpected because the three countries of growing importance (China, Brazil and India) were dropped from the analyses due to missing pharmaceutical R&D data. It is hypothesized that the inclusion of these three countries would have made the impact even stronger. The addition of the United States and Japan always made these coefficients larger. With better data availability in the future, this will be important for studying how much non-OECD countries are impacting the pharmaceutical industry. Other implications are that perhaps, the returns to R&D on patenting in pharmaceuticals will have much stronger effects on specific drugs for chronic diseases such as cancer and heart disease which will likely generate larger revenues. Future research may rely on micro firm-level data.

Author details

Risa Kumazawa

Address all correspondence to: kumazawar@duq.edu

Duquesne University, Pittsburgh, Pennsylvania, USA

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IntechOpen

Chapter 3

Towards More Inclusive IP Analysis by Frontier Tools

Yoshiyuki Osabe and Mari Jibu

Additional information is available at the end of the chapter

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Abstract

This chapter introduces multilateral analysis on IP rights: (1) a new indicator "Innovation Front" and its use, (2) analysis of patent quality, and (3) future prospect in pharmaceutical field. Through these items, more inclusive IP analyses have been conducted. We introduce the origin, trajectory, and destination of knowledge spillovers in the science and technology system, especially in pharmaceutical field. "Innovation Front" is also covered, where it is possible to find major hotspots in basic research, which give a great influence to technologies. Readers of this chapter will find (1) the major hotspots in basic research, (2) patent quality analysis ranging from basic research to application research, and (3) an overview of drug R&D and future competitiveness in the pharmaceutical field.

Keywords: patents, non-patent literature, knowledge spillovers, knowledge flows, patent quality, pharmaceutical, drug pipelines

1. Introduction

There are no doubts about the importance of knowledge spillovers for creation of intellectual properties (IPs) and furthermore economic growth. Because the spillovers allow a better penetration and diffusion of innovation and stimulate cooperation in R&D for innovators to try to internalize knowledge flows, the role of knowledge exchange and dissemination is often as important as the role of direct investment in a knowledge- and technology-driven economy. Various reports have been published to study the origin, pass way, and end products of knowledge spillovers in the science and technology ecosystem. Patents and citations between patents and non-patent literature (NPL) are analyzed to make comprehensive grasp of knowledge spillovers [1] or to estimate patent quality [2].

Recently, we have developed a new indicator, named "Innovation Front" by calculating papers cited in patents by co-citation analysis [3]. Since papers cited in patents are close to

technology, it is possible to find major hotspots in basic research, which give a great influence to technologies.

Apart from our analysis, a new indicator "Patent-Science Link" is developed by the Organisation for Economic Co-operation and Development (OECD). This is able to understand how the technical knowledge has been flowing from the science-based study to the innovation activity [4]. The Patent-Science Link indicates that pharmaceutical patents reckoned the large part of citations made from patents to scientific papers. That is, in the fields of pharmaceutical, the science-based study is much closer to the innovation activity comparing with other fields of technology.

Therefore, we analyzed the intellectual properties in pharmaceutical science using Innovation Front and OECD's Patent-Science Link. Based on these indicators, we clarified how the knowledge flows on each pharmaceutical R&D stage and how a drug has been created as a final end product. In this study, papers, patents, and drug pipelines represent each pharmaceutical R&D stage. Especially, the indicators of the drug pipelines also showed an overview and future prospects of pharmaceutical industries.

This chapter introduces multilateral analysis on IP rights: (1) a new indicator "Innovation Front" and its use, (2) analysis of patent quality, and (3) future prospect in the pharmaceutical field.

Note that the opinions expressed in this chapter are those of the authors and do not represent those of the institutions that the authors belong to.

2. Innovation Front

The citations between scientific papers and patents have been analyzed since Narin started the study of science linkage, which is seen in the administrative process as patent examiners refer scientific papers in examining a patent [5, 6]. Japan Science and Technology Agency (hereafter JST) is one of the funding agencies in Japan with aims of promoting technology transfers and technology-based innovation. As such, it is important to investigate the JST's contribution as a result of its funding. JST has a point of view that non-patent literature (NPL) in patents is seemed to provide a hint of knowledge flows between science-based study and innovation ecosystem. JST has developed as such an indicator, the "Innovation Front" in order to show specific research areas where science significantly influences technology by calculating co-citation between patents and research papers [7].

2.1. Innovation process

For the purpose of stimulating innovation, the innovation process needs to be carefully analyzed. **Figure 1** shows that the innovation develops on the bases of the two internal actions, "knowledge embodiment (in other words, development part in R&D)" and "knowledge creation (in other words, research part in R&D)" [8]. Yamaguchi developed his idea, so-called innovation diagram that shows the way of visualizing an innovation process using two intellectual elements. They represent the element of the "knowledge embodiment (development)" and the element of the "knowledge creation (research)" (see **Figure 1**). Once the

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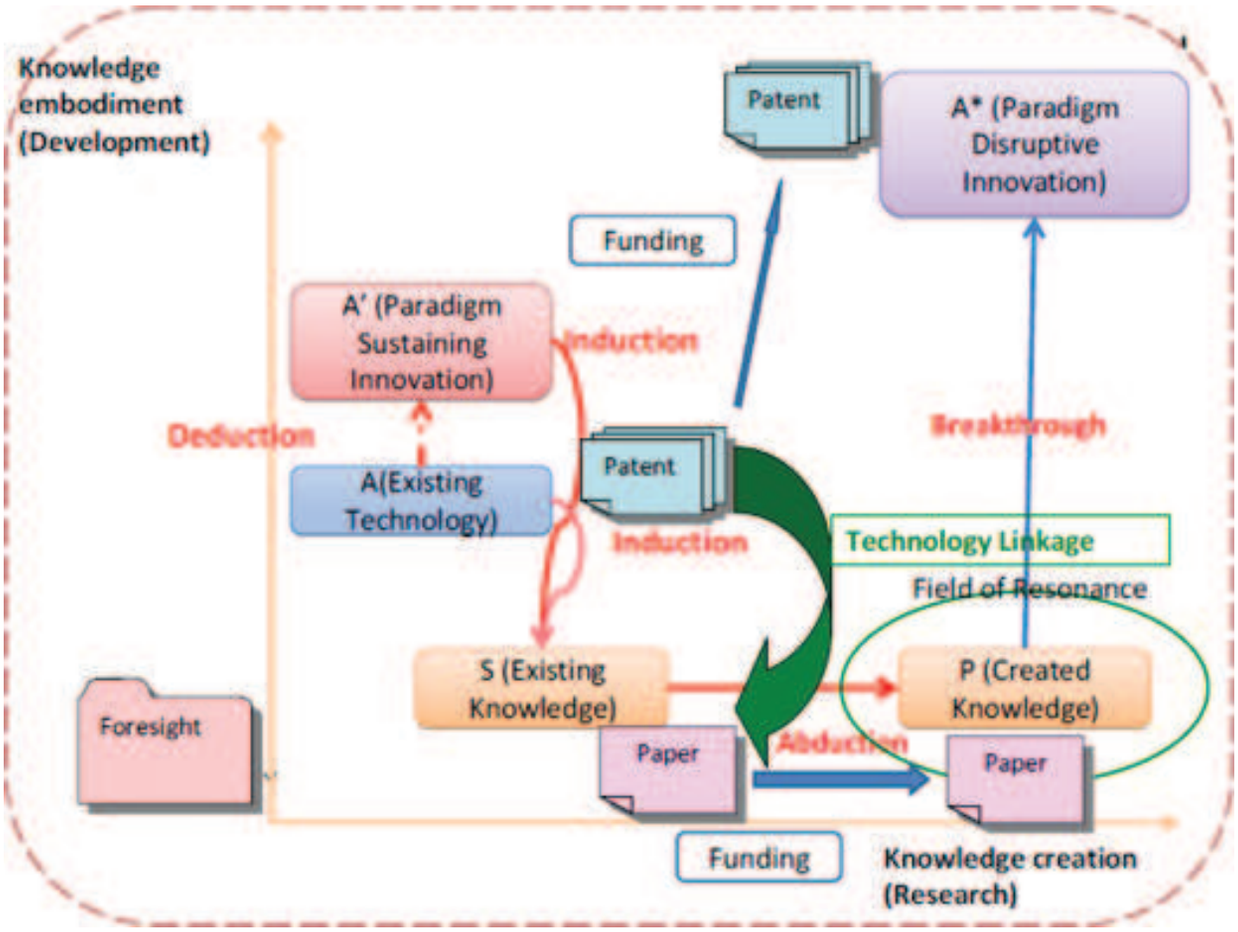

Figure 1. Innovation process and scientometrics.

technological exploitation come to a total deadlock (A" in **Figure 1**), the R&D need going back to the basic scientific knowledge ("Induction" in **Figure 1**) and force it to move with scientific exploitation ("Abduction" in **Figure 1**) for the purpose of creating another innovation by overcoming the deadlock above (A* in **Figure 1**). Making a breakthrough and creating a new innovation will be possible by the actions above. As you see, by linking science-based knowledge to technological information, we can see a whole way of the innovation process, as shown in **Figure 1**.

Figure 1 indicates an overview of how to understand and visualize the innovation process by connecting the results such as patent analysis, bibliometric analysis, and clustering analysis by the following innovation process. In this attempt, **the linkage between patents and papers** is a key to obtain an understanding of the innovation process, which is evidence-based, such as the review of science-based knowledge from technology stage ("induction" in **Figure 1**). Because patent examiners generally cite patent and paper information as a reference, we can develop an index that is called "the science linkage index," that is, the number of forward citations and the NPL share (share of non-patent literature) citations, and the index may show whether a patent is technology-oriented or science-oriented. Many studies show that backward citations to the non-patent literature (NPL) relate the closeness between a patented

invention and science-based knowledge. On the other hand, the importance of a patent for the R&D is related to forward patent citations.

In order to create a new indicator "Innovation Front," we utilized the above-mentioned relationship between patents and papers. As shown in **Figure 2**, pairs of papers are co-cited by different patents. For example, Paper A and Paper B are co-cited by both Patent X and Patent Y. So, we can recognize that Paper A and Paper B are close to each other **in the point of technical (patent) view**. On the other hand, the relationship between Paper A and Paper C or Paper B and Paper C is not technically close because they"do not share a group of patents which co-cite them. In this way, we can create a set of clusters consisted of papers which are technically close to each other.

"Technical closeness" is the keyword in this research. Innovation front is the first indicator who can show the technical closeness between papers by calculating patent co-citations.

2.2. Methodology

2.2.1. Series of database

The series of databases used for the Innovation Front are as follows:

Papers: "Essential Science Indicators," "Web of Science" by Thomson Reuters.

Patents: "Derwent World Patents Citation Index," "Derwent World Patents Index" by Thomson Reuters.

2.2.2. Classification

Papers:

Note that 22 category codes from Thomson Reuters "Essential Science Indicators" for Innovation Front.

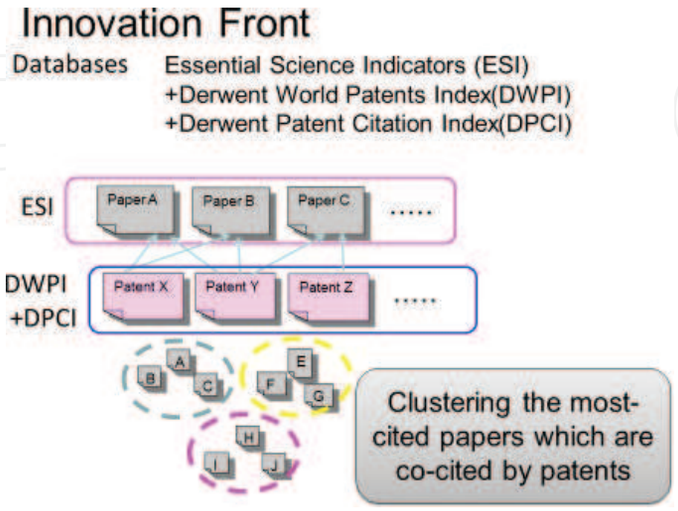

Figure 2. Structure of Innovation Front.

Patents:

(1) International Patent Classification (IPC) codes for Information and Communication Technology (ICT), biotechnology, environment-related technologies, nuclear energy, and fuel cells [1].

(2) ECLA codes for nanotechnology.

2.2.3. Calculation

(1) 1. Extract two papers arbitrarily (the papers were published between 2006 and 2010. These papers were extracted from "Essential Science Indicators."). 2. Calculate the frequency of forward co-citation by patents. This calculation is done with "Derwent World Patents Citation Index." 3. Then, calculate how frequent forward citation patents are in the two arbitrary papers.

(2) Derive cosine coefficient N from Eq. (1).

$$N = \frac{F(A, B)}{\sqrt{F(A) \times F(B)}} \qquad F(A, B) \geq 2 \tag{1}$$

where A and B of formula (1) show arbitrary papers, $F(A)$ and $F(B)$ show the cited frequency of the arbitrary papers, and $F(A, B)$ also shows the co-citation frequency of the arbitrary papers. Note that definition of $F(A, B)$ is larger than 2 or equal to 2.

(3) Then define $N \geq 0.3$ (note that N is larger than 0.3 or equal to 0.3).

(4) 1. Compile the papers that are extracted under the condition (3) above as nodes. 2. Connect the linkage among papers as the edge function. 3. Visualize the network of nodes and linkages, by using Cytoscape Web.

2.3. Analytical results

"Innovation Front" shows scientific hotspots by means of making clusters by co-citation analysis between scientific papers and patents. Since scientific papers cited by patent examiners are approximate to technology in the patent, we can find who are the major researchers and important scientific specialties in terms of papers having an influence on technology. Thomson Reuters publishes a "research front," that is the papers which have a strong impact on Science. It is based on the calculation of co-citation frequency of papers. JST has a similar approach in terms of patent. JST clusters the top 1% in terms of the most frequently cited papers that patent co-cite and show them as a cluster indicating an impact in terms of innovation. It has named as "Innovation Front." The clustering by the Innovation Front is shown in **Figure 3**.

Each node represents a paper and the nodes' colors express 22 kinds of fields. The node's size represents how many citations are there in papers. The line width between nodes represents

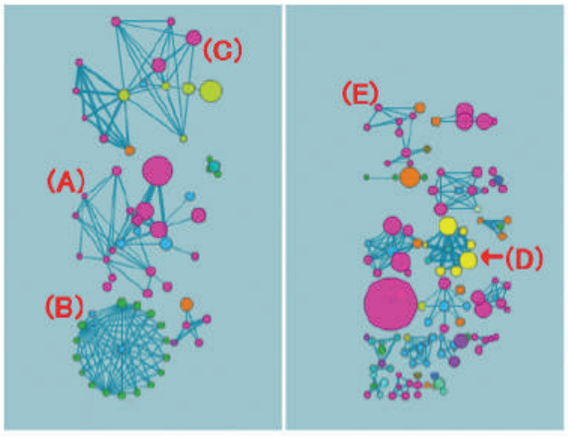

Figure 3. Result of the Innovation Front.

the number of co-citations by patent families. As a result, generated 24 clusters composed of 183 papers in total. The total citations of patent families and those of papers are 1095 and 46,038, respectively. The most frequently published journal is *Science*, with 18 papers and the second top journal is *Nature* with 17 papers. As to subjects of papers in clusters of Innovation Front: the largest subject is clinical medicine (45.4%) and the second top is chemistry (14.2%).

Cluster (A) is the field of induced pluripotent stem (iPS) cells composed of 22 papers. The iPS cells represent "induced pluripotent stem cells" which was discovered by Shinya Yamanaka in Kyoto University in 2006. Among the 22 papers, the title of the core paper is "Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors," written by Shinya Yamanaka et al. This paper was published in *Cell* in 2007.

Cluster (B) is the field of aptamor composed of 18 papers. Aptamor is a peptide or oligonucleotide that binds to a specific target molecule. The main fields of the 18 papers are engineering and chemistry. This is slightly different from the main field of the definition of aptamar above. In terms of 18 papers composing the cluster (B), the title of the core paper is done by Lee et al. in Northwestern University and the title is "Colorimetric Detection of Mercuric Ion (Hg^{2+}) in Aqueous Media using DNA-Functionalized Gold Nanoparticles." This paper was published in *Angewandte Chemie International Edition* in 2007.

Cluster (C) is the field of adipocytokine (cytokine secreted by adipose cells) composed of 15 papers. The main field is clinical medicine, immunology, and biology/biochemistry.

Cluster (D) is the field of meta-material, composed of nine papers. The main field is physics.

Cluster (E) is the field of microRNA and cardiac hypertrophy composed of nine papers. The main fields are clinical medicine and neuroscience and behavior.

Figure 4 shows the detail mapping of cluster A that represents the field of iPS cells composed of 22 papers and the number of citation papers are 7517. Squares indicate papers written by Yamanaka group and the largest square is titled "Induction of Pluripotent Stem Cells from

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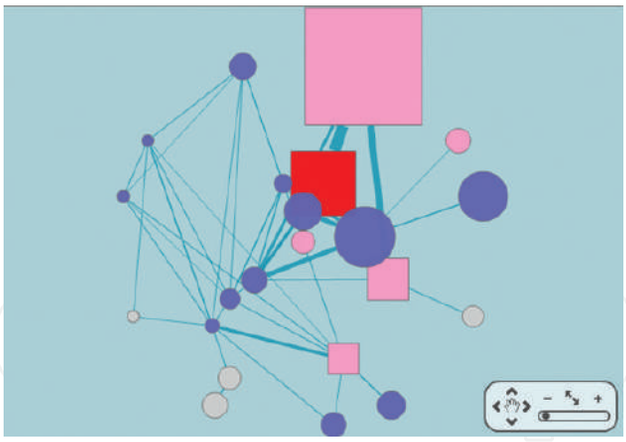

Figure 4. Innovation Front: a cluster of iPS cells.

Adult Human Fibroblasts by Defined Factors," written by Shinya Yamanaka, published in *Cell* in 2007. The aim of the core paper by our indicator is the iPS cells derived from **human fibroblast**. On the other hand, the Nobel Prize in Physiology or Medicine 2012 was awarded jointly to Sir John B. Gurdon and Shinya Yamanaka, and the Press Release by the Nobel Assembly announced" Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors" by Shinya Yamanaka as one of the key publications. This paper's aim is to develop iPS cells derived from **mouse embryonic and adult fibroblast cultures**. As the study advances from basic to practical research, subjects for study are changing from *in vitro*, *in vivo*, mice, apes, and to humans. Our indicator is able to find the papers and fields (clusters) that affect the **technology, which is closer to applied stage than science study**. This represents the result of iPS cell cluster above. In other words, Innovation Front showed the application study papers that target humans instead of *in vitro* study or mouse in the analysis of iPS cell field. Other papers of iPS cells also target humans in cluster (A). The results of Innovation Front composed of roughly six groups are presented below.

As to papers of Node 1, this is by a group of the International Consortium of Stem Cell Networks, which is a consortium of human embryonic stem (ES) cell researchers from around the world. As to Node 2, this is by Yamanaka group, which made a success in converting mice and human skin cells into iPS cells. As to Node 3, this is written by Thomson J. A. (University of Wisconsin) group. Thomson group succeeded in isolating the human embryonic stem (ES) cells in 1998 and also known as a study of human iPS cells. They published the paper related to iPS cells at almost the same time as Yamanaka group, 2007. As to Node 4, this is the group of Schoeler H. R. (Max Planck Institute) group. Schoeler groups succeeded in reprogramming of adult mouse neural stem cells by introducing on 4 October. As to Node 5, this is the group of Jaenisch R. (MIT) group. Jaenisch group had a success in terms of reprogramming from mature, differentiated mouse B cells. Finding alternatives instead of the cancer-causing retroviruses for making iPS cells is also their study. As to Node 6, this is the group of Hochedlinger, K. (Harvard University) group. Hochedlinger group used an adenovirus in order to transport the transcription factors into the DNA.

As shown above, Innovation Front shows "new geography of innovation hotspots." According to analysis by Innovation Front, the hotspots are the science fields of induced pluripotent stem

cells (iPS cells), aptamor, microRNA, cardiac hypertrophy and other fields of pharmaceutical science. Apart from Innovation Front, the OECD also introduced a new indicator called "Patent-Science Link" and indicated that patented inventions in pharmaceuticals account for the majority of citations to scientific papers in patents [4]. Therefore, we have moved forward with our aims to the analysis of intellectual properties in pharmaceutical science fields.

3. Patent quality on pharmaceutical field

Various reports have been published to show the study the origin, pass way, and end products of knowledge flows and the delays in the science and technology system. Patents and citations between patents and non-patent literature (NPL) are analyzed to make comprehensive grasp of knowledge spillovers [1] or to measure patent quality [2].

Pharmaceutical innovation is particularly important for drug discovery. There is a steady decrease in R&D productivity of drugs over the last number of years [10]. According to Scannell and Bosley, inflation-adjusted industrial R&D costs per novel drug increased nearly 100 fold between 1950 and 2010 [11]. R&D efficiency per billion US dollars of R&D spending has declined fairly steady, measured simply in terms of the number of new drugs brought to market by the global biotechnology and pharmaceutical industries. They call this trend "Eroom's Law in Pharmaceutical R&D" [12]. On the other hand, several cases of success have been found recently. For example, the reports present that drugs sourced via open innovation have a higher chance of later-phase clinical success, among 281 biopharma companies, between 1988 and 2012 [13].

We present an analysis of knowledge flows in the pharmaceutical innovation process. Backward citations, citations to NPL and forward citations that link patents, scientific papers and pharmaceutical pipelines data are analyzed and visualized to provide a more holistic understanding in hotspots of R&D. Because new drug discovery is the global issue and based on science knowledge, like biotechnology and chemistry, the analysis related to this field is eligible for science and innovation for global challenges.

3.1. Methodology

3.1.1. Dataset and its preparation

The datasets below by Thomson Reuters, which is covered from 1981 to 2011, are prepared. (1) For patent data, the Derwent World Patents Index (DWPI). (2) For papers' data, the Web of Science (WoS) database. (3) For drug pipeline data, the Thomson Reuters Cortellis for Competitive Intelligence database (hereinafter "Cortellis") including detailed information of drugs. (3) For citations data, the Derwent Patents Citation Index (DPCI). (4) For linkages between patents and papers, the WoS-DPCI Linktable computed by Thomson Reuters and JST that prepares backward citation data from patents to the NPL (non-patent literature) from the DPCI. Data were prepared on December 11, 2013.

Because of interest to find patents and their relationship to the non-patent literature in pharmaceutical fields, we prepared all 833,376 patents having one of the IPC (International Patent Classification) codes A61P that represents "specific therapeutic activity" from the Derwent Patents Citation Index and also we extracted their citations from DPCI, and we named them as "Pharma_Patents." Then, we prepared 57,800 patents that are linked to drug pipeline data from the Cortellis, named as "Drug_Patents (DP)." Then, the DP were subtracted from the patents having A61P resulting in a dataset of 325,576 "Non-Drug Pharma Patents (NDPP)." In other words, NDPP is a patent that has the code "A61P" but is not linked to drug pipelines. **Figure 5** shows the relationship between DP and NDPP.

Finally, all 115,252 NPL for Drug_Patents (DP) and 718,269 Non-Drug_Pharma_Patents (NDPP) were retrieved using the WoS-DPCI Linktable.

3.1.2. Calculation

As to patent quality analysis, patent family size, IPC counts, forward citations, backward citations, and citations to NPL were compared between 701 DP of random sampling and 701 NDPP for logistic regression analysis.

The citation lag: it can be calculated for forward citations to identify the speed by which patents are cited by future patens. It can also be used for backward citations to identify how prompt the existing works are cited by patents, see **Figure 6**. The citation lag is calculated as the average time gap of the years when the focus patent published (see **Figure 6**, patent A) minus the publication years of all cited works (see **Figure 6**, patents B, C, and NLP D). Similarly, the citation lag of all forward citations is defined as the average time gap of the publication years from all citing works (patents E–G in **Figure 6**) to the publication year of the patent A.

The generality index G_X: This is a quantitative index that represents the technical diversity of patents that are cited by a given focal patent (patent A in **Figure 6**). It also represents the technical diversity in terms of a group of patents that cite one focal patent. The count of different IPCs, which are associated with citing and cited patents, is used for calculation of the diversity. The generality index will be high if citing and cited patents occupy a wide spread

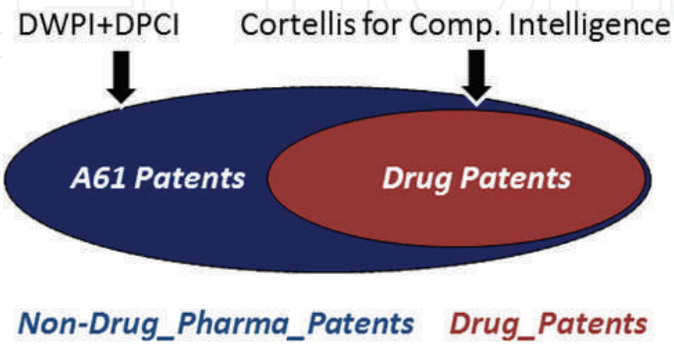

Figure 5. Relationship between Drug_Patents (DP) and Non-Drug_Pharma_Patents (NDPP).

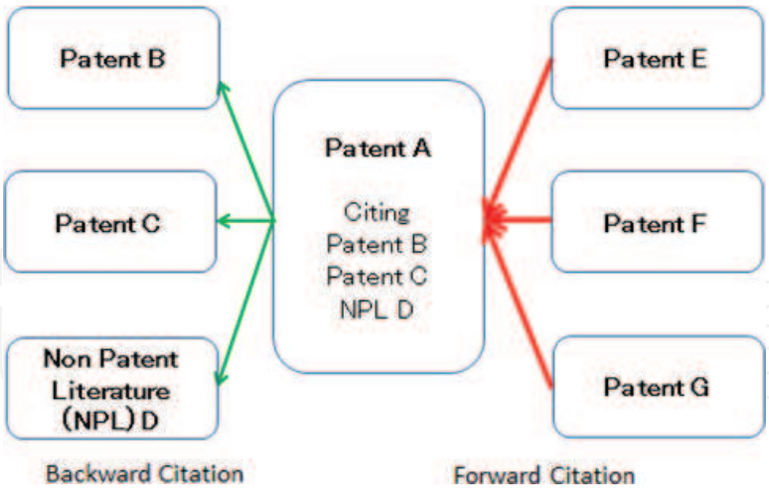

Figure 6. Backward citations to patents and NPL and forward citations to patents.

of technology fields. For example, when x is the focal patent and y_i patents are citing the focal patent x, with $i = 1, \ldots, N$, then G_X can be calculated by following formula:

$$G_x = 1 - \sum_{j=1}^{M_i} \left(\frac{1}{N} \sum_{i=1}^{N} \frac{T_{ji}^n}{T_i^n} \right)^2 \tag{2}$$

Where T_i^n is the total number of IPC n-digit classes in y_i, T_{ji}^n is the total number of IPC n-digit classes in the jth IPC 4-digit class in y_i, and $j = 1 \ldots M_i$ is the cardinal of all IPC 4-digit classes in y_i.

The index was calculated using all different 6-digit IPC subclasses for all patents in Drug_Patents (DP) and Non-Drug_Pharma_Patents (NDPP).

The subject index S_X: this is a new indicator we proposed. It is based on the generality index above, but the difference is that it is computed for NPL. For example, when x is the focal patent which cites y_i, $i = 1, \ldots, N$ scientific papers (NLP), then S_X can be calculated as following formula:

$$S_x = 1 - \sum_{j=1}^{j} \left(\frac{N_{ij}}{N_i} \right)^2 \tag{3}$$

Where N_i is the total number of subject code in y_i and N_{ij} is the total number of subject code in jth the subject code in y_i.

The subject codes attached in each scientific paper are counted using basic element 1. The subject index was calculated for all non-patent literatures cited by patents in DP and NDPP.

The patent scope "SCOPEp": this is often associated with the technological and economic values of patents. It is said that broad scope patents tend to have a higher value (Lerner, 1994). For each patent P, the patent scope is defined as:

$$SCOP\,E_p = n_p; n \in \left\{ IP\,C_1^4; \ldots IP\,C_i^4, \ldots IP\,C_j^4; \ldots;\ IP\,C_n^4 \right\} \text{ and } IP\,C_i^4 \neq IP\,C_j^4 \tag{4}$$

where n_p denotes the number of distinct 4-digit IPC subclasses listed in the patent P and is normalized. The patent scope was calculated for all distinct 6-digit IPC subclasses for all patents in Drug_Patents and Non-Drug_Pharma_Patents.

3.2. Analytical results

3.2.1. Patent quality

Table 1 shows the results of logistic regression analysis. As a result, forward citations ($P < 0.001$), IPC count ($P < 0.001$) and also citations to NPL ($P < 0.05$) are significantly associated with patent quality. Therefore, forward citations, IPC count, and citations to NPL are emerged as new indicators for distinguish genuine patents that have strong linkage with R&D processes from other patents related to drug.

3.2.2. Citation lag: technology delays

Comparison of citation lags for Drug_Patents and Non-Drug_Pharma_Patents shows the dynamics of knowledge spillovers. **Table 2** represents that the forward citation lag of Non-Drug_Pharma_Patents is 2.17 years later on average while Drug_Patents are cited faster—after 1.89 years on average. Here, we can see the high-quality patent (Drug_Patents) tend to be referenced faster than other patent (Non-Drug_Pharma_Patents) The backward citations lag of

	Coefficient	**Std. error**	***z*-value**	***P*-value**	**Sig.**
Intercept	−0.05474	0.0824	−0.664	0.50638	
IPC count	−0.009	0.0018	−4.89	1.01E−06	0.1%
Forward cites by patent	0.020355	0.0031	6.645	3.03E−11	0.1%
Backward cites to patent	0.003728	0.0025	1.516	0.12958	
Backward cites to NPL	0.003718	0.0014	2.626	0.00864	1%
Patent family size	−0.00062	0.0041	−0.153	0.87859	

Table 1. Logistic regression analysis.

	NDPP	**DP**
Forward cites by patents	2.17	1.89
Backward cites to patents	3.40	5.64
Backward cites to NPL	1.69	2.50

Table 2. Forward and backward citation lags.

Non-Drug_Pharma_Patents to patents is 3.4 years earlier on average and they go to much more recent non-patent literature (NPL)—published on average only 1.69 years earlier. Surprisingly, Drug_Patents cite older works comparing with Non-Drug_Pharma_Patents : cited NPL are 2.5 years old on average and cited patents are 5.64 years old. All values are statistically significant at the 1% level. In resume, we can see that Drug_Patents cover wider ranges and are cited more quickly comparing with Non-Drug_Pharma_Patents.

3.2.3. Generality index, subject index: knowledge diversity

The generality index was calculated for 4- and 6-digit IPCs. It was analyzed for backward and forward citations, also for Non-Drug_Pharma_Patents and Drug_Patents, see **Table 3**. Drug_Patents have higher generality index and subject index than Non-Drug_Pharma_Patents. That is, in general, Drug_Patents is based on wider "technologically based knowledge" and is cited by a wider range of set of patents that have more diversified IPCs. All values are statistically significant at the 1% level.

3.2.4. Scope: technology value

The patent scope was calculated for NDPP and DP, see **Table 4**. Contrary to expectation, in the pharmaceutical fields, the scope of DP (Drug_Patents) tends to be narrower than that of NDPP (Non-Drug_Pharma_Patents). This is unexpected as, in general, patents linked to drugs are seemed more valuable than those not linked to drugs.

Some possibilities are conceivable below: (1) NDPPs are used for protect peripheral technologies surrounding one core DP and broader patents are useful to protect an inconsequential broad area, (2) because it takes long time to get an approval of drug, a patent owner has to obtain the other patent which is narrower than original patent, like second use patent or formulation patent, in order to extend a patent term, and (3) pharmaceutical companies might hide their core patent, therefore, Thomson Reuters cannot link drug pipelines to an appropriate patent and so on.

		NDPP	DP
Generality index (4-digits)	Forward citations	0.36	0.37
	Backward citations	0.40	0.54
Generality index (6-digits)	Forward citations	0.46	0.50
	Backward citations	0.52	0.73
Subject Index	Backward citations to NPL	0.22	0.28

Table 3. Generality index.

Scope	NDPP	DP
4-digit	0.13	0.11
6-digit	0.16	0.15

Table 4. Scope for Non-Drug_Pharma_Patents and Drug_Patents.

3.3. Knowledge flows in pharmaceutical innovation

Our study compared and contrasted patents that are linked or not linked to drugs to understand knowledge flows and delays in pharmaceutical innovation. Results are summarized in **Figure 7**. As can be seen, Drug_Patents ("patents linked with drugs" in **Figure 7**) draw from a more diverse set of technologies and are cited more widely across the technology landscape. However, they tend to be more technically specialized (lower scope) than Non-Drug_Pharma_Patents ("patents linked without drugs" in **Figure 7**). Concerning citation lag, Drug_Patents tend to refer to older patents and scientific papers and are cited faster than Non-Drug_Pharma_Patents.

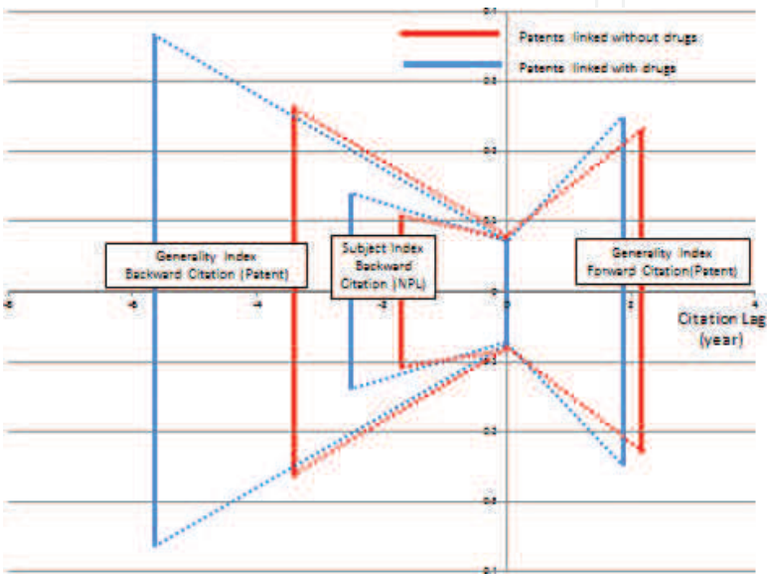

Figure 7. Comparison of Non-Drug_Pharma_Patents and Drug_Patents.

4. An overview and future prospects of pharmaceutical industry

For the sake of providing evidence that contribute to policy making or strategy planning in national governments and pharmaceutical companies, we tried to show an overview and future prospects of the pharmaceutical industry based on data related to science papers, patents, drug pipelines and other various data of enterprises.

As to the evidence for policy making, there have been many analyses on current status, based on drug sales and R&D expense. For example, OECD has published the report overviewing the pharmaceutical industry in a global market based on the indicators of R&D expense, trade balance and term of drug approval in September 2009 [9, 14]. In addition, many reports on drugs of top sales by research companies and publications of in-house products by pharmaceutical companies have been published. What is more, the global competitiveness ranking of pharma companies is announced by collecting and arranging the information. Although these indicators represent the R&D capacity or competitiveness of the past and the present, they cannot foresee the future status.

We aimed to focus on the R&D pipelines that pharmaceutical company in each country have. The results indicated the R&D potential of each country in the current stage and in the future, by compiling the pipeline data in each R&D step, comparing the number of marketed pharmaceuticals and so on.

4.1. Drug development and pipelines

Drug development is the process of bringing a new pharmaceutical lead compound to the market. There are several stages in drug development. It starts from "Basic research" stage, then moves to "Pre-clinical," "Clinical Phase," "Filed and Approved," and finally it goes to "Marketed" stage. Sometimes, it starts from intermediate stage like "Clinical Phase" when a company installs a lead compound from other company by licensing or M&A. Lead compounds in these stages are called as "R&D pipelines" or simply as "pipelines."

"Pre-clinical" is a stage of research that begins before clinical trials. Typically, animal testing and *in vitro* testing (test with microorganisms or cells) will be performed.

"Clinical Phase" is a stage of research on human participants, tested for safety and effectiveness in humans in order to be validated for a therapeutic use by a ruling authority of a government. "Clinical Phase" is composed of three stages. "Phase I" trials determine safety and dosing, usually in healthy volunteers. "Phase II" trials are the test in order to obtain an initial reading of efficacy and presumable safety in small groups of patients suffered by the disease targeted by the lead compound. "Phase III" trials are large and pivotal tests to decide its safety and also efficacy in sufficiently large groups of patients suffered by the targeted disease.

When these trials prove its adequate safety and efficacy, drug development goes to "Filed" stage, where a new drug application is filed to the ruling authority. After safety and efficacy are adequately confirmed by the authority, the application is approved. It means that drug development goes to "Approved" stage. When sales of the drug starts, the stage goes to "Marketed." Because the several stages above are need to be achieved in order to bring a lead compound to the market, it needs immense of R&D expense and dozen years by selecting an appropriate one from several tens of thousands of compounds and bring it to upper stages.

4.2. Methodology

4.2.1. Data acquisition and preparation

Two datasets of Evaluate and Thomson Reuters are used in this analysis. The dataset of Evaluate we used is "EvaluatePharma," which includes the pipelines data (about 45,000), licensing data, and M&A data from big pharma and biotech companies (about 7560 companies) in the world. It includes the data from 1986 to 2012. Also, the dataset of Thomson Reuters we used is "Cortellis for Competitive Intelligence," which includes timely global information on over 61,000 drugs, 6,000,000 patents, and 44,000 deals from big pharma to biotech companies.

4.2.2. Pipelines

Pipelines datasets from the EvaluatePharma of Evaluate are used in this analysis. The EvaluatePharma is the database containing R&D pipelines data, licensing data and M&A data, etc. in about 7560 pharma or biotechnology companies. We extracted 43,057 products, which are drug products and pipelines, related to small molecule drug or biomedicine covering 1986–2012 on May 2013. As to licensing data, we extracted in-licensed and out-licensed data covering January 2006–May 2013 from the EvaluatePharma. The Cortellis for Competitive Intelligence database by Thomson Reuters is also used in the pipelines analysis. Note that 21,086 pipelines are extracted and compiled on 11 December 2013.

4.2.3. Categories of business entities

Focusing on the sizes and categories of the business entities possessing pipelines, we classified 43,057 products data from the EvaluatePharma into eight categories, which are SMEs&VBs (Ventures), Majors, Generics, Specialties, Universities, Government, NGOs, and Others.

4.3. Analytical results

Figure 8 represents the R&D pipelines and marketed drugs covering from 1986 to 2012 in terms of small molecule drugs. **Figure 8** reveals that the number of US "Marketed" is immense, Japan is the second, followed by Germany, Switzerland, the United Kingdom, and France. The same goes for bio-medicines that include recombinant product, bioengineered vaccine, monoclonal antibodies, cell therapy, gene therapy, and DNA&RNA therapeutics. In terms of bio-medicines, the USA is the most competitive among the countries [15]. Later analysis revealed that the R&D pipelines in Korea are also high, however, they include many generic drugs [16].

Then we focused on the types of business entities that have R&D pipelines.

The conventional R&D process was "**closed innovation"** which happened in closed environment, like inside of laboratories in major pharmaceutical companies, where they discovered a lead compound and brought it into the market by themselves. This was because they had strength in chemical synthesis and took advantage of the strength to R&D of small molecular drugs. By bringing a blockbuster to the market, they got huge income to make an investment to the R&D of next drug. However, a new business model has recently been necessary for the pharmaceutical industry in order to cope with higher risk of drug development caused by longer term of R&D, increasing R&D expense. Examples are the capital expansion by a merger of major pharma companies and the role-sharing between major pharma companies and ventures. Recently "**open innovation"** has been attention-getting, which looks for the R&D pipelines outside of companies in order to reduce the higher risk. A report said that the success rate of drug R&D with open innovation would be three times as one with conventional R&D [13].

Therefore, we tried to find what kind of business entities have an important role in the drug R&D process, by analyzing the types, scales, and licensing activities of business entities having

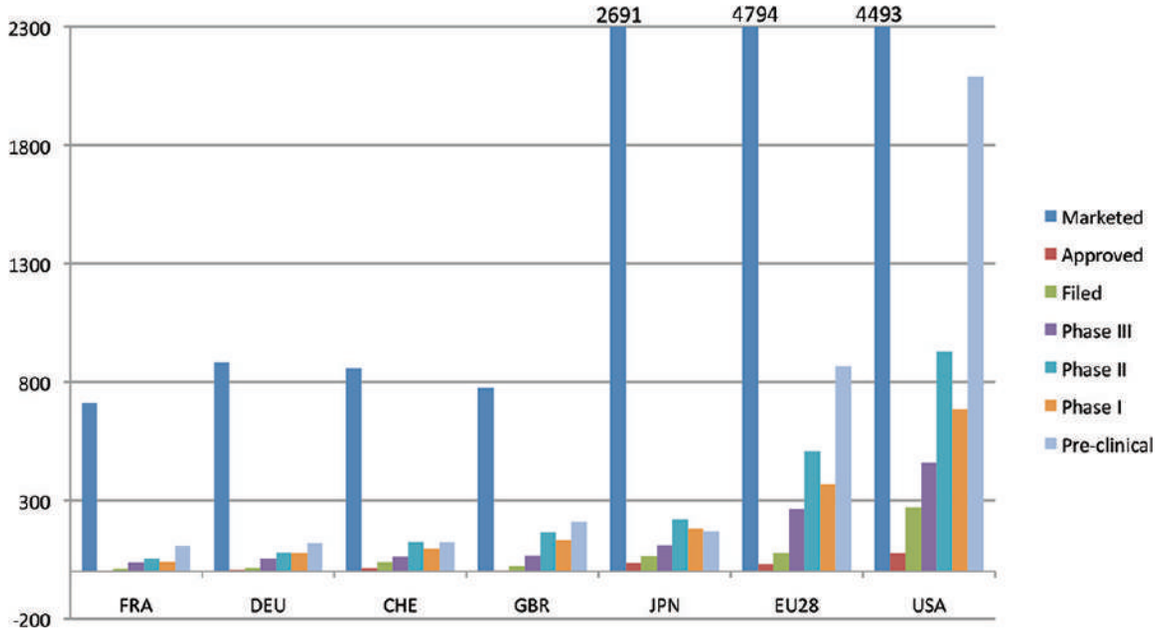

Figure 8. R&D pipelines and marketed drugs by country.

R&D pipelines. The business entities having R&D pipelines are divided into eight categories such as "SMEs, VBs," "Majors," "Generics," "Specialties," "Universities," "NGOs," "Governments," and "Others" by using the database EvaluatePharma. **Figure 9** shows licensing activity by country. The number of licensing in the USA is predominantly large. This is because the USA has the largest number of pipelines and its market is the biggest in the world. Following to the USA, the number of licensing activities in Japan is second large, but about one-third of the USA.

Then, **Figure 10** shows licensing activities by categories of business entities by country. Although the largest number of licensing in the USA is "SMEs, VBs," the largest number in Japan and EU countries are "Majors." As we show the predominance of the USA in **Figure 1**, it seems that a key role of the predominance is strong activity of SMEs and ventures. Later analysis revealed that the pipelines in the USA flowed not only from a university to a major via SME&VB, but also they flowed from a major to a SME&VB and from an SME&VB to other SME&VB. The multilateral flows of pipelines constitute, so to speak, "the roundabout of drug R&D" and that is the strength of the USA [16].

4.4. Drug R&D status by IPC

The International Patent Classification (IPC) has a subclass "A61P" which represents "specific therapeutic activity of chemical compounds or medicinal preparations." We analyzed the R&D status by providing IPC subclass to the therapy field that each pipeline has.

Figure 11 shows the origin countries of marketed drugs by IPC. We prepared the drug data of the countries (the USA, Japan, the UK, Switzerland, Germany, France, and Korea) that have many pipelines. As to the marketed drugs, the fields of infections and cancers are hotspots.

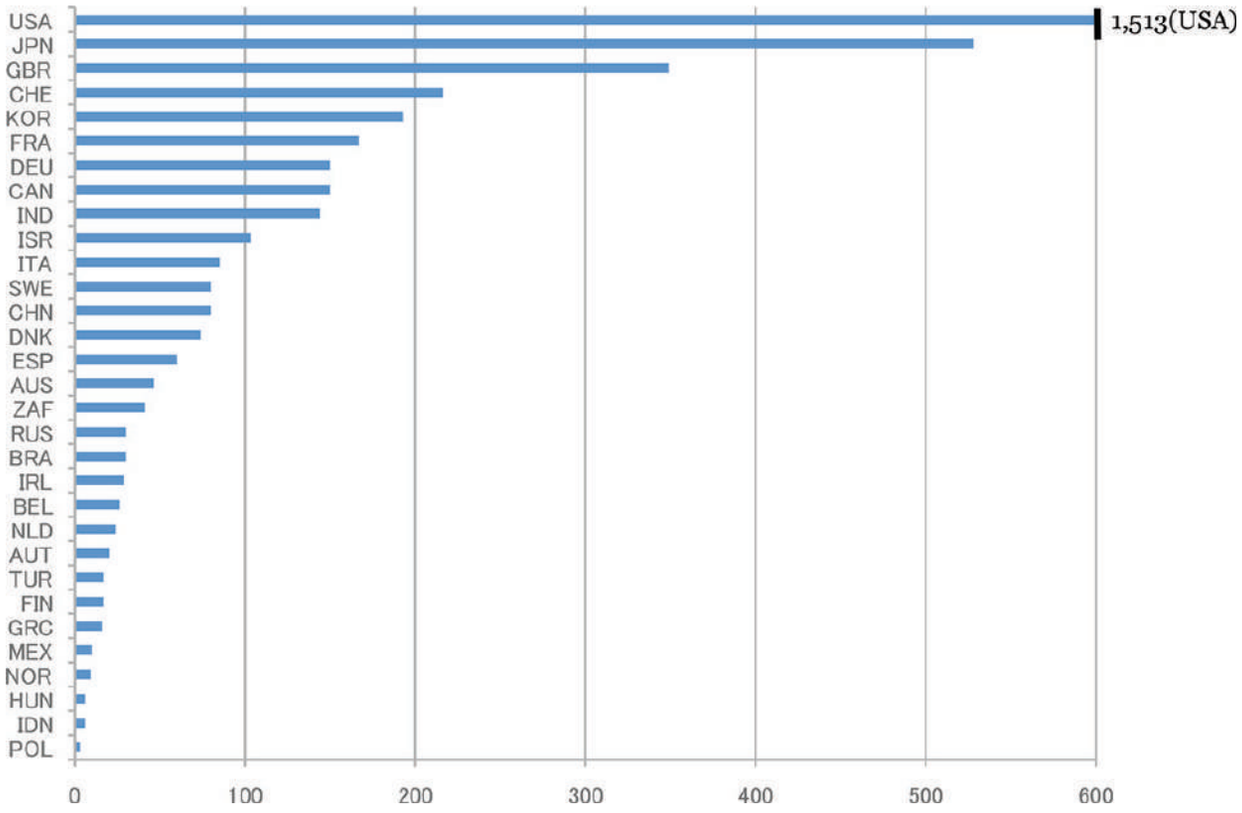

Figure 9. Licensing activities by country.

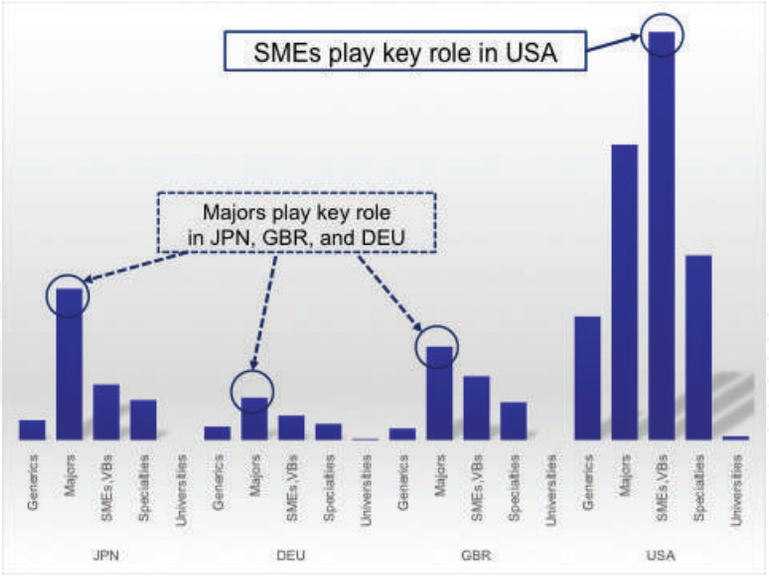

Figure 10. Licensing activity by category of business entities.

The number of Japan's original drugs is also relatively large and the ratio to total is about 20%, although the number of the US origins is the largest (about 44%). **Figure 12** shows the origin countries of R&D pipelines by IPC. In order to overview the present R&D status, **Figure 12**

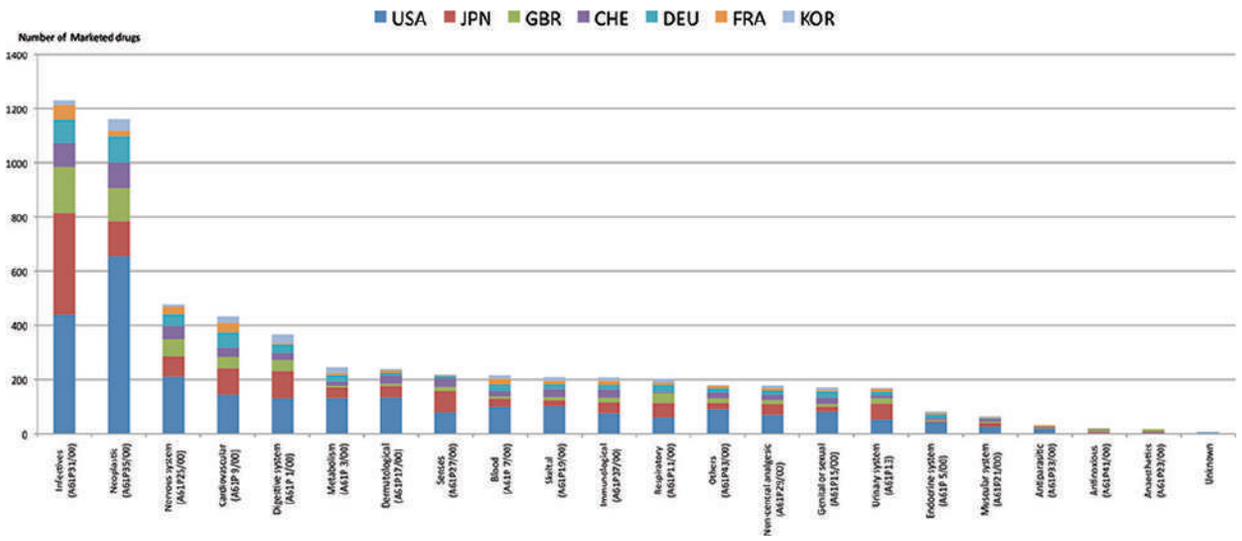

Figure 11. Origin countries of marketed drugs by IPC.

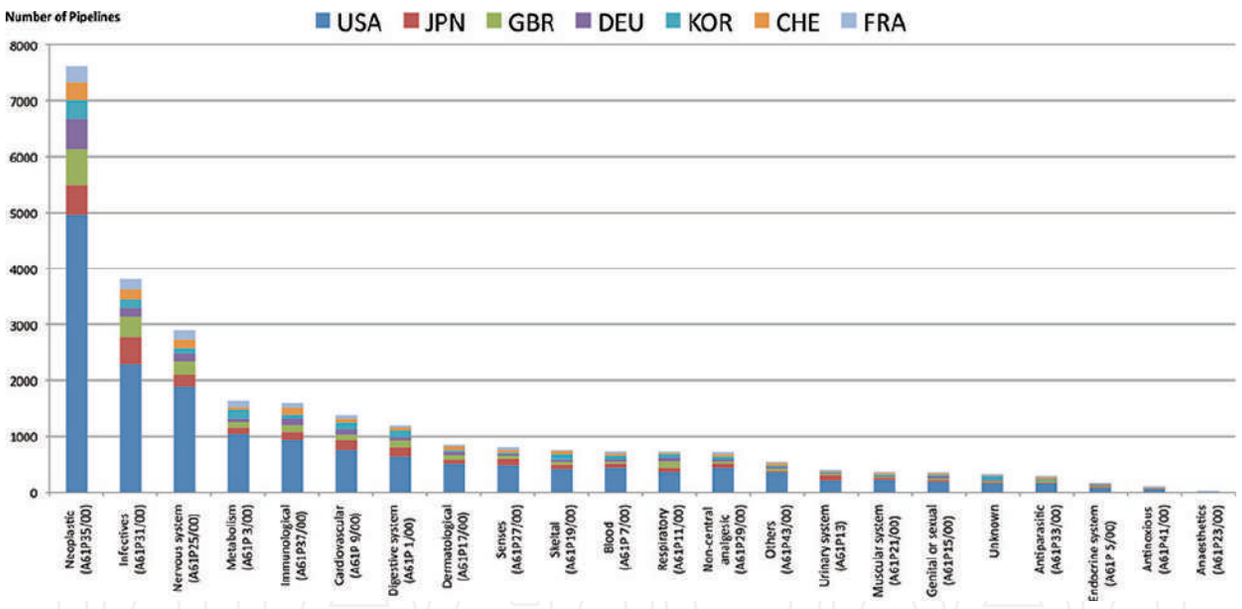

Figure 12. Origin countries of pipelines by IPC.

does not include the marketed drugs. It reveals that, as to drug candidates that are in process of R&D, the fields of cancers, infections, and mental disorders are largest. It also reveals that the pipelines of the US origin are largest.

Cancer is the top rank in cause of mortality among developed countries. It is also the top rank in the DALY (disability-adjusted life year; a new metric based on the sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability) and in the YLD (years lived with disability) [17, 18]. We can see that anti-cancer drugs have been under development by many countries.

As to infection, IPC code A61P31/00 includes antivirus for HIV, influenza, antimicrobials, and antifungal. Infections are a major cause of high mortality and low DALY among developing countries. Disorders of the nervous system (A61P 25/00) include neurodegenerative disorders like Alzheimer's disease or Parkinson's disease, antidepressants, and antipsychotics like schizophrenia. Comparing to "Marketed," the number of pipelines is larger, especially in "discovery" stage that represents basic research and pre-clinical stage. It is noted that this is the field with high future growth potential.

5. Final discussion

This chapter discussed multilateral analysis on IP rights: (1) a new indicator "Innovation Front" and its use, (2) analysis of patent quality, and (3) future prospect in the pharmaceutical field.

In the part (1), a new indicator "Innovation Front" showed scientific hotspots by focusing on "Technical closeness," that is to say, by means of making clusters by co-citation analysis between scientific papers and patents. It shows that the science fields of induced pluripotent stem cells (iPS cells), aptamor, adipocytokine, meta-material, and microRNA are the hotspots. In the part (2), we prepared patent datasets that are linked or not linked to drug pipelines in order to understand knowledge flows in the drug R&D field. The results indicate that DPs (Drug_Patents) are based on a wider range of technologies and are cited wider technology landscape. Contrary to expectation, they have a narrower scope. It means that they tend to be more technically specialized than NDPP (Non-Drug_Pharma_Patents). Concerning citation lag, DPs seem to refer to older documents and are cited faster than NDPPs. In the part (3), we showed an overview and future prospects of pharmaceutical industries, focusing on drug pipelines, size of business entities, and the International Patent Classification (IPC). The intricacies of patenting of pharma products by country-based and business entity-based were discussed.

Since many years, diverse studies have been conducted to study the origin, trajectory, and destination of knowledge spillovers in the science and technology system. The work presented here also contributes to a study for innovation analysis by showing a newly developed indicator (Innovation Front) and a new way of analysis, like comparison of Drug_Patents to Non-Drug_Pharma_Patents. Our next approach will be a linkage of "trademark" database to other database like patents and drug pipelines and also "financial analysis" linked to IP rights.

Author details

Yoshiyuki Osabe[1]* and Mari Jibu[2]

*Address all correspondence to: osabe-yoshiyuki@jpo.go.jp

1 Japan Patent Office (JPO), Tokyo, Japan

2 Japan Science and Technology Agency (JST), Tokyo, Japan

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Chapter 4

Patent Data in Economic Analysis

Rafał Wisła

Additional information is available at the end of the chapter

http://dx.doi.org/10.5772/68100

Abstract

The issues discussed in this chapter constitute a voice in a methodological discussion on the scope and manners of the utilisation of patent statistics in economic research. The discussion comprises the following issues: the gist of a patent monopoly, the evolution of opinions on the benefits and costs of a patent monopoly, and the possibilities and limitations of utilising patent statistics in the quantification of economic processes. This chapter is of a review and has methodological character. The analysis conducted within the text leads to two groups of conclusions. One of them concerns the shortcomings and limitations of patent databases, while the other concerns the identification of scientific exploration fields by means of patent metadata.[1]

Keywords: patent data, patent information, patent statistics, patent statistics as economic indicators

1. Introduction

A patent is an exclusive right to use a new solution of a technical nature; it is considered as one of the strongest rights of intellectual property. In the scientific sense, a patent is the crowning point of research and development activities. In the economic dimension, it is one of the stages of the innovation process. From the point of view of the patent owner, it constitutes a resource and a potential market value. A patent has a relatively high capability for transformation into a production factor. The properties of a patent's description and the exclusive right itself (a patent understood in a narrow sense) cause a situation in which patent

[1]The issues discussed in this chapter were taken also in R. Wisła (2014). The regional patterns of technical knowledge accumulation in Central and Eastern Europe countries, authored monograph, which was published by Polish Scientific Publishers PWN, Warsaw. The book is available in Polish only.

information constitutes a bridge between the results of the research and development (R&D) processes and their potential economic utilisation.

A patent is a body of accumulated scientific, technical, and industrial knowledge with potential to influence the course of economic processes. It is an economic category ascertained in both normative economics and positive economics. In the former case, it is considered on the plane of institutional solutions (an optimum patent policy, the effectiveness of patent systems, and external effects); in the latter, it is regarded as a measure of the dynamics and direction of changes in the economy. An important advantage of the time series of patent applications (and patent awards) is the possibility of their simultaneous use in at least four dimensions, that is time, space, an economic sector, and value.

Before the middle of the 1970s, the average annual number of patent applications (regardless of the mode of applications) had remained at a stable level. In the years 1975–2008, the average annual increase in the number of patent applications was 3.2%, while in the years 1995–2008, this rate rose to 4.9% [1]. If the latter period is extended until 2016, the annual growth exceeds the level of 5%.

The main factors stimulating this trend include (1) the replicability of a patent protection application concerning technical solutions within a single invention, (2) an increase in the effectiveness of research and development activities caused by pressure on the applicability of research results, (3) the emergence of new areas of technological development and/or the greater intensity of the utilisation of the existing ones, and (4) a heightened awareness of the importance of the formal protection of intellectual capital.

Consequently, there appear huge collections of structured data and information (databases of facts). In combination with the rapid technological development in the field of the IT infrastructure of data repositories and the new methods and techniques of data mining, they open up new opportunities for: (1) discovering previously unknown relationships and connections among data, (2) projecting the course of various processes, including economic ones, (3) determining the regularities of such processes, and last, but not least, (4) attempting to formulate general rules for their course, depending on conditions shaping the environment.

An important advantage of patents and collections of information on patents (databases) is their long-term availability (counted even in tens of years). The content of patent databases and long time series describing them allow the aggregation of data at any (microeconomic, mesoeconomic, macroeconomic, or international) level. Patent databases can be used in different ways and for different purposes.

The main reasons for using patent databases include (1) growing demand for analytical work for the needs of science and technology policies, (2) acquiring industrial knowledge described in the patent literature, (3) monitoring patent activities (input resources for future innovative activity), (4) searching for and identifying the directions and dynamics of development trends in particular areas of technology, (5) evaluating the results of scientific and industrial research, and (6) mapping research and development centres (as well as other entities) with respect to cooperation and identifying cooperation networks.

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The new possibilities and methods of creating, collecting, using, transmitting, and processing data, information, or knowledge cause an exponential increase in the supply of their resources. Their acquisition frequently takes place through multifunctional repositories combined with a modern system of services ensuring the acquisition of and access to their resources. From the point of view of social development and the increasing competitiveness of science and economy, such repositories constitute a powerful accelerator for the growing intensity and effectiveness of scientific research. Through access to various facilities, frequently extensive collections of sources, and the integration of distributed databases, they facilitate access to and productive utilisation of their resources.

The abundance of patent descriptions and patent statistics is not utilised sufficiently in the cognitive process in research into economic mechanisms and phenomena.

The topic of patent statistics and its use in economic research is not raised too frequently in the academic literature around the world. The intellectual foundations for the usefulness and possibility of using patent information collections in scientific research comprise the works of such researchers as: Pavitt [2, 3], Griliches [4], Jaffe, Trajtenberg, Henderson [5, 6], Schmoch [7–10], Guellec, van Pottelsberghe [11–13], Cohen, Merrill [14], Hall, Jaffe, Trajtenberg [15, 16], as well as OECD manuals [17], which harmonise the rules of patent statistics as one element of the system measuring technological changes, scientific and innovative activity, as well as the structural changes of the economic environment.

This chapter is organised as follows: Section 2 contains an explanation of the essence of the patent monopoly and presents opinions on its advantages and costs. Section 3 presents the main sources of patent information, the mode of making patent information generally available, the potential methods of using patent metadata, as well as fields of scientific exploration, using this category of source data. Section 4 includes scholarly reflection, based on the evolutionary approach, on the possibility of using patent statistics in economic research. Section 5 comprises a discussion on the methodological conditions for the utilisation of patent information. The issues presented in this chapter constitute participation in a methodological discussion on the scope and manners of the utilisation of patent statistics in economic research.

2. Patent

A patent is a personal property right which is effective towards all, transferable, and inheritable. It constitutes "property" within the meaning of the civil law. The making, using, offering, and marketing of a product and/or the manner constituting the subject matter of an invention are activities covered by exclusivity (the patent monopoly) resulting from the essence of a patent. The material scope of a patent is determined by patent claims included in a patent description (a description of an invention, drawings, constitutional formulae, structures of relationships, sequences, etc.). A patent document contains descriptions of a protected solution together with patent claims, constituting (synthetically formulated) scope of granted protection as the result of comparing the current state of the art with the protected solution.

As an economic mechanism, the patent has been present in the scholarly discourse since the beginning of the development of the economic sciences. However, in the eighteenth century and the first half of the nineteenth century, opinions on the patent were expressed on the margins of the main disputes in the field of political economics: Smith [18], Say [19], de Sismondi [20], Lotz [21], Jakob [22], and Mill [23]. The subsequent two or three decades of the nineteenth century witnessed the vibrant development of the economic literature devoted to exclusive property rights and the presentation of arguments both for and against the patent monopoly. The discussion focused mainly on the following four constructs: the natural law, justification for a temporary monopoly, stimuli for further creative activities, and reward for making knowledge publicly available [24].

From the aforementioned discussion, one could draw not only a tentative but also a very general conclusion that a temporary patent monopoly should be permitted. This opinion was advocated, to a greater or lesser degree, by A. Smith, J. Betham, J.S. Mill, J.H.G. Justi, L.H. Jakob, and J.F.E. Lotz. The clearly opposing opinion was held, among others, by Simonde de Sismondi.

It is difficult to determine unambiguously whether the views of the economists of that period constituted an important reason for work on an international convention on the protection of industrial property initiated in Paris, France, in 1873. (It was mainly the industrial, political, and legal circles that were the most interested in the development and international unification of the patent law.) But this fact had a considerable impact on the dynamics of research on the patent monopoly to be conducted by economists in the subsequent decades. Nevertheless, for the record, it should be emphasised that such scholars as Fisher [25], Marshal [26], Vaughan [27], Clark [28], Plant [29], Robbins [30], Hayek [31], Nordhaus [32], Scherer [33], Horstmann, Macdonald, Slivinski [34], Baumol [35], Gilbert, Shapiro [36], Klemperer [37], Cohen, Nelson, Walsh [38], and Stiglitz [39] presented their positions on the architecture of the patent system (including the issues of exclusivity, territoriality, time limit). In the twentieth century, the system developed very quickly, generating a number of external effects (together with clearly intensifying negative effects).

Summarising, one could state that a patent fulfils the following two main functions: (1) protection, which is related to the controversial institution of the legal monopoly and (2) dissemination of knowledge, thanks to (structured) collections of the patent literature. For this reason, a patent (patent description) may be also understood as a scientific and technical publication similar to an article in an academic journal.

3. Patent databases

The main source of patent information is publicly available patent documentation (application descriptions, patent descriptions of inventions) which contains, first of all, information on the current state of the art in a given field. An important advantage of patent documents is their up-to-date character (in the worldwide sense) and the unambiguous legal status with respect to industrial property protection. Patent literature collections comprise

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official bulletins of national offices and international organisations, bibliographic collections (metadata), as well as articles presenting particular problems, discussions, and past judicial decisions.

Patent information is provided under various procedures, but in practice, access to the full collection of metadata is not easy. The author has identified the following selected barriers against access to complete collections of patent data:

(1) national patent offices do not provide functionalities and tools allowing one to acquire metadata automatically and in bulk,

(2) public digital repositories of collected patent documentation have a relatively simple and functionally limited architecture,

(3) reports drawn up by national and regional patent organisations and delivered to statistical offices are general and superficial; their subsequent visibility in public statistics (statistical offices) does not allow any serious research, and

(4) commercial distributors try to overcome the aforementioned limitations; their acquisition of patent information is not only professional and functional but also expensive to the end user.

The general advantage of the time series (records) of patent applications (and patent awards) is the possibility of their utilisation in research on the development of science, technology, innovative activity, and structural changes in the economy [40–42] in at least four dimensions simultaneously: time, space, an economic sector, and the institution of property.

Rapid technological development in the area of the IT infrastructure of data repositories,[2] including patent information collections, is a strong factor accelerating increase in the quality, intensity, and effectiveness of scientific research.[3] An important advantage of patent information collections is their long-term availability (counted even in tens of years). It offers ample opportunities for their utilisation in scientific research. The content of patent databases and long time series describing them allow the aggregation of data at any level. In the case of research on innovation conducted at the microeconomic, mesoeconomic, and macroeconomic levels, patent databases allow one to describe the following features of innovative activity:

1) the novelty level of products resulting from conducted research and development activities,

2) the types of innovations under development and technological competences,

[2]There exist two basic models of providing access to digital objects (records) in IT systems. One of them is remote access in which, during a harvesting process, metadata of resources remaining in the provider's repository are entered into the system repository and such metadata may be made available to the user and in the other model, material is placed directly in the system's repository base.

[3]The first researchers to discover these potential possibilities and to determine the direction of further research were Scherer (1965) and Schmookler (1966). Following the appearance of new technological possibilities (electronic data collections), Griliches (1984, 1990), Griliches, Pakes, and Hall (1987) started the empirical verification of their usefulness. Schankerman and Pakes (1986) were the first to work with data coming from European countries.

3) the sources of innovations, and

4) the dissemination of knowledge and technology.

Patent applications have been the subject matter of research processes for many years [4, 43–46]. What is frequently emphasised is the relationship among R&D activity, patents, and their impact on the stimulation of further R&D initiatives. Not all patent applications lead to the award of a patent. The difference between the number of applications and the number of patent awards may be used as a measure of the effectiveness of R&D activity.

Every patent provides a detailed description of an invention and is categorised into a particular class, group, or subgroup of the international patent classification. The hierarchical arrangement of the system facilitates research on patent applications with respect to novelty and inventiveness; it also allows precise research into technological trends at both the microeconomic level (innovations under development in a given corporation) and the macroeconomic level (the identification of the economy's technological advantages).

The dissemination of knowledge and technology may take place in the form of patents, unpatented inventions, licences, available know how, trademarks, projects, and designs. Attempts to measure the diffusion of knowledge and technology by means of patent databases or market transactions, or to identify relationships between producers of technical innovations and their users, have been made for at least 30 years. The relevant measurement methodologies developed so far emphasise various aspects of the discussion process, while the process of improving the quality of measuring the force of the dissemination of knowledge and technology is still far from its completion.

Thus, patent databases may be used in various ways. The number of patents awarded to a particular company, industrial sector, branch of the economy, region, and/or state reflects the level of technological dynamics. Examining the pace of changes, searching for relationships with particular patent classes or groups may help identify the directions and dynamics of technological changes.

Information included in patent information collections may be divided into the following three major pillars:

1) the technical specification of potential value of a new solution (a technical classification, the number of citations in other patent descriptions, the number of licences granted, the frequency of changes concerning the patentee),

2) the development of an invention (the structure of the team of inventors and their affiliations, the structure and types of applicants, progress in the development of a "triadic patent family"), and

3) the history of an application, which includes the application submission date (in a particular country, under other modes of the safeguard proceedings, etc.), the date of publication, the date of rejection or withdrawal, the date of patent award, the date of the expiry of the monopoly (failure to pay a fee or to extend a patent), etc.

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The main international patent databases maintained and operated by various international organisations include the following:

1) *The European Patent Register*, *European Patent Register* and *Espacenet:* Databases maintained by the European Patent Office,
2) *Patentscope:* A database maintained by the World Intellectual Property Organisation,
3) *DEPATISnet:* A database and information service maintained by the German patent system,
4) *USPTO:* A full-text documentation base of patent applications and patents awarded in the United States of America, and
5) *Thomson Innovation:* A commercial database allowing the exploration of extensive and organised collections of patent applications and patent awards.

Other databases, usually with a particular thematic profile, include Cippix® (chemistry), GenomeQuest (biology), LexisNexis, MicroPatent and Delphion (integration of the USPTO, EPO, and WIPO databases), JP-NETe, and KPA Search In KIPRIS—Free Services.

The basic source of patent information is patent documents, that is published descriptions of inventions included in databases, which are open to the public. Patent databases include information on millions of submitted inventions. They constitute the richest source of information on the current state of technology in a particular field. Patent documents are (usually) published earlier than the technical literature.

At present, the most frequently used fields of patent statistics, remaining at the beginning stage of development, include the following:

1) patent family statistics, that is a stream of applications or a cluster of rights to an invention granted in more than one patent office; this phenomenon is characteristic of and intensifying mainly among entities operating in economically developed countries,
2) an evaluation of the monopoly's title, that is the value of a patent (different from the value of an invention itself) is estimated based on the scope of a patent family (the number and importance of patent offices, the geographical scope of patent protection), the number of citations in other patent descriptions, the length of the monopoly (incurring fees), the fact of initiating an objection/opposition procedure, the number and types of licences granted under a given exclusive right, the location of a protected solution in technology (significance for technological development[4]), the fact of establishing a new company whose business model is based on the patent monopoly,

[4]A company may have at its disposal a few alternative organisational techniques and processes related to product manufacturing, which may differ from one another in small details concerning the organisation and engagement of the production factors. A set of all available organisational techniques and processes related to the manufacture of final products is referred to as production technology. It is a technology specific for a particular company. A collection of all specific technologies constitutes the technology of a branch. The expansion of the collection of technologies in a particular company expands the technology of a given branch (Gomułka, 1998, pp. 12-13.)

3) patent statistics with respect to regions, and

4) patent statistics with respect to gender.

The weaknesses of patents as characteristic features of innovations are generally known. Many new or improved solutions are not submitted for patenting, while others are protected with numerous patents and/or other forms of protection. Many patents have no technological or economic value, while others are extremely valuable in this respect.

4. Patent statistics as an economic indicator

In 1990, the *Journal of Economic Literature* published an article entitled *Patent Statistics as Economic Indicators: A Survey* by Z. Griliches,[5] who regarded technological changes as the main source of long-term economic growth. The narration and arguments used in this article can be characterised in one sentence as follows: "In this desert of data (necessary to describe the sources of economic growth, technological or structural changes, competitive positions, *author's note*), patent statistics loom up as a mirage of wonderful plentitude and objectivity (i.e. qualities required of the time series of economic variables, *author's note*)". Similar studies on the possibilities of quantifying the relationships between technological changes and economic effects had been undertaken earlier by Schmookler [47, 48], Pavitt [3], Basberg [49], and Schankerman [50].

At the beginning of the 1950s, Schmookler [47] referred to a patent as a result of innovative activity. He identified the course of a patent activity trend (determined on the basis of the number of patent applications and patent awards) with some kind of an innovative activity indicator. In patent data collections, he searched for an explanation for the rising productivity of the American economy. However, what should be stressed is Schmookler's considerable carefulness in this respect. In reality, it was difficult to observe any strong and repeatable relationship between the combined productivity of the production factors and the dynamics of patent activity. Therefore, Schmookler indicated the directions of the potential utilisation of patent statistics rather than a measuring methodology itself. However, it should be remembered that in the 1950s, there was no systematic collection of data on R&D expenditures; what was collected was selected (and dispersed) data on the employment of scientists and researchers as well as the movement of the highly qualified research personnel. Patent statistics remained practically the only database which could be used to describe technological or structural changes as well as competitive positions at the microeconomic and macroeconomic levels.[6]

[5]Zvi Griliches, 1930-1999.

[6]In 1963, the first conference of the science ministers of the countries belonging to the OECD was held. It coincided with the publication of the first methodological guidelines for the collection, processing, and presentation of data related to R&D—*The Frascati Manual*. In 1966, the British "Science Policy Research Unit" initiated its activities. This was the beginning of the multidirectional development of statistics in the area of science, technology, and innovation (S-T-I). Analysing the evolution of the S-T-I methodological approaches, one can easily notice functional changes in this category of public statistics. In the 1990s, statistics concerning science, technology, and innovation entered the period of rapid changes.

Despite these barriers, the early 1960s witnessed the beginning, and the subsequent decades the continuation, of the research programme which, from today's perspective, could be called "an analysis of the rate of return from investments in R&D". The researchers who were especially prominent in these first two decades were Zvi Griliches, Edwin Mansfield, Jacob Schmookler, and Nestor E. Terleckyj.

In the first half of the 1980s, Pakes and Griliches [51, 52] put forward an interesting theoretical construct whose aim was to explain the impact of knowledge created in the industry on the productivity of the production factors. In the analysed contexts, they classified knowledge as "technical knowledge of particular economic value (K), accumulated in a particular period of time $\check{k}\frac{dk}{dt}$". In their original model, the explanatory variables of the category $\check{k}$ (of both the input character and output character), they pointed at: (1) expenditures on R&D activity, (2) expenditures on traditional capital goods, (3) patent activity, (4) the productivity of the traditional production factors, (5) the (market) value of a business enterprise.

In this model, a patent (patent activity) is an imperfect quantitative characteristic of a company's innovative activity in a very close relationship with $\check{k}$, (technological accumulation, technological learning):

$$p_{i,t} = dt + \beta \check{k}_{i,t} + v^*_{i,t}, \tag{1}$$

where $p_{i,t}$ is a logarithm of quantitatively described patent activity, dt is a derivative of the function of the time trend, $v^*_{i,t}$ is an error uncorrelated with $\check{k}$ and with t, and β is the flexibility of patent activity with respect to $\check{k}$ (industrial knowledge accumulation, its direction, and dynamics).

Eq. (1) may be interpreted as a simplified model of patent activity.

The 1980s brought considerably greater opportunities for the empirical verification of associations between patent activity and other economic characteristics. Hausman, Hall, and Griliches [53, 54] looked for a standard relationship between expenditures on R&D and patent applications. They formulated four basic research questions concerning the following areas: (1) the strength of the relationship between R&D expenditures and patent applications (patent awards), (2) the flexibility of patent applications in response to changes in R&D expenditures, (3) the distribution of the time series of the effects of R&D activity, and (4) the singularity of the standards in the time courses of these relationships.

They verified their original econometric model empirically, using a sample of 128 business enterprises (1984); two years later, it was already a sample of 642 entities. The results of their research confirmed the hypothesis about the relationship between the examined companies' R&D expenditures and their patent activity.

However, depending on the size of a given company, its patent policy, and the previous results of R&D activity in correspondence with the effectiveness of conducted business operations, this relationship can have different levels of dynamics and strength.

At the same time, Pakes [55] studied relationships among companies' R&D expenditures, patent awards, and market valuation. The conducted research revealed that unexpected (for

the capital market) changes in R&D expenditures and patent activity caused considerable changes in the market valuation of companies.

Griliches [4] asked two fundamental and still relevant questions concerning the possibilities of using patents as an economic indicator. Firstly, which aspects of economic activity are in fact described by patent statistics? Secondly, what is to be measured by means of patent statistics? Despite such questions and justified doubts, he accepts the assumption that patent activity was a good indicator of the effectiveness of research and development activity.

He regarded R&D expenditures as a measure of contribution to inventive activity, while patents—as the result of this activity. He formulated a hypothesis on a strong relationship between R&D expenditures and the number of patent applications. In order to verify the hypothesis, he built the following knowledge production model [4]:

$$P = \alpha K + v = \alpha R + \alpha u + \mathrm{v}, \tag{2}$$

where P is the patents as a quantitative measure of inventiveness or production of industrial knowledge, K is an unobservable variable expressing the net increase of economically valuable knowledge, R is expenditures on research and development invested in inventive activity, U is other sources of knowledge increase, v is a random component, and a is a structural parameter of the model.

According to the original concept, Griliches considered the parameter a standing next to K, R, and u as the same because he was forced to quantify K as follows: $K = R + u$; he had to look at the dynamics of the net increase of the economically valuable knowledge on the side of expenditures. Griliches's model was verified empirically. The main conclusion resulting from research on industrial knowledge production in the United States of America concerns the positive relationship, observable in the long period of time,[7] between expenditures on R&D activity and the intensity of patent applications ($a = 0.76$).

However, nowadays, there is considerable space for the evaluation of the results of inventive activity and the evaluation of the force of their influence on the scientific, technological, and economic environments.

The rapid development of the IT infrastructure of patent databases which has continued since that period allows a relatively objective quantification of the value of a particular technical solution included in a patent description. The citation intensity of a particular patent description, information on granted licences, information on changes concerning the patentee, and the intensity of "triadic patent families" of the entity submitting an application are the main variables which are subjectable to such quantification. Hence, in its essence, $\check{k}$ in Eq. (1) becomes more and more quantifiable.

The traditional evaluative approach to the economic quality and usefulness of industrial knowledge embodied in a new technical solution is a method based on the extension of the patent monopoly. Fees for subsequent periods of protection need to be paid in advance; a typical increase in fees for subsequent periods is described the best by means of the exponential function. It can

[7]The years were 1953–1989.

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be assumed that for a typical business situation, maintaining the patent monopoly is economically justifiable. The longer the patent monopoly is maintained, the stronger (theoretically) the protected solution incorporates economic value.

Hall et al. [16] put forward an approach including the market valuation of a patent portfolio in correspondence to their citation intensity. They draw clear conclusions which, in fact, are the reflection of many years of their research in which patent information was used—(1) the number of citations of a particular patent claim in other patent claims is more important than an increase in the number of patent applications or patent awards, (2) the number of citations of a patent claim in other patent claims influences the market valuation of the patent holder (valuation of listed securities), and (3) the number of citations of a particular patent is a quantifiable manifestation of the diffusion of industrial knowledge.

5. Comments on the methodology of using patent statistics

A patent application is an economic event, one of the many stages in the innovation development process, (frequently) the crowning point of research and development activities. The acquired protective right constitutes a potential resource for an organisation's commercial activity which may evolve into a production factor. A patent is not an innovation, but its intermediate character causes a situation in which patent information constitutes some kind of a bridge between the results of a particular company's R&D activity and implementation activity.

The methodological discussion on the scope and methods of using patent statistics in economic research is not as intensive as the methodological discussions dedicated to innovation or bibliometry. Nevertheless, what results from the discussion is a catalogue of a few fundamental principles of designing research procedures.

Firstly, depending on a particular branch or sector of the economy, business enterprises are characterised by various expectations and strategies concerning the formal protection of industrial property. For example, industrial sectors with long cycles in which final products are created manifest particular prudence in ensuring long-term and strong systemic protection, while other sectors whose curve of demand and technology changes its position relatively quickly do not use the patent monopoly intensively. In this case, the business model is based mainly on the priority of rent. However, a comparative analysis of the same branches and/or sectors of the economy in a properly selected group of countries or regions is entirely justified. While macroeconomic and mesoeconomic analyses will be proper research tools, this will not be the case with juxtaposing business entities of different sizes operating in the same branch or sector. (This is so because the possibilities of acquiring and maintaining the patent monopoly by large business entities are very much different from those available to small and medium enterprises.)

Secondly, one should remember about the differences in patent procedures characteristic for particular cultures or legal systems. They constitute an important qualitative factor influencing

the number of patent applications and eventually awarded patent rights.[8] This problem does not occur in countries following the procedure of a single regional application (e.g. the patent monopoly award procedure based on European patent applications).[9]

Thirdly, it needs to be emphasised that a considerable percentage of both patent applications and patent awards does not translate into any factual increase in the productivity of production factors. Hence, thorough analyses need to take into consideration such criteria as the number of citations of a particular patent description in other patent descriptions, information on granted licences, and information on changes concerning the patentee. The first criterion allows one to determine the value of a particular patent, while the other two, the factual utilisation of new solutions in production processes.

So far, the fulfilment of the condition of "thorough analysis" has been possible only in the case of data collected, processed, and made available by commercial providers of scientific and technological information in such countries as the United States of America, Germany, the UK, or France. The decisive majority of national patent systems do not collect information of this category or the content of patent descriptions is not attractive enough to be cited, and technical solutions themselves are not interesting enough for their property rights to be licensed.

Fourthly, analyses of the efficiency of national or regional patent systems or the effectiveness of entities submitting patent applications need to take into account time shifts. It is methodologically incorrect to conduct an evaluation within the range of the same year (patent applications vs. patent awards). Also, a simple juxtaposition of the time series of patent applications and patent awards does not result in any analytical content.

Fifthly, taking into consideration technological and economic criteria, patent awards are more valuable than patent applications. Therefore, the results on research on the distribution of the former are more relevant.

Sixthly, many stages of processing patent descriptions within a long patent procedure generate risks of the following types of errors: spelling errors (errors in the spelling of business names of applicants, names of inventors, etc.), factual errors (changes concerning formats and conventions of applicant registration, codes of the International Patent Classification, postal codes resulting from changes in the administrative division, etc.), and delays (registration of changes concerning patentees, granted licences).

6. Conclusions

The recent years have witnessed serious reflection on the factual and potential opportunities related to the use of patent statistics in measuring other processes. The appearance of

[8]For example, the "explosion" of patent applications under the national procedure in China in the years 2011–2016.
[9]Among organisations granting regional patent rights, one could mention the European Patent Organization, Eurasian Patent Organization, African Intellectual Property Organization, and African Regional Industrial Property Organisation.

such paradigms as the information economy, the knowledge-based economy, or the creative economy has been unavoidable. In these aspects, patent information becomes a relatively good reflection of the aforementioned development structures.

In 2010, the Patent Office of the People's Republic of China registered a 25% increase in the number of patent applications over that of 2009 [56]. This is just one of the many examples of the worldwide tendency in the field of patent protection. Consequently, there appear huge collections of data and information. Almost all such publicly accessible collections are adjusted mainly to the requirements of patent clearance analyses. It is frequently impossible to conduct any quantitative analyses based on such databases.

Attempts to bridge this gap are made by commercial providers of databases and analytical applications. Nevertheless, it is necessary to indicate basic information shortcomings characteristic for public registers which are used by commercial providers. Their elimination could improve significantly the quality of research based on the use of patent information. This includes collecting the following types of information: (1) the economic classification codes of entities submitting applications for patent protection (this will improve the effectiveness of sector-based research) and (2) notes on granted licences and changes concerning the patentee (this will allow research into the industrial property's secondary trading market; such information could be collected together with fees for the extension of the patent monopoly for the subsequent period).

In the author's opinion, there is still considerable space for scientific exploration based on the use of patent metadata. There are not only considerable risks but also potential benefits related to research based on patent metadata into the following topics: (1) the identification of the strength of synergy in the case of mergers and acquisitions, (2) cooperation networks and the diffusion of knowledge among business entities from different sectors, (3) the degree of globalisation of business activities, research teams, the development and dynamics of team structures, and the spatial mobility of scientific and industrial inventors, (4) economic forecasting, (5) the diffusion of technologies (based on the use of licence information included in databases), and (6) the industrial property secondary trading market.

Author details

Rafał Wisła

Address all correspondence to: rafal.wisla@uj.edu.pl

Jagiellonian University in Kraków, Institute of Economics, Finance and Management, Poland

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Chapter 5

How to Elaborate and Interpret an Expert Report on the Design Area

Olga Ampuero-Canellas, Jimena Gonzalez-del-Rio,
Begoña Jorda-Albiñana and
Nereida Tarazona-Belenguer

Additional information is available at the end of the chapter

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Abstract

Design has become a strategic element for companies, and every year, there is a growing number of companies and designers who request for industrial property protection (trademarks, patents, industrial designs, etc.). However, all these protection efforts do not prevent cases of unfair competition, and we find many lawsuits and trials focus on possible plagiarism between two designs. Since not all judges or lawyers are trained in this discipline, it is essential to consult a design expert. The expert opinion is summarized in a report that is part of the materials used in the judicial process. This work focuses on these reports centered on design issues, like brands, packaging, graphic design, or industrial products, and has two goals: to give some guidelines for the elaboration of these reports to design experts and to set some keys to interpret and correctly understand this design reports to all that person not expert in design. Methodology, guidelines, and conclusions that appear in this chapter are the result of the work developed by the authors in the last 10 years. Conclusions focus on a set of guidelines to elaborate and interpret correctly an expert report on the design area.

Keywords: expert report, design, plagiarism, industrial property, unfair competition

1. Introduction

Today, design has become a strategic element of vital importance for companies. Whether it is applied in its brand, its products, its packaging, its communications, and so on, the design

becomes an essential part of its offer in the market. And in many cases, this design is the main motivation to purchase for the target audience.

It is therefore not surprising that every year there is a growing number of companies and designers who request protection for their designs through patents, industrial models, trademarks, utility models, and so on [1]. Since the design gives them so many benefits, it is normal to want to make sure that no one else can use it.

However, all these protection efforts do not prevent cases of unfair competition, where one company tries to take advantage of the design created by another and present a product or packaging with similar characteristics. And then, we find many lawsuits and trials focus on possible plagiarism between two design objects (brands, products, packaging, etc.).

Since not all judges or lawyers are trained in this discipline, in order to make a decision in this context, it is essential to consult a design expert to analyze the two objects and to determine if there may or may not be a possible confusion in the market. The expert opinion is summarized in a report that is part of the materials used in the judicial process.

This work focuses on these reports centered on design issues, like brands, packaging, or industrial products, and that are used as an essential part to determine if we are, or not, facing an unfair competition case. Basically, it is a written document that compares two designs and discusses the differences and similarities found between them.

There are guides on how to prepare an expert report in the criminalistics fields, forensic engineering, or psychology. However, in design discipline, this type of documents has not been found, and the expert only has the help of those generic documents that explain what an expert report is.

These reports are written by experts in design: collegial designers, professors, researchers, and so on, and they are addressed to people who are not experts in the graphic design field and who need to understand what values are integrated in it to make an appropriate decision on the subject.

Thinking about that, the work has two goals. On the one hand, to give some guidelines for the elaboration of these reports to all those experts who receive a request of this type. On the other hand, to set some keys to interpret and correctly understand this design reports to all that person not expert in design such as judges, court agents, and lawyers.

We believe that this work will be a great help to the designer who is commissioned to write a text of this type. Here you will find suggestions on how to proceed in the comparative analysis of the designs and what items you should compare, what other analyzes you can do, how to plan your work, and, finally, how to adequately and understandably present your conclusions in a written report.

In turn, it is also addressed to all legal professionals who commission the report or read its content. Lawyers, judges, prosecutors, and so on do not have deep knowledge about design and, therefore, need the opinion of the expert to approach this area correctly. They will find guidelines on how design works and how this operation can be used to discern whether or

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not there is a likelihood of confusion in the marketplace. It will also serve to indicate how an adequate report should be in this area and will give them guidelines for carrying out the commission or guiding the expert in its development.

Methodology, guidelines, and conclusions that appear in this chapter are the result of the work developed by the authors in the last 10 years. Throughout this time, authors have elaborated several reports on design, including branding, graphic design, packaging, and product design. Most of the reports focus on the Spanish market, but some of them also deal with European and international markets. This experience will be reflected in the reference to concrete and real cases throughout the work to improve theoretical explanations.

Throughout the text, we will use the word "design" to refer to any product of the designer's work that can be investigated in an expert's report. Thus, when we say design, we will be referring to any of its applications: brands, packaging, graphic design, industrial design, and so on.

The chapter has five sections. The first and the second serve as an introduction. The first section is a brief tour through the intellectual property legislation and the legal concepts that are usually mentioned in a trial of these characteristics and that should be understood by the expert to be able to attend to the order that is made to him and to understand what is what is he ask for. It is a quick and brief review because we understand that the expert is an experienced person in design and not in legal issues, so he really does not need to know the entire complex of intellectual property legislation to be able to correctly perform a report.

The second section focuses on the expert report concept. Since no references have been found in the design field, it has sought in other disciplines how they have solved this issue to get from there what could be also applied to the design field.

The following sections are already focused on the expert report on design. The third section proposes a work methodology and diverse analyses to do in order to obtain a more reliable valuation of designs. The fourth section is a guide for the writing report, which discusses the style of writing, the graphic aspect, and the contents. By last, the fifth section of the chapter concludes the work and resumes a set of guidelines to elaborate and interpret correctly an expert report on the design area.

2. Protection of design and industrial property

When the design expert is faced with the task of making an expert report, he perceives that not only the knowledge he has about design is enough but he also needs to know some of the legal aspects involved in the process. To this, we are going to dedicate this first section that will also serve to connect the two disciplines with each other.

Design is as much a production of the mind or intelligence as a commercial activity; so, many companies make use of it to configure their offer in the market. As such, it is an activity that is protected by intellectual property laws.

"Intellectual property, very broadly, means the legal rights which result from intellectual activity in the industrial, scientific, literary and artistic fields" [2]. Traditionally, intellectual property is divided into industrial property and copyright. Inventions, industrial designs, trademarks, service marks, commercial names and designations, indications of source, and appellations of origin are collected in the first block, and literary, artistic, and scientific works in the second.

The protection of these creations is something that benefits not only its authors but also the recipients of these creations and the social and economic well-being in general. In fact, the Universal Declaration of Human Rights in its article 27.2 states that "everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."

The regulations on intellectual property are extensive and cover not only national but also international areas, existing agreements that group several countries. There is also a global organization that deals with these issues: The World Intellectual Property Organization (WIPO), which is the global forum for intellectual property services, policy, information, and cooperation.

The first important agreement at the international level concerning the protection of industrial property rights is the Paris Convention, adopted in 1883. It uses the term industrial property in its broadest sense, including patent protection, drawings and industrial models, brands, and trade names.

More recent is the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), which was signed in 1994. It contains a set of basic rules on intellectual property with the intention of harmonizing these systems between the signatory countries and in relation to the World trade.

At European level, Directive 2008/95/EC of the European Parliament and of the Council of 22 October 2008 on the approximation of the laws of the Member States relating to trademarks should be mentioned. We also find the Treaty on the Law of Trademarks (TLT), adopted in 1994, and the Patent Law Treaty (PLT), adopted in 2005, expect to harmonize and streamline national and regional patent and trademark registration procedures, respectively.

From the point of view of design and expert reports, it is important to differentiate between the diverse fields of industrial property protection: trademarks, patents, utility models, industrial designs, and so on. Perhaps what is most characteristic and common to all these fields of industrial property is the requirement of novelty that is demanded for a design to be registered and protected. This requirement means that the design differs from the previous, that is, there is no relevant disclosure or the market does not know the existence of a similar prior design.

Legal design protection is fundamentally aimed at avoiding unfair competition, one of whose forms is any act capable of creating confusion, by any means whatsoever, with respect to the establishment, products, or commercial activity of a competitor (article 10bis Paris Convention for the Protection of Industrial Property). It is therefore essential the products be presented correctly differentiated, without the danger of an undue association between them.

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In determining this likelihood of confusion or association, case law uses the term "average consumer" or "informed consumer." It is a user "normally informed, reasonably attentive and insightful, taking into account social, cultural and linguistic factors" [3]. It is not a consumer without any information but also a professional consumer with a high capacity of discernment but has a normal but critical capacity to analyze the product.

3. The expert report

Many judicial processes deal with social, labor, technical, artistic, and psychological issues unrelated to the judge's knowledge who is the one who should give an opinion in the end. In those cases, "when scientific, artistic, technical or practical knowledge is needed to assess facts or relevant circumstances in the matter or to acquire certainty about them" (Article 335 Law 1/2000, of 7 January, on Civil Procedure, 2015), the legislation usually contemplates the possibility of consulting an expert who contributes his vision of specialist on the subject.

The expert, through his work, "contributes to improve the understanding of the facts in dispute that the court must uphold" [4] and serves as a guide to the judge in his decision-making, providing "clear and substantiated responses to the specific and complex problems about which they are consulted" [5]. In a certain way, "they thereby help to make justice more effective" [5] by providing "the necessary technical knowledge for the assessment of the facts that are the subject of the controversy" [4].

The report drafted by this expert, the expert report, is part of a larger text: the judicial record, which brings together the different documents produced in the different phases of the trial. "It is not a public text but destined to a restricted number of actors: the judge, the lawyers and the court officials" [6].

The expert work is not open to any person, but it is required to demonstrate the knowledge in the subject on which the report is going to be made. In Spain, "the experts must have the official title corresponding to the subject matter of the judgment and the nature of it" (Article 340 Law 1/2000, of 7 January, on Civil Procedure, 2015). Therefore, it is the academic title that confirms the mastery of a certain subject and the greater degree this title has, greater consideration will also have the assessments expressed in the report.

When the report refers to disciplines not included in official professional titles, the existence of unqualified experts, who must be named among "understood persons" in the subject matter (Article 340 Law 1/2000, of 7 January, on Civil Procedure, 2015), is admitted. Therefore, although this possibility exists, "the use of non-official graduates is exceptional" [7].

In summary, we can understand by expert that person "technically suitable and capable, called to give opinion and judgment based on a process, about the verification of facts whose clarification requires special knowledge about a certain activity, technique or art, which is alien to the judge "[4].

At the European level, there is a consensus on the requirements that the expert is required to make in his report: "competence, independence, subjective and objective impartiality and a

strict standard of ethical conduct" [5]. The Spanish legislation focuses on the issue of impartiality because it literally requires the expert to submit his opinion when issuing his judgment, under oath or promise to tell truth, that he has acted with the greatest possible objectivity, taking into account both what can favor and what is liable to cause injury to any of the parties (Article 335 Law 1/2000, of 7 January, on Civil Procedure, 2015).

The expert therefore has to be impartial and "as a collaborator of justice, he must submit to the court a specialized aid in an objective, impartial and independent manner" [4].

Therefore, the aspects that should characterize both the expert and the expert report are professionalism, represented both by a broad knowledge of the discipline and by having proven experience in it; objectivity and impartiality, not to benefit one part to the detriment of the other; clear, rigorous, and orderly presentation of the ideas and the work process; and objective justification of all claims through the use of verifiable data.

The Spanish legislation indicates that these opinions shall be made in writing, "accompanied, where appropriate, by other documents, instruments or materials adequate to present the opinion of the expert on what has been the subject of the expert" (Article 336 Law 1/2000, of 7 January, on Civil Procedure, 2015).

Regarding the contents of this document, at the European level, "a report should be expected to be built around three strands: the statement of facts (…), an analysis of the points at issue and an account of the approach taken by the expert leading to the reasoned position" [5].

Apart from the legal scope, the Spanish Association for Standardization-UNE has a technical standard named "General criteria for the development of expert reports" (UNE 197001) that establishes the structure and minimum requirements of an expert opinion or report in order to guarantee the quality and understanding of the conclusions drawn by the expert.

According to these regulations, an expert report is divided into four sections: identification, index, body of the report, and attached documents. The body of the report includes the contents of the expert's work: objective or purpose of the report, scope or issues raised by the applicant, background, preliminary considerations for the research understanding and the methodology used, reference documents, terminology and abbreviations, analysis carried out, and conclusions.

If we focus on specific disciplines, some authors also address this issue. They propose, starting from the particular characteristics of each activity field, a series of steps or contents that must be contemplated by the expert in his work or in the writing of the report.

Noon [8] proposes that the working process to make a report of an accident, crime, catastrophic event, or failure is structured like a pyramid (**Figure 1**). There is a great deal of evidence and verifiable data at the base or at the beginning of the expert's work. The analysis is then carried out and a smaller number of data is obtained. Finally, the union of evidence and analysis leads to even fewer conclusions.

According to this idea, this author proposes a report format consistent with the pyramid method of investigation (**Figure 1**) with the following sections: report identifiers, purpose,

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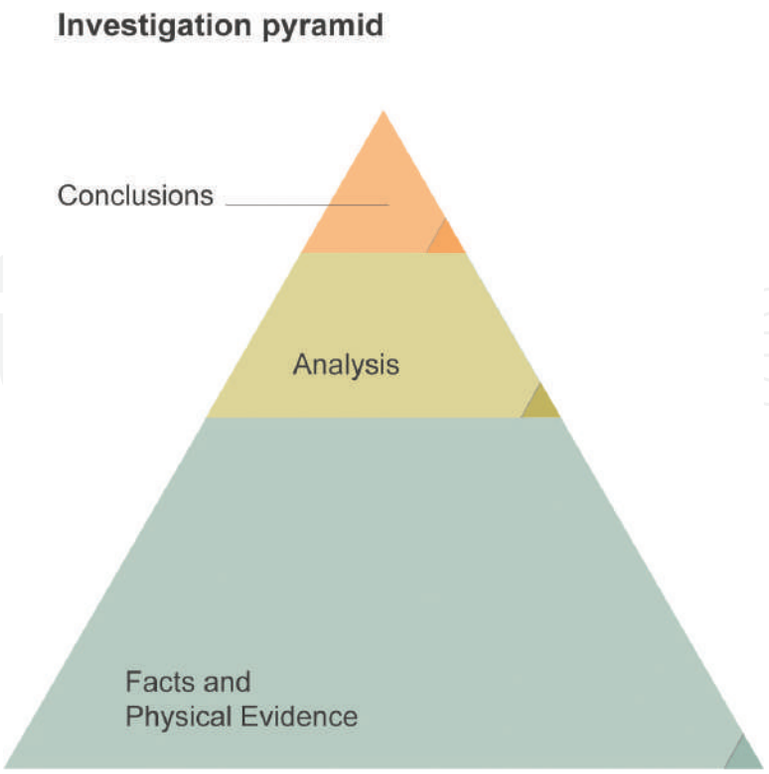

Figure 1. Investigation pyramid [8].

background information, findings and observations, analysis, conclusions, remarks, appendix and attachments.

In the area of criminal investigation, Bar [6] considers that a report should contain the following sections: technical foundations, operations carried out, objects subjected to expertise, and conclusions.

Ávila Espada [9] proposes the following contents for a psychological assessment: introduction, procedures used, derived conclusions and their discussion.

In the economic sphere, the expert report "must indicate what it intends, why, what documentation has been analyzed, what calculations have been made and why and to what conclusions has been reached" [10]. The sections that in this area should at least have a report are scope and understanding of the expert question, documentation analyzed, methodology analyzed, body of the report, and conclusions [10].

Although we find some differences, it seems that all the guidelines analyzed agree on a similar structure: background, documentation studied, methodology, analysis, and conclusions. We always start from a commission associated with a set of facts or documentation that needs to be analyzed. The accomplishment of this analysis and the applied procedures will depend on the habitual practices and own of each discipline. The expert must rigorously explain the processes performed to justify in this way the reliability of the results obtained. Finally, the process must end with the drafting of conclusions that help the judge to decide on the process,

since the expert function is not to reach conclusions regarding the sentence but to facilitate the specialized knowledge for the judge to elaborate it [11].

4. Working methodology for a design expert report

The process of conducting an expert report begins with the assignment of the work and ends with its delivery and, if necessary, with the appearance of the expert before the judge to explain his expertise. Between both extremes, different tasks are carried out that conform the following methodology (**Figure 2**).

4.1. Definition of the objective

The first thing is to be clear about the purpose of the report, that is, what it is intended to achieve with it. Usually, this objective can be extracted from the words with which the work was commissioned.

Most reports in the design field deal with the comparison of two or more designs in order to determine their degree of similarity and thus answer the question of whether there is risk of error or confusion in the market. Therefore, the expert's work is not limited to comparing the designs and to say whether they are the same or not, but to think about the using moment and consumption of the product and to determine if there could exist possibility of error in the consumer.

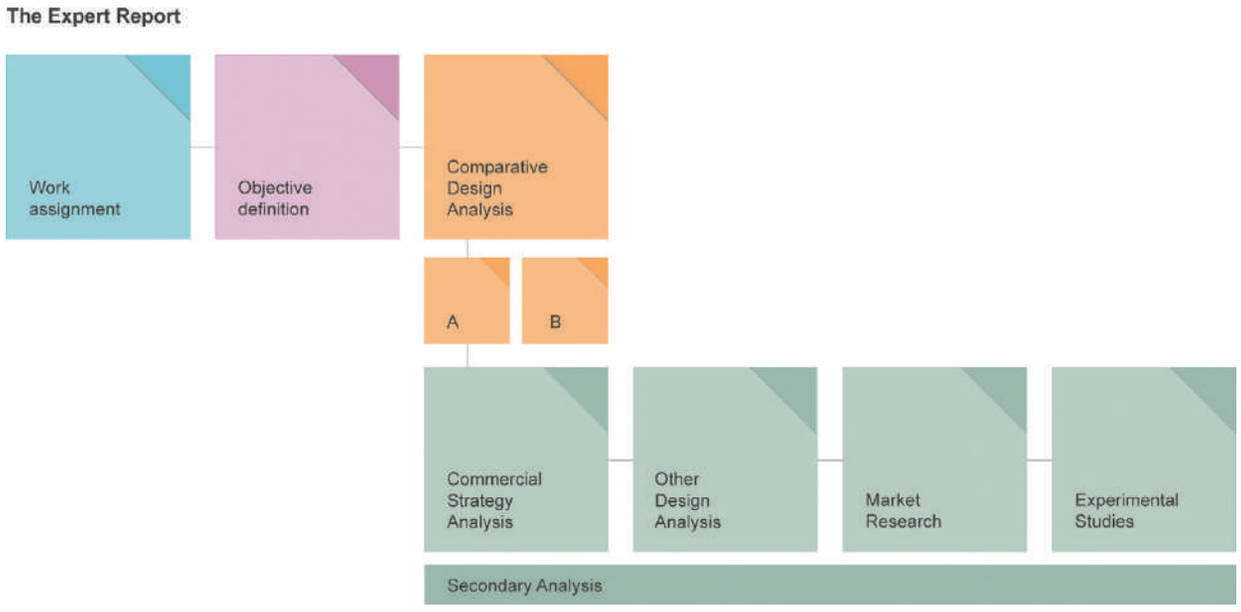

Figure 2. Working methodology for a design expert report.

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Thus, a comparative analysis of two designs could establish enough differences between both, but if these are not significant enough, there would still be the possibility of creating confusion in an informed user. Conversely, there may also be few differences between designs but these reside in key aspects that would make a product perfectly distinguishable from another and therefore there would be no possibility of error.

4.2. Comparative design analysis

The first work developed by the expert is the comparison of the two or more designs under dispute to determine what differences and what similarities there are between them. These designs can be very different in nature: brands, illustrations applied to products, packages, products, and so on. Although they are all inserted in the design scope, they differ in nature and characteristics, so the comparative analysis will vary from one to another.

In the first place, the ideal scenario is that the expert can access to a physical sample of each of the designs that must be compared and that this physical sample means at its disposal throughout the expertise implementation process. The characteristics of the design will be better appreciated if he sees and manipulates it directly than if he does it through a photograph or a model.

If, because of the object bulkiness, it is not possible to always have it present, it is convenient to make detailed photographs of all the elements that make up the object taking into account different perspectives. So, we can turn to them at any time and fill in some way the lack of the physical sample.

Another information source for this comparative analysis is the design registration as a brand, industrial model, patent, and so on, if there was one. Typically, this document is delivered at the time of commissioning, but if this is not the case, the expert can request it or search it through the web at the registration offices. These documents provide a better understanding of the elements that make up the design and which are the most significant characteristics so that special attention can be given to them throughout the report.

To perform the comparative analysis in a more systematic way, it is recommended to start from the theoretical knowledge established in the design plot that we are analyzing: brand design, fashion design, packaging design, product design, and so on. This theory will tell us what elements are key in the design and on which of them we should focus our analysis. This procedure gives as much professionalism in the ideas presentation as exhaustiveness in the analysis approach.

We then write down the sections that each analysis should have according to the analyzed design discipline.

- Graphic design: Color, typography, images, layout [12].
- Branding: According to Costa [13], a brand has a verbal component, name, and three graphic components: logo, symbol, and color.

- Packaging: Hine [14] claims that a packaging has structural and graphics components. Therefore, we will divide the comparative analysis in these two sections: first discussing the structural aspects (shape, size, weight, material, etc.) and then the graphs (colors, typographies, images, etc.).
- Product: In the Ulm school, regarding the product design, the design methods were evaluated, in which all the factors that determine a product were considered: functional, cultural, technological, and economic factors [15].

Once the items to be compared are established, it is recommended to start by making an individual description of each object and then to compare them. In this way, we obtain a more objective and detailed analysis that includes all the elements and characteristics of each design and not only those with more evident differences and similarities. Subsequently, the expert will decide which of them are most significant and relevant to the informed consumer and, therefore, in which to focus their conclusions.

After this analysis, we can proceed to establish whether or not there is risk of confusion in the market and terminate the work. However, in many cases, the expert is required to complement this main analysis with some others that will allow clarification and reinforcement of the comparison findings. We will see what types of analysis can be realized in the following sections.

4.3. The commercial strategy analysis

At the moment, the designs are not used in an isolated way but within a commercial strategy that configures its presentation to the market and, therefore, the image that the consumer has of them. Thereby, if the expert has to decide if there is a risk of confusion in the market, he needs to go beyond the comparison of the designs and also study the commercial strategy that surrounds them.

The commercial strategy of any product (or design) is basically composed of what in 1960 Jerome McCarthy called marketing-mix: product, price, place, and promotion [16]. This concepts combination shows us that the product is not alone, but its presence in the market, in front of its possible consumer, is complemented by a price, a point of sale, and advertising messages.

The data needed to know the marketing-mix of the studied designs can be obtained by going to the company itself or, if this is not possible, by consulting its website, generic or specialized publications, social networks, and so on. In this way, we can know aspects about the product: price, ingredients, packaging, personality, commercial name, color, flavor, and so on; on the price: if it is more or less expensive than the one of the competition; on its distribution: type of stores, places where it is marketed; and about its communications or advertising: media in which it advertises, campaigns messages, and so on.

In order to complete this information, we will also be interested in knowing the type of consumer the design is directed to. This way, we can understand how he perceives the product, how he interacts with it, and what elements are most important at the time of purchase and use.

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All this commercial information will allow the expert to judge both designs in a more real way (not isolated from the other elements of the marketing-mix) and, therefore, to decide with greater certainty if there is, or not, possible confusion in the market. Since a design does not exist in an abstract or isolated way, but it is always immersed in a particular commercial situation, it is important to assess this circumstance when issuing any conclusion.

To clarify more how this information helps in making an expert report, we can put as an example the report developed for two brands in the textile sector that used a graphic mark that, according to the lawsuit filed by one of them, could lead to confusion in the consumer. After the initial study comparing both brands, the market situation of each of them was also analyzed. It was then found that each one was concerned to a different market segment and this was reflected both in the characteristics of the product as in its price, in the stores decoration, in the graphic elements, and the style of communication used in the websites, catalogs, advertising, and so on. Therefore, although there was some similarity in the graphic aspect of both brands, its commercial strategy and, thereupon, its presentation to the consumer were totally different. On the basis of this fact, the findings of the report focused not only on the similarities or graphic differences between the brands but also on the different commercial strategy of each to determine the reduced risk of confusion in the market.

4.4. Other designs analysis

In some cases, the expert will find it useful to also carry out the analysis of other designs of similar characteristics to those in dispute. In this way, he could determine if the similarities he has found between them are due to a clear intention to copy by one of them or that they belong to the same product category or have followed a similar design process.

For example, the expert report on two margarine packaging was completed with a study of other margarine packages on the market. After the analysis, it was determined that all the margarine packages used a structural design, a box with similar characteristics, and that what differentiated some brands from others was the graphics. This allowed the expert to reduce the importance of the similarities found in the structural aspect and to focus his conclusions on the similarities of the graphic aspect.

In other cases, the similarity between two designs may try to justify itself by saying that in the creation process, the same concept has been taken as a reference. The expert should analyze other designs inspired by this concept to determine whether or not the designer has a wide range of design possibilities to represent that idea and, therefore, the similarity between designs is not justified.

In both cases, the work process is similar. We begin by compiling designs that have the characteristics we want by noting in detail which sources we have consulted and then being able to include them in the report. The greater the category and relevance of these sources within the scope of design, the greater the validity of the conclusions that we obtain. Then, a file is made with the parameters to be measured from each design and each one is analyzed. Finally, the conclusions are established indicating the characteristics that the studied designs share.

4.5. Market research

Taking into account the market research used in the marketing field to know the users' opinions, the expert can also raise an inquiry of this type to verify if there is risk or not of confusion in the market. The goal will be to ask informed users if they are able to differentiate between the designs.

In order for the results of this research to be considered valid and reliable, it is recommended to consult a commercial research expert who can guide us on how to choose the sample, how to raise the questionnaire to avoid any kind of bias, how to develop the fieldwork, and, finally, how to analyze the data and draw conclusions.

Raising a reliable market research requires a good investment in time and resources that it may not be willing to take on. In any case, it must be remembered that, if it is possible to do so, its results will be a good help in drafting conclusions and will constitute further evidence on which to base the opinion.

Another more affordable option is to design a smaller research, with fewer questions and a smaller group of users. In this case, it loses validity and reliability, but we have one more data to add to our report and conclusions.

4.6. Experimental studies

We call this way any more detailed analysis of the designs being studied and which involves a procedure other than the simple observation or tactile recognition of the object. In them, the expert can use his knowledge on the use of specialized software in design.

Thus, for example, in a case of comparison of designs applied to a footwear, the illustration that constituted the stamping of each boot was proceeded. The drawings were passed to the computer and different parts of the designs were compared by superimposing the strokes. In this way, it was possible to determine in which specific parts the second design imitated the first and did it in a practically identical way. Something that was visually intuited through this system could be technically demonstrated.

In another case, the photographs' color of both designs was also eliminated with a computer program of image edition. In this way, the similarity between the lines that made up the illustration could be better perceived and, with this documentary support, justify the presence of similarities between the designs.

5. Writing the expert report

Once all the analytical work has been done, the expert goes to write down his work process into a document and to propose a series of conclusions to answer the research objective stated at the beginning. In this section, we will deal with the topics of the writing style, graphic aspect, and contents of this report.

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5.1. Writing style

In the writing of the text will be used a technical, understandable, and very didactic language. The expert must express himself as a skilled person in the subject and, therefore, will use the proper vocabulary and expressions to the design discipline in which the opinion is inserted. But he cannot forget that he is addressing people outside the world of design, judges and lawyers, who must understand his explanations and follow his reasoning, so he will try to be as clear as possible.

The technical words should be defined the first time they appear in the text, either by an insert in the paragraph itself or by a footnote. To include in the annexes, a glossary with the jargon used could also be chosen, but we consider that this is impractical because it slows down the reading process.

In the case of doubting between the use of a very technical term and a more popular one, it is convenient to use the second one so that the idea can be understood by the recipient without having to resort to a dictionary. Although it may seem that the academic or professional level is reduced, reading is also streamlined and the reader can focus on what is really important: not in learning new concepts but in the opinion expressed by the expert.

5.2. Graphic aspect

In these types of reports, it is essential to take care of the presentation. If, at the beginning of it, we introduce ourselves as design experts, this should also be present in the work layout, the fonts and colors choice, the images presentation, and so on. If the written document does not maintain a suitable formal appearance, the reader may doubt our knowledge of the design basics and does not correctly judge our judgments about designs.

In this regard, we recommend following the recommendations that any editorial design manual suggests to create a nice page to read and visualize. For example, use wide margins, a typographic font suitable for large texts, a legible font size, a suitable line length and line spacing, and so on.

It is also important to use good quality images (photographs, graphics, or infographics). In the case of photographs, it is not necessary to use a professional photographer, but at least take care and respect the following tips:

- It should be used light diffusers or, if the size of the object allows, use light boxes.
- To make a good composition, it is essential to use the tripod.
- The focal length should be greater than 35 mm to prevent lines from distorting.
- If reflections appear due to the material (metal, glass, etc.), we must repeat the photograph away from the object.
- Avoid fingerprints or specks on both the object and the lens used for the photograph.
- The resolution of the images should be between 220 and 300 pixels per inch so that they look correctly when printing the document.

5.3. Contents

Based on the sections that the authors consulted establish for an expert report of a general nature (UNE 197001) and of particular disciplines [6, 8–10], we establish nine sections that should be included in an expert report in the design field (**Figure 3**).

In cases where the report is very long, Noon [8] recommends including an executive summary at the beginning of the text. This summary should not occupy more than one page, and it presents the most important content of the research, highlighting the conclusions reached.

5.3.1. Cover page

The most important element of the cover is the title that defines and describes the report content. Usually, the name or the types of products at issue are mentioned. Together with the

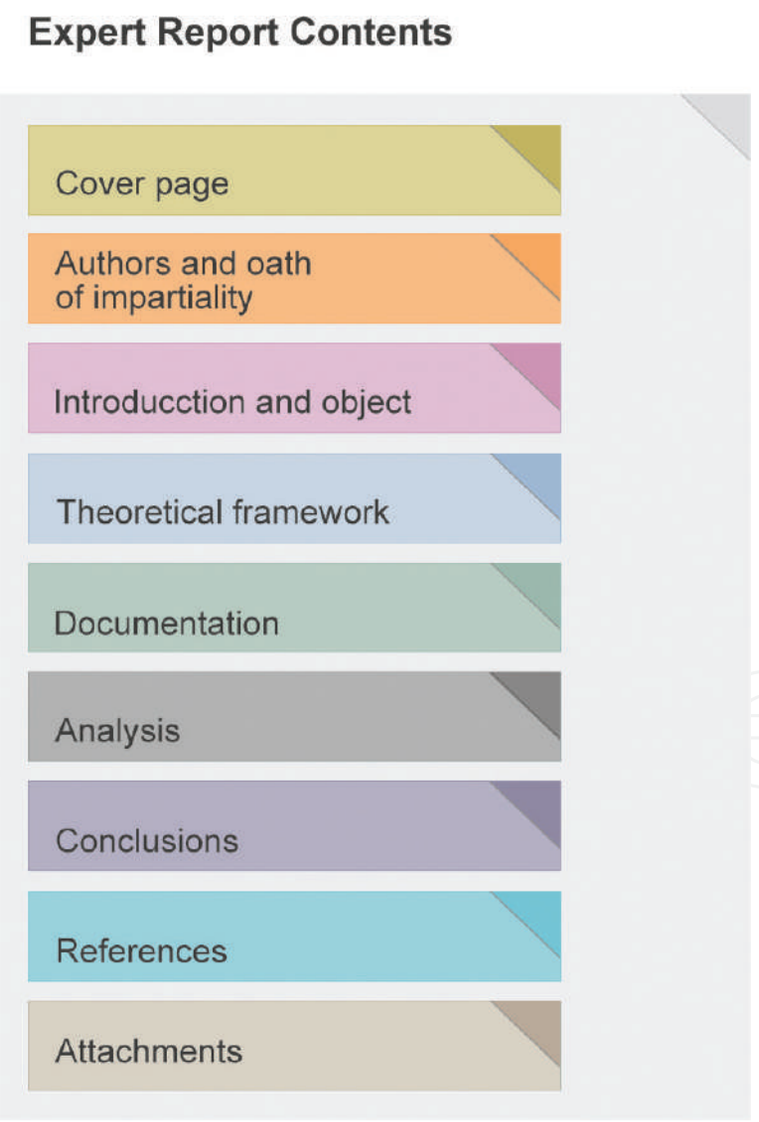

Figure 3. Contents for a design expert report.

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title, the date and place of realization and the authors are indicated. If the experts work within an organization (university, school, professional college, etc.) can also be included the brand of this institution.

5.3.2. Authors + oath of impartiality

On the next page and before the index, the name and surnames of the report author or authors will be recorded. Together with them, we will indicate their titles and/or positions, that will be what will value the content of the report. In this way, the experts are presented as connoisseur and experts in the subject on which the opinion will be based. We recommend to not include titles that are not related to the design discipline, in order to give more emphasize to those titles related to design.

Along with these names should be included the oath of impartiality of the experts. In Spain, it is included in article 335.2 of Law 1/2000, of Civil Procedure. Through this text, the experts state, under oath to speak the truth, that they have acted with the greatest possible objectivity taking into account both what can be favored and what is likely to cause harm to any of the parties, and that they know the Criminal penalties they could incur if they failed to do their duty as experts.

5.3.3. Index

It is recommended to write an index if the report consists of more than 10 pages. This makes it easier to read and, above all, re-read, so that you can quickly access the data or section you are looking for. This index also shows the structure that articulates the work.

5.3.4. Introduction and object

The next section should be an introduction that explains the subject of the report, the motivation, the objective or objectives that are pursued. The methodology used to achieve this objective will be explained, and, in the end, the sections contained in the report will be presented.

5.3.5. Theoretical framework

This point may be considered optional but, in certain circumstances, the expert may consider it useful to include a brief review of the theoretical corpus in which the report is inserted. It is not a scientific article and it is not necessary to explain everything, but we must indicate the most important and necessary so that the report can be properly understood. In a clear language, we can explain the parameters on which the expert report was based.

In order to decide which topics to introduce and which ones not to introduce, it will be useful to ask what aspects of the design discipline the report is about, the recipient needs to know in order to fully understand the text. For example, in the case of a brand, we can briefly explain the process of creation, the parts that make up a brand, how each is called, what requirements must be met, how the consumer perceives the brand, what media is included, and so on.

All this theory should be reinforced by reference to authors considered relevant in the subject. In this way, the expert demonstrates both the knowledge of the subject and that the expert analysis is based on established and recognized knowledge of the discipline.

If you choose to include this section, it should not extend beyond two pages. If it is necessary to be longer, it is recommended to place it as an attachment at the end so that it does not interrupt the reading of the report.

5.3.6. Documentation

The following is a list of each document used, following the same order in which they will appear later in the report. It is also advisable to identify each of them with a code or number so that they can be referred to in the text in a concise manner, without having to write the complete denomination.

It should also be indicated where each document comes from. Some will have been delivered together with the order but others will have been sought by the expert. In the latter case, it will be indicated how the collection work was carried out: sources consulted, search engines used, information collection system, and so on. In this way, we indicate the degree of reliability of the different documents and, therefore, of the conclusions which are based on them.

Also, if desired, you can include here images or photographs of documents consulted. But if the amount of graphic material is considerable, more than five documents, we consider it best to include all the graphic information in one or more attachments.

5.3.7. Analysis

Next comes the compilation of all the analysis work done by the expert to meet the objective marked in the order. Obviously, this section will be the most extensive of all, and, if several analyzes have been done, it is recommended to subdivide it into several sections to make reading and comprehension easier.

We must begin with the comparative analysis of the designs in dispute as it is the most important analysis and the one that the reader will pay the most attention. The rest of the analyses can be considered of secondary character, and their function is to reinforce or to qualify the conclusions drawn from the first one.

When comparing the designs with each other, we will begin by explaining and describing each design individually, identifying the characteristics of each one separately. Afterwards, the results of their comparison will be explained and the similarities and differences found will be exposed.

A two-column layout can be used to present the descriptive analysis of each design in a visual and easy way. On the left side, we would place the analysis relative to design 1 and on the right side, the analysis relative to design 2. Thus, the reader will appreciate more clearly the different items that have been compared and the differences or similarities between them.

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After presenting the results obtained in each analysis, a brief summary of the conclusions will be made, citing both the similarities and the differences found, since, following the oath of impartiality, the expert should not emphasize one position more than another. In addition, in this section of analysis, the expert only describes the methodology of analysis followed and the results obtained, leaving the conclusions for later.

It is also advisable to attach photographs or diagrams to better understand the arguments being presented. If necessary, photographs can include numbers, arrows, or strokes to highlight the details being explained. So, for example, if you want to emphasize that one design has a circular shape and the other oval shape, we can superimpose a circle or an oval to the photographs so that the idea is better appreciated.

We can start the section with a general photograph of the designs, but then, as we comment on the analysis process, partial or detail images should be used to better understand each argument. So, for example, if we are comparing the wheels, we will locate an image where only the wheels are seen and not the whole product.

The secondary analyses that we include after the main comparative analysis (analysis of other similar designs, analysis of the commercial strategy, market analysis, etc.) should be less extensive and occupy less number of pages. The photographs of the documents analyzed are usually included in one or several annexes and within the text, only the methodology of analysis and the results obtained are explained, as well as their relation with the main analysis.

5.3.8. Conclusions

It is best to start by summarizing the documentation analyzed and the work process followed. The reader who goes directly to read the conclusions will know what analysis they come from, and the one who has read it from the beginning will be able to recapitulate and remember the most important of the previous chapters before proceeding to the conclusions.

Obviously, the conclusions try to answer the objective defined in the introduction, so it is better to read it again to remember it. It may also be a good practice, after writing the paragraph, to read the objective again and to verify if it has been clearly answered in the conclusions.

We begin the conclusions by listing and indicating the similarities and differences found between the two designs in the comparative analysis. Then we confront them with the rest of the information extracted from the secondary analyses and interpret the results again.

Finally, we try to respond directly to the research question or objective of the report. In most cases, it will be tried to explain if the existence of both designs could create confusion in the market. This statement should be reasoned as an expert, based on the data revealed by the analysis and providing technical and scientific parameters, so that it is not perceived as a mere personal opinion.

5.3.9. References

This section will indicate the bibliographic documents that have been consulted or taken as a reference both in the preparation of the report and in the analyses carried out. We refer to manuals, dictionaries, scientific journals, daily newspapers, and so on.

5.3.10. Attachments

It has already been mentioned in the previous paragraphs, the existence of a section of annexes where to include that information that does not "fit" within the main text. These are data of secondary or tertiary character whose presence within the text would only prolong without reading the latter. These are materials that you do not need to read to properly understand the report.

6. Conclusions

The increasing use of design as a distinctive element of the companies' offer makes it often attacked. The industrial property regulations that try to protect it are infringed by actions of unfair competition. The judicial processes started to decide on these aspects usually include one or more expert reports that present the expert's point of view on the case to judge.

There are documents with guidelines on how to make an expert report raised both from a generalist level and from a specific discipline such as criminalistics, forensic engineering, and psychology. However, it seems that the design field does not have texts of this type.

This chapter tries to fill this space and presents a series of indications on how to guide and present an expert report focused on design. We consider it very important that there be actions such as this to try to normalize, in some way, the preparation of an expert report and thus obtain professional and effective reports also in this area.

To do this, we have started from what has been exposed in other disciplines to adapt it to the characteristics of the discipline of design and also has taken as reference the expert reports on design drafted over the last 10 years by the authors. The result is a set of notes on how to propose an expertise in the field of design, which obviously do not present as a rigorous regulation that must be fulfilled in any case but rather as recommendations that the expert can take as a reference for, from them, build their own method of work.

We then summarize the recommendations that we consider to be most relevant either because they contribute greatly to improving the content of the report or because they are aspects of design that have not been found referenced in any other discipline.

The first one is the way to present the comparative analysis between the designs beginning with an individual description of each of them and then move on to the comparison and detection of differences and similarities. Throughout our experience in the development of expertise, this method of presenting the analysis has proved to be uniquely clear and systematic both from the point of view of the expert and from the point of view of the reader. The expert thus becomes more objective in explaining how he has performed the analysis and does so in an orderly manner and without forgetting any aspect. The reader, judge or lawyer, accesses

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this information in a gradual way, by parcels, which allows him to bit by bit understand the succession of ideas expressed by the expert and perceiving the exhaustiveness with which the analysis has been carried out.

Second, the comparative analysis of designs should, whenever possible, be supported and nuanced by other analyses that describe how each design is presented in the market. We start from the fact that no design is alone but immersed in a commercial and competitive situation. Both the elements that accompany it in its presentation before the user, packaging, advertising, shops, uniforms, brand, and so on, like the rest of competing designs, influence the perception that the informed user has of a design.

If all products in a particular category tend to be red, then it is suspected that only the two products in dispute are green. But if all or the majority are green, then that circumstance ceases to be so peculiar and suspicious. The "green" characteristic is not a distinguishing sign of either product but of the whole category. Therefore, it is not a relevant similarity in determining whether there is a likelihood of confusion in the market.

Judging whether there is a possibility of confusion in an aseptic environment, where only these two designs are found, is unrealistic. Therefore, the expert must take into account the market situation of each design to correctly assess the differences or similarities between the designs. This results in including in the report the marketing-mix study of each design or the analysis of other similar designs.

When issuing the conclusions, it is important to evaluate the design from the user's point of view, knowing which aspects are most relevant when deciding the purchase. The fact that the similarities founded are in those more relevant aspects will increase the severity of the copy that if the similarities lie in aspects less valued by the public.

The design is not only something graphic or object but it also enters the communicative field. Just as everything in a company communicates, the characteristics of a design also tell a lot about it. Therefore, the expert will take this into account when giving his opinion in the report.

Last, but not least, is the caring of the formal aspect and content of the report. We must not forget that the expert report is an instrument of communication between the issuer (the expert) and the appointees (judge, lawyers, etc.) and, therefore, must take care of especially everything that favors this communication. We talked about both the formal aspect and the content of the report. Since the expert presents himself as an expertise person in design, he can't present a work that lacks it. In terms of content, a precise but understandable language will be used at all times, as the report is intended for non-experts in design.

Author details

Olga Ampuero-Canellas*, Jimena Gonzalez-del-Rio, Begoña Jorda-Albiñana and Nereida Tarazona-Belenguer

*Address all correspondence to: olga@mag.upv.es

Universitat Politècnica de València, Spain

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Chapter 6

Host-Country Patenting and Inventorship in Emerging Countries

Alexander Gerybadze and Daniel Sommer

Additional information is available at the end of the chapter

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Abstract

We analyze the increasing globalization of worldwide research and development (R&D) with a focus on emerging countries, by using patent data as a proxy. The number of host-country patents has skyrocketed in the emerging countries, for example, the number of US patents created with foreign inventors in China and India has more than decupled between 2000 and 2013. At the same time, emerging countries, such as China, Korea, India, Israel, Brazil, and Russia have significantly increased their patenting efforts, with China attaining rank 3 with more than 10% of all worldwide Patent Co-operation Treaty (PCT) patents in 2013, up from position 9 in 2000. Thereby, the former dominance of the Triadic countries has been reduced considerably. We conclude that the flow of innovation in emerging countries is not a one-way street anymore, but rather goes in both directions.

Keywords: host-country patenting, innovation, R&D, internationalization, patent analysis

1. Introduction

Globalization of research and development (R&D) and a rapid build-up of science and technology in many countries of the world can be observed during the period 2000–2016. An increasing number of emerging countries attempts to build-up science and advanced manufacturing and service sectors, in order to attract foreign multinational corporations (MNCs). Increasing R&D investments and the shortening of product lifecycles, together with the need to locate R&D close to markets and production environments, serve as additional drivers for multinational firms to establish distributed R&D centers in different countries, including uprising nations such as China, India, Singapore, Brazil, and many others.

There is a lack of data on outward R&D investment, specifically with respect to emerging countries. While data on inward R&D investment by foreign multinationals in more advanced countries are made available within the Organization for Economic Co-operation and Development (OECD) Main Science and Technology database (MSTI), we still do not know enough about the size and performance characteristics of R&D labs within the uprising non-OECD countries.

One way of analyzing innovation activities in situations where R&D data are not available (or not reliable enough) is to use patent data as a proxy. The Center for International Management and Innovation has thus developed methods of host-country patenting and host-country inventorship. **Host-country patenting** analyzes to which extent multinational corporations file patents for which inventors located in specific countries have made a significant contribution. This information is used as a proxy for estimating the involvement of scientific and engineering work of a specific R&D location in the host-country.

Data on patenting activities of specific researchers in certain locations can then be used for further detailed investigations on **host-country inventorship**. This includes sample data on technical fields of discovery, application areas by product group, collaborative inventorship, as well as patent citations. Detailed patent analysis is then complemented by field studies and interviews.

We use data on patents filed under the Patent Co-operation Treaty (PCT) agreements and analyze changes during the period 2000–2013. As shown in Section 3, the total number of patents has doubled during this period. Furthermore, selected emerging countries as applicants are increasingly active with patents both at the national and the international level. China has attained rank 3 with more than 10% of all PCT patents in 2013, up from position 9 in 2000. Korea has risen from position 8 to rank 5 in 2013. Other important uprising countries are India, Israel, Brazil, and Russia.

This chapter will focus on analyzing changing trends of foreign inventorship in the period 2000–2013. We will first analyze the major source of foreign R&D spenders by MNC and the increased importance of R&D labs in the Brazil, Russia, India, and China (BRIC) countries (Sections 2, 3). These data are differentiated by sectors and product groups. The share of foreign inventorship was going up strongly for companies from the USA, Germany, France, and the UK. More recently, companies from China also increased their share of inventors located in foreign R&D labs.

We then analyze the profiles of the major host-countries and their inventor characteristics. We will focus on China, India, Israel, Singapore, Brazil, Taiwan, Korea, and Russia. Information on strong increases of inventorship in specific technical fields and in specific sectors, together with additional information on collaborative patenting and patent citations, serve as an excellent data source for assessing country-specific development patterns.

2. Globalization of R&D and patenting trends in emerging countries

Since the 1990s, we can observe a persistent trend toward globalizing value chains including production, logistics, as well as research and development (R&D). Multinational corporations are the main drivers of this process that leads to the global dispersion of production and

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R&D-related activities. Between 1990 and 2005, however, foreign R&D investments within multinational firms were primarily concentrated within a rather small group of advanced countries. Major investor countries were the USA, Germany, Switzerland, France, Sweden, Britain, and Japan. MNCs from these countries increased their share of foreign R&D spending continuously, even though they invested primarily in other advanced countries. Still in 2003, the major target countries for R&D investment within MNCs were: (1) the USA, (2) Germany, (3) the UK, (4) France, (5) Japan, (6) Canada, and (7) Sweden followed by Belgium, Italy, and Spain [15]. Other emerging or less developed countries were considered as production location, but not as a destination for establishing R&D laboratories.[1]

This pattern has changed considerably during the period 2005–2015. While foreign R&D spending still followed on upward trends in general, selected emerging countries became an interesting target for MNCs, particularly those that followed a technology-oriented transformation process. The so-called BRIC countries as well as other emerging nations were pursuing strategies of innovation-driven development, with a strong emphasis on attracting R&D labs of foreign MNCs. The UNCTAD World Investment Report in 2005 highlighted the role of transnational corporations and the internationalization of R&D, and emphasized the new role of China and India as potential targets [18].[2] Increasing R&D investments and the shortening of product lifecycles, together with the need to locate R&D close to markets and production environments, serve as additional drivers for multinational firms to establish distributed R&D centers in an increasing number of new high-tech nations.

US-based MNCs in particular have increased their foreign R&D, spending from 28 billion in 2005 to 52 billion in 2014. While major US R&D investments are still concentrated in Europe, China, and India have attracted an annual level of 3 billion of R&D investments each, and rank at position numbers 5 and 6. Both countries have become a more important location for R&D labs within the US-based MNCs than France or Japan [2, 3].[3] Similar patterns can be observed for MNCs from other advanced countries. A survey of foreign R&D spending on German MNCs found that China and India together with Brazil and selected countries in Eastern Europe are seen as important new targets for establishing new R&D centers [7, 8] .[4]

The process of foreign direct investment from an advanced country into an emerging country represents an effective mechanism of inward technology transfer. The effectiveness of this process can be measured by indicators of host-country patenting and host-country inventorship. These indicators as well as the performance of selected target countries will be described in Sections 3 and 4. We assume that a sequential upgrading of technical capabilities as well as of human talent takes place as illustrated in **Table 1**. In an initial phase, foreign MNCs will increase sales revenues as well as production in the target country. Under certain conditions, foreign MNCs will then build-up development centers that support local production and

[1]There were some early exceptions, based on strategies in Singapore, Israel, and China to attract foreign R&D [4].
[2]See UNCTAD (2005), summarizing a survey on R&D investment targets among managers within MNC [18]. For newest version please see Ref. [19]
[3]See the studies of the U.S. Bureau of Economic Analysis in the Survey of Current Research [1, 2, 3]
[4]See EFI ([8], chapter A5) for a survey on outward R&D investment of German MNC as well as EFI ([7], chapter B2) for an in-depth analysis of the new role of global R&D in Germany, as well as [6]

Value-adding activity	As measured by
Increasing export sales	FTO-ratio revenues
Production in host-country	FTO-ratio production
Application-oriented development in host-country	FTO-ratio D
Country-specific research activities	FTO-ratio R
Increased patenting in host-country	Patent indicators at the patent office in host-country
Increasing share of inventors from host-country international patents	FTO-ratio host-country patenting

Table 1. Measuring the performance of R&D capabilities and inventorship in host-countries.

country-specific market requirements. The third phase does not involve much sophisticated R&D work or the formation of inventive activity in the host-country. In later years, however, the target country may provide improved conditions for doing sophisticated research, for example, through local research capabilities, universities, highly educated people, as well as demanding customers. Furthermore, governments may actively support or even require the formation of more advanced R&D labs, as has been observed in Singapore and China. In this case, the MNC builds up more advanced R&D centers of increased size and sophistication. More research-type activities are then organized in the respective country, and such an off-shore R&D center may even develop into a leading center-of-excellence for a certain technology or product group. Local inventors will become involved in discovery processes, and the resulting inventions eventually lead to stronger patent repositories.

The performance of inventors and patenting activities can then be measured using different indicators. In a first step, technology upgrading is measured by patents registered at the national patent office in the host-country. Past studies by the authors have revealed the following patterns for selected Asian countries. In a first phase, patent filing was dominated by foreign multinationals. Later, local firms and applicants increased their share in national patent filing. Additional measures of patent quality can then be used to assess the performance of host-country inventors [7].[5]

The movement from step 5 to step 6 in **Table 1** represents an additional performance improvement for which the quality of local inventorship can then be assessed through the participation of host-country inventors in international patent filing. If inventors from emerging countries appear as major contributors on patent documents filed at the European Patent Office (EPO), at the US Patent Office (USPTO), or under the PCT agreement, it may be concluded that this person's contribution represents inventive work relevant for the international pool of knowledge. In the following sections, we analyze **host-country patenting** as the number resp. the share of inventors

[5]In a case study on China, the author has developed this metric while working as a member of the EFI-Commission (see particularly in EFI ([7], chapter B5). This patent upgrading process was also observed for the early phases of inward technology transfer in Japan and South Korea (see Refs. [12] and [13]).

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located in a certain foreign country (like India), that appear on EPO patents filed by one or more MNC from an advanced country. Over time this share tends to go up for specific corporations and for certain industries. This performance indicator is then used as a proxy for the extent and quality of R&D of a particular location within a specific corporation. The share of host-country patenting tends to be somewhat smaller than the share of foreign R&D. As an example, German MNCs invests about 28–30% of R&D abroad, while the rate of foreign inventorship is only 18%. Still, host-country patenting is a useful proxy in cases where data for foreign R&D expenditures are not published. Furthermore, upward changes in host-country patenting are signaling developmental performance and capability-building within a specific country or region.

3. Patenting trends 2000–2013 and the new role of emerging countries

The Organization for Economic Co-operation and Development (OECD) publishes and processes patent data on a national level as supplied by the European Patent Office (EPO), the U.S. Patent and Trademark Office (USPTO), patent applications filed under the Patent Co-operation Treaty (PCT) that designate the EPO, as well as Triadic patent families [16].

The advantage of EPO and PCT is that applicants only have to apply at one institution for a transnational patent protection. We, as researchers, in turn, benefit from a relatively standardized and comprehensive data set and an overview of the worldwide patenting activities of MNCs in OECD and non-OECD countries, by combining the EPO and PCT data. Through the databases, we determine corresponding patents both filed under the PCT, as well as the EPO treaty, in order to avoid double counting in our analyses [10].

The patent filing process regularly takes at least 2 years, which has the following two implications. First, we have chosen to analyze the priority year, not the filing year, as the former implies a shorter time span to the actual invention, that is, the underlying research activity. Second, we want to contrast the most recent data on patent filing with data for the year 2000. As the most recent reference year, we have chosen the year 2013, since data for later years are still incoherent and incomplete due to the above-mentioned time-lag of 2 years. The data shown and discussed in the following were retrieved and last updated in December 2016.

A total of 202,051 patents were filed under the PCT-Treaty worldwide in 2013, compared to 172,174 in 2010 and 102,702 in 2000. From 2000 to 2013 the annual patent filings have almost doubled with an annual growth rate of 5.3%. This outlines the increasing importance of R&D as a determinant for business success through the proxy of increasing patent filings.

As shown in **Table 2**, the decreasing distance of the number of patents between the USA as rank 1 and its followers suggests that the overall dominance of the USA in R&D activities has decreased, particularly through the new role of countries like China and Korea. China has significantly caught up in terms of patent filing, growing at an annual rate of 22.7% between 2000 and 2013. As a result of strong patenting in uprising countries, the former dominance of the Triadic countries has been reduced considerably [11].

Rank 2013	Country	No. of patents 2000	No. of patents 2013
1	USA	40,839	57,266
2	Japan	10,895	41,739
3	China	1628	23,220
4	Germany	13,313	17,206
5	Korea	1964	11,942
6	France	4695	7729
7	UK	5810	6194
8	Switzerland	2340	4070
9	Netherlands	3299	3951
10	Sweden	3274	3662
	World total	102,702	202,051

Table 2. Overview number of patents by country of applicant.

We now look at the international distribution of inventorship within multinational corporations. We study, where the inventors mentioned on patent documents are located. A "foreign inventor" is defined as a person located outside of the homebase country of an applicant organization, that is, in most cases the location of the company's headquarter. We conducted the

Rank 2013	Home base of applicant	2010		2013	
		Patents with foreign inventors	Share of foreign inv. (%)	Patents with foreign inventors	Share of foreign inv. (%)
1	USA	4345	27.0	6695	23.7
2	Germany	2016	12.5	3482	12.3
3	China	206	1.3	3201	11.3
4	UK	2096	13.0	2854	10.1
5	France	1362	8.5	2102	7.4
6	India	125	0.8	1317	4.7
7	Japan	943	5.9	1233	4.4
8	Switzerland	589	3.7	930	3.3
9	Russia	242	1.5	386	1.4
10	Korea	101	0.6	365	1.3
	World Total	16,083	15.7 (of world patents)	28,235	14.0 (of world patents)

Table 3. Major target countries for R&D as measured by foreign inventorship.

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method of "partial counting" [5] to determine how many patents have been filed by inventors with residence in the respective countries. **Table 3** shows the major target countries for R&D by foreign inventors in the years 2010 and 2013.

Data on patent filing and the share of foreign inventors serve as a proxy to determine the magnitude of research activity and inventiveness in the respective country. As an example, if a US-based automotive supplier files in a certain year 40% of its patents with Chinese inventors, one may safely deduce that China is an important R&D location for this company. However, based on partial counting we may assess the weight of the Chinese contribution. If the US company files one patent with nine US and one Chinese inventors, that patent would be counted as 0.9 for the number of home-based, that is, US patents and 0.1 for the number of patents with foreign inventorship.

While the biggest number of patents usually gets filed with inventors from the country of the respective headquarters, an increasing fraction and absolute number of patents is based on the work of inventors located in foreign countries. In **Table 3**, we analyze the share of foreign inventors for companies headquartered in 10 major home countries. The absolute number of foreign inventors has gone up for most of the countries, even though the relative share of foreign inventorship has slightly been reduced for the USA, UK, France, and Japan. During the same period, Chinese applicants have increased their share of foreign inventorship from 1.3 to 11.3%, while companies from India were increasing this share from 0.8 to 4.7%.

In the following **Table 4**, we will break down the target countries for US- and Germany-based corporations, the two countries with the highest number of foreign inventors. We analyze the international distribution of inventors for US-based corporations. Until 2000, most of the foreign

Rank 2013	Country	No. of patents 2000	No. of patents 2013
1	**China**	**118**	**1300**
2	Germany	788	1202
3	UK	1040	1169
4	Canada	614	830
5	**India**	**66**	**780**
6	Israel	338	580
7	Japan	568	560
8	France	431	505
9	Switzerland	153	294
10	Belgium	246	280
	Total number of patents with foreign inventors	5483	9356

Table 4. Target countries for US-based corporations.

inventors within US applicant were located in the UK, in Germany, Canada, Israel, and Japan. China and India still had a minor role. This changed considerably and in the year 2013, China became the most important location for foreign inventors with US corporations. India has also attained number 5, overtaking countries like Japan, Israel, and France. Other emerging countries in Eastern Europe, Asia, and Latin America are also becoming more important as locations for R&D activities within US corporations.

For German corporations, the ranking of foreign inventors is analyzed in **Table 5**. Four of the most important inventor locations, like the US, France, the UK, and the Netherlands, remain at the top throughout the whole period. China has increased in importance and has even overtaken the role of the neighboring states (like Austria, Switzerland, and Belgium). India, Brazil, and some Eastern European countries have increased their share of foreign patenting within German corporations.

China and India have not only significantly increased their number of patents and the share of foreign inventors; they have also grown in significance as a location for foreign R&D, as shown exemplarily with the case of the US and Germany. This suggests that the flow of innovation is not a one-way street anymore, but rather goes in both directions.

Rank 2013	Country	No. of patents 2000	No. of patents 2013
1	USA	793	984
2	France	228	313
3	UK	132	254
4	Netherlands	111	222
5	**China**	**22**	**214**
6	Austria	255	211
7	Switzerland	186	204
8	Belgium	109	110
9	Italy	67	106
10	Japan	102	98
11	**India**	**17**	**75**
12	Brazil	5	60
13	Sweden	60	58
14	Singapore	17	54
15	Spain	61	47
	Total number of patents with foreign inventors	2263	3207

Table 5. Target countries for German corporations.

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4. The evolution of host-country patenting in BRIC countries

British economist Jim O'Neill first coined the term "BRIC" in 2001 as an acronym for the countries Brazil, Russia, India, and China. These countries, unified by their two-digit GDP growth rates, were assumed to eventually surpass the established Western economies [14]. This group of countries held their first official summit in 2009.

Over the years, the BRIC countries have diverged: while China's economy has consistently grown at a high rate over the last years, other countries have struggled to keep the once high expectations: a plummeting oil price and sanctions in connection to the Ukraine crisis have devitalized the Russian economy, while an unstable political situation, dropping commodity prices, and an increasing indebtedness of the private sector have halted Brazil's economic growth. The concept of BRIC and their importance still prevail, as these countries encompassed 41% of the world's population in 2015 [20].

As shown above, particularly China and India are countries of interest, which shall be examined further. In this section, we will analyze the information and communication technology (ICT) sector, as it is one of the most relevant sectors of R&D in emerging markets [17] and show the innovation development of the biggest companies, by looking at the patent data.

The European Commission publishes in its "Investment Scoreboard" company data annually, including the respective R&D spending of companies worldwide [9]. This in-depth data allow to identify the innovation development of companies and track their development. Through analyses we have identified the Top 100 companies in the ICT sector.

Subsequently, the raw patent data for each company are analyzed, as described above, and aggregated by country of inventor for the 6-year periods 2000–2005 as well as 2006–2011.

We show the most relevant companies of the ICT sector in **Table 6**, sorted decreasingly by their overall number of patents in the period 2006–2011. The displayed nine companies are all the ICT companies with at least two-digit number of patents in either China or India in the period 2006–2011.

The data reveal first that both China and India are highly relevant countries for innovation in the ICT industry, with China having the edge. It also is revealed that several companies exceed the country average, as shown above, by far, meaning that R&D investment is highly diverse.

Depending on the respective business strategy some companies have heavily ramped up R&D investments over the last years in the emerging countries, with Alcatel Lucent, for example, generating almost 20% of their worldwide patents in 2006–2011 with Chinese inventors alone.

In our forthcoming publications, we will put these developments in host-country patenting under scrutiny and explain the reasoning of some companies that are heavily investing in emerging countries.

Company	Country	China		India	
		2000–2005	2006–2011	2000–2005	2006–2011
Samsung	KR	25.5	42.2	12.6	86.3
Alcatel Lucent	FR	43.6	263.5	0.8	75.5
Hewlett-Packard	US	4.1	14.9	32.0	40.1
Intel	US	35.9	88.0	15.5	9.4
Cisco Systems	US	0.0	0.2	8.3	10.3
Google	US	0.0	11.1	0.2	7.0
Fujitsu	JP	3.5	85.6	1.0	1.0
MediaTek	TW	12.0	213.3	0.0	0.3
Hon Hai Precision Industry	TW	7.0	90.3	0.0	0.0

Table 6. Development of patent filings by country of inventor in the ICT industry.

Author details

Alexander Gerybadze* and Daniel Sommer

*Address all correspondence to: gerybadze@uni-hohenheim.de

Chair for International Management and Innovation, University of Hohenheim, Stuttgart, Germany

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