Directorate of Distance Education
NALSAR University of Law, Hyderabad

Reading Material

Post-Graduate Diploma in Patents Law

1.4 International Patent Regime

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Introduction

Rising economies face a crucial dilemma when establishing their position on international patent law. Should they translate their increasing economic strength into political power to further developing countries' interests in lower levels of international patent protection? Or, anticipating a rising domestic interest in stronger international patent protection, should they adopt a position that favours maximal patent protection? We argue that rising economies, after having been coerced into adopting more stringent patent standards, tend to display ambivalent positions, trapped in bureaucratic politics and caught between conflicting domestic constituencies. We find that the recent proliferation of international institutions and the expansion of transnational networks have contributed to fragmentation and polarisation in domestic patent politics.

Moreover, globalization and advancement of technology has played an important role in intellectual property protection for small and medium sized enterprises. The intangible nature of intellectual property creates challenges for those businesses, to protect their inventions, brands, and business in foreign markets. Intellectual property protection is necessary to the success of most companies.

This Module is aimed to help the Patents Law students to familiarise with the different international system of Patent Law, its evolution, current practice and commercialisation attempts. Large sections of this Module has been carefully compiled from several important publications made by USPTO, EPO, JPO, SIPO, WIPO, other Government documents and published articles.

Lastly, sample copies of Court orders from US, UK and Appeal decisions have been added as Annexures for better understanding and in depth study.

CHAPTER I

US PATENT REGIME

Introduction to US Patents

Under United States law, a patent is a right granted to the inventor of a

1) process, machine, article of manufacture, or composition of matter,
2) that is new, useful, and
3) non-obvious.

A patent is the right to exclude others from using a new technology. Specifically, it is the right to exclude others from making, using, selling, offering for sale, importing, inducing others to infringe, and/or offering a product specially adapted for practice of the patent. On July 31, 1790, the first US patent was issued to Samuel Hopkins for an improvement *"In the making of Pot ash and Pearl ash by a new Apparatus and Process"*. This patent was signed by then President George Washington.
United States patent law is codified in *Title 35 of the United States Code*, and authorized by the US Constitution, in Article One, section 8, clause 8, which states:

> *The Congress shall have power ... to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries; .....*

Patent law is designed to encourage inventors to disclose their new technology to the world by offering the incentive of a limited-time monopoly on the technology. This limited-time term of patent is 20 years from the earliest patent application filing date (but this term can be extended via patent term adjustment).

The United States Patent & Trademarks Office (USPTO) is the federal agency for granting US patents and registering trademarks in the US. It is *"unique among federal agencies because it operates solely on fees collected by its users, and not on taxpayer dollars"*. Its *"operating structure is like a business in that it receives requests for services - applications for patents and trademark registrations - and charges fees projected to cover the cost of performing the services [it] provide[s]"*. The USPTO advises the president of the United States, the secretary of commerce, and US government agencies on intellectual property (IP) policy, protection, and enforcement; and promotes the stronger and more effective IP protection around the world. The USPTO furthers effective IP protection for US innovators and entrepreneurs worldwide by working with other agencies to secure strong IP provisions in free trade and other international agreements. It also provides training, education, and capacity building programs designed to foster respect for IP and encourage the development of strong IP enforcement regimes by

US trading partners. The USPTO cooperates with the European Patent Office (EPO) and the Japan Patent Office (JPO) as one of the Trilateral Patent Offices.

Types of US Patents: There are actually three different kinds of patents in the US, each type carrying a different set of requirements:

1) Utility patent: This is the type of patent that the general public is most familiar with. It covers any new, useful, and unobvious process, machine, article of manufacture, composition of matter, or any new, useful, and unobvious improvement thereof.
2) Plant patent: This type of patent protects any distinct and new variety of plant (other than those which are tuber propagated or a plant found in an uncultivated state) which has been asexually reproduced.
3) Design patent: This type of patent covers any new (original) and ornamental design for an article of manufacture. The design patent protects only the appearance of the article and not its function or structure.

I. Patentability Requirements

Patent law is found under *Title 35 of the United States Code*. The *"patentability"* of inventions (defining the types things that qualify for patent protection) is defined under §§ 100–105. Most notably, § 101 sets out *"subject matter"* that can be patented; § 102 defines *"novelty"* and *"statutory bars"* to patent protection; § 103 requires that an invention must not only be new, but also *"non-obvious"*.

§101 - Patentable subject matter

The statutory basis for patent eligible subject matter is set forth in 35 USC § 101:

> *Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.*[1]

The Supreme Court and the USPTO has identified any of the following concepts as patent ineligible:

- laws of nature
- natural phenomenon
- abstract ideas

[1] In addition to being patent eligible, an invention must also satisfy the other statutory requirements for patentability to qualify for patent protection. 35 U.S.C. § 102 (novelty), § 103 (non-obviousness), § 112 (written description, enablement, definiteness). Furthermore, a separate requirement for utility is grounded in the term *"useful"* in 35 USC § 101.

When the patent office reviews a patent application, a patent examiner is appointed to ensure that the application meets the legal requirements for patentability before any patent is granted. One of the issues considered by the examiner is whether the invention described in the application is the right subject matter for protection under § 101 of the Patent Act. This statutory section states that patents may be granted on *"any new and useful process, machine, manufacture, or composition of matter"*. If an invention is not a process, machine, manufacture, or composition of matter, the invention is not patentable because it is not the right type of invention.

If an application has received a § 101 rejection (also referred to as a *"subject matter eligibility"* or *"Alice"* rejection), that means the examiner believes that your claims relate to a type of invention that is ineligible for patent protection. There are two different types of § 101 rejections:

i. either the examiner is saying that your invention doesn't fall within one of the four statutory categories, or
ii. the examiner is saying that your invention falls under one of the patent ineligible exceptions (which is usually either an abstract idea or a natural law/phenomenon).

In the words of the Supreme Court in its *Myriad Genetics*[2] decision, *"[w]e have long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable"*. The Supreme Court has explained that these types of concepts *"are not patentable as they are the basic tools of scientific and technological work"*[3]. The Court argued, if patents were granted on a law of natural or natural phenomenon (or a similar concept), this would impede innovation, whereas the patent system is designed to promote innovation. As a result, the Supreme Court has indicated that patents should not be granted on these patent-ineligible concepts, even though the actual Statute is silent on this matter and does not indicated that abstract ideas or natural phenomenon are to be excluded from patent eligibility.

For many years, courts have grappled with where to draw the line dividing unpatentable inventions from patentable ones. In its Mayo[4] and Alice[5] decisions, the Supreme court has recently developed a *"test"* to make this determination. Unfortunately, the word *"test"* must be in placed within quotes, as

[2] Association for Molecular Pathology et.al. v. Myriad Genetics, Inc., et.al. 133 S.Ct. 2107 (2013) < https://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf>
[3] Mayo Collaborative Services, DBA Mayo Medical Laboratories et.al. v. Prometheus Laboratories, Inc.,. 566 US__, 132 S.Ct. 1289 (2012) < https://www.supremecourt.gov/opinions/11pdf/10-1150.pdf>
[4] Mayo Collaborative Services, DBA Mayo Medical Laboratories et.al. v. Prometheus Laboratories, Inc.,. 566 US____, 132 S.Ct. 1289 (2012) < https://www.supremecourt.gov/opinions/11pdf/10-1150.pdf>
[5] Alice Corporation Pty Ltd. v. CLS Bank International et.al., 134 S.Ct. 2347 (2014) < https://www.supremecourt.gov/opinions/13pdf/13-298_7lh8.pdf>

the test is by no means definite in all cases, and frequently leaves the issue as confused as it was before the test was applied. We do know, however, that this same test applies whether the patent-ineligible concept being evaluated is an abstract idea or a natural phenomenon. We will refer to This test gets referred as the as the *"Alice test"* because it was most clearly articulated in the Alice decision, even though the test properly originates in the Court's Mayo decision from two years earlier.

The Supreme Court has explained that the second step of the Alice test is to determine whether the claim contains an *"inventive concept"* sufficient to transform the claimed abstract idea into a patent-eligible application. This second step originated in the Mayo decision and was clarified by the Supreme Court in Alice:

> *At Mayo step two, we must examine the elements of the claim to determine whether it contains an "inventive concept" sufficient to "transform" the claimed abstract idea into a patent-eligible application. A claim that recites an abstract idea must include "additional features" to ensure "that the [claim] is more than a drafting effort designed to monopolize the [abstract idea]."*

As was the case with phrase *"abstract idea"*, the fact that we lack any clear definition of what constitutes an *"inventive concept"* makes it more difficult to analyse a claim for its existence. Nonetheless, the Alice decision as interpreted by the Federal Circuit has provided some guidance on how to perform step two.

The Supreme Court has explained that Alice test is applied in two parts:

1) The first step requires a consideration as to whether the claims at issue are, in fact, directed to an ineligible concept (e.g., an abstract idea or natural phenomenon). In making this determination, the Supreme Court has emphasized that it is important to *"tread carefully in construing this exclusionary principle lest it swallow all of patent law"*, since, at some level, *"all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas"*. To determine whether the claims are "directed to" the ineligible concept rather than simply embodying or applying that concept, we are to examine both the claims and the specification to determine the *"claimed concept"* (which can also be referred to as the *"focus"* of the claims or the *"claimed advance"*). This claimed concept can then be compared with other inventions that have been found to be directed to abstract ideas or natural phenomenon. If the claimed concept is similar to other inventions previously found to be directed to an ineligible concept, then the claimed concept fails step one and the invention is further analysed under step two. If the claimed concept is sufficiently different, then the invention is patent eligible under step one, and it is not necessary to analyse step two of the test.

2) The second step of the Alice test is to *"consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application".*

Utility refers to the issue of whether the material sought to be patented has commercial use. The need for utility as a criterion to decide patentability is outlined in § 101 of the US patent legislation. The issue of Utility is normally easily resolved in inventions involving most areas of science. Inventions of chemicals involve the issue of utility most often. In these circumstances the question is whether utility is based on the end product or whether even the invention of an intermediary compound can result in fulfilling the requirement of § 101.

§102 – Novelty, Prior Art

Patent novelty refers to the uniqueness of an invention, but it's actually much more specific. An invention is novel if no single prior art reference discloses all the components that form the claimed invention.

So, the two critical pieces of information that must be analysed to determine novelty are:

1) patent claims; and
2) prior art.

Prior Art: Prior art refers to all similar or comparable disclosures prevalent in the particular area or subject matter of the patent. Prior art is any evidence that your invention is already known. Prior art does not need to exist physically or be commercially available. It is enough that someone, somewhere, sometime previously has described or shown or made something that contains a use of technology that is very similar to ones invention. When a patent application is submitted, the inventor normally is required to submit information on the prior art to the patent examiner. The idea is that the patent examiner looks at the invention and the prior art and decides whether the application refers to a product that has so far not been available to the public.

Public domain: This term refers to all things that are available to the public in general and accessible to them.

When a patent examiner assesses the potential novelty of a patent-pending invention, the examiner compares the claims to the prior art. Patent invalidity based on lack of novelty, or anticipation, requires that the invention was known or used by others before it was invented by the patentee.

One way to respond to a § 102 rejection is to argue that the prior art reference does not show all the claim elements seen by the examiner. Patent examiners will not be convinced by conclusory statements, so the applicant requires to elaborate on why the prior art reference fails to show a particular claim element. Another option is to amend the claim. An applicant can amend a claim to clarify an element, add a new element or do both.

Anticipation is the opposite of novelty. If a patent examiner believes that a single prior art references shows all components of a particular claim (*"claim limitations"*), the examiner will issue an Office Action stating that the claim is rejected under § 102 as being *anticipated* by said prior art reference. A claimed invention may be rejected under 35 USC § 102 when the invention is anticipated (or is *"not novel")* over a disclosure that is available as prior art. To reject a claim as anticipated by a reference, the disclosure must teach every element required by the claim under its broadest reasonable interpretation.

§103 - Obviousness

Under § 103, a patentable invention must be a non-obvious improvement over prior art; thus, a rejection under this section means the examiner considers the invention at issue to be obvious. A § 103 rejection can be tricky because, often, the prior art that allegedly teaches the invention at issue is not disclosed in a single reference, but can be inferred from a combination of references. An obviousness determination, then, is intensely fact-specific and subjective in nature. One way to smooth out this legal landscape is to use a reasonable person standard - would a person of ordinary skill in the art of the invention have found it obvious to make at the time the application was files. Even when courts use this standard, however, there can still be room for debate as to what *"ordinary skill"* in a particular art actually means. § 103 rejections are likely the most common first final rejections for these very reasons—obviousness determinations are subjective, and reasonable minds can easily disagree on their outcome.

Any obviousness rejection should include, either explicitly or implicitly in view of the prior art applied, an indication of the level of ordinary skill. A finding as to the level of ordinary skill may be used as a partial basis for a resolution of the issue of obviousness.

The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. Factors that may be considered in determining the level of ordinary skill in the art may include:

i. "type of problems encountered in the art;"
ii. "prior art solutions to those problems;"
iii. "rapidity with which innovations are made;"
iv. "sophistication of the technology; and"

v. "educational level of active workers in the field."[6]

"In a given case, every factor may not be present, and one or more factors may predominate"[7,8]. "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton"[9]. *"[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle"*[10].

In addition to the factors above, Office personnel may rely on their own technical expertise to describe the knowledge and skills of a person of ordinary skill in the art. The Federal Circuit has stated that examiners and administrative patent judges on the Board are *"persons of scientific competence in the fields in which they work"* and that their findings are *"informed by their scientific knowledge, as to the meaning of prior art references to persons of ordinary skill in the art"*[11]. In addition, examiners *"are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art"*[12].

II. Specification - §112

35 USC § 112 dictates the form and content of the specification and the form and content of the patent application's claims. The first paragraph introduces 3 legal concepts, the written description requirement, the enablement requirement, and the best mode requirement. The second paragraph limits the ability of claims to be too open-ended or unclear. The written description requirement is separate and distinct from the enablement requirement[13]. *"[A] specification which 'describes' does not necessarily also 'enable' one skilled in the art to make or use the claimed invention"*. Best mode is a separate and distinct requirement from the enablement requirement[14]. The specification need not teach what is well known in the art. However, applicant cannot rely on the knowledge of one skilled in the art to supply information that is required to enable the novel aspect of the claimed invention when the enabling knowledge is in fact not known in the art.

[6] *In re GPAC*,57 F.3d 1573, 1579, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995).
[7] *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696, 218 USPQ 865, 868 (Fed. Cir. 1983)
[8] *Custom Accessories, Inc. v. Jeffrey-Allan Indust., Inc.*, 807 F.2d 955, 962, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986)
[9] *KSR*, 550 US at 421, 82 USPQ2d at 1397
[10] *KSR*, 550 US at 420, 82 USPQ2d at 1397
[11] *In re Berg*, 320 F.3d 1310, 1315, 65 USPQ2d 2003, 2007 (Fed. Cir. 2003).
[12] *Power Oasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 86 USPQ2d 1385 (Fed. Cir. 2008)
[13] Ariad Pharm., Inc. v. Eli Lilly and Co., 598 F.3d 1336, 1341, 94 USPQ2d 1161, 1167 (Fed. Cir. 2010) (*en banc*)
[14] *In reNewton*, 414 F.2d 1400, 163 USPQ 34 (CCPA 1969).

Specification: The specification portion of a patent application is a written description of the invention. The specification also explains how to make and use the invention. The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. The two primary requirements of the specification is that

1) it must be *"enabling"* and
2) it must describe the *"best mode"* of the invention.

The enablement requirements states that the patent application must describe the invention in such full, clear, concise, and exact terms that any person skilled in the technological area to which the invention pertains will be able to make and use the invention. To meet this requirement, the specification should completely describe the invention, and do it in such a way as to distinguish it from the prior art (old inventions).

The best mode requirement states that the patent application must describe completely at least one specific embodiment of the invention. These specific embodiments must include the best mode contemplated by the inventor for carrying out her/his invention. While it is possible to challenge the validity of an issued patent if the specification is not enabling, recent changes to the patent statute made by the *America Invents Act*[15] have removed the ability to challenge a patent's validity on the ground that the specification failed to disclose the invention's *"best mode"*. There are two factual inquiries to be made in determining whether a specification satisfies the best mode requirement. First, there must be a subjective determination as to whether the inventor knew of a best mode of practicing the invention at the time the application was filed. Second, if the inventor had a best mode of practicing the invention in mind, there must be an objective determination as to whether that best mode was disclosed in sufficient detail to allow one skilled in the art to practice it.[16]

In addition to the description of the invention, the specification also includes a title, a brief abstract of the invention, an initial summary of the invention being claimed, and a brief description of the drawings.
Claims: The patent application must include one or more claims which particularly point out and distinctly claim the subject matter which the applicant regards as the invention. These claims form the heart of any patent which is issued from the application, as they describe the patent's breadth and coverage. Claims are basically brief descriptions of the subject matter of the invention; they recite all

[15] <https://www.uspto.gov/sites/default/files/aia_implementation/20110916-pub-l112-29.pdf>
[16] *Fonar Corp. v. Gen. Elect. Co.,* 107 F.3d 1543, 41 USPQ2d 1801, 1804 (Fed. Cir. 1997)

essential features necessary to distinguish the invention from what is old without including any unnecessary details.

When a patent application is examined by the Patent and Trademark Office, it is the claims that the examiner uses to compare the application with the prior art. If the claims are written too broadly, the examiner will reject the claims as covering the prior art and a patent will be denied. If a claim is too narrow, the patent will have little value as it will not cover competitor's products. Thus, the drafting and amending of claims is the most technical portion of a patent application, and it is here that a skilled patent attorney will earn her money.

Drawings: The patent application will also include one or more drawings of the invention whenever a drawing is required to understand the invention. Most applications, including those for software patents, will include a drawing showing or describing (in a flow chart, for instance) the crucial features of the invention. By law, the drawings must show every feature of the invention specified in the claims. Since drawings are required to be in a very particular format, it is usually necessary to hire a competent draftsperson to make the drawings. It is possible, however, to avoid filing the formal drawings (those which meet all of the Patent and Trademark Office's requirements) until the application has been examined and allowed.

III. Inventor

Under US patent law (similar in most countries), the patent application must identify the true inventor or inventors of the invention. Not only is this a prerequisite for an enforceable patent, but anyone who falsely states that she/he is the inventor in a patent application is subject to criminal penalties. Nonetheless, it is possible to correct an innocent mistake about inventorship in a patent application, such as accidentally omitting an inventor or accidentally naming a person as an inventor who was not an inventor of the invention claimed in the patent application. If two or more persons make an invention jointly, they apply for a patent as joint inventors. A person who makes a financial contribution is not a joint inventor and cannot be joined in the patent application as an inventor. It is also inappropriate to name executives or *"team leads"* as an honorary inventor in a patent application if there were not involved in the actual inventive process.

It is possible for a person to be an inventor without being the owner of the resultant patent. If an inventor is employed to invent things for their employer, the employer will usually be the owner of any patent or invention made by the inventor. Nonetheless, the inventor would have to sign the oath for the patent application, and the patent will be issued in the name of the inventor.

§ 115 – Inventor's Oath & Declaration: The oath or declaration of the applicant is required by law. The inventor must make an oath or declaration that she/he believes herself/himself to be the original and first inventor of the subject matter of the application. In addition, the oath contains other statements as required by law and by the Patent and Trademark Office rules. The oath or declaration must be signed by the inventor in person, or by the person entitled by law to file the patent application on the inventor's behalf.

IV. America Invents Act (AIA)

On September 16, 2011, the *Leahy-Smith America Invents Act (AIA)*, also called the *Patent Reform Act of 2011*, was enacted into law[17]. The changes mostly harmonize US patent law with the rest of the world. The most drastic changes include:

1) conversion from a first-to-invent system to a first-inventor-to-file system;
2) new activities that qualify as prior art;
3) new standards, time lines, and limits for *inter-partes* reexaminations;
4) new post-grant review;
5) new supplemental examination proceedings;
6) the end of the *"best mode"* requirement;
7) limitations on joining parties accused of patent infringement;
8) for all practical purposes, the end of false patent marking claims;
9) new *"virtual"* patent marking;
10) reduced fees for *"micro entities"*; and
11) new review proceedings for business method patents; and
12) the extended ability for third parties to submit prior art in pending patent applications.

A major change is the shift from a first-to-invent system to a first-to-file system. The first-to-file system, which went into effect on March 16, 2013, reveals a few twists relevant to patent protection in the US. First, the inventor who files a later application is permitted to contest inventorship on a previously filed application only if it is shown that the subject matter disclosed in the previous application was derived from the inventor who files the later application. This occurs through a derivation proceeding, which replaces interference proceedings. Second, inventors still have a one-year grace period during which the inventor's own disclosures or disclosures of others who derived their invention from the inventor may not be used as prior art if they occurred within 12 months prior to the effective filing date of the invention.

[17] <https://www.uspto.gov/sites/default/files/aia_implementation/20110916-pub-l112-29.pdf>

Foreign public use and offers for sale are considered prior art under the AIA, whereas previously, use and sale of the invention by third parties abroad were not bars to patent protection in the United States. Though the one-year grace period still allows an inventor to avoid the prior-art effects of his or her own foreign use or sale of the invention within that time period, any of his or her foreign use or sale prior to one year before the effective filing date of the application will bar the inventor from obtaining a patent in the United States.

Previously, a defence to infringement based on prior commercial use was limited to business method patents, but under the AIA, it has been expanded to all inventions. If an inventor owns the invention as a trade secret and subsequently a patent application is filed on the same invention by another entity and issues as a patent, then the trade secret owner is provided with the *"prior user defence"* against a patent infringement claim.

For successful use of a prior user defence, it must be demonstrated that there was internal commercial use or sale of the subject matter by the trade secret owner, in good faith, at least one year prior to the effective filing date of the claimed invention. The person asserting a prior user defence under this section must establish the defence under the *"clear and convincing"* evidentiary standard for proving invalidity.

Ex-parte Reexamination procedures remain mainly unchanged. *Inter-partes* Reexamination proceedings, however, has been replaced by a new type of proceeding called *"Inter partes Review"*, which became available on September 16, 2012. The new *"likelihood of success"* standard already applies to the *Inter-partes* Review proceedings.

Another novel way in which a granted patent can be challenged under the AIA is by *Post-Grant Review (PGR)* proceedings. Under PGR, a person who is not the patent owner may petition the USPTO to review the validity of an issued patent within nine months of its grant or issuance of a reissue patent. PGR rules are effective from September 16, 2012 and are applicable to business method patents under the transitional program, but the PGR process goes into effect only as to *"first-to-file"* patents, which are patents that are filed on or after March 16, 2013.

Assertions of invalidity may be made on any grounds of patentability that one can raise as a defence in patent infringement litigation before the courts, including failure of the claims to define subject matter eligible for patenting, lack of novelty, obviousness and to provide a written description or enablement. A petitioner initiating a PGR proceeding need bear the burden of proving invalidity only by the lower standard of *"by a preponderance of the evidence"* in contrast to the higher *"clear and convincing"* evidentiary standard.

PGR is available only if the challenger has not already initiated a civil action in District Court. PGR proceedings are to be conducted by the Patent Trial and Appeal Board, which has replaced the Board of Patent Appeals and Interferences on September 16, 2012 for proceedings that commence on or after that date. PGR proceedings may be terminated either by settlement or by decision of the Board. There is also estoppel associated with the challenger at the USPTO, the District Courts and the International Trade Commission (ITC) in asserting invalidity on any ground that could have been reasonably raised during PGR.

The AIA provides patent owners the option to request *supplemental examination (SE)* of a patent to *"consider, reconsider, or correct information believed to be relevant to the patent".* SE is also an additional avenue that patent owners may utilize to satisfy their duty of disclosure after a patent has issued. Therefore, patent owners may utilize SE to eliminate defences based on inequitable conduct that may likely be raised against the patent during litigation.

Along with the aspects of patent reform discussed above, the AIA has brought about several more changes that also touch on the fee structure of the USPTO (nearly all fees were increased by 15% ten days after enactment), disclosure of best mode (failure to disclose best mode has been eliminated as an invalidity defence), studies (for example, a study on genetic testing is ongoing and may affect gene patents), patent marking law (only the US government may bring about *qui tam* actions), creation of a micro entity (these entities are eligible for a 75% fee discount) and establishing a satellite office in Detroit (to hire more examiners and staff to work through the backlog).

The AIA has been the recipient of abundant praise and great censure since its enactment, but one may only gain a better understanding of all its ramifications once it goes into effect in its entirety. It holds the promise of creating a more efficient, objective, predictable and transparent patent system and enhancing the quality of patents in the United States.

V. Bayh-Dole Act

The Bayh-Dole Act (Pub. L. 96-517, December 12, 1980[18]) is a US legislation dealing with intellectual property arising from federal government-funded research. The Act was adopted in 1980, is codified at 94 Stat. 3015[19], and in 35 USC §§ 200 - 212[20], and is implemented by 37 CFR 401[21]. The formal name

[18] < https://www.govinfo.gov/content/pkg/STATUTE-94/pdf/STATUTE-94-Pg3015.pdf>
[19] <https://www.govinfo.gov/content/pkg/STATUTE-94/pdf/STATUTE-94-Pg3015.pdf>
[20] <https://www.govinfo.gov/content/pkg/USCODE-2011-title35/pdf/USCODE-2011-title35-partII-chap18.pdf>
[21] <https://www.govinfo.gov/content/pkg/CFR-2010-title37-vol1/pdf/CFR-2010-title37-vol1-part401.pdf>

for the act is the *"Patent and Trademark Act Amendments of 1980"*, and it created a uniform patent policy among the federal agencies that fund research. Criticisms of the previous policy prompted this change. Congress perceived the need for reliable technology transfer mechanisms and for a uniform set of federal rules to make the process work.

The federal government's inability to effectively commercialize technologies derived from federally funded research resulted in hundreds of valuable patents sitting around unused. At the time, the government was not willing to grant licenses to the private sector. The act ultimately has motivated more and more universities to become actively involved in the transfer of technology from the lab to market. The ability of universities, to retain title to and actively license these technologies serves as a tremendous incentive.

The key change made by Bayh-Dole was in ownership of inventions made with federal funding. Before the Bayh-Dole Act, federal research funding contracts and grants obligated inventors (wherever they worked) to assign inventions they made using federal funding to the federal government. Bayh-Dole permits a university, small business, or non-profit institution to elect to pursue ownership of an invention in preference to the government.

Key Provisions

- The University is entitled to retain ownership of any inventions created as a result of federal funding, unless the funding agency informs the University up front that the agency will retain title to inventions derived from the funded projects because of specifically identified *"exceptional circumstances"* or other specified conditions.
- When a University innovator discloses the creation of an invention derived from federally funded research, the University has two months from that date to disclose that information to the appropriate federal agency. The University also must patent all inventions it elects to own and commercialize.
- The University must attempt to develop and commercialize the invention. If an attempt is not made, the federal government retains the right to take control of the invention. The government also may take control of the invention for other reasons, such as a need to alleviate health or safety concerns. This provision is referred to in the law as the government's *"march-in"* rights.
- The University must provide the U.S. government with a non-transferable, irrevocable, paid-up, nonexclusive license (*"confirmatory license")* to use the invention.
- In granting a license to use the invention, the University also generally must give priority to small businesses, while maintaining the fair-market value of the invention.
- When granting an exclusive license, the University must ensure that the invention will be *"manufactured substantially"* in the United States.

- Excess revenue must support research and education.
- The University must share a portion of the royalties with the inventor(s).

VI. Reexamination

Any third party, including a potential or accused infringer in a patent infringement litigation, can petition the USPTO to reexamine the validity of an asserted patent based on printed prior art. A patent holder can also initiate a reexamination of its own patents to argue against invalidity issues raised by third parties based on potential prior art. These *ex-parte* USPTO reexamination proceedings are similar to the patent prosecution process

A reexamination can result in:

1) The cancellation of one or more patent claims.
2) Issuance of amended or additional claims (if the reexamination patent has not expired).
3) Confirmation of the patentability of the original claims.

Inter-partes reexaminations were previously available for patents that were filed on or after November 29, 1999 and must have been filed before September 16, 2012[22]. Under the AIA, on September 16, 2012, *inter-partes* reexaminations were replaced by the new *inter-partes* review[23].

Ex-parte Reexaminations: Anyone can initiate an *ex-parte* reexamination by filing a request for reexamination with the USPTO[24]. The request must identify a *"substantial new question of patentability"* concerning the patent claims based on published prior art references[25]. If the request is granted by the USPTO, the requesting party generally cannot continue to participate in the proceedings, which continue between the USPTO examiner and the patent holder. The patent holder may:

1) Make arguments in defence of the patent's claims.
2) Amend the patent's claims to distinguish them over the cited prior art, add new patent claims, or both.

Inter-partes Reexaminations: Under the AIA, as of September 16, 2012, the *inter-partes* reexamination procedure, which enabled a requesting party to remain involved in the proceedings on a continuing basis, has been replaced by an *inter-partes* review procedure. An inter-partes reexamination allowed

[22] 35 USC §§ 311- 318
[23] 35 USC §§ 311-319, AIA § 6
[24] 35 USC §§ 302-307
[25] 35 USC § 304

for the requesting party's participation throughout the reexamination process. Inter-partes reexamination requests between September 16, 2011 through September 15, 2012 were granted only if the requestor showed that there was a reasonable likelihood that it would prevail on at least one of the challenged claims. Before September 16, 2011, the requestor had to show that a substantial new question of patentability existed. An important distinguishing feature of an *inter-partes* reexamination was that the requesting party could not assert at a later time in any civil action the invalidity of any claim finally determined to be valid and patentable on any ground which it raised or could have raised during the i*nter-partes* reexamination proceedings.

New Patent Review Procedures under the AIA: The AIA provides several new administrative procedures for a party to challenge the validity of another's patent, including:

1) Post-grant review[26].
2) *Inter-partes* review[27].
3) A transitional procedure for business method patent review[28].
4) Pre-issuance submissions[29].
5) Other submissions[30].

These new procedures were effective as of September 16, 2012[31]. However, the availability of each procedure may depend on the patent's filing or issuance date. The USPTO has adopted rules of practice concerning post grant review, *inter-partes* review and the transitional program for covered business method patents.

VII. Infringement & Defences

A patent infringement claim is a federal cause of action that may be brought by a US patent owner (or an entity with sufficient rights in a US patent) against another party that the patent holder asserts is practicing the patented invention without its authority. It is an assertion by the patent holder that an alleged infringer's product or process practices the patent holder's patented invention without authorization.

Types of Infringement

There are two types of infringement:

[26] 35 USC §§ 321-329, AIA § 6
[27] 35 USC §§ 311-319, AIA § 6
[28] 37 CFR §§ 42.300-304, AIA § 18
[29] 35 USC § 122, AIA § 8
[30] 35 USC § 301, AIA § 6
[31] AIA §§ 6, 8, 18

1) *Direct infringement:* The accused infringer practices each element of the patent holder's patent claim. A party is liable for direct infringement if, without authority, it either: makes, uses, imports, offers to sell or sells a patented invention within the US[32].

   Direct patent infringement is a strict liability offense, meaning that intent to infringe the patent is not needed for a finding of direct infringement. An alleged infringer does not have to copy a patented invention or even know about the patent to be held liable for infringement. The alleged infringer must only have performed one of the prohibited acts listed in *35 USC § 271(a)* (making, selling, using, offering to sell or importing into the US) with respect to a product or process that is covered by the patent.

2) *Indirect infringement:* The accused infringer does not practice each element of the patent holder's patent claim but either:

   i. *Contributory infringement:* contributes to direct infringement by another party. A party is liable for contributory infringement if both of the following requirements are met:

      a) The party sells or offers to sell within the US, or imports into the US, a component of a patented invention or a material or apparatus for practicing a patented process.

      b) The only use of the component, material or apparatus is in the patented product or in practicing the patented process[33].

         In light this requirement, a key inquiry for evaluating contributory infringement is whether a component, material or apparatus has a *"substantial non-infringing use"*, and therefore falls outside the bounds of the statute.

      The standard for contributory infringement imposes a knowledge requirement. The contributory infringer must have known that the component, material or apparatus was either:

      a) Used to infringe a patent.

      b) Designed for infringing use[34].

      A further prerequisite of contributory infringement liability is that a third party directly infringe the patent in the US

   ii. *Inducement:* induces another party to engage in direct infringement

      A party who actively induces direct infringement by another party may also be liable for infringement[35]. Like contributory infringement, a prerequisite for inducement liability is direct infringement by a third party.

      A patent holder claiming inducement must establish that the alleged infringer both:

[32] 35 USC § 271(a)
[33] 35 USC § 271(c)
[34] 35 USC § 271(c)
[35] 35 USC § 271(b)

1) Engaged in the conduct of inducing or encouraging a third party to take infringing action.
2) Had knowledge that the induced acts comprise patent infringement[36].

A patent holder must therefore demonstrate not only that the defendant had knowledge of the patent, but that it knowingly intended to persuade another party to take the infringing actions. This requirement is usually met by demonstrating the defendant's actual knowledge. However, it may also be satisfied by a showing of wilful blindness, where the defendant both:

1) Believes there is a high probability that infringement exists.
2) Takes deliberate actions to avoid confirming that fact.

A defendant's mere recklessness or negligence is insufficient for knowledge to be imputed under a wilful blindness theory.

Doctrine of Equivalents: Under the doctrine of equivalents, a patent holder can prove infringement, even if one or more asserted patent claim limitations are not literally present in the accused product or process. Under the doctrine of equivalents, a patent holder can prove infringement, even if one or more asserted patent claim limitations are not literally present in the accused product or process. For any limitation that is not literally present, the patent holder must show that the differences from the literal claim requirement are insubstantial. A common method used to determine whether the equivalent of a claim limitation is present in the accused product or process is the *function-way-result* test. This test asks whether an element of an accused product or process *"performs substantially the same function in substantially the same way to obtain the same result"* as an element of the patented invention[37].

All Elements Rule: To prevail on a patent infringement claim, a patent owner must show by a preponderance of the evidence that each asserted patent claim limitation is found in the accused product or process, either:

1) Literally.
2) Under the doctrine of equivalents.

The requirement that each claim limitation be found in the accused product or process is often called the *"all elements rule"*.

[36] Global-Tech Appliances, Inc. v. SEB S.A., 131 S.Ct. 2060 (2011)
[37] Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc., 637 F.3d 1269, 1279 (Fed. Cir. 2011)

Patent Claim Construction: Claim construction plays a pivotal role in most patent infringement cases. A patent's claim language defines the scope of a patent owner's right to exclude others. Therefore, the meaning of key disputed claim limitations must often be ruled on to determine both:

1) Infringement of a patent claim.
2) Validity of a patent claim over prior art.

The process of resolving disputes between the parties concerning the meaning of disputed patent claim terms is referred to as the claim construction or Markman process.

Markman Process: In *Markman v. Westview Instruments, Inc.*, the Supreme Court ruled that the responsibility for claim construction determinations falls on a judge and not on a jury[38]. After completing the Markman process, the judge provides instructions to the jury on the meaning of disputed patent claim terms. This is similar to the manner in which the judge instructs the jury on issues of law. The jury then applies the court's claim construction in making its factual findings on the issues of infringement and invalidity. The claim construction process generally includes:

1) Each party's identification of the claim terms that they would like the court to construe.
2) Each party's proposals on claim construction.
3) Each party's submission of briefing on claim construction, where it presents its arguments to the court.
4) The Markman hearing.

At the Markman hearing, the court may allow either party to present expert testimony or limit the hearing to attorney argument. Following the Markman hearing, the court issues a Markman Order, ruling on the construction of the disputed claim limitations. The court's construction of the disputed claim limitations becomes part of the jury instructions at the conclusion of the trial.

If the district court does not have local patent rules that govern when a Markman hearing should be held, it can decide to hold the Markman hearing before or after fact or expert discovery. Generally, performing claim construction before expert discovery is more efficient for the parties. During expert discovery, the parties' experts present their positions on infringement and validity issues. If those issues depend on claim construction disputes that are not yet resolved, the experts must outline alternative opinions under each party's proposed claim constructions. The proper methodology for claim construction is set out in *Vitronics*[39] and more recently in *Phillips*[40].

[38] 517 US 370 (1996)
[39] Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576 (Fed. Cir. 1996)
[40] Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*)

Key Patent Infringement Defences: An alleged infringer can assert a number of common defences in response to a patent infringement claim, including:

1) A defence of non-infringement.
2) Invalidity defences based on prior art[41]; these include:
    a) Anticipation[42]; and
    b) Obviousness[43].
3) Invalidity defences based on the patent holder's failure to meet statutory requirements[44].
4) The equitable defence of inequitable conduct arising from the patent holder's conduct during the prosecution process[45].
5) Defences based on the patent holder's express or implied authorization to use the patent (Licenses[46] and Patent Exhaustion[47]).
6) General equitable defences that bar the patent holder from making a claim[48].

Patent Litigation Remedies: Two basic remedies may be obtained by a patent holder who succeeds on its patent infringement claim:

1) Monetary damages.

    Monetary damages in patent infringement can include:

    i. Compensatory damages in the form of:
        a) minimum damages based on a *"reasonable royalty"*[49]; and
        b) lost profits-type of damages[50].
    ii. Enhanced damages up to three times the compensatory damages, in extraordinary cases[51].
    iii. Attorney fees[52].
2) Injunctive relief.

    An injunction is no longer an automatic remedy awarded to the patent holder. Instead, because it can be devastating to the infringer, a court may award injunctive relief only on consideration and balancing of the following equitable factors:

    i. Whether the patent holder has suffered an irreparable injury.

[41] Microsoft Corp. v. i4i Ltd. P'ship, 131 S.Ct. 2238 (2011)
[42] Graham v. John Deere Co., 383 U.S. 1, 17−18 (1966)
[43] KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 416 (2007)
[44] Ariad Pharm., Inc. v. Eli Lilly and Co., 598 F.3d 1336, 1341 (Fed. Cir. 2010) (*en banc*)
[45] Therasense, Inc. v. Becton, Dickinson and Co., 649 F.3d 1276 (Fed. Cir. 2011) (*en banc*)
[46] Zenith Elecs. Co. v. PDI Commc'ns Sys., 522 F.3d 1348 (Fed. Cir. 2008)
[47] Bowman v. Monsanto, 133 S.Ct. 1761 (2013)
[48] Gasser Chair Co. v. Infanti Chair Mfg. Corp., 60 F.3d 770, 773 (Fed. Cir. 1995)
[49] Uniloc USA, Inc. v. Microsoft Corp., 632 F.3d 1292 (Fed. Cir. 2011)
[50] Grain Processing Corp. v. Am. Maize-Prods. Co., 185 F.3d 1341, 1349 (Fed. Cir. 1999)
[51] In re Seagate Tech., LLC, 497 F.3d 1360, 1369 (Fed. Cir. 2007) (*en banc*)
[52] 35 USC § 285

ii. Whether remedies available at law, including monetary damages, are inadequate to compensate for that injury.
iii. After considering the balance of hardships between the parties, whether an injunction is warranted.
iv. Whether an injunction may be a disservice to the public interest.

If the patent holder and the adjudged infringer compete in the same marketplace, the likelihood of obtaining injunctive relief is high. In contrast, it may be difficult for the patent holder to show that injunctive relief is appropriate where any of the following apply:

i. The patent holder does not make a product.
ii. The patent holder does not compete with the infringer.
iii. The patent holder has freely licensed the patent to others in the field.

In the US, federal district courts have exclusive subject matter jurisdiction over patent infringement claims[53]. All patent infringement claims must therefore be brought in federal district court. Any federal district court in any jurisdiction may preside over the case, so long as the requirements of personal jurisdiction and venue are met. Either party may request a jury trial. The success rates of patent owners and alleged infringers in district court cases vary significantly from jurisdiction to jurisdiction. This variation may result from factors that include:

1) The education level and cultural attitudes of the jury pool.
2) The experience level of the particular judges in handling patent infringement cases.
3) The average time to trial.

Unlike non-patent cases, which are appealed to the appropriate circuit court of appeals depending on the district court's geographic location, all appeals of patent infringement claims are heard by the US Court of Appeals for the Federal Circuit (Federal Circuit), which sits in Washington, DC. As with the other circuit courts of appeals, the decisions of the Federal Circuit can be appealed to the US Supreme Court.

There are several non-federal court forums for the resolution of patent-related disputes, including:

1) Section 337 Actions brought before the International Trade Commission (ITC)[54].
2) Patent reexamination proceedings before the USPTO[55].

[53] 28 U.S.C. § 1338
[54] The ITC is a federal agency with the authority under § 337 of the Tariff Act of 1930 (19 USC § 1337) to hear cases between companies domestically exploiting US intellectual property rights and those who import allegedly infringing products.
[55] 35 USC §§ 311- 318

3) Other administrative proceedings before the USPTO provided in the AIA as of September 16, 2012, including:
    a) post-grant reviews[56];
    b) *inter-partes* reviews[57];
    c) transitional business method patent post-grant reviews[58];
    d) pre-issuance submission procedures[59]; and
    e) other third-party submission procedures[60].
4) Alternate dispute resolution, including mediation and arbitration[61].

VIII. Hatch-Waxman Act, FDA & Patent Law

Hatch-Waxman Act, is a 1984 US federal law which encourages the manufacture of generic drugs by the pharmaceutical industry and established the modern system of government generic drug regulation in the United States. The formal name for the act is the *"Drug Price Competition and Patent Term Restoration Act, 1984"*.

Although the Federal *Food, Drug, and Cosmetic Act*[62] made it possible for generic companies to get regulatory approval for drugs by filing an *Abbreviated New Drug Application (ANDA)*[63], in the early 1980s it became clear that very few generics were coming to market. Congress studied the issue and realized that under patent and regulatory law, it was easy for innovator companies to make it difficult for generic companies to successfully file ANDAs and that the regulatory pathway to get ANDAs approved was irregular and uncertain. In response, the Hatch-Waxman Act was negotiated and enacted. Hatch-Waxman amended the Federal Food, Drug, and Cosmetic Act. § 505(j) of the Act, codified as 21 USC § 355(j), outlines the process for pharmaceutical manufacturers to file an Abbreviated New Drug Application (ANDA) for approval of a generic drug by the *Food and Drug Administration (FDA)*[64].The Act provides some protection for drug innovators while facilitating and

[56] 35 USC §§ 321-329, AIA § 6
[57] 35 USC §§ 311-319, AIA § 6
[58] 37 CFR §§ 42.300-304, AIA § 18
[59] 35 USC § 122, AIA § 8
[60] 35 USC § 301, AIA § 6
[61] 35 USC § 294
[62] < https://legcounsel.house.gov/Comps/Federal%20Food,%20Drug,%20And%20Cosmetic%20Act.pdf>
[63] An abbreviated new drug application (ANDA) contains data which is submitted to FDA for the review and potential approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, lower cost alternative to the brand-name drug it references.
[64] The Food and Drug Administration (FDA or USFDA) is a federal agency of the US Department of Health and Human Services, one of the US federal executive departments. The FDA is responsible for protecting and promoting public health through the control and supervision of food

providing incentives for companies to file ANDAs. The Act established an expedited pathway for generic drug companies to obtain FDA approval for their products. Generic drug manufacturers may file an ANDA with the FDA for market approval of a pharmaceutical if the active ingredient of the generic drug is the bioequivalent of the approved drug. Through amendments to both patent law and the food and drug law, the Act intends to facilitate the marketing of generic pharmaceuticals while providing brand firms with incentives to innovate. It requires brand firms to identify to the public any patents that cover their approved products, listed in the *"Orange Book"*[65]. A generic drug manufacturer, when seeking marketing approval from the FDA, must address any Orange Book-listed patents. This was done by delaying marketing of generic products until the relevant patents expire, or by asserting that the patents are invalid, not infringed or unenforceable. This latter assertion constitutes a statutory act of infringement and exposes the generic drug company to a patent infringement suit.

A generic drug company submitting either an ANDA or a § *505(b)(2)*[66] hybrid application must make one of the following four certifications as to each patent listed in the Orange Book for a Reference Listed Drug (RLD)[67]:

1) Paragraph I certification that no relevant patent is listed in the Orange Book;
2) Paragraph II certification that the listed patent has expired;
3) Paragraph III certification that the listed patent, plus any other exclusivity, will expire before the requested approval; and
4) Paragraph IV certification that the listed patent is invalid or will not be infringed by the commercialization of the generic drug and hence unenforceable.

safety, tobacco products, dietarysupplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products.

[65] The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act) and related patent and exclusivity information. For more information on the Orange Book including its history.

[66] A 505(b)(2) application is an NDA submitted under § 505(b)(1) and approved under § 505(c) of the FD&C Act that contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use.

[67] A Reference Listed Drug (RLD) is an approved drug product to which new generic versions are compared to show that they are bioequivalent. A drug company seeking approval to market a generic equivalent must refer to the Reference Listed Drug in its ANDA. By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart.

A generic drug company also may make a statement that the listed patent does not claim a use for which the applicant is seeking approval, which is known as a *Section viii* Statement (or *"carve out"*)[68]. A generic drug company can make both a Paragraph IV certification and a Section viii Statement, for example, when the patent covers both the product and a method of use.

The Act also contains several provisions directed toward its goal of increasing public access to generic drugs by decreasing the time and cost of seeking FDA approval, including:

1) the ability for the generic drug manufacturers to file ANDAs,
2) a 180-day exclusivity period for the first-filed generic drug product,
3) a safe-harbor from infringement when performing testing for regulatory review,
4) the ability to file declaratory judgment actions to resolve potential patent disputes, and
5) the ability to file a counterclaim to a patent infringement action seeking to de-list patents from the Orange Book.

With the passage of the Hatch-Waxman Amendments, the Federal Food, Drug and Cosmetic Act (FD&C Act) included different routes for obtaining approval of two broad categories of drug applications: new drug applications (NDAs) under § 505(b)(1)[69] and abbreviated new drug applications (ANDAs) under § 505(j)[70].

Hatch-Waxman Litigation: Patent litigation may be triggered under the Hatch-Waxman Act when the generic drug manufacturer files a Paragraph IV (P-IV) certification. Under 35 USC § 271(e)(2), *It shall be an act of infringement to submit … an application … for a drug claimed in a patent or the use of which is claimed in a patent … if the purpose of such submission is to obtain approval … to engage in*

[68] The FD&C Act describes only one circumstance in which an ANDA applicant need not certify to a listed patent. Specifically, when a patent is listed only for a method of use, an ANDA applicant seeking to omit that approved method of use from the generic drug's labelling can submit a section viii statement, acknowledging that a given method-of-use patent has been listed, but stating that the patent at issue does not claim a use for which the applicant seeks approval.

[69] A 505(b)(1) application is an NDA and approved under § 505(c) of the FD&C Act that contains full reports of investigations of safety and effectiveness hat have been fully conducted by the applicant.

[70] § 505(j) of the FD&C Act, together with its implementing regulations, generally requires that an ANDA must contain information to demonstrate that the proposed drug product and the applicable RLD are the same with respect to active ingredient(s), dosage form, route of administration, strength, previously approved conditions of use, and, with certain exceptions, labelling. An ANDA must also include sufficient information (1) to demonstrate that the proposed product is bioequivalent to the RLD and (2) to ensure the product's identity, strength, quality, and purity. Consistent with any statutory provisions related to the exclusivity of and patents listed for the RLD, FDA must approve an ANDA unless there is insufficient evidence that these criteria are met or there is inadequate information to ensure the identity, strength, quality, and purity of the drug product.

the commercial manufacture, use, or sale of a drug … claimed in a patent or the use of which is claimed in a patent before the expiration of such patent[71].

As such, the filing of an ANDA with a P-IV certification is a statutory act of infringement because the filing indicates that the generic company intends to engage in the commercial manufacture, use, or sale of a drug claimed in a patent before the expiration of such patent.

Within 20 days after the FDA accepts the ANDA for filing, the generic company is required to provide a Notice Letter to the patentee highlighting the existence of the ANDA. The Notice Letter must provide a detailed statement of the generic drug applicant's basis for believing that the Orange Book-listed patents ostensibly covering the drug at issue, are invalid or not infringed. (21 USC § 355(b)(3)[72] and 21 USC § 355(j)(2)(B)[73]). The patentee has 45 days from this notice to file a lawsuit for patent infringement against the ANDA applicant. An ANDA applicant may bring a declaratory judgment action against an NDA holder (patentee) if the NDA holder does not institute a patent infringement lawsuit within the required 45-day time period (21 USC § 355(c)(3)(D)(i)(aa)[74], 21 USC § 355(j) (5)(C)(i)(I)(aa)[75] and 35 U.S.C. § 271(e)(5)[76]).

If the patentee files a lawsuit within the 45-day period, such lawsuit triggers an automatic 30-month stay of any approval of the ANDA by the FDA. The 30-month stay is meant to

1) allow parallel resolution of the FDA's review of the ANDA and patent case, and
2) to provide certainty for the branded company because the generic drug company cannot launch the drug during this period while there is ongoing litigation.

If a court issues a final order determining that the patent is invalid, unenforceable or not infringed, the 30-month stay terminates (21 USC § 355(c)(3)(C)[77] and 21 USC § 355(j)(5)(B)(iii)[78]).

Under the Hatch-Waxman Act, a *"first ANDA filer"* has the potential to receive a 180-day exclusivity period during which the FDA is not allowed to approve any other ANDAs for the same pharmaceutical

[71] <https://www.govinfo.gov/content/pkg/USCODE-2011-title35/pdf/USCODE-2011-title35-partIII-chap28-sec271.pdf>
[72] <https://www.govinfo.gov/content/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21.pdf>
[73] <https://www.govinfo.gov/content/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21.pdf>
[74] <https://www.govinfo.gov/content/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21.pdf>
[75] <https://www.govinfo.gov/content/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21.pdf>
[76] <https://www.govinfo.gov/content/pkg/USCODE-2011-title35/pdf/USCODE-2011-title35-partIII-chap28-sec271.pdf>
[77] <https://www.govinfo.gov/content/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21.pdf>
[78] <https://www.govinfo.gov/content/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21.pdf>

drug (21 USC § 355(j)(5)(B)(iv)[79]). The term *"first ANDA filer"* refers to all of the applicants who submit substantially complete ANDAs with P-IV certifications on the same day that is earlier than any other ANDA filing (21 USC § 355(j)(5)(B)(iv)(II)(bb)[80]). Multiple ANDA applicants may hold exclusivity concurrently on the same drug if they each apply on the same day and file P-IV certifications concerning at least one of the Orange Book-listed patents for that drug (21 USC § 355(j)(5)(B)(iv)[81] and 21 CFR § 314.107(c)(1)[82]). The first filer(s) may forfeit the 180-day exclusivity under some circumstances (21 USC § 355(j)(5)(D)[83] and 21 USC § 355(q)(1)(G)[84]).

Once the ANDA litigation is filed, it proceeds through the standard stages as of other patent cases. This includes claims construction, in which the district court interprets the scope of the claims, fact and expert discovery, and trial.

However, the size of the brand is not the only factor in determining whether it will receive a P-IV challenge. In fact, brands of all levels of sales have received PIV certifications over the years. Moreover, when a brand receives a P-IV certification can be unpredictable as well. Since 2000, some brands have received a P-IV certification within months of approval but at other times it may be years before it receives its first P-IV certification. The only exception to this general observation is for NCE[85] products which have certain rules around when they can first receive a PIV certification (four years after approval). Since about 2012, many of these *"NCE-1[86]"* products have received multiple ANDA filers at year four. In many instances, there are correlations between pending P-IV cases and citizens petitions filed with the FDA as well as P-IV cases and petitions filed for Inter Parties Review with the USPTO. However, citizens petitions rarely affect a P-IV case and the proceedings often run in parallel with P-IV cases.

[79] <https://www.govinfo.gov/content/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21.pdf>
[80] <https://www.govinfo.gov/content/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21.pdf>
[81] <https://www.govinfo.gov/content/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21.pdf>
[82] <https://www.govinfo.gov/content/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21.pdf>
[83] <https://www.govinfo.gov/content/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21.pdf>
[84] <https://www.govinfo.gov/content/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21.pdf>
[85] A new chemical entity (NCE) is, according to the U.S. Food and Drug Administration, a drug that contains no active moiety that has been approved by the FDA in any other application submitted under § 505(b) of the Federal Food, Drug, and Cosmetic Act.
A new molecular entity (NME) is a drug that contains an active moiety that has never been approved by the FDA or marketed in the US.
[86] An ANDA for a generic version of the drug product covered by NDA could be submitted on the NCE-1 date if it contains a Paragraph IV certification. Such an interpretation of FDC Act § 505(j)(5)(F)(ii) seems to be consistent with FDA's NCE exclusivity *"umbrella policy".*

Exclusivity & Patent Law

Generics account for more than 80% of prescription drugs in the US, and that number continues to grow. With approaching patent expirations of several top selling prescription brand-name drugs, sponsors of innovator drug products and generic manufacturers need to know the ins and outs of patents and exclusivity. Patents. A patent is a property right issued by the USPTO to an inventor *"to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States"* for a limited time, in exchange for public disclosure of the invention when the patent is granted. A company may apply for a patent from the USPTO anywhere along the development lifeline of a drug and can encompass a wide range of claims. However, many other factors can affect the duration of a patent. Patent information is required to be submitted with original *New Drug Applications (NDAs)*[87] and supplements on *FDA Form 3542a*[88] prior to approval. Post-approval, patent information should be submitted on *FDA Form 3542*[89]. The information from FDA Form 3542 is published in the *Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations)*. For patents issued after approval of the NDA, the applicant holder has 30 days in which to file the patent to have it considered as a timely filed patent. Patents may still be submitted beyond the 30 day timeframe but the patent is not considered a timely filed patent. Abbreviated new drug application (ANDA) holders are not required to make a certification to an untimely filed patent if the generic application is submitted before the patent. FDA will not publish in the Orange Book patent information on unapproved applications or on patents beyond the scope of the *Food Drug & Cosmetic Act* (i.e., process or manufacturing patents). The patents that FDA regards as covered by the statutory provisions for submission of patent information are:

- patents that claim the active ingredient(s);
- drug product patents which include formulation/ composition patents;
- use patents for a particular approved indication or method of using the product; and
- certain other patents as detailed on FDA Form 3542.

[87] Every new drug in the US has been the subject of an approved NDA before US. commercialization. The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the US. The goals of the NDA are to provide enough information to permit FDA reviewer to reach the following key decisions:

- Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.
- Whether the drug's proposed labelling (package insert) is appropriate, and what it should contain.
- Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity

[88] < https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM531597.pdf>

[89] <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM531595.pdf>

Exclusivity: Exclusivity is exclusive marketing rights granted by the FDA upon approval of a drug and can run concurrently with a patent or not. It prevents the submission or effective approval of ANDAs or applications described in § *505(b)(2) of the Act*, and was designed to promote a balance between new drug innovation and generic drug competition. Exclusivity is granted upon approval of a drug product if the statutory requirements are met. The length of time that FDA grants new drug exclusivity depends on the type of exclusivity. Note that exclusivity is not added to the patent life. Hatch Waxman exclusivity (5-year, 3- year, and 180-day) is described in 21 CFR. 314.108[90]. There are four types of exclusivity that fall under the NDA statutory requirements:

1) Orphan Drug Exclusivity (ODE) - 7 years:
    - Granted to drugs designated and approved to treat diseases or conditions affecting fewer than 200,000 in the U.S. (or more than 200,000 and no hope of recovering costs)
    - Runs from time of approval of NDA or BLA[91]
    - Bars FDA from approving any other application (ANDA, 505(b)(2) or *"full"* NDA or BLA) for the same drug for the same orphan disease or condition for seven years
    - Covered under the Orphan Drug Act and 21 CFR 316.31[92].
2) New Chemical Exclusivity (NCE) - 5 years:
    - Granted to a drug that contains no active moiety that has been approved by FDA under § 505(b)
    - Runs from time of NDA approval
    - Bars FDA from accepting for review any ANDA or 505(b)(2) application for a drug containing the same active moiety for: - *five years* if an ANDA or 505(b)(2) does not contain a paragraph IV certification to a listed patent - *four years* if an ANDA or 505(b)(2) is submitted containing a paragraph IV certification to a listed patent
    - Described in 21 CFR 314.108[93].

[90] <https://www.govinfo.gov/content/pkg/CFR-2012-title21-vol5/pdf/CFR-2012-title21-vol5-part314.pdf>

[91] The Biologics License Application (BLA) is a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce (21 CFR 601.2). The BLA is regulated under 21 CFR 600 – 680. A BLA is submitted by any legal person or entity who is engaged in manufacture or an applicant for a license who takes responsibility for compliance with product and establishment standards. Form 356h specifies the requirements for a BLA. This includes:

- Applicant information
- Product/Manufacturing information
- Pre-clinical studies
- Clinical studies
- Labelling

[92] <https://www.govinfo.gov/content/pkg/CFR-2012-title21-vol5/pdf/CFR-2012-title21-vol5-part316.pdf>

[93] <https://www.govinfo.gov/content/pkg/CFR-2012-title21-vol5/pdf/CFR-2012-title21-vol5-part314.pdf>

3) *"Other"* Exclusivity - 3 years for a *"change"* if criteria are met:
    - Granted to drug when application or supplement contains reports of new clinical investigations (not bioavailability studies) conducted or sponsored by applicant and essential for approval
    - Runs from time of NDA approval
    - Bars FDA from approving, for a three year period, any ANDA or 505(b)(2) application that relies on the information supporting the approval of the drug or the change to the drug for which the information was submitted and the exclusivity granted
    - Described in 21 CFR 314.108[94].
4) Paediatric Exclusivity (PED) - 6 months added to existing Patents/Exclusivity

    • Grants an additional 6 months of market protection at the end of listed patents and/or exclusivity for sponsor's drug products containing the active moiety, when the sponsor has conducted and submitted paediatric studies on the active moiety in response to a Written Request from FDA

    • Paediatric exclusivity takes on characteristics of five year, three year or orphan exclusivity when it attaches to those protections.

    • Described in the *Best Pharmaceuticals for Children Act (BCPA)*[95] and § 505(A) of the *Food and Drug Administration Modernization Act of 1997*[96].

Note also that under the *Generating Antibiotic Incentives Now (GAIN)*[97] Title VIII of the *FDA Safety and Innovation Act (FDASIA)*[98], at the time of approval FDA will grant an additional five years to

[94] <https://www.govinfo.gov/content/pkg/CFR-2012-title21-vol5/pdf/CFR-2012-title21-vol5-part314.pdf>

[95] The Best Pharmaceuticals for Children Act (BPCA) became law in 2002. It was reauthorized in 2007 under the Food and Drug Administration (FDA) Amendments Act, in 2012 under the FDA Safety and Innovation Act, and again in 2017 under the FDA Reauthorization Act
- <https://www.govinfo.gov/content/pkg/PLAW-107publ109/pdf/PLAW-107publ109.pdf>

[96] < https://www.govinfo.gov/content/pkg/PLAW-105publ115/pdf/PLAW-105publ115.pdf>

[97] Generating Antibiotic Incentives Now (GAIN) was passed in 2012 as part of the Food and Drug Administration Safety and Innovation Act (FDASIA). It addresses the public health threat of antibacterial drug resistance by stimulating the development and approval of new antibacterial and antifungal drugs – <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM595188.pdf>

[98] The Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) is a piece of American regulatory legislation signed into law on July 9, 2012. It gives the US Food and Drug Administration (FDA) the authority to collect user fees from the medical industry to fund reviews of innovator drugs, medical devices, generic drugs and biosimilar biologics. It also creates the breakthrough therapy designation program and extends the priority review voucher program to make eligible rare paediatric diseases - < https://www.govinfo.gov/content/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf>

certain exclusivity periods for products that have been granted a *Qualified Infectious Disease Product (QIDP)*[99] designation (with some exceptions).

180-Day Exclusivity: FDA may also grant exclusivity to abbreviated new drug applications (ANDAs) for generic drugs. Under the Drug Price Competition and Patent Term Restoration Act, or the Hatch-Waxman Act, a company can seek approval from FDA to market a generic drug before the expiration of a patent relating to the brand name drug upon which the generic is based. The first company to submit an ANDA with the FDA has the exclusive right to market the generic drug for 180 days. This is called 180-day exclusivity.

- Provides an incentive of 180 days of market exclusivity to the *"first"* generic applicant who challenges a listed patent by filing a paragraph IV certification and running the risk of having to defend a patent infringement suit
- Begins either from the date the sponsor begins commercial marketing of the generic drug product, or from the date of a court decision finding the patent invalid, unenforceable or not infringed, whichever is first
- In some circumstances, an applicant who obtains 180-day exclusivity may be the sole marketer of a generic competitor to the innovator product for 180 days
- FDA does not send letters to the sponsor indicating the grant of exclusivity. The Orange Book is the official vehicle for dissemination of this information.

Note that some drugs have both patent and exclusivity protections while others have just one or none. Patents and exclusivity may or may not run concurrently and may or may not encompass the same claims.

CDER Exclusivity Board: CDER has established an Exclusivity Board to provide oversight and recommendations regarding exclusivity determinations made by the Center, with a primary focus on clarity and consistency of decisions. The CDER Exclusivity Board oversees certain exclusivity determinations, including whether and what type of exclusivity should be granted and the appropriate scope of exclusivity grants.

[99] Qualified Infectious Disease Product (QIDP) designation is offered by the US FDA to help incent the development of treatments for infectious diseases. Title VIII of FDASIA, Generating Antibiotic Incentives Now (GAIN), added § 505E of the Food, Drug & Cosmetic Act, providing incentives for the development of antibacterial and antifungal drugs for human use intended to treat serious and life-threatening infections (21 CFR § 317.2, 2017). In order to counter the threat of antibiotic resistance, the Act provides incentives and additional guidance to pharmaceutical companies developing innovative antibiotic products. Innovative includes both 505(b)(1) as well as 505(b)(2) drug candidates.

The Board will focus on

1) 5-year new chemical entity (NCE) exclusivity,
2) 3-year new clinical trial exclusivity, and exclusivity for biological products.

The Board will not review or make recommendations with respect to all exclusivity determinations in these areas, but will assist the Center in resolving certain matters, including issues that arise in the context of specific requests for exclusivity.

IX. Patent Term Extensions & Restorations

Present US patent laws consist of four forms of patent extension:

1) Extension arises when Congress enacts private legislation (Least common).
2) Extension of a patent term for delays within the USPTO during patent prosecution[100].
3) Extension comes from the *Uruguay Rounds Agreements Act*[101] enacted in 1994 - the Act amended so that patents filed on or after June 8, 1995 have a patent term of twenty years from the date they are filed[102]. Previously, patents had a seventeen-year term from the date they issued. However, design patents still only have a fourteen-year term from the date of patent grant. According to § *154(c)*[103], all patents (other than design patents) that were in force on June 8, 1995, or that issued on an application that was filed before June 8, 1995,have a term that is the greater of the twenty years from filing or seventeen years from issue (almost unused at present).
4) Commonly called a patent term restoration, was created in 1984 when Congress passed the *Drug Price Competition and Patent Restoration Act* also known as the *Hatch-Waxman Act* - permitting patent term extension for patents on products (or processes for making or using the same) that are human drug products, medical devices, food additives, and colour additives subject to regulation under the *Federal Food, Drug and Cosmetic Act*[104]. The Act restores a portion of the patent term during which the patentee is unable to sell or market a product while awaiting government approval, such as the FDA review of a prescription drug. Maximal extension possible is up to 5 years.

[100] 35 USC § 154
[101] < https://www.govinfo.gov/content/pkg/BILLS-103hr5110enr/pdf/BILLS-103hr5110enr.pdf>
[102] 35 USC § 154
[103] <https://www.govinfo.gov/content/pkg/USCODE-2011-title35/pdf/USCODE-2011-title35-partII-chap14-sec154.pdf>
[104] 35 USC § 156

In 1988, the *Generic Animal Drug and Patent Term Restoration Act*[105] in 1988 added animal drug and veterinary biological products to the list of products eligible for a term extension.

Many businesses may be able to benefit from a patent term extension if they had to obtain regulatory approval for a drug or medical device. The extension offsets some of the delay required during agency approval of the drug, device, or process. The patent term extension allows the patent owner to capture economic benefits associated with an invention that could not be obtained during the agency review. Thus with an extension, some lost market time is made up and the patent remains enforceable for the product or process that was submitted to the government agency.

There are limitations that restrict the availability and length of a patent term extended under the Hatch-Waxman Act:

1) The product must be the subject of a regulatory review period before its commercial marketing or use.
2) Only one restoration period can be sought.
3) A restoration period cannot be obtained for agency review of a subsequently approved drug covered by the same patent whose marketing also is delayed for reasons of FDA procedures; such term extension would not cover the subsequent drug.
4) An applicant for patent extension must file the request with the USPTO within 60 days of product approval by the agency.

The restoration period is calculated by the USPTO using the regulatory review period as the basis for a patent extension. The review period is generally limited to the testing and approval phases of review. By way of example, the regulatory review period for a prescription drug would start upon the filing of an Investigational *IND*[106], include the submission of the marketing application *NDA* and end after approval of the marketing application. Each phase of the regulatory review period is reduced by any time when the applicant fails to act with due diligence. The restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed fourteen years following agency approval. After the FDA calculates the regulatory review period, it is published so that a third party may challenge the application for patent term extension. Any person may file a due diligence petition with the FDA within 180 days after the publication of the review period and allege

[105] <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ActsRulesRegulations/ucm049100.htm>

[106] An Investigational New Drug Application (IND) is a request for Food and Drug Administration (FDA) authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved new drug application.

that the patent extension applicant did not act with due diligence during the regulatory review period. Information regarding the filing, format, and content of petitions, applicant's response to petition and standard of due diligence is available in the Patent Term Restoration regulations[107]. Any person may also request within 60 days after the publication of FDA's due diligence determination that FDA conduct an informal hearing on the due diligence determination. Information regarding the request for a hearing, notice of hearing, hearing procedures, and administrative decision is available in the Patent Term Restoration Regulations[108]. The restoration period does not extend to all products encompassed by the patent claims, but only to the product on which the extension was based[109]. In other words, the patent may contain claims that are not extended by the Act and practicing those claims after the original patent term expires may not constitute infringement. The USPTO lists patents which have been extended under § 156 of the statute on its website[110].

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[107] 21 CFR PART 60
[108] 21 CFR PART 60
[109] Merck & Co., Inc. v. Kessler, 80 F.3d 1543 ,1547 (Fed. Cir. 1996)
[110] < https://www.uspto.gov/patent/laws-and-regulations/patent-term-extension/patent-terms-extended-under-35-usc-156>

CHAPTER II

EUROPEAN PATENT REGIME

Introduction to European Patents

European patent law covers a wide range of legislations including national patent laws, the *Strasbourg Convention*[1] of 1963, the *European Patent Convention*[2] of 1973, and a number of European Union directives and regulations in countries which are party to the *European Patent Convention*. For certain states in Eastern Europe, the *Eurasian Patent Convention*[3] applies.

Patents having effect in most European states may be obtained either nationally, via national patent offices, or via a centralised patent prosecution process at the *European Patent Office (EPO)*[4]. The EPO is a public international organisation established by the European Patent Convention. The EPO is not a *European Union*[5] or a *Council of Europe Institution*[6]. A patent granted by the EPO does not lead to a single European patent enforceable before one single court, but rather to a bundle of essentially independent national European patents enforceable before national courts according to different national legislations and procedures. Similarly, Eurasian patents are granted by the *Eurasian Patent Office* and become after grant independent national Eurasian patents enforceable before national courts. European patent law is also shaped by international agreements such as the WTO's Agreement on *Trade-Related Aspects of Intellectual Property Rights* (TRIPs Agreement)[7], the *Patent Law Treaty* (PLT)[8] and the *London Agreement*[9].

In the late eighteenth and early nineteenth centuries patent laws were passed in numerous countries, including the US in 1790, France in 1791, Spain in 1811, Prussia in 1815, and the Netherlands in 1817. The importance the industrial revolution placed on technical change was a major factor in the adoption of these laws. The French law became the model for most European and Latin American patent laws. France's 1791 law *"presents intellectual property as a natural right of the individual, of the same kind as any other type of property"*. France's view was that an invention's value was to be judged by society,

[1] <https://www.wipo.int/edocs/trtdocs/en/coe/trt_coe.pdf>
[2] <https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/EPC_conv_20180401_en_20181012.pdf>
[3] < http://agepi.gov.md/sites/default/files/law/international/eurasian_patent_convention-en.pdf>
[4] < https://www.epo.org/index.html>
[5] < https://europa.eu/european-union/index_en>
[6] < https://www.coe.int/en/web/children/coe-institutions>
[7] < https://www.wto.org/english/docs_e/legal_e/27-trips.pdf>
[8] < https://www.wipo.int/export/sites/www/patent-law/en/pdf/plt_features.pdf>
[9] < http://www.icls.de/dokumente/imt_london_agreement.pdf>

and not by the government. Any problems or claims were to be solved by the judiciary. Limited durations of five to fifteen years were granted on patents under this law[10].

The first relevant international convention to the European Patent System was the *Paris Convention* in 1883. Although the major focus of this convention was not patent law, it marked the first time that there was international cooperation in patent law. Even though relatively few aspects of patent law were discussed during the Paris Convention, the Convention opened the door for future cooperation.

The US began to press for international agreements to include patent rights, and the result was the Trade Related IP agreements (TRIPs) of 1994. On June 19, 1970, in Washington, DC, the Pate*nt Cooperation Treaty* (PCT)[11] was signed. Although the current European Patent System is independent from the PCT, the PCT is still relevant because it shows how the European System interacts with the rest of the world. Procedurally, the PCT allows an applicant to file what is known as an international application in any of the ratifying countries. As long as all formal requirements are complied with, the international application has the potential to become a patent in every ratifying country which the applicant designates in the international application.

While international agreements were being made with respect to patent law, Europe was developing its own agreements exclusively among European nations. The *Council of Europe*[12], established in 1949, provided a forum for discussion that would lead to European patent law's further internationalization. The *Strasbourg Convention* came out of talks to unify Europe on both procedural and substantive requirements of patent law. The key purpose of this convention was to unify the patent system throughout Europe, thereby encouraging industry and invention in all of Europe. The Council of Europe also called for implementation of the EPO. Officially titled *"The Convention on the Grant of European Patents"*[13], the EPC took place between September 10 and October 05, 1973. It is only open to European countries. In establishing the internal rules for a European patent, the EPC's primary function was to set up the EPO. *"The EPO is a stand-alone body, unrelated to other European institutions such as the European Commission"*. Its administrative council is comprised of member-state representatives. The EPO is financed through application and renewal fees as well as fees from member states.

[10] Domnique Guellec & Bruno Van Pottelsberghe de la Potterie, "The Economics of the European Patent System: IP Policy for Innovation and Competition", Oxford Scholarship Online (2007).
[11] < https://www.wipo.int/export/sites/www/pct/en/texts/pdf/pct.pdf>
[12] < https://www.coe.int/en/web/portal>
[13] < https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/EPC_conv_20180401_en_20181012.pdf>

In 1975, the *Community Patent Convention* (CPC)[14] set out to solve this problem via the community patent system.74 This system had already been discussed and attempted during the Strasbourg Convention; however, that attempt was unsuccessful because the United Kingdom did not join.

I. European Patent Convention

A patent is a legal title granting its holder the right – in a particular country and for a certain period of time - to prevent third parties from exploiting an invention for commercial purposes without authorisation. The EPC has established a single European procedure for the grant of patents on the basis of a single application and created a uniform body of substantive patent law designed to provide easier, cheaper and stronger protection for inventions in the contracting states[15].

In each contracting state for which it is granted, a European patent gives its proprietor the same rights as would be conferred by a national patent granted in that state. If its subject-matter is a process, protection is extended to products directly obtained by that process. Any infringement of a European patent is dealt with by national law.

A published European patent application provides provisional protection which is no less than that conferred by a contracting state for a published national application and which must at least include the right to reasonable compensation in the event of wrongful infringement[16].

The standard term of a European patent is twenty years as from the date of filing. Provided that the annual renewal fees are duly paid, patents remain in force for the maximum term[17].
However, there are circumstances in which the term of a patent can be extended or a longer term granted. This option of extension by means of a *Supplementary Protection Certificate (SPC)* is intended primarily for medicinal or plant protection product patents, where the administrative approval procedure takes so long that the useful life of the patent is diminished[18].
European patents may also be effective in some countries that have not acceded to the EPC (extension and validation states)[19].

[14] < https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1976:017:0001:0028:EN:PDF>
[15] The contracting states are: Albania, Austria, Belgium, Bulgaria, Cyprus, Croatia, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.
[16] Article 64 EPC.
[17] Article 67 EPC.
[18] Article 63(2) EPC.
[19] At present these are Bosnia and Herzegovina and Montenegro (extension states) as well as Morocco, the Republic of Moldova, Tunisia and Cambodia (validation states).

A European Patent Application, that is, an application filed under the EPC, must be filed in one of the EPC's official languages: English, French, or German. European Patent Applications are to be filed in Munich at the EPO's main office, or through a national patent office. If a patent is granted as a result of a European Patent Application, then the resulting patent has the same effect in all designated EPO countries as a national patent in each designated country would. This concept is generally called a *"bundle of patents"*. In essence, obtaining such a bundle is simple: A single European Patent Application is filed with the EPO. The applicant designates EPC member countries in which he or she wishes to have patent rights should a European Patent ultimately be granted. If the patent is granted, the applicant now has a patent enforceable in all EPC countries that he or she has designated. This system allows an applicant to avoid filing an application in every European country, a process that would be quite expensive and time-consuming. Also, under this system, member countries are able to maintain sovereignty over patent enforcement because the EPC established that patent rights must be administered and enforced in each designated country.

The EPC is the law in Europe, but it is not without problems. It has drawn criticism for being expensive and difficult to navigate. For decades the European Commission has attempted to create a more unified and user-friendly system with a single court system for enforcement.

The 16th edition of the European Patent Convention (published June, 2016) is currently available. It contains:

1) the Convention on the Grant of European Patents (EPC) as in force since December 13, 2007.
2) the EPC Implementing Regulations as in force since May 01, 2016 but also including an amendment that entered into force on November 01, 2016.
3) the rules of procedure of the EPO boards of appeal and Enlarged Board of Appeal, included for the first time in an edition of the EPC.
4) the protocols forming integral parts of the EPC (Protocol on the Interpretation of Article 69 EPC, Protocol on Centralisation, Protocol on Recognition, Protocol on Privileges and Immunities, Protocol on the Staff Complement).
5) an extract from the EPC Revision Act of November 29, 2000.
6) the Administrative Council's decision of June 28, 2001 on the transitional provisions under Article 7 of the Revision Act.
7) the Rules relating to Fees.

It also contains an index of decisions and opinions of the Enlarged Board of Appeal published in the EPO's Official Journal[20], a list cross-referencing the EPC 2000 provisions with their EPC 1973 equivalents[21] and an alphabetical keyword index.

II. European Patent Office

The European Patent Office (EPO) is one of the two organs of the European Patent Organisation[22], the other being the Administrative Council[23]. The EPO acts as executive body for the Organisation while the Administrative Council acts as its supervisory body as well as, to a limited extent, its legislative body. The actual legislative power to revise the European Patent Convention lies with the Contracting States themselves when meeting at a Conference of the Contracting States.

Within the European Patent Office, examiners are in charge of studying European patent applications, filed by applicants, in order to decide whether to grant a patent for an invention. The patents granted by the European Patent Office are called European patents.

The EPO grants European patents for the Contracting States to the European Patent Convention. The EPO provides a single patent grant procedure, but not a single patent from the point of view of enforcement. Hence the patents granted are not European Union patents or even Europe-wide patents, but a bundle of national patents.

Currently the EPO is comprised of thirty-eight member states, two extension states and four validation states. The European Patent System is quite *"complex and costly . . . as a patent must . . . be validated, put in force, and renewed in each national patent system, with its own legislation and its own fees structure".* Usually *"applicants start with a national filing, commonly called a priority filing"*. The priority filing establishes the priority date of a patent application. For one year after the priority date, an applicant may extend an application to other countries under the Paris Convention. The applicant

[20] Annex I.
[21] Annex II.
[22] The European Patent Organisation (sometimes abbreviated EPOrg) is a public international organisation created in 1977 by its contracting states to grant patents in Europe under the European Patent Convention(EPC) of 1973. The European Patent Organisation has its seat at Munich, Germany, and has administrative and financial autonomy. The European Patent Organisation is not legally bound to the European Union (EU) and has several members which are not themselves EU states.
[23] The Administrative Council is made up of members of the Contracting States and is responsible for overseeing the work of the European Patent Office,[23] ratifying the budget and approving the actions of the President of the Office. The Council is also competent for amending the Implementing Regulations of the EPC and some particular provisions of the Articles of the EPC. Each Contracting State on the Administrative Council has one vote,[27] except under certain circumstances provided for by Article 36 EPC.

may also obtain a thirty-month period to decide which countries to designate by filing an international application with the WIPO under PCT rules. *"Partly as a function of a consideration of expected profits and targeted markets, applicants must [m]ake the decision of whether to file nationally, regionally, and/or internationally"*. As a result, EPO applications are usually secondary from a PCT application or an EPC member application.

If an applicant wishes to receive protection in only one country, the applicant will probably file a national patent application in that state, rather than through the EPO. This is so because it is less expensive to obtain a national patent than a European patent.96 An applicant could likewise file in several countries, or even all EPC member countries, and obtain the same rights conferred as a European Patent, although this latter option would neither be cost-effective nor efficient.

III. Patentability Requirements

In the EPO, there are four basic requirements for patentability[24]:

1) there must be an *"invention"*, belonging to any field of technology;
2) the invention must be *"susceptible of industrial application"*;
3) the invention must be "new"; and
4) the invention must involve an *"inventive step"*.

Inventions

The EPC does not define what is meant by *"invention" but* contains a non-exhaustive list of things which are not regarded as inventions[25]. It will be noted that the items on this list are all either abstract (e.g. discoveries or scientific theories) and/or non-technical (e.g. aesthetic creations or presentations of information). In contrast to this, an *"invention"* within the meaning of Article 52(1) must be of both a concrete and a technical character. It may be in any field of technology. The list of exclusions primarily include:

1) Discoveries;
2) Scientific theories;
3) Mathematical methods;
4) Aesthetic creations;
5) Schemes, rules and methods for performing mental acts, playing games or doing business;
6) Programs for computers; and
7) Presentations of information.

[24] Article 52(1) EPC.
[25] Article 52(2) EPC.

Any invention the commercial exploitation of which would be contrary to *"ordre public"* or morality is specifically excluded from patentability[26]. European patents are also not granted in respect of *"methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods"*[27]. Hence, patents may be obtained for surgical, therapeutic or diagnostic instruments or apparatuses for use in such methods. The manufacture of prostheses or artificial limbs could be patentable.

In principle, biotechnological inventions are patentable under the EPC[28]. Biotechnological inventions are also patentable if they concern an item on the following non-exhaustive list:

1) Biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature. Hence, biological material may be considered patentable even if it already occurs in nature.
2) Although the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions, an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. Such an element is not *a priori* excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to produce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing itself[29].

   The examination of a patent application or a patent for gene sequences or partial sequences is subject to the same criteria of patentability as in all other areas of technology[30]. The industrial application of a sequence or partial sequence must be disclosed in the patent application as filed;
3) Plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety and if said plants or animals are not exclusively obtained by means of an essentially biological process. Inventions which concern plants or animals are patentable

[26] Article 53(a) EPC.
[27] Article 53(c) EPC.
[28] *"Biotechnological inventions"* are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. *"Biological material"* means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.
[29] EU Dir. 98/44/EC, rec. 21.
[30] EU Dir. 98/44/EC, rec. 22.

provided that the application of the invention is not technically confined to a single plant or animal variety[31]. However, said plants or animals must not be exclusively obtained by means of an essentially biological process. If a technical feature of a claimed plant or animal, e.g. a single nucleotide exchange in the genome, might be the result of either a technical intervention (e.g. directed mutagenesis) or an essentially biological process (a natural allele), a disclaimer is necessary to delimit the claimed subject-matter to the technically produced product; or

4) A microbiological[32] or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

Industrial Application

"An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture". "Industry" is understood in its broad sense as including any physical activity of *"technical character"*, i.e. an activity which belongs to the useful or practical arts as distinct from the aesthetic arts; it does not necessarily imply the use of a machine or the manufacture of an article.

Methods of testing generally are regarded as inventions susceptible of industrial application and therefore patentable if the test is applicable to the improvement or control of a product, apparatus or process which is itself susceptible of industrial application.

"Susceptibility of industrial application" is not a requirement that overrides other restrictions. On the other hand, although an invention must be *"susceptible of industrial application"* and the description must indicate, where this is not apparent, the way in which the invention is thus susceptible, the claims need not necessarily be restricted to the industrial application(s).

State of the Art

An invention is *"considered to be new if it does not form part of the state of the art"*. The *"state of the art"* is defined as *"everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application"*. The width of this definition is to be noted. There are no restrictions whatever as to the geographical location where or the language or manner in which the relevant information was made available to the public; also no age limit is stipulated for the documents or other sources of the information. There are, however, certain specific exclusions. However, since the *"state of the art"* available to the examiner will mainly consist

[31] EU Dir. 98/44/EC, rec. 29.

[32] "Microbiological process" means any process involving or performed upon or resulting in microbiological material.

of the documents listed in the search report, deals with the question of public availability only in relation to written description (either alone or in combination with an earlier oral description or use).

The principles to be applied in determining whether other kinds of prior art (which could be introduced into the proceedings e.g. by a third party[33]) have been made available to the public.

A written description, i.e. a document, is regarded as made available to the public if, at the relevant date, it was possible for members of the public to gain knowledge of the content of the document and there was no bar of confidentiality restricting the use or dissemination of such knowledge. For instance, German utility models[34] (are already publicly available as of their date of entry in the Register of utility models[35] which precedes the date of announcement in the Patent Bulletin[36]. The search report also cites documents in which doubts with regard to the fact of public availability (for *"in-house state of the art"*) and doubts concerning the precise date of publication of a document have not, or not fully, been removed.

If the applicant contests the public availability or assumed date of publication of the cited document, the examiner needs to consider whether to investigate the matter further. If the applicant shows sound reasons for doubting whether the document forms part of the *"state of the art"* in relation to his application and any further investigation does not produce evidence sufficient to remove that doubt, the examiner does not pursue the matter further. The only other problem likely to arise for the examiner is where:

1) a document reproduces an oral description (e.g. a public lecture) or gives an account of a prior use (e.g. display at a public exhibition); and
2) only the oral description or lecture was publicly available before the *"date of filing"* of the European application, the document itself being published on or after this date.

In such cases, the examiner starts with the assumption that the document gives a true account of the earlier lecture, display or other event and therefore regards the earlier event as forming part of the *"state of the art"*. If, however, the applicant gives sound reasons for contesting the truth of the account given in the document then again the examiner does not pursue the matter further.

[33] Article 115 EPC.
[34] *"Gebrauchsmuster*"
[35] "*Eintragungstag"*
[36] *"Bekanntmachung im Patentblatt"*.

Novelty

An invention is considered to be new if it does not form part of the state of the art. For a definition of *"state of the art"*. It is to be noted that in considering novelty, it is not permissible to combine separate items of prior art together. It is also not permissible to combine separate items belonging to different embodiments described in one and the same document, unless such combination has specifically been suggested[37].

Furthermore, any matter explicitly disclaimed (with the exception of disclaimers which exclude unworkable embodiments) and prior art acknowledged in a document, in so far as explicitly described therein, are to be regarded as incorporated in the document.

It is further permissible to use a dictionary or similar document of reference in order to interpret a special term used in a document. An unclear term cannot be used to distinguish the invention from the prior art.

In determining novelty, a prior-art document is to be read as it would have been read by a person skilled in the art on the relevant date of the document. By *"relevant"* date is meant the publication date in the case of a previously published document and the date of filing (or priority date, where appropriate) in the case of a document[38].

Subject-matter described in a document can only be regarded as having been made available to the public, and therefore as comprised in the state of the art[39], if the information given therein to the skilled person is sufficient to enable him, at the relevant date of the document, to practise the technical teaching which is the subject of the document, taking into account also the general knowledge at that time in the field to be expected of him. In considering novelty, it is to be borne in mind that a generic disclosure does not usually take away the novelty of any specific example falling within the terms of that disclosure, but that a specific disclosure does take away the novelty of a generic claim embracing that disclosure. In the case of a prior-art document, the lack of novelty may be apparent from what is explicitly stated in the document itself. Alternatively, it may be implicit in the sense that, in carrying out the teaching of the prior-art document, the skilled person would inevitably arrive at a result falling within the terms of the claim. In determining novelty of the subject-matter of claims, particularly for claims directed to a physical entity, non-distinctive characteristics of a particular intended use are to be disregarded.

[37] T 305/87
[38] Article 54(3) EPC.
[39] Article 54(1) EPC.

Inventive Step

An invention is considered as involving an inventive step if, having regard to the state of the art, it is not obvious to *"a person skilled in the art"*[40]. Novelty and inventive step are different criteria. The question - *"Is there inventive step?"* - only arises if the invention is novel.

Thus the question to consider, in relation to any claim defining the invention, is whether before the filing or priority date valid for that claim, having regard to the art known at the time, it would have been obvious to the person skilled in the art to arrive at something falling within the terms of the claim. If so, the claim is not allowable for lack of inventive step. The term *"obvious"* means that which does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art, i.e. something which does not involve the exercise of any skill or ability beyond that to be expected of the person skilled in the art. In considering inventive step, as distinct from novelty, it is fair to construe any published document in the light of knowledge up to and including the day before the filing or priority date valid for the claimed invention and to have regard to all the knowledge generally available to the person skilled in the art up to and including that day.

The EPC does not require explicitly or implicitly that an invention, to be patentable, must entail some technical progress or even any useful effect. Nevertheless, *an advantageous effect*, if any, with respect to the state of the art should be stated in the description, as any such effect is often important in determining *"inventive step"*.

IV. European Patent Application

The European procedure has not superseded the national grant procedures. So when seeking patent protection in one or more EPC contracting states one have a choice between following the national procedure in each state for which you want protection and taking the European route, which in a single procedure confers protection in all the contracting states that you designate. If one decides a European patent, one has a further choice between the direct European route and the Euro-PCT route. With the

[40] The *"person skilled in the art"* is presumed to be a skilled practitioner in the relevant field of technology, who is possessed of average knowledge and ability and is aware of what was common general knowledge in the art at the relevant date. He is also presumed to have had access to everything in the *"state of the art"*, in particular the documents cited in the search report, and to have had at his disposal the means and capacity for routine work and experimentation which are normal for the field of technology in question. If the problem prompts the person skilled in the art to seek its solution in another technical field, the specialist in that field is the person qualified to solve the problem. The skilled person is involved in constant development in his technical field. Assessment of whether the solution involves an inventive step must therefore be based on that specialist's knowledge and ability. There may be instances where it is more appropriate to think in terms of a group of persons, e.g. a research or production team, rather than a single person. It is to be borne in mind that the skilled person has the same level of skill for assessing inventive step and sufficient disclosure.

direct European route, the entire European patent grant procedure is governed by the EPC alone; with the Euro-PCT route, the first phase of the grant procedure (the International Phase) is subject to the PCT, while the regional phase before the EPO as designated or elected Office is governed primarily by the EPC.

A European patent is granted after an examination designed to establish whether the European patent application and the invention to which it relates comply with the patentability requirements of the EPC. The grant procedure is conducted by the EPO's Receiving Section, search divisions and examining divisions; if they decide against your application, one can file an appeal before the boards of appeal of the EPO. Once a European patent has been granted, there follows a nine month period in which third parties are entitled to file a reasoned notice of opposition; and at the end of the resulting opposition proceedings, either the patent is maintained as granted or as amended or it is revoked. The decision taken in the opposition proceedings applies to all designated contracting states and can also be appealed before the EPO's boards of appeal. Once it has been granted, one can file a request for limitation or revocation of one's own patent. European patents have a uniform wording and a uniform extent of protection for all designated contracting states and offer a high presumption of validity. Patent law in the contracting states has been extensively harmonised with the EPC in terms of patentability requirements. However, as grant procedures continue to be differently structured and are conducted in parallel by several offices, the national route generally leads to national rights with differing extents of protection.

Filing options

There are a number of options for filing European patent applications with the European Patent Office:

1) Online: European patent applications can be filed online using either the EPO's Online Filing software, the new online filing (CMS) application or via the web-form filing service.
2) By post, fax or by hand: Applications for European patents can be filed by post, fax (excluding authorisations and priority documents) or by hand at the EPO's headquarters in Munich, its branch in The Hague and its Berlin sub-office.
3) Via automated mailbox: Automated mailboxes, which can be used at any time, are located in Munich and Berlin.
4) Filing with the National Patent Offices: European patent applications can also be filed with the central industrial property offices of participating contracting states.

Request for Extension / Validation

At the request of the applicant/owner, European patent applications and patents may be extended to or validated in third countries for which an extension or validation agreement has entered into force.

Any European patent application is deemed to be a request to extend/validate the effects of the European patent application and the European patent granted in respect of it to all states not party to the EPC with which extension or validation agreements are in force on the date on which the application is filed. However, the request is deemed withdrawn if the extension fee or validation fee, whichever is applicable, is not paid within the prescribed time limit. The time limits for paying extension and validation fees are governed by the national laws of the extension/validation states, according to which extension and validation fees are to be paid within six months from the date on which the European Patent Bulletin mentions the publication of the European search report. If the extension or validation fee is not paid in due time, the request for extension or validation is deemed withdrawn. If the extension or validation fee for a state is not paid within the basic period, the applicant can still pay it, together with a surcharge within two months of expiry of the basic period (*"grace period"*). Re-establishment of rights is not available in respect of payment of the extension or validation fee[41].

Oppositions

Opposition to any European patent granted by the EPO under the EPC may be filed by any member of the public except for the proprietor himself. Opposition must be filed within nine months of the publication of the mention that the patent has been granted. The procedure may involve multiple opponents. Opposition can only be based on the grounds specified[42]:

1) that the subject-matter of the patent is not patentable[43],
2) that the invention is not disclosed clearly and completely enough for a person skilled in the art to carry it out,
3) that the patent's subject-matter extends beyond the content of the application as filed.

Notice of opposition must be filed online or in writing with the EPO (Munich, The Hague or Berlin), and an opposition fee is payable. Oppositions can be filed either online using EPO software or by submitting the EPO opposition form (Form 2300[44]), which contains all the necessary information to ensure that the opposition is admissible. There are three possible outcomes at the end of the proceedings:

1) the opposition is rejected, and the patent is maintained as granted,
2) the patent is maintained in an amended form, in which case a new patent specification is published,
3) the patent is revoked.

[41] Article 122 EPC.
[42] Article 100 EPC.
[43] Articles 52-57 EPC.
[44] < https://www.epo.org/applying/forms/forms.html>

The opposition applies to all states designated in the European patent. As with any other final decision of first-instance divisions, decisions by opposition divisions can be appealed within two months from the date of notification of the decision.

National Validation

A European patent shall, in each of the contracting states for which it is granted, have the effect of and be subject to the same conditions as a national patent granted by that state, unless otherwise provided in the EPC[45]. As regards national translation – the requirements are clearly laid down[46].

Any contracting state may, if the European patent as granted, amended or limited by the EPO is not drawn up in one of its official languages, prescribe that the proprietor of the patent supply to its central industrial property office a translation of the patent as granted, amended or limited in one of that state's official languages at his option or, where that state has prescribed the use of one specific official language, in that language[47].

All EPC contracting states have prescribed[48], in accordance with, that in the event of failure to observe the relevant national provisions, the European patent will be deemed to be void ab initio. The circumstances in which such a loss of rights occurs are determined by the national law of the contracting states concerned. In most contracting states the time limit for filing the translation is non-extendable.

Appeals

An appeal can be filed against decisions of the departments of first instance of the European Patent Office (EPO). The appeal is filed with the EPO's boards of appeal in a judicial procedure in which a board acts as the department of final instance in grant, opposition, limitation and revocation procedures before the EPO.

An appeal must be filed in writing (including fax or online filing with EPO software) within two months of notification of the contested decision. It is not valid unless the appeal fee has been paid. Then, within four months from the date of notification of the decision, a written statement must be filed that sets out the grounds of appeal. The above time limits are not extendable.

[45] Article 2(2) EPC.
[46] Article 65(1) EPC.
Article 1(1) of the London Agreement.
[47] Article 65(1) EPC.
[48] Article 65(3) EPC.

The board of appeal examines whether the appeal is admissible, and, if it is, whether it is allowable. It then rules as to whether it will correct the decision or remit the case to the relevant department for further prosecution. Oral proceedings may be held at the request of the EPO or any party to the appeal, i.e. applicant, patentee or opponent. They are held in Munich and are public, unless otherwise specified. A decision is often taken at the end of the proceedings.

V. Infringement & Defences

European patents are granted by the European Patent Office (EPO) under the legal provisions of the European Patent Convention (EPC). However, European patents are enforced at a national level, i.e. on a per-country basis. *"Any infringement of a European patent shall be dealt with by national law"*[49], with the EPO having no legal competence to deal with and to decide on patent infringements in the Contracting States to the EPC[50]. A few, limited aspects relating to the infringement of European patents are however prescribed in the EPC.

Proposals have been long discussed to create a true unitary European patent system across Europe and especially across the EU, i.e. a European patent system wherein the enforcement of European-wide patents would be dealt at a supranational level rather than at a national level. These projects include the EU patent (formerly named *"Community Patent")* and the E*uropean Patent Litigation Agreement (EPLA)*[51]. The EU patent is about to come to fruition, whereas the EPLA proposal has been dropped.

At present, the European patent system is undergoing a series of major reforms with the aim of *''unifying''* the patent litigation system. It currently operates on a national basis, rather than a trans-national one, with national courts possessing the right to adjudicate patent disputes within their territories. The current fragmented system is often criticized for creating unnecessary costs and complexities for patent litigants. The new EU-led reforms will create a European Patent with Unitary effect (EPU, also known as the unitary patent) in all member states of the European Union that have adopted the reform package, as well as a Unified Patent Court (UPC), which will be competent to issue judgments with unitary effect across all participating jurisdictions[52]. By locating court venues across

[49] Article 64(3) EPC.

[50] *''Patent Litigation in Europe''* provides an updated overview of the national patent litigation systems across the European Patent Organisation's 38 Member States. It also provides information on the future Unified Patent Court. This study presents an at-a-glance description of the different national revocation, nullity and infringement procedures currently in place. The competent courts dealing with these matters at first instance and appeal are also depicted.

[51] <https://www.ipeg.com/_UPLOAD%20BLOG/EPLA%20agreement_draft.pdf>

[52] Spain, Poland and Croatia are currently the only EU member countries not participating in the Unified Patent Court, which thus covers 25 out of 28 EU member states. At present, Spain and Croatia are the

the participating EU member states—including a range of local, regional and central divisions—the UPC aims to strike a balance between the legal certainty provided by the centralization of the adjudication of patent disputes across Europe and the benefits of local adjudication of patent disputes[53].

VI. Supplementary Protection Certificates

Supplementary protection certificates (SPCs) are an intellectual property right that serve as an extension to a patent right. They apply to specific pharmaceutical and plant protection products that have been authorised by regulatory authorities. The EU wishes to provide sufficient protection for these products in the interest of public health and to encourage innovation in these areas to generate smart growth and jobs.

SPCs aim to offset the loss of patent protection for pharmaceutical and plant protection products that occurs due to the compulsory lengthy testing and clinical trials these products require prior to obtaining regulatory marketing approval.

The aim of an SPC is to restore 15 years of effective patent life between grant of the first marketing authorisation in the EU for the product to which the patent relates and expiry of the SPC. The duration of the SPC is therefore equal to the period which has elapsed between the filing of the patent application and grant of the first EU marketing authorisation, less five years. An SPC can be granted even if this calculation produces a negative result. However, an SPC is not usually useful unless it has a positive duration. SPCs having a negative duration are sometimes sought because EU legislation enacted in 2007, concerning paediatric medicines, provides for a six month extension of the basic SPC term in certain circumstances. This can bring a negative duration into the positive.

An SPC may be granted in respect of a patented active ingredient, or mixture of active ingredients, of a medicinal or plant protection product. However, the product must be one which must undergo a regulatory procedure (in accordance with certain EU directives) to obtain a *"marketing authorisation"* before it can be placed on the market in the EU.

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only EU member states that have not signed up to the European patent with unitary effect, or unitary patent (since Italy has dropped its opposition and joined up).
Regulation (EU) No. 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection;
Council regulation (EU) No. 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of Unitary patent protection with regard to the applicable translation arrangements.

[53] The UPC consists of a Court of First Instance and a Court of Appeal. The Court of First Instance comprises a Central division and several local and regional divisions. The central division has its seat in Paris with specialized sections in London (chemical and pharmaceutical patents) and Munich (mechanical engineering). The Court of Appeal has its seat in Luxembourg.

A medicinal product may be one for the treatment of humans or animals. Plant protection products include preparations which protect plants or plant products against harmful organisms or prevent the action of those organisms, as well as preparations which influence the life processes of plants or destroy undesirable plants or plant parts.

An SPC has the effect of extending the term of the patent in respect of the particular active ingredient only (or mixture of active ingredients) for which the SPC is granted. Where a patent covers several active ingredients, which have been incorporated in different products each of which was the subject of a regulatory procedure, separate SPCs must be sought for each active ingredient for which extension of the term is required.

An SPC may be based on any patent which protects:

1) the active ingredient(s) of the authorised medicinal or plant protection product;
2) a method of producing the active ingredient(s);
3) an application of the active ingredient(s); or
4) a preparation containing the active ingredient(s) (at least in the case of plant protection products).

The patent must be in force, in the country where the SPC is sought, at the time the SPC application is filed. The patent may have been obtained either directly from a national patent office or from the European Patent Office (EPO).

If there is more than one relevant patent, the patentee has a free choice as to which of his patents an SPC is based on.

An SPC application in a country must be based on the first marketing authorisation in that country for the product which incorporates the active ingredient (or mixture) for which SPC protection is sought. A copy of this authorisation must be included in the SPC application and the authorisation must be valid at the time the SPC application is filed. In addition, the SPC application must give brief details of the first marketing authorisation in the EU, since the date of this determines the term of the SPC.

SPCs for medicinal products and for plant protection products can be obtained in all member states of the EU as well as in Norway and Iceland by virtue of those countries' membership of the European Economic Area (EEA). In addition, some other European countries, most notably Switzerland, which are not members of the EU or of the EEA, have their own national system for granting SPCs based on local patents and authorisations.

An SPC can extend a patent right for a maximum of five years. A six-month additional extension is available[54] if the SPC relates to a medicinal product for children for which data has been submitted according to a *Paediatric Investigation Plan (PIP)*[55]. PIPs are required to support the authorisation of medicines for children. They ensure that enough data is collected on the effects of the medicine on children. The extension compensates for the additional clinical trials and testing that PIPs require.

The regulations have been created SPCs at EU level for patented pharmaceutical andplant protection products[56]. These regulations make it possible to rectify disparities in national systems in EU countries. On May 28, 2018, the Commission adopted a proposal for a regulation to amend Regulation (EC) No 469/2009 on SPC for medicinal products. This initiative proposes to introduce an exception to let EU firms manufacture certain pharmaceuticals for export to non-EU markets during the term of the SPC. This initiative was first considered in the Single Market Strategy of 2015[57], in the context of a targeted recalibration of certain aspects of patent and SPC protection. It is supported by a series of studies and was the subject of a public consultation in October 2017.

VII. EU Directives

The European Union is based on the rule of law. This means that every action taken by EU is founded on treaties that have been approved democratically by the members. EU laws help to achieve the objectives of the EU treaties and put EU policies to practice. There are two main types of EU laws – primary and secondary. The EU can pass laws only in those areas where its members have authorised it to do so, via the EU treaties.

[54] Regulation (EC) No 1901/2006.

[55] A Paediatric Investigation plan (PIP) is a development plan aimed at ensuring that the necessary data are obtained through studies in children, to support the authorisation of a medicine for children. All applications for marketing authorisation for new medicines have to include the results of studies as described in an agreed PIP, unless the medicine is exempt because of a deferral or waiver. This requirement also applies when a marketing-authorisation holder wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorised and covered by intellectual property rights.

[56] Council regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products (codified as Regulation (EC) no 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products).
Regulation (EC) No 1610/96 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products.

[57] The Single Market refers to the EU as one territory without any internal borders or other regulatory obstacles to the free movement of goods and services. A functioning Single Market stimulates competition and trade, improves efficiency, raises quality, and helps cut prices. The European Single Market is one of the EU's greatest achievements. It has fuelled economic growth and made the everyday life of European businesses and consumers easier.

Legislative acts are adopted following one of the legislative procedures set out in the EU treaties (ordinary or special). Non-legislative acts do not follow these procedures and can be adopted by EU institutions according to specific rules.

Directives

Directives require EU countries to achieve a certain result, but leave them free to choose how to do so. EU countries must adopt measures to incorporate them into national law (transpose) in order to achieve the objectives set by the directive. National authorities must communicate these measures to the European Commission. It can be distinguished from regulations, which are self-executing and do not require any implementing measures. Directives normally leave member states with a certain amount of leeway as to the exact rules to be adopted. Directives can be adopted by means of a variety of legislative procedures depending on their subject matter.

The text of a draft directive (if subject to the co-decision process, as contentious matters usually are) is prepared by the Commission after consultation with its own and national experts. The draft is presented to the Parliament and the Council—composed of relevant ministers of member governments, initially for evaluation and comment then subsequently for approval or rejection.

Transposition into national law must take place by the deadline set when the directive is adopted (generally within 2 years). When a country does not transpose a directive, the Commission may initiate infringement proceedings[58]. Directives are often used to help enforce the free trade, free movement and competition rules across the EU. They can also be used to establish common social policies, and thus can affect employment issues, labour law, working conditions, and health and safety. They can therefore they can significantly affect businesses.

Even though directives were not originally thought to be binding before they were implemented by member states, the European Court of Justice developed the doctrine of direct effect where unimplemented or badly implemented directives can actually have direct legal force. In the important case of Francovich v. Italy[59], the ECJ extended the principle of *Van Gend en Loos*[60] to provide that

[58] According to EU treaties, the Commission may take legal action – an infringement procedure – against an EU country that fails to implement EU law. The Commission may refer the issue to the Court of Justice, which in certain cases, can impose financial penalties.

[59] *Francovich v Italy* (1991) C-6/90 was a decision of the European Court of Justice which established that EU member states could be liable to pay compensation to individuals who suffered a loss by reason of the member state's failure to transpose an EU directive into national law.

[60] *Van Gend en Loos v Nederlandse Administratie der Belastingen* (1963) Case 26/62 was a landmark case of the European Court of Justice which established that provisions of the *Treaty Establishing the European Economic Community* were capable of creating legal rights which could be enforced by both natural and legal persons before the courts of the Community's member states. This is now called

Member States who failed to implement a directive could incur liability to pay damages to individuals and companies who had been adversely affected by such non-implementation.

Some of the major Directives in the domain of Intellectual Property include:

1) Patentability of computer-implemented inventions *(proposed, then rejected)*
The Proposal for a Directive of the European Parliament and of the Council on the patentability of computer-implemented inventions (Commission proposal COM(2002) 92), procedure number 2002/0047 (COD) was a proposal for a EU directive aimed to harmonise national patent laws and practices concerning the granting of patents for computer-implemented inventions, provided they meet certain criteria. Following several years of debate and numerous conflicting amendments to the proposal, the proposal was rejected on July 06, 2005 by the European Parliament by an overwhelming majority.

2) Directive on the legal protection of topographies of semiconductor products (87/54/EEC 16 December 1986).
Council Directive 87/54/EEC of December 16, 1986 on the legal protection of topographies of semiconductor products is an obligation on Member States to adopt legislation to protect topographies in so far as they are the result of their creator's own intellectual effort and are not commonplace in the semiconductor industry.

3) Trademark Directive (89/104/EEC 21 December 1988)
Council Directive No. 89/104/EEC (Repealed by EU Directive 2008/95/EC), to approximate the laws of the Member States relating to trade marks, was introduced into EU law on December 21, 1988. Its provisions were required to be introduced into national law by December 29, 1991. On this date the Directive therefore became law with direct effect in each of the member states of the European Union.

4) Rental and lending rights (92/100/EEC).
Council Directive 92/100/EEC of November 19, 1992 on rental right and lending right and on certain rights related to copyright in the field of intellectual property is a European Union directive in the field of copyright law, made under the internal market provisions of the Treaty of Rome. It creates a *"rental and lending right*" as a part of copyright protection, and sets out minimum standards of protection for the related rights of performers, phonogram and film producers and broadcasting organisations.

5) Directive on the coordination of certain rules concerning copyright and rights related to copyright applicable to satellite broadcasting and cable retransmission (93/83/EEC 27 September 1993).

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the principle of direct effect. The case is acknowledged as being one of the most important, and possibly the most famous development of EU law.

Council Directive 93/83/EEC of September 27, 1993 on the coordination of certain rules concerning copyright and rights related to copyright applicable to satellite broadcasting and cable retransmission is a EU directive which governs the application of copyright and related rights to satellite and cable television in the EU. It was made under the internal market provisions of the Treaty of Rome.

6) Harmonising the term of copyright protection (Copyright Term Directive) (93/98/EEC 29 October 1993).

   Council Directive 93/98/EEC of 29 October 1993 harmonising the term of protection of copyright and certain related rights is a European Union directive in the field of copyright law, made under the internal market provisions of the Treaty of Rome. It was replaced by Directive 2006/116/EC of the European Parliament and of the Council of December 12, 2006 on the term of protection of copyright and certain related rights.

7) Database Directive (96/9/EC 11 March 1996).

   The Directive 96/9/EC of the European Parliament and of the Council of March 11, 1996 on the legal protection of databases is a directive of the EU in the field of copyright law, made under the internal market provisions of the Treaty of Rome. It harmonises the treatment of databases under copyright law and the *sui generis* right for the creators of databases which do not qualify for copyright.

8) Patentability of biotechnological inventions (98/44/EC 6 July 1998).

   Directive 98/44/EC of the European Parliament and of the Council of July 06, 1998 on the legal protection of biotechnological inventions is a EU directive in the field of patent law, made under the internal market provisions of the Treaty of Rome. It was intended to harmonise the laws of Member States regarding the patentability of biotechnological inventions, including plant varieties (as legally defined) and human genes.

9) Legal protection of designs (98/71/EC).

   Directive 98/71/EC of the European Parliament and of the Council of October 13, 1998 on the legal protection of designs is a EU directive in the field of industrial design rights, made under the internal market provisions of the Treaty of Rome. It sets harmonised standards for eligibility and protection of most types of registered design.

10) The Information Society Directive (2001/29/EC 22 May 2001) – also known as the *"EU Copyright Directive"* (EUCD).

    The Copyright Directive (also known as the Information Society Directive) is a directive of the EU enacted to implement the WIPO Copyright Treaty and to harmonise aspects of copyright law across Europe, such as copyright exceptions. The directive was first enacted in 2001 under the internal market provisions of the Treaty of Rome and updated on March 26, 2019.

The first directive was subject to unprecedented lobbying and was considered a success for Europe's copyright laws. The 2001 directive gave EU Member States significant freedom in certain aspects of transposition. Member States had until December 22, 2002 to implement the directive into their national laws, although only Greece and Denmark met the deadline. The updated directive, which had been contested by lobbying groups on both sides of the issues, gives EU members until 2021 to revise their own country's laws to meet the new Directive's requirements.

11) Directive on the re-use of public sector information (2003/98/EC 17 November 2003).

Directive 2003/98/EC on the re-use of public sector information, otherwise known as the PSI Directive, is an EU directive that encourages EU member states to make as much public sector information available for re-use as possible. Previous to the creation of this directive this area was left to member states to regulate. This directive now provides a common legislative framework for this area. The Directive is an attempt to remove barriers that hinder the re-use of public sector information throughout the EU.

12) Enforcement of intellectual property rights (Civil) (2004/48/EC 29 April 2004).

Directive 2004/48/EC of the European Parliament and of the Council of April 29, 2004 on the enforcement of intellectual property rights (also known as *"(IPR) Enforcement Directive" or "IPRED"*) is a European Union directive in the field of intellectual property law, made under the internal market provisions of the Treaty of Rome. The directive covers civil remedies only - not criminal ones.

Under Article 3(1), Members States can be censured in the European Court of Justice if their civil procedures on the infringement of intellectual property rights are *"unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays"*. Otherwise the Directive harmonises the rules on standing, evidence, interlocutory measures, seizure and injunctions, damages and costs and judicial publication.

13) Enforcement of intellectual property rights (Criminal) *(withdrawn)*

The EU directive on criminal measures aimed at ensuring the enforcement of intellectual property rights (2005/0127/COD) was a proposal from the European Commission for a directive aimed *"to supplement Directive 2004/48/EC of April 29, 2004 on the enforcement of intellectual property rights (Civil enforcement)"*. The directive was proposed on July 12, 2005 by the Commission of the European Communities.

Being the second directive on the enforcement of *"intellectual property rights"*, it is commonly called *IPRED2* (Second Intellectual Property Rights Enforcement Directive). The first directive on the enforcement of Intellectual property rights, Directive 2004/48/EC deals with civil enforcement of intellectual property rights (*"IPRED1"*). IPRED1 was hastily passed before the Fifth Enlargement of the European Union of May 01, 2004 and did originally include criminal sanctions provisions, but this rather controversial part was omitted in order to be able

to meet the deadline of May 01, 2004. As announced in Official Journal C 252 of September 18, 2010 the European Commission decided to withdraw the proposal for a directive. Criminal sanctions for enforcement of intellectual property rights are therefore not currently formally proposed, even if it is part of the EU acquiescence the Lisbon Treaty.

14) Directive on Copyright in the Digital Single Market *(proposed)*

The Directive on Copyright in the Digital Single Market, is an EU directive intended to ensure *"a well-functioning marketplace for the exploitation of works and other subject-matter... taking into account in particular digital and cross-border uses of protected content"*. It extends existing EU copyright law and is a component of the EU's Digital Single Market project. The European Council (EC) describes their key goals with the Directive as protecting press publications; reducing the *"value gap"* between the profits made by Internet platforms and by content creators; encouraging collaboration between these two groups, and creating copyright exceptions for text- and data-mining.

The Directive was introduced by the European Parliament Committee on Legal Affairs on June 20, 2018, and a revised proposal was approved by the parliament on September 12, 2018. The final version, which resulted from negotiations during formal trilogue meetings, was presented to the parliament on February 13, 2019. The measure was approved by on 26 March 2019. In order for the text of the directive to become law in the EU, it must be approved by the EC, scheduled to occur on April 09, 2019. If thus approved, member states would have two years to pass appropriate legislation to meet the Directive's requirements, or face infringement proceedings and potential fines by the EU.

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CHAPTER III

JAPANESE PATENT REGIME

Introduction to Japanese Patents

The first article of the Patent Act of Japan[1] states that *"the purpose of this Act is, through promoting the protection and the utilization of inventions, to encourage inventions and thereby to contribute to the development of industry"*[2]. Underlying to this statement is the fact that several problems would occur if no such system to protect inventions existed.

The research and development process required to create a new invention costs time and money ; accordingly, if it was possible to use an invention without the authorization of the entity who created it, nobody would ever try to create new inventions, and industrial development would be hindered. For this reason, the Japan Patent Act provides for the grant of a patent right to the person who has created a novel invention, in order to protect the invention. However, granting an unlimited protection to an invention would deprive third parties from the possibility to use it. Accordingly, taking into account both the necessity to protect inventions and the necessity to maintain equity of use, the Japan Patent Act stipulates that patent rights are to be granted for a limited period to the entity who created a new invention and disclosed it, thus encouraging technical progress and industrial development by providing other parties with the possibility to use the disclosed invention.

It can therefore be said that the ultimate objective of the Japan Patent Act is, by controlling the protection and use of inventions, to contribute to progress and to industrial development. From the viewpoint of inventors and companies, patent rights are therefore a crucial tool to ensure profits, due to the fact that they provide an exclusive right over protected inventions. In concrete terms, the first company to create an invention must compensate for the financial investments incurred during the R&D process and the commercialization process. If it is unable to exclude from the market competitors which did not incur the same considerable development expenses, it might be difficult for the company to fully compensate its initial investment. By granting an exclusive right to implement the patented invention, and thus by making it possible to exclude competitors from the market, patent rights therefore play a crucial role. Accordingly, the main objectives pursued when obtaining a patent are to recover the invested capital and to ensure profits.

[1] This English translation of the Patent Act has been prepared (up to the revisions of Act No. 109 of 2006 (Effective September 30, 2007) in compliance with the Standard Bilingual Dictionary (March 2007 edition).
<http://www.cas.go.jp/jp/seisaku/hourei/data/PA.pdf>
[2] Article 2 of the Japan Patent Act.

The persons able to acquire patent rights for a given invention are the actual inventor and its successor(s). *"Actual inventor"* refers to the person responsible for the actual manufacturing process of the invention; assistants or investors are not considered as inventors. *"Successor"* refers to the entity which took over from the inventor the right to obtain a patent.

Non-Japanese must meet at least one of the following requirements to be entitled to the rights related to patent:

1) To have a domicile or residence (or a place of business in the case of a legal entity) in Japan;
2) To be a national of a country which grants Japanese nationals equal national treatment or of a country which follows the principle of reciprocity; or
3) Requirements as provided for by other conventions.

I. Invention

An invention according to Japanese patent law differs from the standard understanding generally associated to the word invention[3]. The Japan Patent Act defines an invention as *"an highly advanced creation of technical ideas utilizing the laws of nature".* Consideration for an invention includes:

1) The utilization of the laws of nature being a requisite, laws of nature themselves (such as gravity law), purely mental activities (such as mnemonics), laws based on pure scholarship (such as mathematic laws) and human conventions (such as trade methods) are not inventions under Japanese patent law.
2) An invention must be a technical idea; accordingly, it must be a concrete way of achieving a determined result, must be reproducible and must be likely to be implemented.
3) An invention being an act of creation, the mere discovery of pre-existing natural phenomena is not an invention under Japanese patent law.
4) The reference to an invention being "highly advanced" is used to distinguish patent inventions from utility model inventions.

The history of Japanese patent law began with the opening of the country that began in the Meiji era. *Fukuzawa Yukichi*[4] introduced the concept of the patent to Japan in his 1867 writings. The next

[3] Article 2 Section 1 of the Japan Patent Act.

[4] Fukuzawa Yukichi (1835 - 1901) was a Japanese author, writer, teacher, translator, entrepreneur, journalist, and leader who founded Keio University, *Jiji-Shinpō* (a newspaper) and the Institute for Study of Infectious Diseases. Fukuzawa was an early Japanese advocate for reform. Fukuzawa's ideas about the government work, and the structure of social institutions made a lasting impression on a rapidly changing Japan during the Meiji period. Fukuzawa is regarded as one of the founders of modern Japan.

year, the Meiji Restoration occurred, and the modernization of Japan began. In 1871 - the fourth year of the *Meiji era*[5], an experimental patent system was implemented. It was abandoned the following year. The first substantial patent law in Japan was established by the *"Patent Monopoly Act"* on April 18, 1885[6]. The Patent Monopoly Act was replaced by the Patent Act in 1888; the Patent Act was replaced by the Patent Law of 1899, which was completely revised in 1909. After the Meiji era, the Patent Act was completely revised twice, in 1921 and 1959. The 1959 Japanese patent law was amended several times, especially pertaining to opposition proceedings, the term of patent, and compliance with the Patent Cooperation Treaty (PCT) in relation to criteria of novelty.

II. Patentability Requirements

In order to obtain a patent, the invention must be worthy of receiving a patent before Japanese patent law. Further, documents as determined by the Japan Patent Act must be submitted to the Japan Patent Office (JPO) for examination. Requirements for patentability are provided for by the Japan Patent Act. A substantive examination to assess whether or not the requirements are met must be conducted.

Considerations by the JPO include:

1) Industrial applicability[7]: The invention must have industrial implementability. *"Industrial"* is taken here in a broad acceptation and includes domains of economic activity not related to the manufacturing of goods, such as services or transport.
2) *Novelty*[8]: No matter how wonderful an invention might appear, an objective lack of novelty will prevent it from meeting the patentability requirements.

   Indeed, since the grant of a patent right implies the disclosure of a novel invention in exchange for protection, granting an exclusive right regarding an already known technology would go against the purpose of the patent system.
3) *Inventive Step*[9]: Even if an invention has novelty, it isn't deemed to meet the inventive step requirement in the case that it could have easily been made by a person having common knowledge in the technical field to which the invention pertains based on the existing prior art.

[5] The Meiji period or Meiji era, is an era of Japanese history which extended from October 23, 1868 to July 30, 1912. This era represents the first half of the Empire of Japan, during which period the Japanese people moved from being an isolated feudal society at risk of colonisation by European powers to the new paradigm of a modern, industrialised nation state and emergent great power, influenced by Western scientific, technological, philosophical, political, legal, and aesthetic ideas. As a result of such wholesale adoption of radically-different ideas, the changes to Japan were profound, and affected its social structure, internal politics, economy, military, and foreign relations. The period corresponded to the reign of Emperor Meiji and was succeeded upon the accession of Emperor Taishō by the Taishō period.

[6] In 1954, the Ministry of International Trade and Industry of Japan declared April 18 to be Invention Day in Japan.

[7] Article 29-1 of the Japan Patent Act.

[8] Article 29-1 of the Japan Patent Act.

[9] Article 29-2 of the Japan Patent Act.

For example, inventive step is not recognized in the case of a ship comprising a publicly-known screw propeller from a screw propeller ship and a publicly-known aerial propeller from a aerial propeller ship, since it could have been achieved easily by a person having common knowledge in this technical field.

4) *Earliest Application (first-to-file principle)*[10]: In the case that a third party has filed an earlier application, the application filed by the third party, provided it meets all requirements for patentability, will be registered, even if the applicant of the second application created the invention first.
5) *The invention hasn't been disclosed in the description of an earlier application*[11]: Due to the fact that the content of a patent application is disclosed after a determined period following the date of filing, there is a possibility that earlier applications haven't been disclosed yet at the time of filing of a new application. Accordingly, in some cases, the fact that an earlier application relating to a similar invention has been filed before the new application is known after the filing of the new application. The consequence, in such a case, is that the new application won't be considered as the earliest application and that the related invention won't be considered as being a new invention. Accordingly, if the invention related to the new application and the invention described in the application documents of the earlier application are identical, the new application cannot, in principle, be granted a patent.
6) *Not contrary to public order, morality or public health*[12]: Inventions liable to injure public morality, public order or public health shall not be patented.
7) *Discloses the invention in a manner sufficiently clear and complete for a person skilled in the art to carry it out*[13]: Sufficiency of disclosure or enablement is a requirement according to which a patent application must disclose a claimed invention in sufficient detail for the notional person skilled in the art to carry out that claimed invention.
8) *The statement of the claims is clear*[14].
9) *The application meets the requirement for unity of invention*[15]: Basically, a patent application can relate only to one invention or a group of closely related inventions. The purpose of this requirement is administrative, as well as financial.
10) *Format of the specification and application documents*: The JPO provides a specific format for the application documents. A patent application must comprise a specification, a set of claims and (if required) drawings. The objective is to enable the JPO to disclose the technical details of the invention, and to allow for easy reference of the scope of the right after registration.

[10] Article 39 of the Japan Patent Act.
[11] Article 29(2) of the Japan Patent Act.
[12] Article 32 of the Japan Patent Act.
[13] Article 36 of the Japan Patent Act.
[14] Article 36 of the Japan Patent Act.
[15] Article 37 of the Japan Patent Act.

A six-month grace period is provided for disclosures made through an experiment, publication, presentation at a study meeting or an exhibition or for if the invention becomes known to public against the applicant's will. Such disclosures do not form part of the prior art[16].

III. Japanese Patent Application

The procedures for obtaining a patent right in Japan is described in detail on the website of Japan Patent Office.[8] The patent prosecution procedure under Japanese law is similar to that in most other patent systems.

Application

A person desiring to obtain a patent has to submit a request, specification, claims, any drawings necessary, and the abstract to the commissioner of the Japan Patent Office[17]. An application in foreign languages is also allowed (currently only in English) if the applicant submits a Japanese translation within two months from the filing date[18]. However, the applicant may not amend the foreign language file[19]. In 2007 there was a revision of Japan Patent Law. Pursuant to a 2007 revision of the law, the period for filing a Japanese translation for a Foreign Language Application is 14 months from the filing date or the priority date[20].

Publication

Patent applications are published without a search report after 18 months has expired from the filing date[21]. The applicant may request for early publication[22].

Examination

Completing an invention isn't sufficient to make a patent right become effective. To obtain a patent right, it is necessary to file an application to the JPO. Once the filing of the application is complete, the JPO, following the submission within a determined period of a Request for examination asking the JPO to conduct a substantive examination of the application documents, undertakes their examination. Request for examination and payment of examination fee are needed for an application to be examined[23]. The applicant, or a third party, may request examination within three years from the filing

[16] Article 30 of the Japan Patent Act.
[17] Article 36 of the Japan Patent Act.
[18] Article 36*bis* of the Japan Patent Act.
[19] Article 17 of the Japan Patent Act.
[20] "*2007 Revisions to Japanese Patent Law*" in Shobayashi International Patent & Trademark Office < http://www.sho-pat.com/e/documents/Details_of_2007_Revisions_to_JP_Patent_Law.pdf>
[21] Article 64 of the Japan Patent Act.
[22] Article 64*bis* of the Japan Patent Act.
[23] Article 48*bis* of the Japan Patent Act.

date[24], if they stand examination fee[25]. The examination is conducted based on written documents due to the necessity to render the content of the application as clear as possible, taking into account the fact that the examination will determine the grant of a patent right, that is of a powerful and exclusive right. By comparing the invention with the prior art, the JPO Examiner determines whether or not there are reasons to refuse the application related to the invention. Reasons for refusal are provided for by the Japan Patent Act, and include failure to meet the novelty requirement and failure to meet the inventive step requirement.

If no reasons for refusal are found, the JPO issues, as examination result, an administrative disposition called Decision to grant a patent. If one or several reasons for refusal have been found, the JPO issues a Notification of reasons for refusal and gives the applicant an opportunity to submit an Amendment and/or an Argument. Then, following the study of the Amendment and/or Argument and in the case that they do not resolve the reason(s) for refusal, the JPO issues an administrative disposition called Decision of refusal. If the applicant is dissatisfied with the Decision of refusal, it is possible to file an Appeal against the Decision of refusal.

Trial against Examiner's Decision

Applicants dissatisfied at the decision of refusal may demand a trial within 3 months from receiving a copy of the decision[26] (Article 121) and amendments are allowed when they demand for the trial[27]. If amendments are made, an examiner re-examines the application[28]. Usually the examiner who made the decision of refusal is appointed for re-examination. The examiner then issues a decision to grant a patent, or reports to the Commissioner if there are reasons for refusal that have not dissolved by the amendments[29].

In case amendments were not made, or the examiner reported that reasons for refusal still remain, a group of three or five qualified trial examiners[30] conduct the trial by communicating with the applicant in letters[31].

[24] Article 48*ter* of the Japan Patent Act.
[25] Article 195 of the Japan Patent Act.
[26] Article 121 of the Japan Patent Act.
[27] Article 17*bis* of the Japan Patent Act.
[28] Article 162 of the Japan Patent Act.
[29] Article 164 of the Japan Patent Act.
[30] Article 136 of the Japan Patent Act.
[31] Article 145 of the Japan Patent Act.

A person dissatisfied at the trial may demand a retrial[32], or may sue the commissioner of the Japan Patent Office in quest of the patent[33].

IV. Patent Rights

Following the issue of a Decision to grant a patent, the remittance of the registration fee allows the patent right to be registered by the JPO and to become effective[34]. The duration of the right is set to twenty years after the filing date (or to a maximum of twenty-five years in the case of an extension of the duration of the patent right).

The effect of the patent right can be divided between active effect and negative effect, the former referring to the ability to work the invention on an exclusive basis and the latter to the ability of preventing third parties from working the invention.

The patent right may be an exclusive right ; however, this does not mean that it is unlimited. Limitations to the patent right are determined so as to promote public interest and industrial development (as is the objective of the Japan Patent Act) and in order to maintain a balance with the rights of other parties. For example, the effect of the patent right does not apply with regard to the working of the invention for experimental or research purposes, as such working may lead up to the creation of a better invention. The effect of the patent right doesn't apply either to vessels or aircrafts merely passing through Japan or to the machines or other products used on said vessels or aircrafts. This is motivated by the fact that, while the degree of infringement of the goods is very limited due to the short time passed on Japanese territory, the application of an injunction is bound to severely obstruct public transport. Further, in connection with the necessity to maintain a balance with the rights of other parties, the effect of the patent right is limited in the case that the patented invention uses a patented invention related to an earlier patent application or to a utility model owned by a third party or interferes with a third party's trademark right or design right, or in the case that the patented invention is worked by a legitimate licensee.

Trial for invalidation: Anyone may demand the commissioner of the patent office a trial for invalidation of a patent against the patentee[35]. A group of three or five trial examiners[36] conduct the trial, gathering the parties to the patent office[37]. The patentee may demand restriction of claims, or

[32] Article 171 of the Japan Patent Act.
[33] Article 178 & 179 of the Japan Patent Act.
[34] Article 68 of the Japan Patent Act.
[35] Article 123 of the Japan Patent Act.
[36] Article 136 of the Japan Patent Act.
[37] Article 145 of the Japan Patent Act.

correction of errors or ambiguity[38] to avoid the invalidation. A lawsuit against patent infringement may be suspended until a trial decision of the patent office has become final and conclusive[39].

V. Infringement & Defences

The Japanese legal system is based primarily on codified law. The Patent Law is the principal source of substantive law governing patents. The Code of Civil Procedure and Rules of Civil Procedure are the principal sources of law and regulation relating to the procedural aspects of patent litigation in Japan. The Civil Provisional Remedies Law governs provisional relief in connection with patent infringement, including preliminary injunctions.

In Japan, prior court judgments, such as decisions and orders, do not have a legally binding effect on the courts. In theory, courts are free to render judgments contrary to precedents. However, precedents set by higher courts, especially the Supreme Court, substantially function as a source of law for lower courts. Lower courts hesitate to render judgments that contradict rulings established by higher courts, as they are likely to be overruled by these courts. Generally, cases, including patent infringement cases, are first tried in a district court. Judgments of district courts can be appealed to a high court (*Koso* appeal) and then to the Supreme Court (*Jokoku* appeal).

Literal infringement

A patentee has an exclusive right to work the patented invention commercially[40]. Therefore, the unauthorised commercial working by a third party of a claimed invention constitutes patent infringement. Under the Patent Law, *"working"* means the following acts[41]:

1) In the case of an invention of a product (including a programme): the production, use, assignment, lease, export, import, or the offer for assignment or lease, of the product.
2) In the case of an invention of a process: the use of the process.
3) In the case of an invention of a process for manufacturing a product: the use, assignment, lease, export, import, or offer for assignment or lease, of the product manufactured by the process, in addition to the use of the process.

Doctrine of Equivalents

In view of the fact that Japan adopts a statutory law system, and therefore every statute is supreme as the primary legal source. Judicial judges were hesitant to adopt the doctrine of equivalents to find

[38] Article 134*bis* of the Japan Patent Act.
[39] Article 168 of the Japan Patent Act.
[40] Article 68 of the Japan Patent Act.
[41] Article 2(3) of the Japan Patent Act.

infringement beyond the letter of a claim. In fact, until 1998 the courts had never held an infringement under the doctrine of equivalents. However, on February 24, 1998, the Supreme Court has provided a guideline in favour of the doctrine of equivalents[42]. Specifically, the following five requirements must be satisfied for successfully asserting the doctrine of equivalents:

1) The part replaced is an insubstantial part of the claimed invention;
2) The replacement of the part achieves the object of the claimed invention and produces the same result as the claimed invention;
3) The replacement of the part would have been obvious to a skilled person at the time of making the accused product (the time of infringement);
4) The accused product was novel and non-obvious at the time when the application was made, which means that the accused product could be patentable; and
5) There is no proof showing that the applicant intentionally excluded the accused product from the claimed invention during the prosecution.

In the *Ball Spline Shaft Patent* case (24 February 1998)[43], the Supreme Court held that the scope of patent protection can be extended beyond the literal wording of the claim to cover a technological idea that can be regarded as equivalent, even if the product in question does not literally infringe the patent (doctrine of equivalents).

In Japan, the Intellectual Property High Court (IPHC) established in 2005 has jurisdiction to handle intellectual property cases as second instance, and registered IP cases appealed against trial decisions of the Japan Patent Office (JPO) as first instance. Any lawsuits at first instance related to patents, utility models, rights to circuit design, and copyright for computer programmes must be filed with the Tokyo District Court or the Osaka District Court.

Besides litigation before courts, the JPO provides the system of invalidation trial for determining whether a patent is valid. An invalidation trial may be filed by a person or an entity who has interest in determining whether a patent shall be invalidated, and discussions in the trial are implemented orally between the claimant and the patent holder. A final trial decision shall be rendered by the JPO, and it may be reviewed by the court (in this case, the IPHC shall examine the case at first instance). In addition to them, post-grant objection proceedings before the JPO are introduced by the amendment of the Patent Act in 2014. Any person or entity may request objection proceedings to the JPO within 6 months after the date of publication of a grant of patent. In this procedure, the discussion shall be exchanged in writing mainly between the patent holder and the JPO. A final objection decision shall be rendered by

[42] Supreme Court of Japan, 3d Petit Bench; 1998
[43] Supreme Court of Japan, 3d Petit Bench; 1998

the JPO, and it may be reviewed by the court (Also in this case, the IPHC shall examine the case as first instance). The following remedial measures are available:

1) Civil remedies
    a) Injunction: The patentee may exercise a right to demand an injunction against the person who infringes or is likely to infringe its rights[44]. A "person who infringes or is likely to infringe the patent rights" in that paragraph means a person who works a patented invention without the patentee's permission, or a person who commits an act of indirect infringement[45]. In making a demand for an injunction, the patentee may also demand measures necessary for the prevention of an act of infringement, including the disposal of products constituting the act of infringement and the removal of facilities used for the act of infringement[46].
    b) Damages: Since a patent right is also a kind of property right, an act of infringement of a patent right constitutes a tort, and a patentee who sustains damages as a result of an act of infringement may demand damages from the infringer in tort[47]. Unlike an ordinary tortious act however, in the case of the infringement of a patent right, it is often difficult to prove the amount of the loss, as well as intent or negligence on the part of the infringer. For that reason, the Patent Act contains a special provision for calculating the amount of loss[48], a provision on the presumption of negligence[49], and a provision permitting the determination of a reasonable amount of loss[50].
2) Criminal penalty

    Japanese patent law provides that patent infringement is a crime. A person who has infringed a patent right must be engaged in penal servitude for at most ten years, and/or must pay a fine of at most ten million Yen[51]. In addition to the above penalty for an infringer, a firm that the infringer belongs to must pay a fine of at most 300 million Yen[52].

In the event there is clear and convincing evidence that a patent is invalid, a claim for injunction, damages, or other claims based on such patent is beyond the scope of rights intended by the act, except in extenuating circumstances.

[44] Article 100(1) of the Japan Patent Act.
[45] Article 2(3) of the Japan Patent Act.
[46] Article 100(2) of the Japan Patent Act.
[47] Article 709 of the Civil Code.
[48] Article 102 of the Japan Patent Act.
[49] Article 103 of the Japan Patent Act.
[50] Article 105-3 of the Japan Patent Act.
[51] Article 196 of the Japan Patent Act.
[52] Article 201 of the Japan Patent Act.

VI. Patent Term Extensions

Patents have a 20-year patent life from the date of the filing of the patent application[53]. The effective patent term is frequently less than 20 years in the field of pharmaceuticals and agrochemicals due to the requirements in the relevant laws that these products receive government approval before marketing. In order to encourage inventions in these fields, the patent life is extended to compensate patent holders for marketing time lost while developing the product and awaiting government approval[54]. Sometimes, though, an applicant might not be able to work the invention right away and want to extend the expiration date of the patent.

Unlike with the USPTO, the JPO does not automatically give an extension based on delays in the examination process. However, the Japanese Patent Act allows for an extension if there is a period when the patented invention cannot be worked by means of producing, using and assigning the invention of a product, due to specific regulative delays caused by other laws[55]. A Japanese patent attorney can request to extend the expiration date of a patent *up to 5 years*.

The Patent Act gives the requirements for extending the duration of the patent right may be extended, upon the filing of a request for the registration of extension of the duration, by a period not exceeding 5 years[56].

1) where there is a period during which the patented invention is unable to be worked because approvals prescribed by relevant Acts that are intended to ensure the safely, etc., or
2) any other disposition designated by Cabinet Order as requiring considerable time for the proper execution of the disposition in light of the purpose, procedures, etc., of such a disposition is necessary to obtain for the working of the patented invention.

If multiple patents for the same product exist, each patent may be extended, based on its own application date alone[57]. As a result, each patent may end up expiring on a different date, and the part of the invention whose patent expires earlier would no longer be protected.

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[53] Article 67(1) of the Japan Patent Act.
[54] Article 67(2) of the Japan Patent Act.
[55] Article 67(2) of the Japan Patent Act.
[56] Article 67(2) of the Japan Patent Act.
[57] Article 67(2) of the Japan Patent Act.

CHAPTER IV

CHINESE PATENT REGIME

Introduction to Chinese Patents

Patent law in modern mainland China began with the promulgation of the *Patent Law of the People's Republic of China*, in 1984. In 1985, China acceded to the *Paris Convention for the Protection of Industrial Property*, followed by the *Patent Cooperation Treaty* in 1994. When China joined the *World Trade Organization (WTO)* in 2001, it became a member of the *TRIPS agreement*.

To comply with its international obligations, as well as to facilitate its development into an innovative country, China has since amended its Patent Law three times: first in 1992, then again in 2000, and most recently in 2009.

Patents in China are granted by the *China National Intellectual Property Administration, (CNIPA)*[1], which was renamed in English on August 28, 2018 from *State Intellectual Property Office (SIPO)*.

There are three types of patents available in China:

1) Invention patents: any new technical solution relating to a product, a process or an improvement thereof;
2) Utility model patents: any new solution relating to the shape, the structure or their combination, of a product, which is fit for practical use., and
3) Design patents: any new design regarding the shape, pattern, or their combination thereof, which creates an aesthetic feeling and is fit for industrial application.

Invention patents are substantively examined, while utility model patents are subject only to a formal examination.

The term for invention patents in China is 20 years from the filing date. The duration of utility model and design rights is 10 years, which is also calculated from the date of filing. In China the 20-year term for invention patents cannot be extended. The Chinese Patent Law does not include any provisions on patent term extensions or supplementary protection certificates (SPCs).
Information about patents in Macao is available on the Macao Special Administrative Region Economic Service website[2]. Information about patents in Hong Kong is detailed on the website of the Intellectual

[1] < http://english.sipo.gov.cn/>
[2] <https://www.economia.gov.mo/en/navh;jsessionid=6EC515CF7F730B35CF778133AF4DB15D>

Property Department of the Hong Kong Special Administrative Region[3] of the People's Republic of China.

I. Patentability Requirement

Patentable Subject Matter: China Patent Law defines an *"invention"* as *"any new technical solution relating to a product, a process, or improvement thereof"*[4]. Thus, to understand what inventions can be patented, numerous terms such as *"technical solution"* must be properly defined. The terms *"technology"*, *"technical problem"*, *"technical effect"*, and *"technical feature"* are clearly defined in the Patent Law or the Regulations and the Guidelines but the Chinese Patent Law contains a non-exhaustive list of things which are not regarded as inventions According to the Chinese Patent Law[5], the following items are not patentable in China:

1) any invention-creation that is contrary to the law or social morality or that is detrimental to public interest;
2) invention-creations relying on genetic resources of which the acquisition or use is not consistent; with the provisions of the laws and regulations;
3) scientific discoveries;
4) rules and methods for mental activities;
5) methods for the diagnosis or treatment of diseases;
6) animal and plant varieties;
7) substances obtained by means of nuclear transformation;
8) two-dimensional designs of images or colours or combinations of the two that mainly serve as indicators.

Computer programs as such cannot be patented, but they may be protected under the Regulations on Computers Software Protection[6], formulated in accordance with the Copyright Law. An invention containing a computer program may be patentable if the combination of software and hardware as a whole can actually improve the prior art, bring about technical results and constitute a complete technical solution.

Requirements for the Grant of Patent Right Invention Patent and Utility Model Patent In order to be granted a patent right, the invention or utility model must possess

[3] < https://www.ipd.gov.hk/eng/home.htm>
[4] Articles 2.
[5] Articles 5 & 25.
[6] < http://www.china.org.cn/english/DAT/214781.htm>

1) **Novelty**

   Novelty means that, before the date of filing, the same invention or utility model has not been publicly used or made known to the public in China or abroad.

2) **Inventiveness**

   Inventiveness means that, as compared with the technology existing before the date of filing, the invention has prominent substantive features and represents a notable progress and that the utility model has substantive features and represents progress.

3) **Practical Applicability**.

   Practical applicability means that the invention or utility model can be made or used industrially and can produce effective results.

Applications for patents for invention are subject to substantive examination (novelty, inventive step and industrial applicability). Utility model applications undergo a formal examination only. However, in infringement disputes relating to utility model patents, the China National Intellectual Property Administration (CNIPA) will on request examine conformity with the relevant provisions and produce an evaluation report.

Design Patent: Any patentable design must possess novelty, i.e. it must not be identical with nor similar to any design which, before the date of filing, has been publicly disclosed inside or outside China.

***"Service"* and *"Non-service"* Inventions:** In China, a service invention is an invention made by an employee of a company in the performance of his duties. In such cases, the right to apply for a patent belongs to the company, which will also be the patent holder after grant. Non-service inventions are those made by individual inventors.

II. Chinese Patent Application

For applying for a patent of invention or utility model, an application shall be filled first, a request, a description and its abstract and claims shall be submitted. Utility models cannot be converted into invention patents in China. However, the dual filing of applications for invention patents and utility models is possible to obtain early protection. Upon notification of grant of the patent, the utility model must be abandoned. it is possible to file invention and utility model applications in parallel to obtain early protection in China. The applications must be filed by the same applicant, on the same day. They must relate to the same invention, and the fact that both applications were filed must be stated. Upon notification of grant of the patent, the utility model must be abandoned.

For applying for a patent for design, an application shall be filed first, a request, drawings or photographs of the design shall be submitted, and the product incorporating the design and the class to which that product belongs shall be indicated.

Any document submitted under the Chinese Patent Law and its Implementing Regulations must be in Chinese. Patent Cooperation Treaty (PCT) applications can be filed in either Chinese or English. However, one must submit a Chinese translation of the application within 30 months of the priority date (extendible to 32 months subject to payment of a surcharge). If a foreign applicant, enterprise or organisation does not have a residential or business address in China, they must appoint a legally established patent agent to represent them in the patent prosecution procedure in China.

Registration Channels: Foreign applicant may obtain Chinese granted patent by filing national application directly in China. The *ad hoc* authority is the State Intellectual Property Office (SIPO) in Beijing, China. Foreign applicants can also designate China when they file a PCT (Patent Cooperation Treaty) application, with respect to the inventions and utility models.

Priority: According to Paris Convention, of which both China and India are the members, the inventor can claim *"priority"* (12 months for invention or utility patents, 6 months for design patents). This means that after filing for a patent in India, the inventor may file in China with the priority date, i.e. the application date in India. This reduces the risk of having the novelty destroyed by publications and use. Official Fees The applicant has to pay the official fees timely for patent registration, such as filing fee, additional charge (if any), granting fee, etc. In order to maintain the patent, the patentee has to pay the annual fee.

Procedure of National Application

Registration of Invention Patent: The application documents consist of an application form, specification and its abstract, claims, and drawings (if any). An application for invention patent shall go through five phases, i.e., acceptance, preliminary examination, publication, substantive examination and granting. An application will normally take 2-3 years to be granted.

In the substantive examination procedure, the time limit for responding to the first office action is four months. The usual time limit specified by examiners in their various notifications is two months. For less complicated actions, a period of one month or less may apply. The time limit is calculated from the date on which the party concerned is presumed to have received the notification. One can also request extensions of time limits specified by examiners at the Chinese Patent Office if you are unable to perform a certain act or procedure within the time limit concerned. One must explain the reasons why you are asking for an extension and pay a fee. However, there are certain time limits which may not be extended.

Registration of Utility Models and Designs Patent: Comparing with invention patent, the examination for utility models and design patent are carried out much faster and simpler, because they only subject to a preliminary examination, which is only related to the documental formalities and obvious violation to the law.

The substantive examination for utility models and design patents will be carried out only within an invalidation procedure, when a dispute occurs.

At present, the examination period for utility model takes 8-10 months, and about 6 months for designs.

Re-examination: If the application is rejected by SIPO, and the applicant is not satisfied with the decision, a request for a re-examination can be filed to the Patent Re=examination Board (PRB) within three months from the date of receipt of notification. And the decision of PRB can also be further subject to judicial review.

Third-party Observations: China has a similar third-party observations system to that of the European Patent Convention (EPC). Any person may submit observations on the lack of conformity of an application with the provisions of the patent law to the China National Intellectual Property Administration (CNIPA). This can be done at any time from the date of publication of the application to the announcement of the decision to grant.

Opposition: The opposition system was abolished in China in 2001. The only way to a challenge a granted patent is through the invalidation procedure. Requests for invalidation can be filed at any time, even after the patent has expired.

Restoration: If one misses the deadline for payment of the annual fees, there is a six-month grace period. If you do not pay them (plus surcharge) within this period, the patent lapses.

In China one can request restoration of a patent within two months from the date of receipt of the notification of lapse. One must give reasons for your request and pay a restoration fee. Under certain conditions of *force majeure,* restoration may be requested up to two years from the date of expiry of the time limit for payment.

III. Patent Rights & Enforcements

While there is still ongoing controversies' surrounding IP laws and their enforcement in China, at the same time there has been a lot of development in this area. Ultimately, effective IP enforcement in China is a strategic use of the IP protection options that are already available while understanding the commercial and at times, political landscape. The key is to effectively combine the available options (both from a commercial and legal standpoint) to achieve the desired commercial result. Additionally, due to China's size and its rapidly developing economy and legal system, the difference between theory and practice may be quite large, especially in more remote areas. Consequently, often one size does not fit all.

The enforcement options available when developing a strategy to enforce IP in China includes:

1) **Administrative Action**

   Internal rules and regulations can be place-specific and often there are hidden issues that do not suit every case. Generally, an IP owner may file a complaint with relevant local enforcement authorities, for example:

   (i) The State Administration for Industry and Commerce ("SAIC")[7] and its local branches regulate trade mark infringement and unfair competition acts;

   (ii) The National Copyright Administration ("NCA")[8] and its local offices regulate cases of copyright infringement; and

   (iii) The State Intellectual Property Office ('SIPO")[9] and its local offices deal with patent infringement.

   An administrative agency can take a range of investigative actions, including entering the infringer's premises; questioning the infringer; inspecting and sealing or seizing the infringing goods and/or confiscating documents which relate to infringing acts.

   If, upon further investigation, an infringement is proven, the agency can then destroy infringing products, order the infringements to stop and impose a fine.

   Some of the main advantages of administrative proceedings are that they are relatively inexpensive and quick. Another benefit is that penalty decisions may later be admissible as evidence in court. Disadvantages are that administrative action only has a low deterrent effect (fines are generally low) and administrative agencies normally only accept clear-cut infringement cases. Another drawback, particularly in remote places, may be that administrative agencies are reluctant to act because of local ties with the infringer or because the infringer is a large local employer etc. and the system may not be as transparent consistently.

[7] < http://home.saic.gov.cn/english/Home/>
[8] < http://www.ncac.gov.cn/>
[9] < http://english.sipo.gov.cn/>

2) Civil Litigation

Only the Chinese courts have the power to issue preliminary and permanent injunctions, and to order infringers to pay damages to the IP owner.

Historically, foreign IP owners have been reluctant to use the Chinese court system to enforce their IP. However, there are now an increasing number of excellent and specialised judges, especially in the Beijing, Shanghai and Guangzhou IP Courts and in China's larger cities. Some of the main advantages of court litigation in China is it can be quite quick compared to overseas. Moreover, Chinese courts can award damages and may order interlocutory asset and evidence preservation orders. If infringement is found, the courts have the jurisdiction to order infringers to publicise their apology in the media, which is effective in deterring other infringers in the market.

Chinese courts are also rapidly improving their levels of sophistication. There are specialised IP Courts, specialist panels or tribunals of expert judges to hear IPR cases. For example, the tribunals recently installed in Wuhan, Nanjing, Chengdu and Suzhou.

However, one of the main drawbacks to civil litigation in China are its high evidentiary burden and case filing formalities. For documents from outside of China to be admitted as evidence, they have to be notarized, legalised, and translated. This process is cumbersome and time consuming, not to mention, expensive. Moreover, since China does not have a discovery procedure, evidence gathering could be challenging. Another important drawback is that damages are generally not very high. However, this trend may be changing. There have been several reported IP cases where significant damages were awarded, including a recent case where the Beijing IP Court granted 49 million CNY in damages and a full compensation of lawyers' fees[10].

3) Criminal Action

Under the PRC Criminal Law, IP infringements which reach certain monetary thresholds constitute criminal offences, and are investigated by the Public Security Bureaus ("PSB"). In practice, the PSB most often relies on complaints filed by IPR owners to take action.

The PSB normally first conducts criminal investigations and if the evidence obtained warrants an indictment of the infringer, the case can be transferred to the Procurator ate, which then decides on prosecution before a People's Court.

[10] Dispute was brought by Plaintiff Beijing Watchdata System Co., Ltd. (“Watchdata”) against Defendant Beijing Hengbao Co., Ltd., (“Hengbao”) over an invention patent on security tokens used for online banking.

While criminal actions have a very strong deterrent effect on infringers, an IPR owner may find it hard to convince the local PSB to accept a case and start up investigations, since the PSB handles all kinds of crimes and may not see IP enforcement as a priority.

4) Customs Action

While most countries only have entry customs screenings, China has both entry and exit customs screenings. In fact, most seizures of counterfeits are done on goods leaving the country. Since the vast majority of seizures are done on the basis of a pre-recorded right, recordal of IP with Customs is essential. The procedure is inexpensive and easy.

Once a seizure is made, customs actions bring several benefits for an IP owner: the seized products may prove useful as evidence in a civil litigation in China against the shipper or the manufacturer of the counterfeits; and the seizure also provides the IPR owner with useful evidence about the overseas buyers of the Chinese infringer.

Customs procedures are fairly simple, yet strict: when customs finds any suspicious goods, customs can detain them and notify the IPR owner. The IPR owner then has a very short term of three working days to pay a bond and request seizure of the goods. If the IPR holder does not consider the goods to be infringing, or if the bond is not paid on time, customs will release the goods.

IV. Infringement & Defences

Most judges have no technical background. Expert testimony and reports from judicial appraisal centres and court-appointed appraisers can be used to help judges identify and understand the technical facts of a patent case. The patent owner can submit an application to the court to request one or two expert assistants to testify in court and provide opinions on technical issues in the case. Expert assistants can offer opinions to the appraisal reports or questions asked by the judicial appraiser.

Since the end of 2014, China established three IP courts in Beijing, Shanghai and Guangzhou. Within the IP courts, there is a network of technical investigation officers. Judges have the discretion to designate an investigation officer to participate in any civil and administrative patent cases. The investigation officers can offer opinions on the technical issues in the cases and answer judges' questions on technical issues.

In addition to the IP courts, China has established 15 IP tribunals across 10 provinces and two municipalities. These IP tribunals have cross-regional jurisdiction and exclusive jurisdiction over certain IP disputes (generally including disputes involving patents, trade secrets involving technology, software, integrated circuit designs and new plant varieties, recognition of well-known trademarks and

disputes involving damages above a certain amount) in the first instance. The system of IP courts and IP tribunals is expected to improve the expertise of judges adjudicating IP cases and harmonise the interpretation and application of IP law throughout China.

A single judge or a panel of judges decides civil cases, depending on the complexity of the case. A three-judge panel decides most patent cases. Jury trials do not exist in China.

Expert witnesses are used to help judges investigate relevant technical facts in patent cases, not non-technical facts. Both the plaintiff and defendant can question expert witnesses. The courts determine the acceptability of an expert witness.

China applies the doctrine of equivalents. In addition to considering the literal scope of a patent claim, the patent scope is determined by considering features that are not specifically covered by, but are equivalent to, the technical features of a patent claim. Equivalent features are those that:

1) use substantially the same means, perform substantially the same function and produce substantially the same effect as the claimed technical features; and
2) could have been contemplated by a person with ordinary skill in the art without inventive labour before the date of the alleged infringement.

Patent owners or interested parties may obtain preliminary injunctions (although it is rare for one to be granted in a patent case) from a court if the following are sufficiently demonstrated:

1) the patent owner or an interested party has a valid patent right or an interest in the valid patent right;
2) the party that the injunction is sought against is performing or is going to perform infringing acts;
3) the acts will likely cause irreparable harm; and
4) guarantee.

Under the Patent Law, damages are determined as follows:

1) actual losses due to infringement;
2) gains of the infringer from infringement (if actual loss is difficult to determine);
3) an appropriate multiple of a reasonable royalty fee (if actual loss and gains are difficult to determine); or
4) statutory damages of between CYN 10,000 and CYN 1 million (if actual loss, gains and royalty fees are difficult to determine).

In the fourth Patent Law amendment, statutory damages are amended to between CYN 100,000 and CYN 5 million. Punitive damages are not available under the Patent Law, but under the fourth Patent Law amendment (draft for review) enhanced damages of up to three times the damages originally awarded are available for wilful infringement.

The amount of damages awards for patent infringement in China continues to increase. According to data from the Beijing IP Court, the average damages award relating to foreign IP owners is higher than for domestic IP owners.

Among the judgments by the Beijing IP Court, the average damage awards in 2015, 2016 and the first half of 2017 were CNY 350K, 1.024 million and 1.103 million (about USD 52K, 150K, 162K), respectively.

In March, 2018, the Beijing Higher Court entered a final judgment (Second Instance) in the dispute over patent infringement between patentee Xidian Jietong Wireless Network Communications and Sony Mobile Communication Products (China) Co., Ltd., dismissing Sony's appeal and maintaining the First-Instance Judgment by the Beijing IP Court. Sony had to pay CNY 9.10 million (about USD 1.34 million) in damages for infringing a single patent that was adopted in a national standard.

In November, 2017, the Fujian Higher Court made a final judgment (Second Instance) in Huawei v. Samsung relating to an invention entitled *"Method for displaying and processing assembly and user equipment"*, dismissing Samsung's appeal and maintaining the First-Instance Judgment by the Quanzhou Middle Court. During the First Instance, both the plaintiff (Huawei) and the defendant (Samsung) failed to prove actual losses of the plaintiff and actual gains of the defendant. The Quanzhou Middle Court estimated the defendant's gains from CNY 2.65 billion to CNY 10.91 billion based on relevant evidence. Instead of determining damages on the statutory level (the upper level is CNY 1 million), the Court awarded Huawei damages of CNY 80 million (about USD 11.8 million).

According to statistical data from the Beijing IP Court, the rate in favour of rights owners in patent infringement litigation is 81.7% among 142 judgments issued by the Beijing IP Courts from November, 2014 to June, 2017. Among 13 judgments relating to foreign rights owners, 10 judgments were in favour of the right owner, and the success rate is 76.9%. The average damages compensation relating to foreign rights owners is CNY 1.022 million (about USD 151K), while that relating to domestic rights owners is CNY 757K (about USD 112K). Based on the above data, it can be seen that Chinese courts, for example, the Beijing Intellectual Property Court, have basically realized equal treatment between domestic and foreign rights owners.

For the wilful infringing act of a patent right, the court may determine the damages above one time and no more than three times of previous level, in consideration of factors such as the particular circumstances, the scale and the consequences of damages of the infringing act. Furthermore, the upper level of the statutory damage is increased to CNY 5 million (about USD 740K).

China is in the process of setting up a National Policy to strengthen IP protection, including increasing amounts of damage, introducing punitive damage as a supplement to compensatory damage and supporting awards to recover attorney fees and enforcement costs.

In China, determination of patent validity and patent infringement is bifurcated, with the Patent Review Board determining patent validity and the court determining patent infringements. Any party (including the patent owner) can bring an invalidation action against a granted patent by filing an invalidation application with the Patent Review Board. A patent may be invalidated based on the following limited grounds:

1) Confidentiality examination requirements for inventions made in China were not satisfied before filing of the patent outside China.
2) There is a lack of novelty, inventiveness or usefulness.
3) There is insufficient disclosure.
4) The description does not support the claims.
5) Amendments to the patent application documents exceed the original scope.
6) Independent claims fail to state the essential technical features of the solution to the technical problem.

A patent cannot be invalidated solely on the basis that the listed inventors are not the actual creators of the invention. The patent owner or an interested party (e.g., a licensee) can bring a patent infringement claim against a defendant by filing a complaint with a court. The party bringing the claim must demonstrate that it is the patent owner or an authorised interested party.

There is no requirement to file an invalidation application with the Patent Review Board before filing a patent infringement claim or vice versa. A defendant to a patent infringement claim before a court will often file an invalidation application with the Patent Review Board. In such cases, the court will decide whether to stay the infringement proceedings until final determination of the invalidation action. If the court decides not to stay the infringement proceedings, both the infringement proceedings and the invalidation proceedings will continue. The Patent Review Board will continue the invalidation action regardless of the court's decision. As a result, there is a possibility that the rulings of the court and the Patent Review Board will be inconsistent (ie, the court may find that the patent was infringed, while

the Patent Review Board finds that the patent is invalid). In such cases, a party can appeal or request a retrial by presenting the invalidation decision as new evidence.

To mitigate the possibility that the Patent Review Board's invalidity ruling will not be rendered in time to be considered in court, defendants can rely on the prior art defence. Under the prior art defence, defendants are not held liable for infringement if they can prove that all of the technical features claimed in the patent that they are accused of infringing are the same as, or not substantively different from, the features of an existing technology and are thus covered by the prior art. Through the prior art defence, the courts can (although this right is limited) find that a patent has not been infringed without making a determination on validity (which is reserved for the Patent Review Board) if it considers the patent covers technology already existing in the prior art.

A successful patent owner can be awarded court fees and seek reasonable costs incurred in stopping the patent infringement, including reasonable attorneys' fees. In patent infringement cases, the courts can grant successful plaintiffs the following remedies:

1) preliminary injunctions;
2) final injunctions;
3) reasonable fees for pre-grant use between the publication date and patent grant date (available only for invention patents);
4) damages for post-grant infringement; and
5) court fees and reasonable costs incurred for stopping the patent infringement, including reasonable attorneys' fees.

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CHAPTER V

STANDARD SETTING & PATENT LAW

I. Standards

Standards influence almost every facet of our lives. They influence the food we eat, our means of communication, travel, work, play and endless other activities. Almost every product available in the marketplace has been developed in compliance with one or more voluntary or mandatory standards. Mandatory standards generally pertain to health, safety or the environment and are set and enforced by, or on behalf of, the relevant government. Most standards are voluntary.

The *International Organization for Standardization (ISO)*[1] defines a formal standard as a document, established by consensus that provides rules, guidelines or characteristics for activities or their results." A standard, therefore, is generally a set of characteristics or qualities that describes features of a product, process, service, interface or material. A standard may also describe how properties are measured, the composition of a chemical, the properties of an interface, or performance criteria against which a product or process can be measured.

Apart from health, safety and environmental concerns, standards are important for a number of other reasons. For example, the existence of standards makes it possible to develop compatible or interoperable products by competing firms. In other words, they ensure the compatibility between complementary products and even between the various parts of a particular product. Product standards are often critical to the effective functioning of markets and play an important role in international trade. For consumers/users, standards provide information and serve a quality assurance function.

Technological standards are a central component of the modern network economy and can have significant welfare effects. As a consequence, mechanisms behind standard development and implementation represent a major policy concern. Most modern standards are created by consensus-driven *Standard Setting Organizations (SSOs)*, and involve the voluntary participation and collaboration of many different entities: firms, government agencies, individuals, academic institutions and research laboratories. Their willingness to disclose and license *Standard Essential Patents (SEPs)*[2] is crucial for standard implementation and its future success. SSOs play a pivotal role in this process

[1] < https://www.iso.org/home.html>

[2] In the course of the standardization process, there are usually many equally viable paths towards a technological solution, and SSOs often choose only one of them. In doing so, SSOs transform relevant patents into *"Standard Essential Patents"* and may allow their owners to command high royalties, even when other patents could have offered comparable value, had a different technological path been chosen.

by ensuring that concerns about *ex-post* hold-up are minimized through proper disclosure of SEPs and fair, reasonable and non-discriminatory (FRAND) licensing commitments made by patent owners.

Complying with certain standards is generally considered to be in the overall interest of producers of goods and providers of services. By way of illustration, there are unlimited possibilities concerning the shapes and sizes of nuts, screws and bolts which, if they were to proliferate, would mean that no standard screwdrivers or spanners could be manufactured that are fit for their purpose. Similarly, in the digital world, in the absence of standards for CDs, CD-ROMs, DVDs, JPEG and a number of other systems that enable different companies to make products that are compatible, there would be insurmountable problems for products of one company to interface with, connect to, or be used in, equipment made by other companies. Standards for interoperability are particularly important for network markets, such as railroads, electricity, telegraph/faxes, telephones, cellular phones, and the Internet.

Standards & Patents

In today's competitive context, where companies invest significantly in the development of new technologies and products, which are often protected by intellectual property rights (IPRs), it is not uncommon that the best technology for a technical standard is a proprietary technology, protected by one or more patents. The development of standards more and more frequently anticipates technology rather than following it, leading to conflicts between standards and patents. If patented technology is incorporated into a standard without the patent holder's agreement to share its patent rights, then the patent holder may be the only entity able to comply with the standard.

This raises important questions for companies that own such protected technology, for individuals and companies involved in the standards-setting process as well as for all those enterprises which will then use or adopt the standard for their products or processes. Additionally, several other concerns arises in this regard:

1) Should a technology protected by IPs be incorporated in a technical standard?
2) Do companies willing to adopt a standard need to obtain a license from the IP/patent holder? If so, under what terms and conditions?
3) Do companies involved in the standards-setting process have a duty to disclose information, to the other members of the standards-setting committee, about their patents or patent applications?
4) What happens if the patent holder(s) refuse(s) to provide licenses for the use of patented technology?

Technical standards are generally developed and revised collaboratively by technical committees of *Standard Development Organizations (SDOs)* comprising a number and variety of stakeholders (including consumer/user interests and experts in the relevant technical fields). The membership of such committees may be open or closed, and is often by invitation only. During the development of technical standards, participants may be required to draw the attention of the committee to the fact that there may be one or more "essential patent(s)" that are needed for meeting the standard, i.e. it would be impossible for someone to comply with the standard without employing the technology protected by the patent(s). So the permission of the patent-holder would be needed and that could mean signing a license agreement and paying royalties to the patent holder.

Obviously, it would not be very productive to adopt a standard if an IP holder can block the implementation of that standard by either refusing to grant a license or requiring such high royalties as to make it impossible for its dissemination and adoption as a standard. Examples of international ISO standards that include patented technologies abound, such as the MPEG-2 standard for visual and audio compression, for which the number of patents required for implementing the standard is of the order of 100s.

Many SDOs discourage the use of proprietary or patented technology in standards; they support it only in *"exceptional cases"* where justified by *"technical reasons".* In such cases, the patent holder of a technology considered to be crucial for meeting the requirements of a standard may be contacted by the technical committee of an SDO and asked whether the patent holder would agree to negotiate licenses with users of such standards on fair, reasonable and non-discriminatory terms and conditions (generally referred to as FRAND terms and conditions). However, IP policies of SDOs generally do not really explain as to what may be considered to be FRAND terms and conditions. Some SDOs go beyond the FRAND terms and conditions, requiring technologies to be licensed on a *royalty-free basis* (generally referred to as RF basis); for example, this is true of certain consortia dealing with Internet standards.

The SDOs classifies patents into two different types:

1) Essential/major patents (type H innovations) are depicted in this model by the assumption that there is a single route to implement the corresponding functionality, so the patent cannot be bypassed; actually, we assume that it cannot even be duplicated within the context of the standard setting process. As a consequence, unless an SSO participant comes up with the relevant IP during the SS process, the functionality will not be embedded in the standard as there might be no reasonable technical solution, in which case compliance with the standard is infeasible.
2) Minor patents (type L innovations) are patents corresponding to an easier innovation, and for which there exists an alternative route. But in order to find this alternative route within the

timeframe of standard setting, the SSO must build upon the knowledge embedded in the existing patent; put differently, the SSO cannot find a solution from scratch within the time frame. We further assume that bypass of the patent requires redefining the functionality in such a way that it is consistent with the alternative route; so bypass for simplicity is feasible at the SS stage, but not after the standard has been set

Adopting a Standard

Any company, large or small, that plans to adopt a standard for its products, processes or services, should first and foremost verify if there is/are any *"essential"* patent(s) for which a license is required and the broad terms and conditions under which the license will be granted. This information is generally available from or through the relevant SDO. If the license is to be obtained directly from the patent holder, then the patent holder should be contacted and a licensing agreement negotiated and signed prior to taking any concrete steps to adopt the standard for a company's products or process.

There may also be cases in which, in order to comply with a given standard, a company may have the option of choosing from a series of alternative technologies that could be used, some of which may include the use of protected or patented technology. In all such cases, the patents would not be considered to be *"essential patents"* but *"useful patents",* as adopters of the standard have other ways of complying with the standard that do not require use of a patent. Moreover, there may be cases in which there are a number of essential patents which may be pooled by the patent holders (i.e. a *"patent pool"* is established enabling companies to obtain licenses for a group of patents through a single agreement) to facilitate dissemination of the standard. This was the case, for example, in the case of MPEG-2.

In any case, it is crucial to understand that in order to comply with a given standard or technical regulation, a company may have to (or choose to) use one or more patented technologies. In all such cases, the company is required to obtain a license from the patent-holder and this must be done prior to using the patented technology to conform to the requirements of the standard. On occasions, patent-holders may agree to grant royalty-free licenses, but this may not always be the case. It is important to know the rules of the game so that you are able to negotiate the best possible terms and conditions for use of a proprietary or patented technology that you need for meeting the requirements of a standard.

Standards-setting Process

In certain cases, the product specifications of a dominant supplier in the market may become the *de facto* standard for all others if they wish to enter the market. In this article, we are not concerned with these type of standards. Here, we focus on development and use of collaboratively developed standards,

which are adopted by consensus. On occasions, however, a proprietary *de facto* standard may be adopted by consensus by the relevant standard-setting body to become the *de jure* standard.

Standards are developed at various levels by standards-setting technical committees created by international, regional, national or subnational Standard Development Organizations (SDOs) and/or by professional, industry or trade associations, alliances or consortia. Most countries have a National Standards Body (NSB)[3], which is accredited to the International Organization for Standardization (ISO). The national NSB, in turn, may accredit a number of public and private SDOs that adhere to the criteria of the NSB (generally including on IP matters) for developing voluntary standards. A standards-setting technical committee of an SDO may have an open or closed membership. In addition to ISO, there are other multilateral bodies such as the *International Electrical Commission (IEC)*[4] and the *International Telecommunications Union (ITU)*[5].

Companies, big or small, may wish to participate in a standards-setting committee in order to influence and steer the standards-setting process in the direction that best serves their interests. However, it may not be possible for a company to participate in the standards-setting process if the membership of the standards-setting committee is closed to, for example, members of an association, alliance or consortium. While the use of an open standards-setting process usually lessens antitrust or competition concerns over the exercise of market power, open standards-setting procedures may lessen efficiency because of the need for consensus among competitors, each of whom may have its own proprietary technology. This means that companies would want to ensure that the standard being adopted does not make any of their own technologies irrelevant and, on occasions, companies may seek to have their own patented technology become essential (or useful) to comply with a standard. This may be especially true for a company that has complimentary assets, which could give it a competitive edge.

While there may be no duty to do a patent search of the patent portfolio of the participating company or of any other companies, yet the participants in the standards-setting process may be required to reveal information about IPRs, especially patents (and, in certain cases, also patent applications) that may be owned by the company and are likely to be essential for complying with the proposed standard. The IP policies of SDOs vary widely in this respect and have often been revised over the past years. IPRs or Patent policies of SDOs follow different practices about if, when and how much information on IPRs, especially patents (or patent applications) needs to be disclosed.

[3] The term *National Standards Body* (NSB) generally refers to the one-per-country standardization organization that is that country's member of the ISO.
The term *Standards Developing Organization* (SDO) generally refers to the thousands of industry or sector-based standards organizations that develop and publish industry specific standards.
[4] <*https://www.iec.ch/*>
[5] <*https://www.itu.int/*>

Therefore, it is important for a company that plans to participate in the standards-setting process to be well informed about the details of the IP policy of the relevant SDOs. It is important to note that in some cases, non-disclosure of patents or patent applications during the standard-setting process may lead to the patent being unenforceable and/or result in investigations by the anti-trust or competition law enforcement agencies to prevent abusive use of IPs/patents by participants in the standards-setting process.

There may be situations in which mere membership of an SDO (or, more specifically, membership of a technical committee) creates a *"default"* licensing of a company's IPs. It should also be borne in mind that contributions to a standards-setting process are generally not confidential; so, all technical information revealed to the members of a standards-setting committee may be considered "prior art" for the purpose of examining or invalidating a future patent application pertaining to it.

Concerning *copyright*, SDOs also have different policies. Many SDO's policies on IPs are limited to patents and do not deal with other intellectual property rights, such as copyright, which is generally dealt with on an *ad hoc* basis. The IP policy of some SDOs clearly states that its policy on patents also applies to any works protected by copyright, which may be required to meet the standard. Other SDOs, however, have decided not to have a policy that addresses proprietary copyrighted material, such as source code. An additional issue is copyright ownership over written contributions to the standards-setting process, on which policies also vary significantly between SDOs. Similarly, the issue of copyright over the finalized standard document becomes relevant if the copy of the standard is to be sold as a priced publication; the policies of SDOs vary on this question too.

Whether your company holds patents (or has filed patent applications) that may potentially become essential or useful for meeting a standard, or whether your company intends to manufacture products or deliver services that comply with a given standard, it is advisable to become familiar with the IP or patent policy of the relevant SDO. If there is a need to obtain a license from a holder of an essential patent, it will generally be necessary to contact the patent holder directly and sign a license agreement under negotiated terms and conditions that are acceptable to both the parties.

The importance of private standard setting is growing in IP management. IP managers have to consider IP laws and antitrust laws as well to avoid the adverse implications in standard setting. The National Telecom Policy (2012) of India intends to increase standardization and intellectual property creation. Standardization has various concerns with respect to competition and IP law. This article analyses the private standard setting organisation's policy in the context of competition law and IP law. It also discusses the role of competition authorities in the standard setting process, IP, the emerging scenarios and suggests an approach for India. Standardization is essential for economic development. There is

need of standards based on consensus, openness, due process and transparency. India needs to develop a comprehensive strategy on standards by coordination with government, industry, SSOs, consortia, consumer groups and academia. International standards are must for international trade. The active involvement of government in central and state level is key to successful standards.

II. Standard Essential Patent

A standard-essential patent (SEP) is a patent that claims an invention that must be used to comply with a technical standard[6]. Standards organizations, therefore, often require members disclose and grant licenses to their patents and pending patent applications that cover a standard that the organization is developing.

If a standards organization fails to get licenses to all patents that are essential to complying with a standard, owners of the unlicensed patents may demand or sue for royalties from companies that adopt the standard. This happened to the GIF and JPEG standards, for example.

Determining which patents are essential to a particular standard can be complex. Standardisation organizations require licences of essential patents to be on fair, reasonable, and non-discriminatory (FRAND) terms.

III. SSOs & SEPs

SSOs can be governmental, quasi-governmental or private. These are responsible for setting, developing, coordinating, interpreting and maintaining standards. The *Bureau of Indian Standards*[7] is India's national SSO. In the Information and Communications Technologies sector the *Telecom Engineering Centre*[8] is the only formally recognized telecom standards/ specification/type approval body in India. *Global ICT Standardization Forum for India*[9], *Telecommunications Standards*

[6] A technical standard is an established norm or requirement in regard to technical systems. It is usually a formal document that establishes uniform engineering or technical criteria, methods, processes, and practices. In contrast, a custom, convention, company product, corporate standard, and so forth that becomes generally accepted and dominant is often called a *de facto* standard.
A technical standard may be developed privately or unilaterally, for example by a corporation, regulatory body, military, etc. Standards can also be developed by groups such as trade unions and trade associations. Standards organizations often have more diverse input and usually develop voluntary standards: these might become mandatory if adopted by a government (i.e., through legislation), business contract, etc.
[7] < *https://bis.gov.in/?lang=en*>
[8] < *www.tec.gov.in/*>
[9] < *https://www.gisfi.org/*>

Development Society, India (TSDSI)[10], and *Development Organization of Standards for Telecommunications in India (DOSTI)*[11] are private SSOs in the Indian ICT sector.

The *Institute of Electrical and Electronic Engineers*[12] and *International Telecommunication Union*[13] are prominent SSOs in the cellular and Wi-Fi space. The TSDSI is the first SSO which was established in India in 2013 with an aim to develop and promote India specific requirements in the field of telecommunications.

The SSO-SEP framework confers considerable power on the SEP holder. An entity that wishes to use a technological standard must obtain permission from an SEP holder, which the latter may choose to withhold by refusing to license its Patent. The FRAND declaration attempts to balance inequalities with the idea that an entity should have the right to obtain a license to desired technology on FRAND terms. However, working out a FRAND encumbered agreement and determining what constitutes a FRAND practice is controversial. Also, in practice, it is almost impossible to determine what a FRAND royalty actually amounts to.

The important conditions with respect to adoption of SEPs are that,

1) the members must disclose, prior to the adoption of a standard, IP rights that would be essential to the implementation of a proposed standard, and
2) the members must commit to license their SEPs to third parties at FRAND rates.

These policies have to be adhered to ensure the widespread adoption of standards, the very purpose for which a SSO is made. Therefore, licensing SEP on FRAND terms is a voluntary contract between the SSO and the SEP holder. However, the meaning of FRAND has not been defined by SSOs; it depends upon the nature of the transactions between the SEP holder (*"licensor"*) and the SEP implementer (*"licensee"*).

IV. FRAND

FRAND is the acronym for fair, reasonable and non-discriminatory. It generally arises in antitrust cases where an owner of intellectual property rights (IPR) refuses to grant a licence or refuses to grant a licence on FRAND terms.

[10] < *https://tsdsi.in/*>
[11] < http://dosti.org.in/>
[12] < *https://www.ieee.org/*>
[13] < *https://www.itu.int/*>

Failing or refusing to license IP on FRAND terms can be an infringement according to antitrust rules. For example, the EU Commission recently sent a statement of objections to Motorola Mobility over its attempt to enforce a patent injunction against Apple in Germany (i.e. the Commission has come to the preliminary conclusion that Motorola has infringed the antitrust rules). The patents in question relate to GPRS, a part of the GSM standard, which is used to make mobile phone calls. Motorola accepted that the patents were standard essential patents and had, therefore, agreed that they would be licensed to Apple on FRAND terms. However, in 2011 Motorola tried to take out and enforce an injunction against Apple in Germany based on those patents, even although Apple had said that it was willing to pay royalties, as determined by a German court, to use the patented technology. Samsung has also been the recipient of a statement of objections from the EU Commission. It sought injunctions to prevent Apple infringing patents despite Apple apparently being willing to pay a licence fee and negotiate a licence on FRAND terms.

However, what is fair, reasonable and non-discriminatory to one person, or in one context, may be unfair, unreasonable and discriminatory to others, or in a different context. This means that the exact conditions under which a licence will be FRAND compliant are not a universally accepted norm.

1) **Fair:** it is generally relatively easy to identify licence provisions that are clearly unfair. For example, it would be unfair to demand from a licensee concessions that are independent of the licence deal (e.g. purchase agreements, subcontracted production), or to tie the grant of the licence to unrelated obligations. What is fair, is subjective and more difficult to define.
2) **Reasonable:** this is also a subjective concept but a good starting point for assessing reasonableness would be to benchmark against widespread industry practice.
3) **Non-discriminatory:** the key issue here is whether all licensees that are in equivalent circumstances are treated in the same way. Where licensees are treated differently, there should be an objective justification for doing so.

The FRAND commitment typically arises in one of two ways:

1) as a function of the SSO's by-laws or other governing documents that members agree to, or
2) by separate explicit agreements that SSO members execute in connection with the adoption of each standard. (For instance, the IEEE requires that its members declare patents standard essential through *"letters of assurance"* as part of its process of adopting a standard.)

   Either way, the FRAND obligation is a commitment that an SEP owner makes to the SSO, not to the general public. Accordingly, thorny issues arise concerning who can actually enforce a FRAND commitment.

Typically, courts have allowed SSO members to enforce FRAND commitments on the theory that they are third-party beneficiaries of the FRAND agreements between the SEP owner and the SSO; but this

body of law is still developing and it remains to be seen whether non-members who use the standards will also be considered third-party beneficiaries of the FRAND commitment[14].

Because the FRAND commitment arises as a contractual obligation, the governing law will not be uniform. They typically are written under the law of an SSO's home jurisdiction, which means the FRAND obligation is not standardized — even assuming the wording is the same from one FRAND commitment to the next (perhaps an unfair assumption), each jurisdiction's law still may be different. In some jurisdictions, for instance, a contract is not enforceable unless all terms are definite, including price; but price is *the* open term subject to negotiation under a FRAND obligation. Similarly, some jurisdictions may not recognize that a third-party beneficiary has standing to sue[15].

In addition to third-party beneficiary doctrine, commentators have suggested other possible theories to enforce a FRAND obligation.5 Each has its own infirmity. One theory is promissory estoppel, but to prevail on this theory a potential licensee must show knowledge of the FRAND commitment, reliance on that commitment, and that the SEP owner had reason to know that the user expected to benefit from the owner's FRAND commitment; presumably owner and user will have different mental states about the expectations of the user-infringer. Another theory is implied license, where a court could find that the SEP owner *invited* the infringing use by agreeing to the FRAND commitment; but this theory requires highly specific supporting facts and generally is hard to satisfy. Similarly, equitable estoppel may apply if the SEP owner's conduct was misleading and the potential licensee shows both reliance and material prejudice; but the FRAND commitment by definition is not misleading because it signals the SEP owner's intent to enforce the patent on FRAND terms. Therefore, third-party beneficiary doctrine is likely to remain the most promising of the proposed avenues of enforcement.

Typically, the existence of the FRAND obligation is not at issue in litigation; the focus is the exact form of relief that may be recovered. Although a district court has authority to award both damages and injunctive relief, courts are increasingly reluctant to issue injunctions when FRAND-encumbered patents are at issue. As the U.S. Court of Appeals for the Federal Circuit recently explained in *Apple*

[14] *Microsoft Corp. v. Motorola, Inc.*, 854 F. Supp. 2d 993, 999 (W.D. Wash. 2012) *("Microsoft, as a member of both the IEEE and the ITU, is a third-party beneficiary of Motorola's commitments to the IEEE and ITU"*).;
Apple, Inc. v. Motorola Mobility, Inc., 886 F. Supp. 2d 1061, 1085 (W.D. Wash 2012) (*"As a potential user of the standards at issue and a perspective licensee of the essential patents, Apple is a third-party beneficiary of the agreements between Motorola and IEEE and Motorola and ETSI.").*

[15] *In the Matter of Certain Electronic Devices, Including Wireless Communication Devices, Portable Music and Data Processing Devices, and Tablet Computers*, No. 337-TA-794 (I.T.C. July 5, 2013) ("*Samsung v. Apple*").

Inc. v. Motorola, Inc., there is no *per se* rule barring injunctions to enforce FRAND-encumbered patents, but the FRAND obligation does create *"unique aspects of - establishing irreparable harm"*[16]. The International Trade Commission ("ITC") is a regulatory forum that adjudicates patent infringements but can only issue exclusion orders as a remedy - akin to an injunction preventing importation - and cannot award damages. ITC exclusion orders are subject to presidential review, typically delegated to the U.S. Trade Representative (USTR), and the USTR recently vetoed an exclusion order in the *Samsung v. Apple* investigation involving FRAND-encumbered patents. The ITC had found that there was no *per se* bar to an exclusion order if a FRAND-encumbered patent was at issue and granted an exclusion order; according to the ITC, a FRAND obligation only requires good faith negotiation and does not require that a license ultimately issue. The USTR blocked that exclusion order, the first such veto since 1987, stating that while a FRAND obligation is not a *per se* bar to an exclusion order, exclusion orders should only be granted where a potential licensee refused to accept a FRAND license or refused to negotiate at all, but are not available where the negotiations simply were unsuccessful.

Since a FRAND obligation is contractual, enforcement of a FRAND commitment arguably should occur under state law and in state courts (absent another reason for federal jurisdiction) even though such litigation will inevitably affect the underlying patents at issue. In other words, it will be a function of how the complaint is framed - if the SEP owner sues for infringement then it will be a patent lawsuit in federal court and a FRAND *"license"* might be a defence; but if the party user brings a contract-related action based upon the FRAND obligation then the lawsuit could be heard in state court[17].

Moreover, even if there is a basis for federal jurisdiction, parties may not be able to have their appeals heard in the Federal Circuit if they lose at the district court level. As the Ninth Circuit noted in its 2012 *Microsoft Corp. v. Motorola, Inc.* decision, *"not all cases involving a patent claim fall within the Federal Circuit's jurisdiction … Microsoft's complaint sounds in contract and it invokes the district court's diversity jurisdiction"*[18]. Notably, Microsoft had filed its interlocutory appeal concerning injunctive relief to the Ninth Circuit, but initially appealed the final judgment to the Federal Circuit. In a May 05, 2014 nonprecedential order, however, the Federal Circuit granted Microsoft's motion to transfer the appeal to the Ninth Circuit over Motorola's objection. The Federal Circuit held that since the Ninth Circuit previously considered and *"rejected the position that [the Federal Circuit] had*

[16] No. 2012-1458, 2014 U.S. App. LEXIS 7757, at *106 (Fed. Cir. Apr. 25, 2014); *cf. Realtek Semiconductor Corp. v. LSI Corp.*, 946 F. Supp. 2d 998, 1006-07 (N.D. Cal. May 20, 2013) ("In promising to license on RAND terms, defendants here admit that monetary damages, namely a RAND royalty, would be adequate compensation for any injury it has suffered as a result of Realtek's allegedly infringing conduct."); *see also* European Commission Decision No. IP/14/489 (Apr. 29, 2014).
[17] *Holmes Group, Inc. v. Vornado Air Circulation System*, 535 U.S. 826 (2002).
[18] 696 F.3d 872, 881 (9th Cir. 2012).

jurisdiction over the matter", the Ninth Circuit had already decided jurisdiction under the law of the case doctrine.

All of this begs the question of how a court should set a FRAND rate, which was only recently answered. In April 2013 Judge Robart, in deciding *Microsoft v. Motorola*[19] looked to the well-recognized *Georgia-Pacific* factors for that answer[20]. Named for the 1970 *Georgia-Pacific Corp. v. U.S. Plywood Corp. case*[21], the 15 *Georgia-Pacific* factors quickly became the go-to guidance for courts setting a reasonable patent royalty (the minimum for patent infringement damages[22]. Judge Robart's decision, however, modified the 15 factors for the FRAND setting:

1) The owner of an SEP is ***under the obligation to license*** its patents on [F]RAND terms, whereas the owner of a patent uncommitted to [F]RAND has monopoly power over its patent and may choose to withhold licensing.
2) The hypothetical negotiation almost certainly will not take place in a vacuum: the implementer of a standard will understand that it must take a license from many SEP owners, not just one, before it will be in compliance with its licensing obligations and able to fully implement the standard[23].

   Other courts setting FRAND rates have further modified the *Georgia-Pacific* factors[24].

   The *Georgia-Pacific* factors may also need to be modified based on whether the court is setting a royalty rate range for the jury to apply or is actually finding the FRAND rate itself, and whether the court has already determined that the patents at issue are SEP and/or infringed prior to determining the FRAND rate. If the court has not already made a determination that the patent is essential to practice the standard, for instance, the hypothetical *Georgia-Pacific* negotiation would include skepticism over the patent's essentiality to the standard; if it has already been determined to be an SEP, there is no need to adjust the FRAND rate in light of pre-litigation uncertainty about whether a given patent is or is not standard essential and infringed.

[19] < https://www.essentialpatentblog.com/wp-content/uploads/sites/64/2013/04/2013.04.25-D.E.-681-Findings-of-Fact-and-Conclusions-of-Law-setting-RAND-royalty1.pdf>
[20] 2013 U.S. Dist. LEXIS 60233 (W.D. Wash. Apr. 25, 2013)
[21] 318 F. Supp. 1116 (S.D.N.Y. 1970).
[22] 35 USC § 284.
[23] 2013 U.S. Dist. LEXIS 60233
[24] I*n re Innovatio IP Ventures, LLC*, No. 11 C 9308, 2013 U.S. Dist. LEXIS 144061 (N.D. Ill. Oct. 3, 2013) (applying the *Microsoft v. Motorola* modification to the *Georgia-Pacific* factors; see accompanying table); *Ericsson Inc. v. D-Link Sys.*, No. 6:10-CV-473, 2013 U.S. Dist. LEXIS 110585 (E.D. Tex. Aug. 6, 2013) (instructing jury with all 15 *Georgia-Pacific* factors without modification, but tacking on a 16th factor: the *"obligation to license its technology on [F]RAND terms"*).

Although there has been much activity in this area in recent years, FRAND licensing and its enforcement remain in flux. With several FRAND litigations pending, and some that have already settled pre-litigation, it remains uncertain how the courts will ultimately determine who can enforce the obligations, what type of relief they can seek, how a FRAND rate should be determined, and in what courts these various issues will be decided.

V. Major issues involved in SEP litigation

1. *Patent holdup*

   Once a patent is adopted as a standard and achieves commercial acceptance, it becomes *'locked-in'*. It is necessary for a manufacturer to use the same; otherwise his product would be incompatible with other companies' products and hence unmarketable. Such a situation strengthens the SEP holder's bargaining power because the licensee does not have alternatives to the same technology. Patent holdup occurs when a SEP holder takes advantage of a locked-in patent by trying to impose unreasonable royalty rates. Unless constrained by a SSO to comply with FRAND licences, the SEP holder can exploit the locked in position to obtain significantly higher royalties than it would have obtained before the patent was incorporated as a standard. However, even after committing to FRAND such a situation arises due to the vague nature of FRAND.

   In the cases of *Micromax and Intex*[25] the CCI noted, *"hold-up can subvert the competitive process of choosing among technologies and undermine the integrity of standard-setting activities. Ultimately, the high costs of such patents get transferred to the final consumers."* Further, in such cases the licensor binds the licensee by a non-disclosure/confidentiality agreement with respect to the terms of the license which restrains the other licensees from acquiring knowledge of the royalty rates imposed on such previous licenses. This acts as an impediment in the conduct of licensing negotiations between the parties and thus leads to major competition concern in FRAND litigations.

2. *Royalty Base*

   The reasonableness of a royalty amount depends on the correct selection of the royalty base. The SEP holders tend to impose the royalty rate on the net sale price of the final product rather than only on the component which comprises the infringed patent. This means even if SEP is used in a single component of a multi component product, the implementer would be liable to pay the royalty on the components which do not include the SEP. In such cases, the whole idea of FRAND diminishes as calculating a royalty on the entire product carries a considerable risk

[25] Micromax v Ericsson, Case No. 50/2013, Competition Commission of India, (November 12, 2013)

that the patentee will be improperly compensated for non-infringing components of that product.

In *Virnetx Inc. v. Cisco Systems Inc.*[26], the US Court of Appeals for the Federal Circuit held that the royalty base must be closely tied to the claimed invention rather than the entire value of the product.

3. *Royalty Stacking*

Royalty stacking is the situation where royalties are layered upon each other leading to a higher aggregate royalty. This happens when different SEP holders impose similar royalties on different components of same multi component product, leading the royalties to exceed the total product price.

This concern was raised by the CCI in the cases of Micromax and Intex[27] wherein the Delhi High Court[28] had ordered Micromax to pay royalty to Ericsson on the basis of net sale price of the phone rather than the value of technology used in the chipset incorporated in the phone which was said to be infringed. CCI noted that *"For the use of GSM chip in a phone costing Rs. 100, royalty would be Rs. 1.25 but if this GSM chip is used in a phone of Rs. 1000, royalty would be Rs. 12.50. Thus increase in the royalty for patent holder is without any contribution to the product of the licensee. Higher cost of a smartphone is due to various other softwares/technical facilities and applications provided by the manufacturer/licensee for which he had to pay royalties/charges to other patent holders/patent developers. Charging of two different license fees per unit phone for use of the same technology prima facie is discriminatory and also reflects excessive pricing vis-a-vis high cost phones."*

4. *Availability of Injunctive relief*

Threat of injunction becomes a powerful weapon when used by a SEP holder for enforcing its royalty rates, as in such a case an SEP implementer would think that accepting an unreasonable royalty would be less risky than curbing an action of infringement. The use of injunctive relief against willing licensees is prima facie breach of FRAND commitment as the FRAND royalty rates by itself are an adequate remuneration to the SEP. Such an action is also considered to be abusive of dominant position and hence a violation of competition laws. Therefore, an injunction should only be claimed when the licensee is unwilling to pay the judicially determined FRAND royalty or where monetary compensation is not an adequate remedy.

The underlining principle behind granting of injunction is that a party must suffer an irreparable damage if the same is not granted. The law on injunction in India is based on the principles of equity. In the said case, the remedy available to the SEP holder is in the form of royalty. The only thing which is to be determined is whether the quantum of the same is adequate. Further,

[26] < https://www.law.berkeley.edu/wp-content/uploads/2016/05/VirnetX-vCisco767_F.3d_1308.pdf>
[27] Ericsson v Micromax, CS(OS) 442/2013 (12 November 2014).
[28] < http://lobis.nic.in/ddir/dhc/VIB/judgement/30-03-2016/VIB30032016CW4642014.pdf>

a SEP holder indulging in setting up a SSO, inevitably accents to license the technology on FRAND terms. In such a case, even if the royalty is low, injunction should not be granted unless there is irreparable injury caused to the SEP holder.

The law with respect to SEP is unclear and judgements with respect to the same have differed from territory to territory. It has to be realised that SEPs are not used by the licensees due to a lack of choice of alternatives, but the same is done in order to maintain operability and compatibility between the symbiotic technologies. It has to be realised that a country such as India cannot afford to lose its global image on the basis of lack of development of IP jurisprudence. While companies must be mandated to pass their technology on the basis of FRAND commitments, it is also pertinent to note that rights of the patent holder are also to be safeguarded. Therefore, in the disputes related to SEP it would be prudent if adequate trial is given to both the parties and rates are determined by the Court without prejudice to any party and keeping in mind the interests of the end consumers at large.

VI. Patent Pools

In patent law, a patent pool is a consortium of at least two companies agreeing to cross-license patents relating to a particular technology. The creation of a patent pool can save patentees and licensees time and money, and, in case of blocking patents, it may also be the only reasonable method for making the invention available to the public. Competition law issues are usually important when a large consortium is formed.

One of the first patent pools, Sewing Machine Combination, was formed in 1856, by sewing machine manufacturers Grover, Baker, Singer, and Wheeler & Wilson, all accusing the others of patent infringement. They met in Albany, New York to pursue their suits. Orlando B. Potter, a lawyer and president of the Grover and Baker Company, proposed that, rather than sue their profits out of existence, they pool their patents.

Patent pools can be defined as an agreement between two or more patent owners to license one or more of their patents to one another or to third parties. Often, patent pools are associated with complex technologies that require complementary patents in order to provide efficient technical solutions. Generally, these patent pools cover mature technologies. Pools also frequently represent the basis for industry standards that supply firms with the necessary technologies to develop compatible products and services. In that case, they rather concern technologies that are yet to be fully developed.

Patent pools have been the subject of ongoing discussions from both a legal and an economic perspective. On the one hand, patent pools may have positive effects on competition and innovation. By sharing intellectual property assets, companies may develop new products and reduce their

transaction costs. On the other hand, under specific circumstances, patent pools may provide an opportunity for a possible anti-competitive behaviour: like any cooperation among competitors, they involve an inherent risk of collusive behaviour. In other words, a patent pool may be regarded as a cartel. In addition, there may be competition-related concerns regarding the licensing practices and restrictions they entail. The so-called *'patent thickets'* (i.e., overlapping patent rights controlled by rights holders that require innovators to reach licensing deals for multiple patents from multiple sources) can lead to increased transaction costs and to chilling effects on the development of new products.

Although there is a general consensus on the positive and efficiency-enhancing effects of patent pools, there may be instances where the creation of patent pools may lead to possible competition rules violations depending on the applicable antitrust rules:

(i) The creation of patent pools may distort competition if pro-competitive aspects do not outweigh the (potential) limitations on competition;

(ii) The licensing clauses may limit the rights of the patent holders and therefore infringe applicable antitrust statutes; and

(iii) The patent pool may lead to anti-competitive collusion among competitors.

In a patent pool, patent rights are aggregated amongst multiple patent holders. Then, the pooled patents are made available to member and non-member licensees and typically the pool allocates a portion of the licensing fees it collects to each member in proportion to each patent's value. A patent pool may take the form of a joint venture[29], created by two or more patent holders for the purpose of sharing their intellectual property rights.

Historically, patent pools have been concentrated in Europe and the United States although recently Asian companies increased their participation in patent pools given their growing role in technological innovation. Whether patent pools may trigger antitrust scrutiny depends, among other factors, on the concerned technologies or patents. As for the nature of the pooled technologies/patents, they can be categorized as

a) complementary or
b) substitutes and,
c) in a standard setting environment, as
    (i) essential or
    (ii) non-essential.

[29] It is possible that the creation of a joint venture needs to be filed with the relevant competition authority as a merger agreement.

Two patents are considered substitutes if they cover alternative technologies and are non-blocking5 . The technologies covered by substitute patents can be used in parallel without infringing the other patent. They are therefore potentially competing with each other.

From a technological point of view, complementary patents must be used together to produce a specific output and are not substitutes for each other. Thus, from a technical point of view it is necessary to use complementary patents together in the production process. Therefore, it is required to either be the owner or a licensee of the complementary patents to produce the desired output. In addition, two mutually blocking patents are complementary from a legal point of view. Mutually blocking patents can be described as two patents that infringe on each other. Hence, patent licensing agreements are necessary to produce the desired output to avoid patent infringement claims. It is also possible that patents are one-way blocking, meaning that one patent infringes another patent while the latter doesn't necessarily infringe the first patent.

Mutually blocking patent rights are the result of cumulative innovation, where no technological component can be marketed individually without the technological complements protected by patent rights of different companies.

Differentiating between complementary and substitute (or competing) patents is important when assessing the effects of patent pools on competition. Substitute patents compete with each other and should therefore, from a competition point of view, not be bundled in a pool because, as a result, competition between such substitute technologies would be eliminated. In general, this concern does not apply to complementary patents because actual or potential competition is not lessened. In line with these considerations, antitrust recommendations in both the US and Europe state that pooling complementary patents is generally pro-competitive.

For instance, in *Summit vs. VISX*[30], two US firms engaged in a patent pool and developed their own technology for performing laser eye surgery. Both companies successfully applied for individual patent protection. This type of technology was not available on the market. The Federal Trade Commission (FTC, one of the US antitrust enforcement agencies) concluded that the patents were substitutes rather than complements. Therefore, the FTC found that the patent pool restricted competition that would have existed otherwise in the absence of the patent pool.

This differentiation between substitute and complementary patents, however, is only one aspect of the competitive analysis. While the pooling of complementary patents might not have a negative effect on

[30] <www.ftc.gov/opa/1998/08/sumvisx.shtm>

price competition on the downstream market, it might still adversely affect subsequent innovation. According to some research, patent pools may discourage outside firms to invest in R&D if they increase the threat of litigation. In addition, pools may slow innovation if they redirect R&D by outside firms towards technologies that are not covered by pool patents, especially if those technologies are inferior substitutes to innovation. Adverse effects of pools on innovation is a topic that requires further research, but should be taken into account when assessing the pro- and anti-competitive effects of patent pools.

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CHAPTER VI

TRANSACTIONS OF IP

I. IP Transactions

The accounting definition of a business transaction, according to the online business dictionary, is *"an economic event that initiates the accounting process of recording it in a company's accounting system"*. This definition may, however, leave out many small endeavors. Needless to say, selling an item at a garage sale where no accounting system is in place also can be a business transaction. When the economic event involves a form of Intellectual Property (IP), it gets looked upon as an IP transaction. In reality, on a broader scale, often, intellectual assets also get included over and above registered IPs.

In recent years, there has been a huge surge in such IP transactions globally. There are quite a few examples of high-value transactions that can be cited. Among others, this trend has led to an increase in pressure from board rooms of different companies, resulting in their increased importance. The boards of a large number of companies are showing increased importance for their IP strategy and are putting a great deal of pressure for monetizing their IP. It is growing at such a pace that in many companies, such pressures have resulted in P&L-led business units having aggressive targets on the monetization of their Intellectual Property or rather intellectual assets. This trend has even led to Wall Street taking interest in such business routes. Most companies are trying more and more to internalize their IP management with clear and structured IP strategy, both for the short and long term, leading to a process of bucketing their IPs into different strategic portfolios. Often, it is observed that the size of such strategic portfolios does matter in the final valuation, although the debate between quality and quantity has been never ending. Other factors pushing such a trend include increase in the year-to-year patent grant increase in the number of SEPs, and legislative or judicial changes. Needless to say, the importance of damage cases and increase in related litigations globally have also contributed their part. However, it should be kept in mind that in most such IP transactions, neither the cost nor earning is usually linear.

The underlying tone for all IP transactions is: how all parties involved will make money because of these deals. Most IP transactions are led either by a well-planned strategy or are litigation-driven. But often, the fear of litigation, i.e., to avoid litigation, plays a pivotal role in opening doors for many IP transactions. IP-licensing internal programs are becoming increasingly common in many companies. In addition to operating companies or research institutes/universities, other players who often get involved in IP transactions include NPEs, trolls, aggregators, and financiers.

IP transactions broadly include licensing, assignments, and technology transfers. The key to success for IP licensing or other forms of transaction lies in IP owners doing their homework really well. Preparation of licensing or any other form of IP transaction requires a comprehensive preparation—no less than preparation for litigation. IP licensing would call for a well-defined strategy which involves understanding overall IP management, the value of IP, assessing competitive landscapes, evaluating new partnership opportunities, and so on. Several models for IP valuation are available and extensively used. IP valuation is essential for both offensive and defensive disputes, licensing negotiations, M&A support, royalty rate assessments, and so on.

A few common issues in many IP transactions include:

1) Understand that not only rights but also a lot of information is getting transferred. If this is not digested well initially, integration of the same in subsequent stages will become cumbersome.
2) Is the valuation agreed upon and compensation paid fine? It is best to involve professionals who are experienced rather than those who are aspiring to get experience in this domain. One may even choose to outsource to a third-party licensing firm for professional help.
3) Be completely conscious of all liabilities and risks that may be associated with this transaction. List down remedies that might be available right at the beginning.
4) Be clear of termination rights, should that be a situation in future and have your plans, backup plans, in place.

For the requirement of evaluation and analysis, the usual practice is to undertake an IP audit or due diligence. The execution of an NDA[1] is usually the starting point for all IP transactions. However, it may be a good idea to consider the following even before or at least at the time of executing the NDA:

1) Does the NDA give the desired protection adequately?
2) Will pre-disclosures include confidential material for review?
3) What will be the rights on the IP that is pending?
4) What will be the termination rights?
5) Are there any limitations on receiving parties? If so, what are they?
6) What could be the different alternative considerations?

[1] A NDA (Non Disclosure Agreement), also known as a CA (Confidentiality Agreement), CDA (Confidential Disclosure Agreement), PIA (Proprietary information Agreement) or SA (Secrecy Agreement), is a legal contract between at least two parties that outlines confidential material, knowledge, or information that the parties wish to share with one another for certain purposes, but wish to restrict access to or by third parties. t is a contract through which the parties agree not to disclose information covered by the agreement.

Among others, in a similar path, the IP audit[2] or due diligence[3] should especially give importance to the following concerns:

1) What is being actually contributed?
2) Is there adequate protection for the contributed IP?
3) What is the contemplated territory?
4) What are the IP risks that exist?
5) Is any portion of the contributed IP subject to third party rights?
6) Are ownership, confidentiality, non-compete, and license issues clean?
7) Are there logical zones of expansion?
8) Does it fit the existing growth plan of the current business?

Needless to say, goals in the IP audit or due diligence vary a lot for the seller or target from that of the buyer or acquirer. The seller focuses on determining the requirements of the buyer and increasing the value of the deal. It would always be a good idea to show a clear value of the IP by showing the use in competitive products and linking the usage to revenue. Inclusion of a broad range of technologies in the portfolio that may contribute to numerous aspects rather than one or two can considerably add to the value of the portfolio. Detailed economic damage modelling with supporting claim charts is an absolute necessity.

Additionally, highlighting a continuous business risk by clearly demonstrating infringement allegations well beyond a few cited patents will ease the process of licensing decision. The idea is to have clear and convincing evidence leading to a meaningful conclusion that license is not only required but rather inevitable.

The first and foremost requirement of the buyer is to try and understand the business of the target in as much depth as possible. One needs to understand the assets and liabilities in clear terms. The evaluation and analysis should lead to clear identification of green and red flags that exist in the business. These flags come in quite handy during price determination and negotiation with the seller. It is best that the due diligence process leads to the determination of a value of the considered IP of the target. Last but not the least, the buyer should obtain as much information as possible, which can lead to an informed and conscious decision. Yet another point is to time the deal appropriately for maximum benefit. Sellers and buyers often find it difficult to synchronize on the price or value - valuations that are either too high

[2] An IP Audit is defined as a systematic review of the IP assets owned, used or acquired by a business.
[3] Due diligence is an investigation or audit of a potential investment or product to confirm all facts, such as reviewing all financial records, plus anything else deemed material. It refers to the care a reasonable person should take before entering into an agreement or a financial transaction with another party.

or low. The frequent disconnect between seller, appraiser, and buyer suggests that a more flexible approach might be needed that anticipates a variety of conditions, contexts, and possible deployments. Under the best of circumstances, providing an accurate IP valuation is never quite easy.

Valuations are typically conducted for several purposes such as litigation, licensing, taxes, and M&A. A cash flow model applied to the assets that are already licensed may not always be helpful. Encumbrances or prior licensing agreements can make these intellectual assets less valuable to a new owner. The value of intellectual assets is not constant and is a function of time - they take up different figures at different intervals of time. How a buyer plans to use a group of assets can only help to determine the price it eventually sells for as well as perceived need, cash position, and strength of their current coverage. Valuation models employed can both underestimate and overestimate the price. Nice-to-have IP is one price; need-to-have is another; litigation quality is still another; some, but not all, of this is in the eye of the beholder.

Needless to say, the bottom line for acquiring any IP asset is always for their revenue-generating potential. Large operating companies often buy IP assets for two primary reasons:

1) For defensive purpose – to have business continuity by stopping the possibility of these IPs being enforced against them.
2) For strategic reasons – for potential future growth of the business; to be used in the days to come.

Sometimes, keeping relevant IP assets out of the hands of competitors is of sufficient value to pay a premium to the market, especially if the competitor runs a poor R&D program. Such purchases keep the assets out of the hands of companies who could possibly harm them. IP owners must determine which is appropriate after a close evaluation and analysis of their own portfolios—sales or licensing. This is also dependent on whether you wish to get upfront money, milestone payments, or assured annual income in the form of royalties. IP licensing promises the highest total return on monetizing any IP portfolio because an IP owner can license the same asset to multiple different licensees and simultaneously retain the legal right to use the same for his/her own requirement.

In today's world, innovation is happening at an exponential speed. The number of patents and other forms of IP that many companies possess is extremely large, leading to the formation of what is commonly called a *"Patent Thicket"* or *"Chinese Wall"*. In such a situation of the day with a litigious environment, cross-licensing is gaining a lot of popularity by which two or more companies mutually benefit by granting licenses of their respective IP to each other. Cross-licensing additionally encourages companies to collaborate on certain projects of interest while sharing technical know-how and their IP portfolios with each other.

This not only leads to greater revenue for all parties but also results in significant cost savings. Cross-licensing is getting further extended in the form of *"IP Pooling"*, wherein companies engaged in similar businesses come together and share their IP with each other. The pooled in IP from all members is non-exclusively licensed to all members. This leads to a significant decrease in litigation and reduction of transaction costs, thus resulting in a win-win scenario for all members.

Similar to the fact that no two people see the same rainbow, critics often look at every deal from different perspectives. And the allegations that *"I could have got more value out of this deal"* or *"You should have got this done for much less"* will never stop. One simple way is to have the board convinced that the value of the deal is accurate or as expected and planned, provided individuals handling such transactions get an opportunity to present their data and experience to the board. Consider reducing the number of patents in the market that may be used against you by having a strategy against them.

The fact still remains that the process followed by all for similar IP transactions may not be identical but remains closely similar, within the respective budgetary plans: execute an NDA, carry out a thorough due diligence, identify red and green flags, negotiate hard, and appropriately time the deal. Use professional resources in every step to maximize your findings and minimize your efforts. As the deal matures with time; the real value of all IP transactions will become apparent. Finally, an individual IP is like a brick and a portfolio is like a collection of bricks. Now, bricks can pile up as a heap or be assembled into a strong, attractive building - the value of the collection will depend accordingly.

II. IP Licensing

One of the key challenges for businesses today is to remain profitable in a slowing but increasingly global economy. They are under pressure to create new opportunities and new revenue streams from existing assets. Often businesses need new or original innovations and/or creative expressions to create new products, enhance existing products, and explore new markets. These crucial innovations and expressions, which are increasingly valuable economic assets in today's economy, need to be protected by using the tools of the intellectual property system before revealing or sharing them. Only then can a business leverage these economic assets as IP assets for gaining and retaining competitive advantage.

There are four main options open to a business to use IP assets to gain and retain its competitive edge; it can:

1) do everything in-house to create the needed IP in a stand-alone mode;
2) create a spin-off or a start-up business to nurture its IP in a focused manner;
3) merge with or acquire another business which has complementary IP;
4) share or team up with others to share IP assets for mutually beneficial results.

Most businesses and entrepreneurs choose to share or team up with others for mutual benefit. This can be done in various ways such as outsourcing, joint ventures, consultancy, arms-length licensing, or entering into strategic alliances for one or more business purposes. Businesses enter into these types of partnership arrangements as part of their endeavour to do everything legally and ethically possible to improve their bottom line and sustain or increase profits. Many of these situations require formal contractual arrangements that involve *"licensing in"* or *"licensing out"* of one or more types of IP. Often businesses do both; engaging in *"cross licensing",* where both parties license IP to each other.

While the mechanism of licensing provides enterprises with a wide variety of possibilities for improving their market position, it has its pitfalls and risks. Therefore, from a business perspective, it is important to weigh the advantages of licensing against its disadvantages in comparison with other alternatives for commercializing products and services.

The word license simply means permission - one person grants permission to another to do something. A license agreement is a formal, preferably written, document recording the circumstances under which a promise shall be legally binding on the person making it. An IP licensing agreement occurs between an IP rights owner (*"licensor"*) and someone who is authorised to use the rights (*"licensee"*) in exchange for monetary value in the form of a fee or a royalty. The two parties agree on the terms and conditions via negotiation, with the outcome dependent upon the bargaining power of each side. The licensor is always the owner of the licensed IP, and one licence can cover patent and design rights, related know-how and a trade mark. The agreement between the two parties can allow the licensor to tap into the licensee's productive capacity and relevant local expertise, thus increasing the licensor's overall knowledge.

There are at least two essential parties:

1) the licensor, the party who owns the IP and is agreeing to let it be used, and
2) the licensee, the party who receives rights to use the IP in exchange for payment.

Therefore, a license agreement is a partnership between an IP owner (licensor) and another who is authorized to use such rights (licensee) under certain conditions, usually for a monetary compensation in the form of a flat fee or running royalty that is often a percentage or share of the revenues gained from use of the invention. Simply put, a license grants the licensee rights in property without transferring ownership of the property.

For a license of IP to be effective, four basic conditions must be met:

1) the licensor must have ownership of relevant IP or authority from the owner to grant a license;
2) the IP must be protected by law or at least eligible for protection;

3) the license must specify what rights with respect to IP it grants to the licensee; and
4) the payment or other economic or IP assets to be given in exchange for the license must be clearly stated.

There are many different types of IP licenses such as technology licenses, publishing and entertainment licenses, and trademark and merchandising licenses.

Many companies have a portfolio of patents, utility models, proprietary know-how, trademarks, and other IP assets that can be licensed. There are many reasons for a company to license out some or all of its IP rights in some or all of its IP assets in such a portfolio. Additionally, there are various ways in which a license agreement can give the licensor and licensee the possibility of increasing revenues and profits and enlarging market share.

Licensing of IP may run into problems for both licensor and licensee if government regulatory agencies consider it to be anti-competitive or collusive in nature. And of course, licenses are complex and, if all material terms are not carefully studied and reviewed by legal counsel, licenses can be damaging. However, with advance preparation and legal counsel, IP licenses are an essential business tool that can have benefits for both parties.

An IP licence may also provide a company with the ability to get its products or services to a market or geographical territory in less time, allow risks to be shared, revenue to be generated, lead to an increase in market penetration, a reduction in costs and time, access to expertise, competitive advantage, collaboration and the opportunity to minimise capital investment.

IP that can be licensed includes:

1) Patents for technology (products and processes)
2) Trade marks for branding of products and services
3) Registered product designs
4) Copyright for literature or artistic work
5) Confidential information & Trade secrets.

The different types of IP licenses are:

1) Sole

   Only the IP owner and licensee can use the IP.
2) Exclusive

   Only the person who is granted a licence, the licensee, can use the IP. The licensor is not entitled to use the IP.

3) Non-exclusive

The IP owner may use and license to more than one licensee.

Some advantages of IP licensing are:

1) Sharing Risk

   Where a licensor licenses the right to manufacture and sell products, the licensor receives revenues from that licensing but does not take the risk of manufacturing, promoting and selling those products. On the other hand, the licensee has the right to use the IP without the expense and risk of the research and the costs of developing the product.

2) Revenue Generation

   An owner of IP may commercialise the IP itself and may obtain additional income by licensing the IP to someone else to commercialise it in a different field.

3) Increasing Market Penetration

   An owner of IP may license another business to sell in territories that the owner cannot cover.

4) Reducing Costs

   A business may *'buy-in'* innovation to reduce its research and development costs.

5) Saving Time

   A business may get its products or services to market more quickly by acquiring a licence to use existing IP, instead of re-inventing the wheel (sometimes referred to as an *"engineering workaround"*).

6) Accessing Expertise

   By taking a licence, a business may tap into expertise that it does not have in-house.

7) Obtaining Competitive Advantage

   By acquiring a licence to use IP, a business may obtain an advantage over its competitors.

8) Collaboration

   Businesses may want to work together to develop new products and services.

Whenever one thinks about taking or granting a licence of any IP the first step should be to assess the needs and objectives of your business and how licensing might help meet them. Taking a licence to use someone else's IP will be necessary if you want to use that IP without infringing their rights. Often granting or taking a licence will bring advantages (money or new IP) to your business, or it may even be the corner stone of your business - for instance, where you supply services or sell products that are based on someone else's IP.

But granting or taking a licence is not always appropriate. For instance:

1) A business, which has the ability to commercialise its own IP, may better achieve its objectives by keeping that IP to itself.

2) Businesses should be wary of licensing their IP in circumstances where the value of that IP may be diminished.
3) The prospective licensor may want to charge royalties that are too high and may restrict the growth of the business.
4) The IP to be licensed may be too weak - if a competitor could work round it and take away market share, it may not be worth investing in a licence.
5) The IP to be licensed may not be valid, for example where a patent is open to challenge or because the prospective licensor does not own and does not have the right to license the IP.

Merits of licensing IP are convincing and licensing should be a vital component of the business strategy of all companies. Still, it is important to consider the very preliminary question as to whether licensing is the right strategy to adopt or not. Even though there is much to be gained from a license agreement by both parties involved, the risks with it cannot be neglected. A license agreement can be seen as an instrument for the distribution of risks between the licensor and the licensee.

III. Technology Transfer

Technology transfer (TT) is a process to transfer information and technologies necessary to manufacture of a product consistently or technology transfer is the process of taking an invention from its inception in a laboratory to a commercialized product.

In today's business setting, interest in the profitable exploitation of a firm's technological assets, through technology transfer, has intensified. Factors that have facilitated international technology transfer include globalisation of business, liberalisation of the economic regimes of many countries, and the impetus given to the protection of IP. These factors have collectively resulted in commercial transfer of technology becoming an important element of the international business setting. Experience over the decades has shown that the technology transfer process can be problematic and transferees often lack the skills to manage it effectively. Firms have many ways of exploiting their technological assets for profitability and growth. While internal exploitation of technological assets, through designing, developing, manufacturing, and selling products and processes continues to be important, interest in their external exploitation through technology transfer has intensified in recent years.

However, the importance of technology transfer from a development perspective is nothing new. More than three decades back, Mansfield (1975) pointed out that, *"One of the fundamental processes that influence the economic performance of nations and firms is technology transfer. Economists have long recognized that the transfer of technology is at the heart of the process of economic growth, and that the progress of both developed and developing countries depends on the extent and efficiency of such*

transfer. In recent years economists have also come to realize (or rediscover) the important effects of international technology transfer on the size and patterns of world trade"[4].

Technology transfer (TT) is an area of interest not just to business, economists, and technologists but also to other disciplines such as anthropology and sociology[5]. While anthropologists emphasize the impact of TT on changes in patterns of culture and society, sociologists are more concerned with its role as a vehicle to develop the capacity of individuals and societies to cope with modernization and related changes accompany it. For economists, as argued by Mansfield (1975), the focus is on economic growth and achievement of economic goals[6].

However, from the perspective of business and technologists the main focus of TT is to improve the competitive advantage of firms through the enhancement of customer value[7]. It is envisaged that, through the improvement of competitive advantage, a firm and its partners collaborating in the TT will gain financial and other strategic benefits. Mayer and Blaas point out that, in recent decades, SMEs have begun to utilize technology transfer as a strategic means of meeting challenges posed by the globalisation of business. Due to their small size and skill resource constraints, they cannot carry out internal R&D to generate their own technologies but still need a flow of new technology to be able to compete[8]. This need has created a new niche-market for technology transfer[9]. The importance of technology transfer, from an economic and competitiveness perspective, has also stimulated university–industry technology transfer. This is evident from the emergence of technology transfer offices in most research offices and universities[10]. Ramanathan shows that in today's international business setting, depending on the attributes of the technology, its intended use, and the motivations of the transferee

[4] Mansfield, E., 1975. East-West technological transfer issues and problems, international technology transfer: Forms, resource requirements, and policies. American Economic Review, 65(2), 372-376.
[5] Zhao, L.M. and Reisman, A., 1992. Toward meta research on technology transfer. IEEE Transactions on Engineering Management, 39(1), 13-21.
[6] Mansfield, E., 1975. East-West technological transfer issues and problems, international technology transfer: Forms, resource requirements, and policies. American Economic Review, 65(2), 372-376.
[7] Ramanathan, K., 2001, E-strategies for technological capability development, Proceedings of the Portland International Conference on Management and Technology, July 29-August 02, Portland, US.
[8] Mayer, S. and Blaas, W., 2002. Technology transfer: an opportunity for small open economies. Journal of Technology Transfer, 27(3), 275-289.
[9] Morrissey, M.T. and Almonacid, S., 2004. Rethinking technology transfer. Journal of Food Engineering, 67(1-2), 135-145.
[10] . Siegel, D.S., Waldman, D.A., Atwater L.E. and Link, A.N., 2004. Toward a model of the effective transfer of scientific knowledge from academics to practitioners: Quantitative evidence from the commercialisation of university technologies. Journal of Engineering and Technology Management, 21, 115-142.

and transferor, a wide range of TT modalities are available. The focus need not merely be on the purchase of plant and equipment or licensing[11].

However, planning and managing a technology transfer project, especially an international technology transfer (ITT) project, is not easy. Based on the experience gained over three decades, Godkin provided a comprehensive list of problem areas associated with technology transfer[12]. Many of these problems still persist and with rapidly changing technological and business trends new problems have emerged. The productive entities that have been most affected by these problems are small and medium enterprises (SMEs). While large organizations may be able to gain access to the resources needed to overcome these problems this is usually not the case with SMEs. Evidence exists to show that governments, international agencies, and non-governmental organizations (NGOs) have all attempted to alleviate these problems by introducing various supportive measures. Yet, many of these measures make the tacit assumption that technology transfer (TT) is a relatively predictable process whereby buyers of technology (transferees) acquire, assimilate, and then improve the purchased technology, often with assistance from government policies[13]. This approach tends to oversimplify the magnitude of the problem faced by SMEs in planning and implementing TT projects.

At times, the biggest impediment in the introduction of new technology into an organisation is company culture. People do not like change and they would rather stick to what they are familiar with, rather than introducing something new. Another obstacle, which can also be associated with culture, is the mindset to introduce a new technology and then put a lot of effort into protecting and defending it. This might not be the best strategy. An organisation is not married to the technology it employs. Organisations must see technology as an expendable tool and if the need change, so must the tool.

The initial step in the transfer of technology process is the recognition of a need. This need must be satisfied by current technology applied differently, or it must be satisfied by new technology. Needs can arise from the following:

1) Scientific changes
2) Competition
3) The market
4) Legislation

[11] Ramanathan, K., 2000. A Taxonomy of International Technology Transfer Modes, Proceedings of the Third International Conference on Operations and Quantitative Management, Sydney, 17-20 December.
[12] Godkin, L., 1988. Problems and practicalities of technology transfer. International Journal of Technology Management, 3(5), 587-603.
[13] Cusumano, M.A. and Elenkov, D., 1994. Linking international technology transfer with strategy and management: A literature commentary. Research Policy, 23, 195-215.

5) Human inquisitiveness
6) Innovation as company policy

When identifying technology it should be evaluated in order to find the most suitable technology. Aspects that should be addressed in the evaluation process include:

1) Strategic implications
2) Effect on market and customer
3) Operational changes
4) Personnel
5) Training

Transfer of technology takes place via certain mechanisms. These mechanisms can be identified per area of technology.

Technology in the form of knowledge is conveyed through the following mechanisms:

1) In print through technical journals
2) In print through learned journals
3) Scientific magazines
4) Patents
5) Orally at conferences
6) Orally at learned societies
7) In discussions with colleagues
8) In discussions with acquaintances
9) In discussion with consultants
10) Courses
11) Service bulletins
12) Data packs
13) Specifications

Technology in the form of skills is acquired by doing something can be conveyed by:

1) Watching someone doing something
2) Watching a video of someone doing something
3) Demonstrations at courses
4) Hands on training

Technology in the form of equipment is conveyed via the following mechanisms:

1) Products

2) Trade magazines
3) Trade conventions
4) Sales representatives
5) Advertisements
6) Direct mail
7) Contacts in other companies

Technology can be transferred between countries or regions, but most technology transfer happens between companies. Not only is research and development done by institutions in the public domain like universities, but also by private companies outside the public domain. Research done by private companies not always delivers the results they anticipated. For instance technology was developed to be used in a product that does not fit in with their current product portfolio, or the return on a product is too small. This potential product may however, be suitable to another company to develop further. Somehow the cost of research must be covered and if a company cannot properly utilise a product, the cost of research will be lost. A good strategy would be joint ventures with other organisations, which benefits both parties. Company-to-company transfer is usually beneficial to both parties, except in the case where transfer is attempted between a large established company and a small start-up company. Larger companies are reluctant to put effort into a smaller company to help with their development without a proportional stake. Many governments, however, believe that the future prosperity of their countries, will depend on the speed and effectiveness of small companies to implement technology spin-offs from larger private and public institutions. The success will therefore be dependent on the relationship between the companies.

All transfer models can be divided into three major categories, with reference to the level of activity in applying the technology in the transfer process:

1) Passive

   The technology transfer mechanism presents the technology to the potential user, without assistance regarding it's application. Only the knowledge part of technology is transferred. The skills surrounding the technology are not transferred. These mechanisms can include presentations in a report.

2) Active

   The provider of the technology assists with the application of the technology. These mechanisms include training, etc.

3) Semi-active

   There is intervention from a third party in the transfer process. This is usually in the form of a transfer agent, whose role of the transfer agent is limited to that of adviser. Very often the transfer agent only screens information in the relevant field of interest and passes it on to the

final user. He therefore ensures the relevance of the information, because of his knowledge, not only about the user's needs, but also because of his knowledge about the technology.

Technology Transfer is often also looked upon as a process of realizing the value of intellectual assets, often by licensing technology to an existing company or by creating a company dedicated to taking research to market. The technology transfer and commercialisation process often starts much early and most Universities and Research Institutes on many occasions follow the following ten general steps:

1) **RESEARCH:** Observations and experiments during research activities often lead to inventions. It is important to keep good, reliable laboratory records of the research activities for several reasons. It is important to contact the Technology Transfer Team before one send or receive any research materials from external sources. In addition, before sharing the results of any research, or publishing it is important to discuss with the appropriate member of the Technology Transfer Team whether the document or disclosure contains any innovation or discovery that could be patented.
2) **PRE-DISCLOSURE:** The Inventor(s) should contact the Technology Transfer Team early to discuss the invention in order to determine if the timing is appropriate to submit an invention disclosure form. Multiple researchers often contribute to an invention, and determining inventorship is important because the law specifies that only those who have made independent, conceptual contributions to an invention are inventors.
3) **INVENTION DISCLOSURE:** The inventor(s) will complete and submit an Invention Disclosure Form to the Technology Transfer Team and/or Patent Technology Associate. This written disclosure begins the formal technology transfer process. An invention disclosure remains a confidential document, and should fully describe your invention so that the options for commercialization can be evaluated and pursued.
4) **ASSESSMENT:** Invention Disclosure Forms received by the Technology Transfer Team are usually logged in, assigned a docket number, and evaluated and presented to the patent committee meeting. The technology is evaluated with the input of the inventor(s), any necessary patent searches are conducted, and market research is conducted to confirm the invention's commercialization potential. The evaluation process will guide the Technology Transfer Team's strategy on whether to focus on licensing to an existing company or to help the inventor(s) create a new start-up business.
5) **PROTECTION:** Based on the assessment, one needs to determine whether or not it will file for patent protection on the invention. Patent protection may not sought for all invention disclosures received due to the high cost of filing. The inventor(s) should provide the chosen patent attorney with any details that make the invention novel, and non-obvious and any other information that may be required, to obtain meaningful patent protection.

6) **MARKETING:** With the inventor's involvement, the Technology Transfer Team will conduct market research and identify candidate companies that have the expertise, resources, and business networks to bring the invention to market. The inventor's active involvement in preparing information to be presented to companies can dramatically enhance the success of this process. Both non-confidential summaries of the technology and confidential information, protected by a confidentiality agreement, may be used during the marketing stage.
7) **LICENSING:** The Technology Transfer Team drafts customized contracts between the University and third parties. The rights to an invention are licensed, without relinquishing ownership. Typically two licensing paths can be pursued when licensing technology.
    a. **Traditional License**: A representative from the Technology Transfer Team licenses the invention to a third party. Once a licensee has been identified negotiating specific licensing terms for different materials will take different amounts of time.
    b. **Start-up Company**: If the invention is a platform technology and the inventor is interested in forming a start-up company, a representative from the Technology Transfer Team may work with the inventor to explain the requirements necessary to proceed further.
8) **LICENSE MANGEMENT:** The Technology Transfer Office will maintain and catalog the license for the life of patent. The performance of a license will be reviewed periodically and monitored.
9) **PRODUCT DEVELOPMENT:** This primarily entails product design, engineering and testing.
10) **COMMERCIALIZATION:** The licensee company continues the advancement of the technology and makes other business investments to develop the product or service. This step may entail further development, regulatory approvals, sales and marketing, support, training, and other activities.

IV. Patent Trolls

A patent troll is a person or company that buys patents solely for enforcement in court against alleged infringers. In many cases, patent trolls do not intend to further develop or sell the patented technology but use the patent as a way to increase profits in the form of licensing fees or reparations. A patent troll's litigious actions may be referred to as patent trolling. The term patent troll originates from an educational video, *The Patents Video*[14], released in the early 1990s.The goal of the video was to alert corporations and individuals to what some call the weaponization of patents, as well as to dissuade

[14]< https://www.youtube.com/watch?v=lOGoZFzHkhs>

potential future trolls. The term has since gained currency and is now widely used to characterize the activities of non-practicing entities (NPEs) or patent assertion entities (PAEs).

Technology companies are increasingly spending more time and money defending themselves in court against patent infringement lawsuits. These lawsuits often pit one tech company against another, but these suits are also initiated by trolls or firms that exist mainly to buy and enforce the patents of other people.

As the foregoing suggests, defining a troll is very difficult. Some would even claim that Thomas Edison, one of the most prolific inventors in the US, was an early troll, seeking licenses for patents that he did not plan to manufacture. The monetization of patents in the marketplace can spur innovation and drive economic growth and job creation. Many inventors just like to invent. Some have no interest in manufacturing anything, but would prefer to go back to the lab and hunt for the next new breakthrough. In trolls, inventors and others in the secondary market have a purchaser willing to pay for valuable patents: an entity that will help them reap the benefits of their efforts. It is widely recognized that patents are property and, like any other property, can be freely bought and sold, as long as there are no antitrust issues.

Until the onset of the troll era, small inventors, creditors in bankrupt companies with large patent portfolios and companies with many patents in technologies that they no longer planned to use, had few options to monetize them. In some instances, large companies refused to purchase or license these assets, taking a gamble that they could continue infringing because the costs of asserting patents preempted the owners' ability to enforce their rights. The evolving use of patents by trolls required new strategies and new business plans for many powerful companies. The disruption caused by abusive litigation behaviour in the corporate world has generated uncertainty and fear.

A patent troll may work a variety of ways, though each positions patent ownership as a way to generate revenue without producing any material benefits by using the patent in question. A good analogy would be earning the right to charge tolls on a toll road without performing any kind of improvements to the roadway. The patent troll would earn money from either charging huge fees to those who want to use the roadway or imposing severe penalties for those who use the road without knowing the terms of use. Patent trolls are more common in the US because they are able to exploit structural issues within the patent and court systems.

In June 2013, then President Obama said of patent trolls while directing the USPTO to address the abusive practice: *"They don't actually produce anything themselves, they're just trying to essentially leverage and hijack somebody else's idea and see if they can extort some money out of them"*[15].

Patent trolls are less of a problem in Europe because many European countries stipulate that losers in such court cases pay the legal expenses of both parties. This has the effect of eliminating some frivolous lawsuits. In April 2014, however, the US Supreme Court ruled on *Octane Fitness, LLC v. ICON Health & Fitness, Inc*[16]. to make it easier for the courts to impose legal costs on losers.

Patent trolling may involve one or more the following practices, though the full breadth of patent trolling would be hard to fully explain because of the many methods that are used:

1) Enforcing a patent without any intent of manufacturing a product or providing a service based on that patent, or without using it to conduct research, or otherwise utilizing it for the greater good;
2) Pursuing patent infringement claims that are baseless, may stifle manufacturing at a competitor, and may be easier and cheaper to settle than to litigate;
3) Buying a patent (usually from a bankrupt company at auction) with the intent of suing a competing company under the claim that it has a product that infringes upon the newly purchased patent;
4) Any utilization of a patent to solely enforce patent rights;
5) Patent trolling may involve venue shopping. For example, in 2015 some 45% of patent cases in the US were filed in the Eastern District of Texas, home to a judge with both patent expertise and a track record of favouring plaintiffs. This practice has since been limited by the US Supreme Court[17].

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[15] < https://www.patentprogress.org/2013/02/14/obama-acknowledges-patent-troll-problem-w-transcript/>

[16]< https://www.supremecourt.gov/opinions/13pdf/12-1184_gdhl.pdf>

[17] < https://thehill.com/regulation/court-battles/334548-supreme-court-limits-venue-shopping-for-patent-cases>

United States Court of Appeals for the Federal Circuit

MILLENNIUM PHARMACEUTICALS, INC.,
Plaintiff-Appellant

v.

SANDOZ INC., ACCORD HEALTHCARE, INC., ACTAVIS LLC, MYLAN LABORATORIES LIMITED, AGILA SPECIALTIES INC., DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC., SUN PHARMACEUTICAL INDUSTRIES LIMITED, SUN PHARMA GLOBAL FZE, APOTEX CORP., APOTEX INC., TEVA PHARMACEUTICALS USA, INC., GLENMARK PHARMACEUTICALS LTD., GLENMARK GENERICS LTD., GLENMARK GENERICS INC., USA, HOSPIRA, INC., WOCKHARDT BIO AG, WOCKHARDT USA LLC,
Defendants-Appellees

2015-2066, 2016-1008, 2016-1009, 2016-1010, 2016-1109, 2016-1110, 2016-1283, 2016-1762

Appeals from the United States District Court for the District of Delaware in Nos. 1:12-cv-01011-GMS, 1:12-cv-01490-GMS, 1:12-cv-01750-GMS, 1:13-cv-01874-GMS, 1:14-cv-01156-GMS, 1:15-cv-00040-GMS, 1:15-cv-00539-GMS, 1:15-cv-00540-GMS, 1:15-cv-00804-GMS, 1:16-cv-00034-GMS, Judge Gregory M. Sleet.

Decided: July 17, 2017

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Before NEWMAN, MAYER, and O'MALLEY, *Circuit Judges.*

NEWMAN, *Circuit Judge*.

Millennium Pharmaceuticals, Inc. is the exclusive licensee of U.S. Patent No. 6,713,446 ("the '446 Patent"), issued March 30, 2004 and assigned to the United States. Millennium developed the patented product for treatment of oncology disease, particularly multiple myeloma and mantle cell lymphoma. The product has the brand name

Velcade®. Appellees in Appeal Nos. 15-2066, 16-1008, 16-1009, 16-1010, 16-1110, 16-1283, and 16-1762 (collectively, "Sandoz") all filed abbreviated new drug applications ("ANDAs"), admitting infringement and seeking to invalidate various claims of the '446 Patent. Based on the litigation that ensued, the district court held that claims 20, 31, 49, and 53 of the '446 Patent were invalid,[1] leading to this appeal.

Millennium filed a notice of appeal in Appeal No. 16-1109 after the district court entered final judgment against Millennium in separate cases arising from ANDAs filed by Apotex and Teva, based on collateral estoppel arising from the district court's judgment of invalidity of claims 20, 31, 49, and 53 of the '446 Patent in the Sandoz-Millennium action. We consolidated the appeals in the Sandoz, Apotex, and Teva actions.

On review of the record and the applicable law, we conclude that the district court erred in the Sandoz litigation and that invalidity was not established. We reverse and enter judgment in favor of Millennium in the Sandoz litigation. We also vacate the district court's judgment in the action between Millennium, Teva, and Apotex based on our decision in the Sandoz litigation and remand that action for further proceedings.

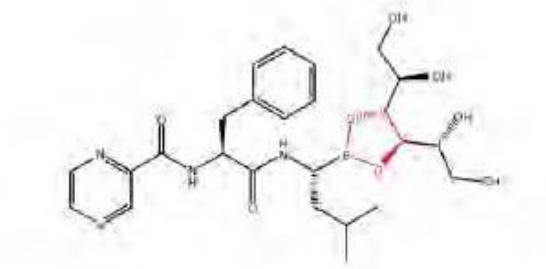
I. BACKGROUND

A. The '446 Patent

The '446 Patent describes the chemical compound D-mannitol N-(2-pyrazine)carbonyl-L-phenylalanine-L-leucine boronate. The compound is described as a boro-

[1] *Millennium Pharm., Inc. v. Sandoz Inc.*, No. 12-1011, 2015 WL 4966438 (D. Del. Aug. 20, 2015) ("Dist. Ct. Op.").

nate ester of bortezomib (a boronic acid) and D-mannitol (a hydroxy compound) and has the following chemical structure, with Millennium's highlight of the bonds between the bortezomib moiety and the D-mannitol moiety:



Millennium Br. 13. The lyophilized compound is claimed in Claim 20:

> 20. The lyophilized compound D-mannitol N-(2-pyrazine)carbonyl-L-phenylalanine-L-leucine boronate.

Other asserted claims include the new compound as a lyophilized cake, the method of preparation of the new compound, and its reconstitution with a pharmaceutically acceptable carrier. Dist. Ct. Op. *2.

Bortezomib and its properties as a proteasome inhibitor were previously known and are described in United States Patent No. 5,780,454 ("the Adams Patent"). However, despite its known efficacy against various cancers, bortezomib never achieved FDA approval and market status because of its instability, its rapid degradation in liquid formulations, and its insolubility. The record states that these problems remained unsolved despite extensive research effort by the inventor Dr. Adams and others at Millennium and its predecessor company. Dr. Adams' team attempted to develop a stable liquid formulation of bortezomib, but after evaluating approximately 20 different formulations, the team failed to develop a formulation that was stable enough for transportation, storage, and

administration to patients under conditions of clinical use and distribution.

The inventor of the '446 Patent was associated with the National Cancer Institute and the University of Kansas, and was consulted by Dr. Adams after years of unsuccessful attempts to solve formulation and stability problems with bortezomib. Despite preparing approximately twenty-five different liquid formulations, these efforts encountered the same stability and solubility problems as had other researchers attempting to solve this problem.

After failing to develop a viable liquid formulation, researchers began work on a lyophilized formulation for injection. The process of lyophilization (freeze-drying) is not intended to change the chemical structure of the active pharmaceutical ingredient. After experimenting with multiple variables that affect the lyophilization process, including solvents and bulking agents, researchers produced a promising lyophilized formulation using mannitol, a known bulking agent. It was discovered that the reason for the dramatic improvement in dissolution and stability for this formulation was the formation of a new chemical compound during lyophilization: the claimed ester of bortezomib and mannitol. The mannitol ester of bortezomib acts as a "prodrug," a compound that converts to or releases the active pharmaceutical ingredient upon administration to a patient. This discovery is described and claimed in the '446 Patent.

The ensuing drug product (Velcade®) became "a cancer treatment that changed the decades-old standard of care for multiple myeloma and has saved thousands of lives. The FDA approved Velcade® in record time, despite its novel structure and mechanism of action." Millennium Br. 1.

B. Proceedings in Sandoz Litigation

After the Sandoz defendants each filed an ANDA seeking FDA approval for the commercial manufacture, use, and sale of generic counterparts of Velcade®, Millennium filed patent infringement suits alleging that the products infringe at least claims 20, 31, 49, and 53 of the '446 Patent. The defendants stipulated to infringement of all asserted claims, and raised the defense of patent invalidity based on obviousness.

The district court held that the claims were obvious because they were the inherent result of an allegedly obvious process, *viz*., lyophilizing bortezomib in the presence of the bulking agent mannitol. Millennium argued that a person of ordinary skill would avoid lyophilization in developing a formulation involving bortezomib because "bortezomib was known to be unstable even in the dry state as a freestanding solid compound." Dist. Ct. Op. *6. The court was not persuaded by this argument and instead relied on the testimony of Sandoz's witness, Dr. Repta, to find that, as of the '446 Patent's priority date, lyophilization "was well-known in the field of formulation" and that it was considered an obvious alternative "when a liquid formulation provided limited success." *Id.*

The district court did not find that the prior art taught or suggested that the claimed new compound would be formed, or taught or suggested making the claimed new compound by any method, or taught or suggested that this new compound would have the properties of stability, solubility, and dissociability that it exhibited. No reference taught or suggested reacting bortezomib with mannitol, and no reference hinted that such an esterification reaction might occur during lyophilization. No reference taught or suggested that the product of such lyophilization would be a new chemical compound that would solve the problems that had inhibited development of bortezomib in oncology. However, the

district court concluded that lyophilizing bortezomib with mannitol was an obvious option "from which the prior art did not teach away." *Id.* at *7. The district court found that the Adams Patent "pointed directly to mannitol" despite the Adams Patent's failure to mention mannitol. *Id.*

The district court received testimony from the inventor and others that the formation of this new compound was not expected or intended when they conducted the lyophilization. There was no contrary evidence. Nonetheless, the district court held the claims invalid on the ground of obviousness, agreeing with Sandoz that "Millennium conceded as a matter of law that the ester is the 'natural result' of freeze-drying bortezomib with mannitol." *Id.* at *8. The court reasoned that the "natural result" of a chemical procedure is inherent in the procedure, and thus the product thereof "would have been obvious to a person of ordinary skill," in the words of § 103.

On the evidence of objective indicia of obviousness, the district court found that Millennium did not establish unexpected results because it did not compare the claimed invention to a glycerol ester of bortezomib. *Id.* at *9. The court also rejected long-felt need as objective evidence of non-obviousness, stating that "the lyophilized mannitol ester of bortezomib did not solve any problem having persisted over a long period of time without resolution by the prior art." *Id.* at *10 (quoting *Hitachi Koki Co. v. Doll*, 620 F. Supp. 2d 4, 30 (D.D.C. 2009)).

C. Proceedings in Apotex and Teva Litigations

Millennium also filed suit against Appellees Apotex and Teva after each filed an ANDA seeking approval for the commercial manufacture, use, and sale of a generic

version of Velcade®.[2] After the district court invalidated claims 20, 31, 49, and 53 of the '446 Patent in the Sandoz litigation, Apotex moved to dismiss Millennium's infringement claims, arguing that the district court's opinion created collateral estoppel barring Millennium from re-litigating the validity of the asserted claims. Eventually the parties stipulated that collateral estoppel warranted entry of judgment and dismissal in favor of Apotex and Teva.

II. DISCUSSION

A. Sandoz Litigation

In this Hatch-Waxman litigation, the district court invalidated the '446 patent on the ground of obviousness. The determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based on underlying facts. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966). After a bench trial, appellate review of the district court's factual findings is for clear error, and conclusions of law receive de novo review. *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1290 (Fed. Cir. 2013) (citation omitted). Invalidity of an issued patent must be shown by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011). "While we afford deference to a district court's factual findings, however, we retain plenary review to determine whether, as a legal matter, the evidence satisfies the clear-and-convincing standard of proof." *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1069 (Fed. Cir. 2012) (citing *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 993-94 (Fed. Cir. 2009)).

[2] The district court consolidated Millennium's litigation against Teva and Apotex.

1.

Recognizing our obligation to give deference to a district court's greater familiarity with the record and authority to reach factual conclusions therefrom, we conclude that the district court erred in its evaluation of obviousness. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419-20 (2007) (the question of law is whether the prior art rendered the invention obvious). In the case at bar, the question is whether a person of ordinary skill, seeking to remedy the known instability and insolubility and to produce an efficacious formulation of bortezomib, would obviously produce the D-mannitol ester of bortezomib, a previously unknown compound.

The prior art contains no teaching or suggestion of this new compound, or that it would form during lyophilization. Sandoz identifies no reference or combination of references that shows or suggests a reason to make the claimed compound. No reference teaches or suggests that such a new compound would have the long-sought properties of stability and solubility, and sufficiently dissociate to release bortezomib at an effective rate in the bloodstream, all critical to effective use for treating multiple myeloma.

The D-mannitol ester of bortezomib is a new compound with distinct chemical properties. We consider whether the prior art "would have supplied one of ordinary skill in the art with a reason or motivation to modify a lead compound to make the claimed compound with a reasonable expectation of success." *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1292 (Fed. Cir. 2012); *see also Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc.*, 752 F.3d 967, 973 (Fed. Cir. 2014) ("To establish obviousness in cases involving new chemical compounds, the accused infringer must identify some reason that would have led a chemist to modify a known compound."); *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511,

518 (Fed. Cir. 2012) (affirming district court conclusion that "the Defendants did not demonstrate the required motivation for selecting Sandoz Compound 1b as a lead compound"). The parties agree that bortezomib is the proper lead compound for this analysis. It is not disputed that the Velcade® compound provided unexpected properties, solving the problems that accompanied bortezomib.

The district court clearly erred in its obviousness analysis. There is no teaching or suggestion in the references to produce the claimed mannitol ester. No reference shows or suggests ester formation at freeze-drying conditions, or that any such ester might solve the problems of instability and insolubility of the free acid while dissociating rapidly in the bloodstream. No reference provides a reason to make the mannitol ester of bortezomib.

Sandoz argues that lyophilization was generally known in formulating pharmaceutical products. It states that bulking agents were known for use in lyophilization, and that mannitol was a known bulking agent. All true. However, the prior art does not teach or suggest that lyophilization of bortezomib in the presence of mannitol would produce a chemical reaction and form a new chemical compound, or provide a reason to make this specific new chemical compound, or that this new compound would solve the previously intractable problems of bortezomib formulation. Although mannitol was a known bulking agent, and lyophilization was a known method of drug formulation, nothing on the record teaches or suggests that a person of ordinary skill should have used mannitol as part of a synthetic reaction to make an ester through lyophilization. A result is obvious when it is "the natural result flowing from the operation as taught," or a "property that is necessarily present" when applying a process disclosed in the prior art. *Par Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1195 (Fed. Cir. 2014) (emphasis omitted) (first quoting *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981); then quoting *Alcon Research, Ltd. v.*

Apotex Inc., 687 F.3d 1362, 1369 (Fed. Cir. 2012), and *In re Kubin*, 561 F.3d 1351, 1357 (Fed. Cir. 2009)). Sandoz failed to show that it was obvious to use mannitol to make an ester during lyophilization, or that the ester would solve the problems experienced with bortezomib.

Sandoz defends the district court's ruling by citing three groups of references that purportedly provide the required teaching or suggestion. The first group shows that lyophilization is a known technique to prepare pharmaceutical formulations, although no reference shows lyophilization of bortezomib. The second group shows that mannitol is a known inert bulking agent, although no reference shows mannitol as a bulking agent for bortezomib. The third group starts from the Adams Patent that states that boronic acids can form esters, although mannitol is not included in the ester-forming alcohols mentioned in the Adams Patent. None of these references, alone or in combination, suggests or teaches that the solution to the problems of creating an efficacious formulation of bortezomib lay in freeze-drying bortezomib with mannitol to form an ester having the necessary properties for stability, storage, and treatment.

Nor does the Adams Patent provide the requisite teaching. As noted, bortezomib is described in the Adams Patent. That reference states that bortezomib is a boronic acid and that esters may be made, and it lists ten alcohols for this purpose. Adams Patent, col. 10, ll. 15–18. Mannitol is not mentioned. Nor does the Adams Patent teach or suggest that the esters provide a solution to the problems of instability and insolubility of bortezomib.

None of the experts presented by the many defendants stated that they were aware of prior art to fill any of the gaps in teaching or suggestion of the Velcade® product—although they variously opined that this long-sought discovery was obvious. Sandoz's expert Dr. Repta, who offered an opinion of obviousness, conceded that he had

"never worked with any boronic acid compound and has not performed or supervised any lyophilization experiments since 1983." Repta Dep. Tr. at 190, l. 10–192, l. 8. Dr. Repta cited seventeen references, none of which teaches or suggests the claimed new compound, or proposes lyophilization in the presence of mannitol to produce a new compound, or suggests that such new compound should be prepared in order to obtain the necessary stability, solubility, and dissociability for treatment of multiple myeloma.

Sandoz argues in this appeal that a Brown reference[3] and the Adams Patent teach that esters are more stable to oxidation than boronic acids. Sandoz Br. 33 (citing Adams, scheme 1, col. 29–30; Brown at 4526). However, Sandoz's witness Dr. Repta testified that (1) he could not identify any portion of the Brown reference making this point, Repta Dep. Tr. at 291, l. 18-292, l. 16, and (2) the Adams Patent says nothing about the stability of any ester, *id.* at 214, ll. 5–12. In *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007), the court held that, in determining obviousness, the challenger bears the burden of establishing that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." Here, neither the requisite motivation nor expectation of success is found in the prior art.

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[3] Herbert C. Brown and J.V.N. Vara Prasad, *Chiral Synthesis via Organoboranes. 9. Crystalline "Chelates" from Borinic and Boronic Esters. A Simple Procedure for Upgrading Borinates and Boronates to Materials Approaching 100% Optical Purity*, 51 J. ORGANIC CHEMISTRY 4526 (1986).

No reference supports the district court's conclusion that "skilled formulators would be motivated to create a mannitol ester to improve bortezomib's stability and solubility." Dist. Ct. Op. *8. No reference suggests producing this ester for this purpose. The undisputed facts are of failed attempts to achieve a stable formulation with the necessary properties of solubility and dissolution in the bloodstream.

We take note of Sandoz's reliance on selected portions of Dr. McCubbin's testimony in another case, for Sandoz does not mention that he also testified that Millennium could not have predicted that bortezomib would be stabilized by forming the mannitol ester. *See* McCubbin Dep. Tr. at 333, l. 24–334, l.4 ("But for any specific compound, you don't know what that stability is or whether it truly stabilizes it. There's examples where you can't form that ester or you form the ester, but it's not particularly stable. There – It's very mixed. It's a very compound-specific analysis that one has to do to really justify its stability difference.").

The sole reason Sandoz provides for choosing mannitol to make a new ester of bortezomib is because mannitol is one of a relatively small number of bulking agents used in lyophilization. Sandoz provides no reason why a person of ordinary skill who is seeking to make esters of bortezomib would look to lyophilization bulking agents. Dr. Anderson explained that mannitol is used as a bulking agent in lyophilization, and he also explained that persons experienced with bortezomib would know of crystallization-and boroxine-related concerns, but would not expect the bulking agent to react with the bortezomib to form a new compound.

2.

The district court also clearly erred in its determination that lyophilizing bortezomib with mannitol to form an ester was a "suitable option from which the prior art

did not teach away." Dist. Ct. Op. *7 (citing *Par Pharm.*, 773 F.3d at 1198). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Urbanski*, 809 F.3d 1237, 1244 (Fed. Cir. 2016) (quoting *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)). Millennium offered persuasive evidence that the chemical modification of bortezomib would have been unattractive to a person of ordinary skill for fear of disturbing the chemical properties whereby bortezomib functions effectively as an anti-cancer agent; in particular, a person of ordinary skill would have noted that the ester blocks a portion of the bortezomib molecule. Without the knowledge that the D-mannitol bortezomib ester dissociates in the bloodstream at a rate of pharmaceutical efficacy, a person of ordinary skill would not have been led to create the ester. Dr. Repta's testimony that dissociation of boronic esters would be "virtually instantaneous" was contradicted on cross-examination, and is not supported by the Adams Patent, which does not discuss the dissociation or stability of the esters.

We agree with Millennium that a person of ordinary skill would have avoided creating an ester with mannitol because several different esters, each with different chemical and possibly biological properties, could have formed. Dr. Adams testified that he was surprised when he learned that such a multiplicity of mannitol esters did not form with bortezomib.

3.

The district court also clearly erred in its consideration of inherency. "A party must . . . meet a high standard in order to rely on inherency to establish the existence of a claim limitation in the prior art in an obviousness analysis." *Par Pharm.*, 773 F.3d at 1195–96. "The mere

fact that a certain thing may result from a given set of circumstances is not sufficient" to render the result inherent. *In re Oelrich*, 666 F.2d at 581 (quoting *Hansgirg v. Kemmer*, 102 F.2d 212, 214 (CCPA 1939)).

The district court stated that Millennium "conceded as a matter of law that the ester is the 'natural result' of freeze-drying bortezomib with mannitol." Dist. Ct. Op. *8. However, "[t]he inventor's own path itself never leads to a conclusion of obviousness; that is hindsight. What matters is the path that the person of ordinary skill in the art would have followed, as evidenced by the pertinent prior art." *Otsuka*, 678 F.3d at 1296. This oft-cited principle is explained in, for example, *In re Kratz*, 592 F.2d 1169, 1175 (CCPA 1979):

> However, making weight of the method appellant used in finding the invention is beside the point. The last sentence of 35 U.S.C. § 103, with great clarity, excludes such methodology in stating that "(p)atentability shall not be negatived by the manner in which the invention was made."

See also, e.g., Life Techs., Inc. v. Clontech Labs., Inc., 224 F.3d 1320, 1325 (Fed. Cir. 2000) ("[T]he path that leads an inventor to the invention is expressly made irrelevant to patentability by statute.").

Sandoz argues that although lyophilization in the presence of mannitol produced an unexpected result, the result was "inevitable" and thus "inherent," and thus not "inventive." Sandoz Br. at 1, 12-17. However, invention is not a matter of what the inventor intended when the experiment was performed; obviousness is measured objectively in light of the prior art, as viewed by a person of ordinary skill in the field of the invention. "Those charged with determining compliance with 35 U.S.C. § 103 are required to place themselves in the minds of those of ordinary skill in the relevant art at the time the invention was made, to determine whether that which is

now plainly at hand would have been obvious at such earlier time." *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138 (Fed. Cir. 1985). No expert testified that they foresaw, or expected, or would have intended, the reaction between bortezomib and mannitol, or that the resulting ester would have the long-sought properties and advantages.

4.

We conclude finally that the district court clearly erred in its examination of the objective indicia of unexpected results and long-felt need. All of the *Graham* factors must be considered, including the objective indicia when present, before any conclusion regarding obviousness is reached. *In re Cyclobenzaprine*, 676 F.3d at 1075–76 (citation omitted); *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579 (Fed. Cir. 1997); *see Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008) (stating that objective indicia are "not just a cumulative or confirmatory part of the obviousness calculus but constitute[] independent evidence of nonobviousness").

Evidence of objective indicia "can be the most probative evidence of nonobviousness in the record," and objective indicia enable "the court to avert the trap of hindsight." *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1358 (Fed. Cir. 2013) (quoting *Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1310 (Fed. Cir. 2010)). These indicia cannot be set aside in the analysis of obviousness.

i.

"Unexpected results are useful to show the improved properties provided by the claimed compositions are much greater than would have been predicted." *Leo Pharm.*, 726 F.3d at 1358 (quoting *In re Soni*, 54 F.3d 746, 751 (Fed. Cir. 1995) (internal quotation marks omitted)).

Nonobviousness may be established when an invention "yield[ed] more than predictable results." *Crocs, Inc.*, 598 F.3d at 1309; *see also In re Soni*, 54 F.3d at 750–51; *In re Chupp*, 816 F.2d 643, 646–47 (Fed. Cir. 1987) (considering improved properties as selective herbicide); *In re May*, 574 F.2d 1082, 1093 (CCPA 1978) (considering non-addictive property of analgesic compound). "[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art." *Kao Corp. v. Unilever U.S., Inc.*, 441 F.3d 963, 970 (Fed. Cir. 2006) (quotation and citation omitted); *Pfizer*, 480 F.3d at 1370–71 (quoting same).

Millennium presented expert testimony that the lyophilized mannitol ester of bortezomib yielded unexpected results as compared to bortezomib, *viz.*, greatly improved stability, solubility, and dissolution. However, the district court ruled that bortezomib itself was not the closest prior art, and declined to consider the advantages and benefits of the Velcade® product. The district court's error stems from its determination that Millennium should have compared the glycerol bortezomib ester, for the Adams Patent included glycerol as one of ten "[p]referred . . . dihydroxy compounds"[4] for "boronate esters." Adams Patent, col. 10, ll. 11-18.

The bortezomib glycerol ester was not specifically disclosed, prepared, or tested in the Adams Patent. Although Sandoz now argues that the bortezomib glycerol ester is "generically" encompassed by the Adams Patent, Sandoz has not argued that any glycerol ester is specifically disclosed or actually identified in the Adams Patent (or in any other reference).

[4] Glycerol is a trihydroxy compound.

Nor does the Adams Patent disclose the stability or solubility of any ester compound. Unexpected results are shown in comparison to what was known, not what was unknown. *See Pfizer*, 480 F.3d at 1370–71; *see also Kao*, 441 F.3d at 970. Millennium was not required to create the glycerol ester, when the product had not been created in the prior art. *See In re Geiger*, 815 F.2d 686, 690 (Fed. Cir. 1987) (Newman, J., concurring) ("The applicant is not required to create prior art, nor to prove that his invention would have been obvious if the prior art were different than it actually was.").

We conclude that the district court should have treated bortezomib as the closest prior art compound, and acknowledged the unrebutted evidence that the D-mannitol ester of bortezomib exhibited unexpected results compared with bortezomib, including unexpectedly superior stability, solubility, and dissolution.

ii.

The existence of a long-felt but unsolved need that is met by the claimed invention is further objective evidence of non-obviousness. *See In re Cyclobenzaprine*, 676 F.3d at 1081–83 ("[W]here . . . the obviousness determination turns on whether . . . a particular formulation of [a drug] would be [a] successful . . . [or] effective treatment[,] objective indicia of . . . longfelt need [is] particularly telling."). Evidence of long-felt need is "particularly probative of obviousness when it demonstrates both that a demand existed for the patented invention, and that others tried but failed to satisfy that demand." *Id.* at 1082–83 (citing *In re Piasecki*, 745 F.2d 1468, 1475 (Fed. Cir. 1984); *Alco Standard Corp. v. Tenn. Valley Auth.*, 808 F.2d 1490, 1500 (Fed. Cir. 1986) (finding nonobviousness where the relevant industry had searched for a

solution, and major manufacturers tried but failed to develop a reliable solution)).[5]

The district court's conclusion that the lyophilized mannitol ester of bortezomib did not meet a long-felt need was both perfunctory and clearly erroneous. There is no dispute that there was a long-felt need for a product to treat multiple myeloma, for treatments prior to Velcade® gave poor remission and low survival rates. Although it is agreed that bortezomib is the effective product in the body, bortezomib alone is not an available product. Sandoz offered no evidence of successful solution of the problems that had barred bortezomib from clinical approval.

The district court clearly erred in attributing Velcade®'s commercial success to bortezomib alone, as bortezomib is not a viable commercial product and had been denied FDA approval because of its instability. The D-mannitol ester was responsible for Velcade®'s successful results, for the D-mannitol ester is necessary to provide the required solubility and stability.

---

[5] Sandoz argues that there was no "failure of others" because the Adams Patent blocked others from bringing a bortezomib formulation to market until patent expiration in 2017. This question is not before us. We have noted that, although long-felt need is closely related to failure of others, these considerations are distinct and we treat each separately. *See, e.g.*, *In re Cyclobenzaprine*, 676 F.3d at 1081–83; *Graham*, 383 U.S. at 17-18. Although "[e]vidence is particularly probative of obviousness when it demonstrates both that a demand existed for the patented invention, and that others tried but failed to satisfy that demand," a patent owner may establish a long-felt need without presenting evidence of failure of others. *In re Cyclobenzaprine*, 676 F.3d at 1082.

On the entirety of the record, we conclude that the district court clearly erred in finding that a person of ordinary skill would obviously make the D-mannitol ester in order to solve the problem of providing an effective form of bortezomib. The unexpected properties of an unexpectedly produced new compound, and the ensuing pharmaceutical efficacy and benefit, negate the district court's ruling of obviousness. We therefore reverse the district court's invalidity determination.

B. Apotex and Teva Litigation

Apotex, Teva, and Millennium agree that, if the judgment in the Sandoz case is reversed, the dismissal of the litigation between Millennium and Apotex and Teva should be vacated and remanded, so that Apotex and Teva have the opportunity to present their case. Apotex Br. 18; Millennium Reply Br. 31. Because we reverse the judgment in the Sandoz litigation, we vacate and remand the Apotex and Teva litigation to the district court for appropriate further proceedings.

III. CONCLUSION

We conclude that the Sandoz group of defendants did not establish the obviousness of the asserted claims of the '446 Patent by clear and convincing evidence. The district court's judgment of invalidity is reversed, and judgment is entered in favor of Millennium as to the Sandoz defendants. We remand for any appropriate further proceedings in that action.

The judgment between Millennium and Apotex and Teva is vacated, and remanded for further proceedings in those actions.

REVERSED-IN-PART AND REMANDED-IN-PART;
VACATED-IN-PART AND REMANDED-IN-PART

COSTS

Costs to Millennium in Case Nos. 15-2066, 16-1008, 16-1009, 16-1010, 16-1110, 16-1283, and 16-1762.

No costs in Case No. 16-1109.

United States Court of Appeals for the Federal Circuit

06-1179

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS,
WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC
and WARNER-LAMBERT EXPORT, LTD.,

Plaintiffs-Appellees,

v.

RANBAXY LABORATORIES LIMITED
and RANBAXY PHARMACEUTICALS INCORPORATED,

Defendants-Appellants.

Rudolf E. Hutz, Connolly Bove Lodge & Hutz LLP, of Wilmington, Delaware, argued for plaintiffs-appellees. With him on the brief were Jeffrey B. Bove, Collins J. Seitz, Jr., Mary W. Bourke, and William E. McShane.

William R. Zimmerman, Knobbe, Martens, Olson & Bear, LLP, of Irvine, California, argued for defendants-appellants. With him on the brief were Darrell L. Olson, John P. Giezentanner, Douglas G. Muehlhauser, and Payson LeMeilleur, of Irvine, California; and Joseph M. Reisman and Darryl H. Steensma, of San Diego, California. Of counsel on the brief were Jay R. Deshmukh and George E. Heibel, Ranbaxy, Inc., of Princeton, New Jersey.

Appealed from: United States District Court for the District of Delaware

Judge Joseph J. Farnan, Jr.

United States Court of Appeals for the Federal Circuit

06-1179

PFIZER, INC., PFIZER IRELAND PHARMACEUTICALS,
WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY, LLC,
and WARNER-LAMBERT EXPORT, LTD.,

Plaintiffs-Appellees,

v.

RANBAXY LABORATORIES LIMITED
and RANBAXY PHARMACEUTICALS, INCORPORATED,

Defendants-Appellants.

DECIDED: August 2, 2006

Before MICHEL, Chief Judge, SCHALL and DYK, Circuit Judges.

MICHEL, Chief Judge.

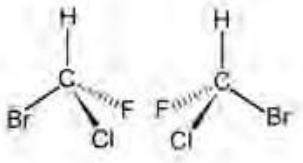
In this patent case concerning the prescription drug Lipitor®, which is used to reduce low-density lipoprotein (LDL) cholesterol levels, defendants-appellants Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals, Inc. (collectively "Ranbaxy") appeal from a final judgment of the United States District Court for the District of Delaware. Plaintiffs-appellees Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Co., Warner-Lambert Co. LLC, and Warner-Lambert Export, Ltd. (collectively "Pfizer") filed four complaints, later consolidated into a single action,

alleging that the product described in Ranbaxy's Abbreviated New Drug Application ("ANDA") No. 76-477 infringed United States Patent Nos. 4,681,893 and 5,273,995 under 35 U.S.C. § 271(e)(2). Ranbaxy appeals the following rulings by the district court: (1) that claim 1 of the '893 patent was infringed; (2) that the '893 patent term extension was not proven invalid; (3) that claim 6 of the '995 patent was infringed; (4) that claim 6 was not proven invalid for failure to comply with § 112, ¶ 4; as anticipated or obvious; or for non-statutory double patenting; and (5) that the '995 patent was not proven unenforceable due to inequitable conduct.

Because we agree with the district court's claim construction of claim 1 of the '893 patent, we affirm the finding of infringement. We also affirm the ruling that the '893 patent term extension was not invalid. With respect to the '995 patent, however, we reverse on the question of invalidity under § 112, ¶ 4 and find the other issues moot.

I. BACKGROUND

Stereochemistry is the study of the three-dimensional structure of molecules. Stereoisomers have the same molecular formula or atomic composition, but different spatial arrangements. Enantiomers are a pair of stereoisomers that are non-superimposable mirror images of each other and often have distinct physical properties.[1] In organic chemistry, enantiomeric pairs include compounds that have one or more chiral centers, i.e., carbon atoms with four non-identical substituent atoms or groups of atoms. For example, the enantiomers of bromochlorofluoromethane are displayed here. A solid wedge is



[1] Thalidomide is a well-known example: one enantiomer is effective against morning sickness while the other causes birth defects.

used to indicate that the chlorine atom is projecting out of the page, while a hashed line indicates that the fluorine atom is behind the page.

To distinguish between different enantiomers of the same compound, chemists use various naming conventions. Enantiomers are sometimes called optical isomers because a pure enantiomer rotates plane-polarized light in a particular direction. If the light rotates clockwise, then that enantiomer is labeled "(+)" or "d" for dextrorotatory; its counterpart will rotate the light counterclockwise and is labeled "(-)" or "l" for levorotatory. A racemate (or racemic mixture) is an equal mixture of two enantiomers. A racemate is labeled "(±)" because it is not optically active (i.e., will not rotate plane-polarized light in either direction since its constituent enantiomers cancel each other out). Another system labels biochemical molecules "D" or "L" (unrelated to the labels "d" and "l", described above) by reference to the isomers of glyceraldehyde. Yet another nomenclature system labels each chiral center "R" or "S" according to Cahn-Ingold-Prelog priority rules.[2] Racemates are designated "RS" because they are comprised of both R-enantiomers and S-enantiomers.

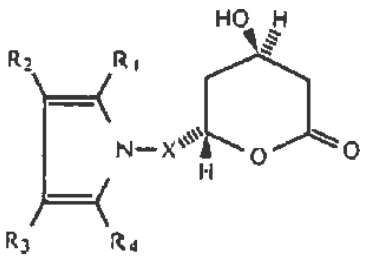
The terms "cis" and "trans" refer to the relative spatial arrangement of two particular substituents: "cis" means they are on the same side of a plane, while "trans" means they are on opposite sides. In organic compounds, the "plane" is typically a

[2] These rules are briefly summarized as follows. Each substituent is assigned a "priority" based on the molecular weight of the atom closest to the chiral center. If more than one substituent starts with the same type of atom, then the molecular weight of the next closest atom is used as a tiebreaker, so an ethyl group ($-C_2H_5$) has a higher priority than a methyl group ($-CH_3$). If there are multiple bonds, the atoms are counted once for each bond so a vinyl group ($-CH=CH_2$) has a higher priority than an ethyl group ($-C_2H_5$). The lowest priority (i.e., lowest molecular weight) substituent is then pointed away from the viewer. If the remaining three substituents are arranged from highest priority to lowest priority in a clockwise direction, then the molecule is labeled "R." If counterclockwise, then it is labeled "S."

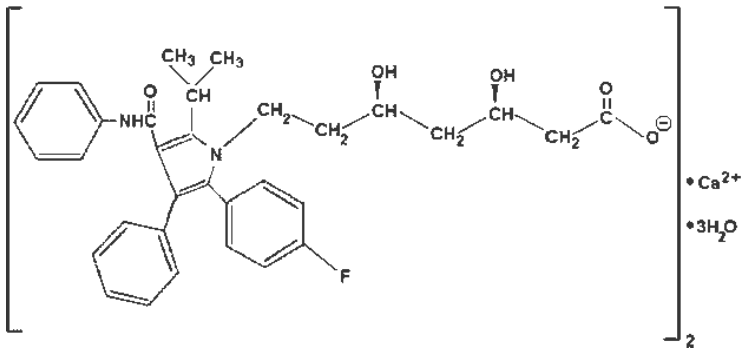
central ring structure. If there are two chiral centers on the aromatic ring, then there are four possible isomers: R-trans, S-trans, R-cis and S-cis. An equal mixture of R-trans and S-trans enantiomers is called the trans-racemate. An equal mixture of R-cis and S-cis enantiomers is called the cis-racemate.

* * *

Pfizer asserted claims 1-4, 8, and 9 of the '893 patent. Claim 1 is the only independent claim. It recites a compound having structural formula I (as shown), where there is a pyrrole ring on the left with four substituent groups (labeled R_1, R_2, R_3, and R_4), a pyran (or lactone) ring on the right and an alkyl chain (labeled X) joining the two rings. Claim 1 expressly defines the possible substituent groups represented by X, R_1, R_2, R_3, and R_4. Claim 1 also covers "a hydroxyl acid or pharmaceutically acceptable salts thereof, corresponding to the opened lactone ring of the compounds of structural formula I above."



Originally, the '893 patent was to expire on May 30, 2006, but Pfizer filed for a patent term extension pursuant to 35 U.S.C. § 156. Pfizer presented evidence that the active ingredient in Lipitor® is atorvastatin calcium or [R-(R*,R*)]-2-(4-fluorophenyl)-β,δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid, calcium salt (2:1) trihydrate. Its structural formula is:



On July 15, 1998, the United States Patent and Trademark Office ("PTO") agreed that this compound was within the scope of the '893 patent and extended the patent term to September 24, 2009.

As for the '995 patent, Pfizer only asserted dependent claim 6.[3] The relevant claims are:

> 1. [R-(R *,R*)]-2-(4-fluorophenyl)-β,δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)-carbonyl]-1H-pyrrole-1-heptanoic acid[4] or (2R-trans)-5-(4-fluorophenyl)-2-(1-methylethyl)-N,4-diphenyl-1-[2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl]-1H-pyrrole-3-carboxamide;[5] or pharmaceutically acceptable salts thereof.
>
> 2. A compound of claim 1 which is [R-(R*R*)]-2-(4-fluorophenyl)-β-δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid.
>
> 6. The hemicalcium salt of the compound of claim 2.

A bench trial commenced on November 30, 2004. The district court issued its findings of fact and conclusions of law on December 16, 2005, concluding that both patents were infringed, not invalid and not unenforceable. Pfizer Inc. v. Ranbaxy Labs., 405 F. Supp. 2d 495 (D. Del. 2005). Judgment was entered on January 4, 2006. The next day, Ranbaxy filed its notice of appeal. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

Following a bench trial, a district court's conclusions of law are reviewed de novo while its findings of fact are reviewed for clear error. Allen Eng'g Corp. v. Bartell Indus.,

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[3] At oral argument, counsel for Ranbaxy revealed that Pfizer had entered into a covenant not to sue under independent claim 1 of the '995 patent. The parties also stipulated that claim 6 was a dependent claim.

[4] This compound is also known as atorvastatin acid.

[5] This compound is also known as atorvastatin lactone.

Inc., 299 F.3d 1336, 1343-44 (Fed. Cir. 2002). A factual finding is clearly erroneous if, despite some supporting evidence, "the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." United States v. U.S. Gypsum Co., 333 U.S. 364, 395 (1948).

A. '893 Patent.

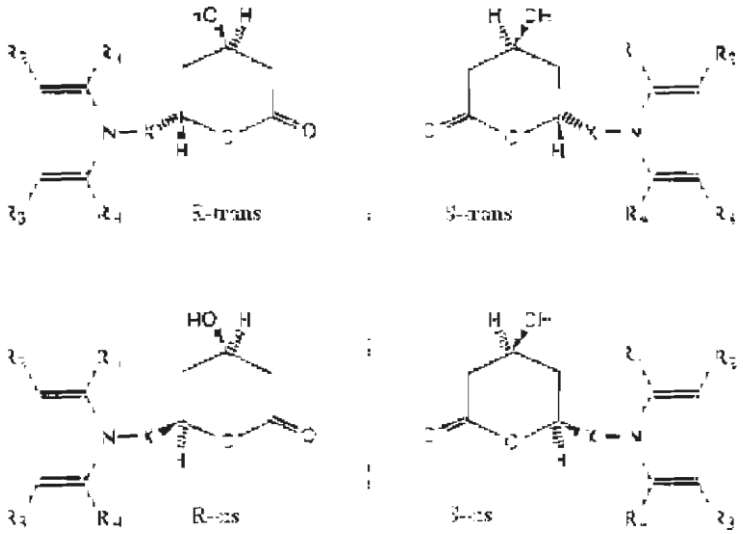
1. Correct Claim Construction.

Claim construction is a question of law reviewed de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454-56 (Fed. Cir. 1998) (en banc). We determine the ordinary and customary meaning of claim terms as understood by a person of ordinary skill in the art, using the methodology first set forth in Vitronics Corp v. Conceptronics, Inc., 90 F.3d 1576, 1582-83 (Fed. Cir. 1996), and reaffirmed in Phillips v. AWH Corp., 415 F.3d 1303, 1312-19 (Fed. Cir. 2005) (en banc). The subsequent infringement analysis is reviewed "for clear error if performed by the court and for substantial evidence if performed by a jury." Young Dental Mfg. Co. v. Q3 Special Prods., 112 F.3d 1137, 1141 (Fed. Cir. 1997).

The parties agree that under the district court's claim construction, Ranbaxy's ANDA product infringes claim 1. On appeal, Ranbaxy argues that the district court erred in construing structural formula I "to embrace all trans-form isomers, including enantiomeric atorvastatin calcium" in lieu of accepting its proffered construction limiting claim 1 to racemates. Pfizer, 405 F. Supp. 2d at 507. Instead, Ranbaxy contends that structural formula I is limited to racemates, because (1) one skilled in the art would represent a racemate by depicting one of its constituent enantiomers; (2) the specification only discloses reaction sequences that produce racemates; (3) during

prosecution of foreign counterparts to the '893 patent, the patentee represented that its references to "trans" should be read as "trans-(±);" and (4) during prosecution of the '995 patent, the patentee argued that the '893 patent was limited to mixtures of enantiomers rather than the R-isomer. Thus, Ranbaxy argues, its ANDA product does not infringe claim 1 of the '893 patent because it is the R-enantiomer of atorvastatin calcium. We disagree.

It is undisputed that the drawing in claim 1 depicts an R-trans enantiomer. All four isomers of structural formula I are shown here.



These compounds are labeled "R" and "S" based on the stereochemistry of the chiral center at the top (i.e., 4-hydroxy position) of the pyran-2-one ring. The "cis" and "trans" designations refer to the spatial relationship between the hydroxyl group (-OH) and the alkylpyrrole group relative to the plane of the pyran-2-one ring.

The district court correctly observed that the '893 patent consistently describes the invention as a class of "trans" compounds. The specification of the '893 patent explains at col. 3, ll. 45-54:

> The compounds of structural formula I above possess two asymmetric carbon centers . . . [which] gives rise to four possible isomers, two of which are the R-cis- and S-cis-isomers and the other two of which are the R-trans- and S-trans-isomers. This invention contemplates only the trans-form of the compounds of formula I above.

We read this language to mean that the invention would otherwise encompass all four isomers of the compounds of structural formula I, but for the patentee's express disclaimer of the R-cis- and S-cis-isomers. There is no further disavowal of claim scope that would limit the '893 patent to trans-racemates. Indeed, as noted by the district court, the terms "racemate" or "racemic mixture" do not appear in the '893 patent; nor is claim 1, unlike claim 5, limited by a "trans-(±)" designation. In sum, the district court correctly found that no intrinsic evidence limits claim 1 of the '893 patent to trans-racemates, as opposed to an R-trans enantiomer, an S-trans enantiomer or any (equal or unequal) mixtures thereof.

We are not persuaded by Ranbaxy's arguments to the contrary. First, even accepting Ranbaxy's contention that a racemate is commonly represented by depicting one of its constituent enantiomers, it does not follow that the depiction of an R-enantiomer always represents only a racemate. Here, only an R-trans enantiomer is depicted in the '893 patent, yet the specification expressly indicates that there are four possible isomers of the compounds of structural formula I and limits the invention to the trans- form. If one skilled in the art would have understood the drawing of structural formula I to limit the scope of claim 1 to trans-racemates, then an express disclaimer of the cis- form would not have been necessary.

Second, while the examples do describe reaction sequences that produce racemates, restricting claim 1 on this basis would improperly import limitations from the

specification into the claims, which should be avoided unless the patentee clearly "intends for the claims and the embodiments in the specification to be strictly coextensive." Phillips, 415 F.3d at 1323. But here, the specification, at col. 10, ll. 36-38, states that "[t]hese examples are illustrative and are not to be read as limiting the scope of the invention as it is defined by the appended claims."

Third, we agree with the district court's conclusion that the statements made during prosecution of foreign counterparts to the '893 patent are irrelevant to claim construction because they were made in response to patentability requirements unique to Danish and European law. See TI Group Auto. Sys. (N. Am.), Inc. v. VDO N. Am. LLC, 375 F.3d 1126, 1136 (Fed. Cir. 2004). Likewise, statements made during prosecution of the later, unrelated '995 patent cannot be used to interpret claims of the '893 patent. See Goldenberg v. Cytogen, Inc., 373 F.3d 1158, 1167-68 (Fed. Cir. 2004) (finding statements in another patent or its prosecution history irrelevant to claim construction "[a]bsent a formal relationship or incorporation during prosecution" of the patent at issue); cf. Abbott Labs. v. Dey L.P., 287 F.3d 1097, 1104-05 (Fed. Cir. 2002) (finding arguments made during prosecution of a commonly-owned but unrelated patent did not create prosecution history estoppel). Finally, insofar as Ranbaxy restates the same argument under the guise of judicial estoppel, we are not persuaded.

Because claim 1 was correctly construed to include the enantiomeric trans-forms of the compounds of structural formula I, we affirm the finding of infringement.

2. Term Extension.

Under the Hatch-Waxman Act, if a patented product has been subject to a regulatory review period before its commercial marketing or use, an extension of the

patent term may be obtained. 35 U.S.C. § 156(c). In applying for a patent extension, the patentee has a duty of candor and good faith towards the PTO and must disclose any "material information adverse to a determination of entitlement to the extension sought." 37 C.F.R. § 1.765(a). The Director of the PTO is charged with deciding whether the patent is entitled to term extension, a decision which is given "great deference." Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392, 399 (Fed. Cir. 1990).

On appeal, Ranbaxy asserts that, when correctly construed, the '893 patent does not cover enantiomeric atorvastatin calcium, i.e., the active ingredient in Lipitor®, so it was not eligible for a patent term extension under 35 U.S.C. § 156. In the alternative, Ranbaxy argues that the term extension is invalid due to inequitable conduct because Pfizer failed to disclose the statements Warner-Lambert made during prosecution of the '995 patent and the foreign counterparts to the '893 patent.

Ranbaxy's first argument depends on its proffered claim construction, which we have already rejected. As to its allegations of inequitable conduct, the district court found that the allegedly withheld information was not material, and consequently did not need to be disclosed to the PTO, because those statements were "irrelevant to a determination of the scope of the claims of the '893 patent." Pfizer, 405 F. Supp. 2d at 512. This factual finding was not clearly erroneous. We thus agree that Ranbaxy failed to establish by clear and convincing evidence that the term extension was invalid.

B. '995 Patent.

With respect to the '995 patent, numerous issues have been raised on appeal. Rather than considering them in the order presented by the appellants, we first direct our attention to the question of validity under 35 U.S.C. § 112, ¶ 4, which provides:

> Subject to the following paragraph [concerning multiple dependent claims], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

As described above, Pfizer only asserted dependent claim 6 of the '995 patent. This claim reads: "The hemicalcium salt of the compound of claim 2." Claim 2, in turn, is dependent on claim 1, which recites the following compounds: (1) atorvastatin acid; or (2) atorvastatin lactone; or (3) pharmaceutically acceptable salts thereof. Claim 2 itself, however, only recites atorvastatin acid. Notably, it does not include the pharmaceutically acceptable salts of atorvastatin acid.[6] Ranbaxy asserts that the district court erred in refusing to invalidate claim 6, even though it does not "incorporate by reference all the limitations of the claim to which it refers" and "then specify a further limitation of the subject matter," as required by § 112, ¶ 4. In other words, claim 6 does not narrow the scope of claim 2; instead, the two claims deal with non-overlapping subject matter.

The district court explicitly recognized that "there may be a technical problem in the drafting of claim 6." Pfizer, 405 F. Supp. 2d at 508. Yet, it declined to find that "this drafting problem is sufficient to render the claim invalid if the claim is read consistently with its meaning to those skilled in the art" because it was unable to find any Federal Circuit precedent applying § 112, ¶ 4 to invalidate a patent. Id. at 508-09. The district court understood § 112, ¶ 4 "to be limited to matters of form, rather than matters of

[6] Theoretically, a claimed acid could be liberally construed to include the corresponding salts. See Merck & Co., Inc. v. Teva Pharms. USA, Inc., 347 F.3d 1367, 1372 (Fed. Cir. 2003). But here, given the absence of the "pharmaceutically acceptable salts thereof" language which was used in claim 1, the intrinsic evidence would not have supported such an interpretation of claim 2.

substance," noting that the PTO treats a claim that fails to comply with this provision "as a matter to be addressed through an objection" rather than rejected as unpatentable. Id. at 509. In any event, it emphasized that no objections were made to claim 6, (or any of the other similarly-worded dependent claims), during prosecution. Id. at 509 n.7.

It is true that at the time the district court wrote its opinion, there was no applicable Federal Circuit precedent. More recently, however, we have suggested that a violation of § 112, ¶ 4 renders a patent invalid just as violations of other paragraphs of § 112 would. Curtiss-Wright Flow Control Corp., 438 F.3d 1374, 1380 (Fed. Cir. 2006). In Curtiss-Wright, the issue was one of claim differentiation. The court reasoned that "reading an additional limitation from a dependent claim into an independent claim would not only make that additional limitation superfluous, it might render the dependent claim invalid" for failing to add a limitation to those recited in the independent claim, as required by 35 U.S.C. § 112, ¶ 4. Id. Indeed, "[i]nvalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title" is expressly included among the available defenses to an infringement suit. 35 U.S.C. § 282(3) (emphasis added).

We recognize that the patentee was attempting to claim what might otherwise have been patentable subject matter.[7] Indeed, claim 6 could have been properly drafted either as dependent from claim 1 or as an independent claim—i.e., "the hemicalcium salt of atorvastatin acid." But, we "should not rewrite claims to preserve

[7] The district court found that claim 6 was unambiguous to the extent that the patentee intended to claim the hemicalcium salt of atorvastatin acid. Pfizer, 405 F. Supp. 2d at 507. The court further recognized that "[a]s a matter of standard chemical nomenclature, chemists typically refer to a salt of an acid, even though they are aware that the complete acid is technically no longer present in the salt form." Id. at 508.

validity." Nazomi Commc'ns, Inc. v. Arm Holdings, PLC, 403 F.3d 1364, 1368 (Fed. Cir. 2005); see also Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed. Cir. 1999) ("[I]f the only claim construction that is consistent with the claim's language and the written description renders the claim invalid, then . . . the claim is simply invalid."). Ranbaxy correctly argues that claim 6 fails to "specify a further limitation of the subject matter" of the claim to which it refers because it is completely outside the scope of claim 2. We must therefore reverse the district court with respect to this issue and hold claim 6 invalid for failure to comply with § 112, ¶ 4.

Although the district court was reluctant to find the fourth paragraph of § 112 to be an invalidating provision, doing so does not exalt form over substance. Rather, it is consistent with the overall statutory scheme that requires applicants to satisfy certain requirements before obtaining a patent, some of which are more procedural or technical than others. See, e.g., 35 U.S.C. § 102(b) & (d) (establishing statutory one-year bars to patentability); 35 U.S.C. § 111(a)(2)(C) (requiring submission of an oath by the applicant); 35 U.S.C. § 111(a)(3) (requiring submission of a fee with the application); 35 U.S.C. § 116 (requiring joint inventors to apply for a patent jointly).

In light of this holding, appellants' remaining arguments concerning the '995 patent are rendered moot. We therefore decline to reach the remaining issues raised.

III. CONCLUSION

For the aforementioned reasons, we affirm-in-part, reverse-in-part and remand so the district court can modify the permanent injunction in a manner consistent with this opinion.

AFFIRMED-IN-PART, REVERSED-IN-PART and REMANDED.

Trinity Term
[2017] UKSC 48
On appeals from: [2015] EWCA Civ 555 and 556

JUDGMENT

Actavis UK Limited and others (Appellants) *v* Eli Lilly and Company (Respondent)
Eli Lilly and Company (Appellant) *v* Actavis UK Limited and others (Respondents)
Eli Lilly and Company (Appellant) *v* Actavis UK Limited and others (Respondents)

before

Lord Neuberger, President
Lord Mance
Lord Clarke
Lord Sumption
Lord Hodge

JUDGMENT GIVEN ON

12 July 2017

Heard on 4, 5 and 6 April 2017

Actavis and others
Daniel Alexander QC
Thomas Raphael QC
Isabel Jamal
(Instructed by Bird & Bird LLP)

Eli Lilly and Company
Thomas Mitcheson QC
Andrew Waugh QC
Stuart Baran
(Instructed by Hogan Lovells International LLP)

LORD NEUBERGER: (with whom Lord Mance, Lord Clarke, Lord Sumption and Lord Hodge agree)

1. The issue raised on this appeal and cross-appeal is whether three products manufactured by the Actavis group of companies ("Actavis") would infringe a patent whose proprietor is Eli Lilly & Company ("Lilly"), namely European Patent (UK) No 1 313 508 ("the Patent"), and its corresponding designations in France, Italy and Spain.

2. This judgment was circulated in draft to the parties' legal representatives in the normal way on 5 July 2017, on the basis that it would be handed down a week later. On the following day, just after midday, Actavis's solicitors emailed the Court expressing concern about the potential prejudice which their clients could suffer if they did not know of the outcome of this appeal until 12 July. Not least because publication of our decision could have an effect on the share prices of Actavis or Lilly or both of them, the Court proposed to the parties' respective solicitors that we should announce our decision at once, while maintaining the intention, in accordance with this Court's usual practice, to hand down the judgment a week after circulation of the draft. This was agreed by both solicitors, and accordingly on 7 July at 11.30 am, the following announcement appeared on the Court's website:

> "The Supreme Court allows Eli Lilly's appeal and holds that Actavis's products directly infringe Eli Lilly's patent in the United Kingdom, France, Italy and Spain. The Court dismisses Actavis's cross-appeal on the basis that if its products did not directly infringe, they would indirectly infringe to the extent held by the Court of Appeal."

Accordingly, these are technically the reasons for those conclusions.

The factual and technical background

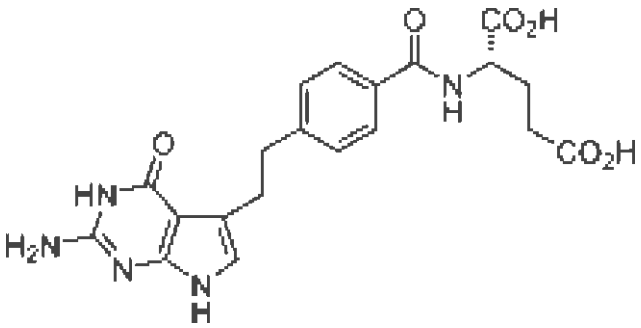
The factual background

3. Pemetrexed is a chemical which has been known for some time to have therapeutic effects on cancerous tumours. However, when used for that purpose on its own, pemetrexed can often have seriously damaging, sometimes even fatal, side-effects. Accordingly, its use as an anti-cancer drug was effectively precluded in

practice. The essential disclosure of the Patent was that the damaging side-effects could largely be avoided if a compound called pemetrexed disodium was administered together with vitamin B12. This has enabled pemetrexed disodium to be used for treatment in the form of a medicament which includes the vitamin. Such a medicament has been successfully marketed, under the brand name Alimta, by Lilly since 2004.

4. The Patent primarily claims the use of pemetrexed disodium in the manufacture of a medicament for use in combination with vitamin B12 (and, optionally, folic acid) for the treatment of cancer.

5. Pemetrexed itself is a member of a class of chemicals known as antifolates, and its molecular structure is shown below, with C, N, O and H being respectively the chemical symbols for carbon, nitrogen, oxygen and hydrogen; and the unallocated points on the chains and the rings being carbon.



6. The presence of the two -CO_2H units results in pemetrexed being an acid (hence it is also known as pemetrexed diacid), or as it is sometimes called, a free acid. When pemetrexed is dissolved in water, the hydrogens in those two units separate from the rest of the molecule as positively charged entities, protons, and the rest of the molecule becomes a negatively charged entity called an anion. The structure of pemetrexed disodium is similar except that, instead of the two -CO_2H units, it has two -CO_2Na units (Na being the symbol for sodium). Pemetrexed disodium dissolves in water, where the two sodiums separate from the rest of the molecule as positively charged entities called cations, and the rest of the molecule becomes an anion. Because it is the pemetrexed anion which is of interest, the sodium cation is often referred to as a counter-ion. A substance such as pemetrexed disodium, where the acidic hydrogens have been replaced, is known chemically as a salt.

7. Although one might have thought that the actual invention should have been characterised as a disclosure that pemetrexed could be administered safely if it was combined in a medicament with vitamin B12, the claimed invention in the Patent is,

as mentioned in para 4 above, the manufacture of such a medicament. This formulation was required by the then-prevailing law contained in article 52(4) of the European Patent Convention 1973 ("EPC 1973"), which prohibited from patentability any method of treatment of humans or animals. This led to inventions which otherwise might have been expected to be expressed as being new therapeutic treatments being cast as manufacturing claims. Such claims are known as Swiss form claims, and they were illuminatingly discussed by Kitchin J in *Ranbaxy (UK) Ltd v Astrazeneca AB* [2011] FSR 45, paras 42 to 60. As he explained, the prohibition was substantially modified in article 53 in the European Patent Convention 2000 ("EPC 2000"), but that modification had not come into force when Lilly applied for the Patent.

8. Actavis's proposed products involve pemetrexed compounds being used together with vitamin B12 for cancer treatment. However, rather than pemetrexed disodium, the active ingredient in those products ("the Actavis products") is (a) pemetrexed diacid, (b) pemetrexed ditromethamine, or (c) pemetrexed dipotassium. In other words, rather than including the disodium salt referred to in claim 1 of the Patent, the Actavis products include as the active ingredient (a) pemetrexed itself (ie the free acid), or pemetrexed with the hydrogens on the two $-CO_2H$ units replaced by (b) tromethamine, or (c) potassium. Actavis contend that, because they intend to use the Actavis products which do not include pemetrexed disodium, the claims of the Patent, which are expressed as involving the use of pemetrexed disodium, would not be infringed. By contrast, Lilly contends that there would be either direct or indirect infringement of the Patent if Actavis launch any of the Actavis products on the market in the UK or in France, Italy, or Spain. The allegation of direct infringement is based simply on the proposition that marketing or use of the Actavis products would infringe the Patent; indirect infringement is said to arise because pemetrexed disodium is claimed to be involved in the preparation of the Actavis products before they are administered.

9. After a four-day trial, Arnold J decided that none of the Actavis products would directly or indirectly infringe the Patent in the UK or in France, Italy or Spain - [2015] Bus LR 154; [2015] RPC 6. The Court of Appeal allowed Lilly's appeal to the limited extent of holding that there would be indirect infringement in the four jurisdictions, but they agreed with the Judge that there would be no direct infringement - [2015] Bus LR 1068. Lilly appeals against the rejection of its case that there would be direct infringement, and Actavis cross-appeal against the rejection of their case that there would be no indirect infringement.

10. As Floyd LJ explained in the Court of Appeal, the appeal raises the issue of the correct approach under UK law (and the law of the three other states) to the interpretation of patent claims, and in particular the requirement of EPC 2000 to take account of "equivalents", and also the extent to which it is permissible to make use of the prosecution history of a patent when determining its scope. The issue on the

cross-appeal is rather more fact-specific, namely whether the application of the law of contributory infringement justifies a finding of indirect infringement in this case.

11. It is appropriate to start by setting out the relevant provisions of the Patent and the knowledge of its assumed addressee, topics on which my account is largely taken from the clear judgment of Floyd LJ in the Court of Appeal. I will then turn to the issue of direct infringement, which involves considering the proper approach to that issue generally, and also the relevance of the prosecution history. I will then consider the position in the three other states and finally I will address the issue of indirect infringement.

The specification and claims in the Patent

12. The Patent is entitled "Combination containing an antifolate and methylmalonic acid lowering agent", and it has a claimed priority date of 30 June 2000.

13. The specification begins at para [0001] by stating that "[p]otentially, life-threatening toxicity remains a major limitation to the optimal administration of antifolates". It then explains at para [0002] that antifolates work by inhibiting anti-folate-requiring enzymes by competing with reduced folates for binding sites on those enzymes. The specification identifies several antifolate drugs as being in development, including Lilly's branded product Alimta.

14. The specification then explains at para [0003] that a limitation to the development of these drugs is that they may be associated with substantial toxicity, including mortality, for some patients. These toxicity effects had led to the abandonment of the development of some antifolates. In para [0004] the specification explains that previous work had been done on the use of folic acid as a treatment for toxicity in this area. It also records work on vitamin B12 as a predictor of cytotoxic events.

15. The specification then states in para [0005]:

> "Surprisingly and unexpectedly, we have now discovered that certain toxic effects such as mortality and non-hematologic events, such as skin rashes and fatigue, caused by antifolates, as a class, can be significantly reduced by the presence of a methylmalonic acid lowering agent as vitamin B12, without adverse adversely affecting therapeutic efficacy. The present invention thus generally relates to a use in the manufacture of

> a medicament for improving the therapeutic utility of antifolate drugs by administering to the host undergoing treatment with a methylmalonic acid lowering agent as vitamin B12."

16. Para [0006] of the specification continues:

> "Additionally, we have discovered that the combination of a methylmalonic acid lowering agent as vitamin B12 and folic acid synergistically reduces the toxic events associated with the administration of antifolate drugs. Although, the treatment and prevention of cardiovascular disease with folic acid in combination with vitamin B12 is known, the use of the combination for the treatment of toxicity associated with the administration of antifolate drugs was unknown heretofore."

17. These early, general statements are made in relation to antifolates as a class. However, at para [0010] the specification says, in what is known as a consistory clause, that the invention:

> "specifically provides the use of the antifolate pemetrexed disodium in the manufacture of a medicament for use in combination therapy for inhibiting tumour growth in mammals wherein said medicament is to be administered in combination with a methylmalonic acid lowering agent selected from vitamin B12 and pharmaceutical derivatives thereof."

18. Having referred specifically to pemetrexed disodium, the specification reverts to generality at para [0016], where it states:

> "The current invention concerns the discovery that administration of a methylmalonic acid lowering agent such as vitamin B12 or a pharmaceutical derivative thereof, in combination with an antifolate drug such as pemetrexed disodium reduces the toxicity of the said antifolate drug."

19. Para [0022] contains a definition:

> "The terms 'antifolate' and 'antifolate drug' generally refer to a chemical compound which inhibits at least one key folate-requiring enzyme of the thymidine or purine biosynthetic

> pathways ... by competing with reduced folates for binding sites of these enzymes. The 'antifolate' or 'antifolate drug' for use in this invention is Pemetrexed Disodium (ALIMTA®), as manufactured by Eli Lilly & Co."

20. The invention is then illustrated by reference to a number of examples relating to animal and human tests, in which the only antifolate used is pemetrexed disodium. At para [0035] the specification states that animals were treated with "pemetrexed disodium (ALIMTA®) (100 mg/kg or 150 mg/kg) once daily … by intraperitoneal injection alone or along with folic acid". The specification also indicates at para [0044] that, in a typical clinical evaluation using cancer patients, the antifolate is to be administered in four doses over a two-week period by rapid intravenous injection.

21. Turning to the claims, it is only necessary for present purposes to refer to claims 1 and 12, which are in these terms:

> "1. Use of pemetrexed disodium in the manufacture of a medicament for use in combination therapy for inhibiting tumour growth in mammals wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof [which it then specifies]."

> "12. A product containing pemetrexed disodium, vitamin B12 or a pharmaceutical derivative thereof said pharmaceutical derivative [which it again specifies], and, optionally, a folic binding protein binding agent selected from [a specified group of chemicals including folic acid], as a combined preparation for the simultaneous, separate or sequential use in inhibiting tumour growth."

The notional addressee of the Patent

22. A patent is interpreted on the basis that it is addressed to a person or group of persons who is or are likely to have a practical interest in the claimed invention, ie through the eyes of a person or persons skilled in the art. There is now no challenge to the Judge's conclusion that the notional addressee of the Patent would be a group consisting of an oncologist and a chemist, a conclusion upheld by the Court of Appeal.

23. The Judge found that the common general knowledge of an oncologist as at the relevant time, 2001/2002, included the following:

i) Antifolates were used in cancer chemotherapy, but their use caused toxic side effects which it would be desirable to avoid or reduce.

ii) Pemetrexed was the subject of clinical trials for use in chemotherapy, and it targeted multiple enzymes and was administered intravenously.

iii) The only form of pemetrexed which had been shown to be effective and safe to any extent was pemetrexed disodium, which was manufactured by Lilly under the trade mark Alimta.

iv) The characteristics of both vitamin B12 and folic acid were well understood, and it was well known that there were many different safe and effective forms of both available.

24. The Judge also concluded that oncologists did not think about drugs such as pemetrexed in their ionic form, nor did they consider issues regarding the choice of counter-ion or the effect, if any, of counter-ions on the efficacy, safety or other properties of the drug. This was the province of the chemist and, because the properties of different salt forms and free acids were difficult to predict, a chemist would need to address any such issue by conducting experiments.

25. The Judge made the following findings as to the common general knowledge of a chemist as at 2001/2002:

i) Where a drug is or is based on an acid, different salts of the parent acid can be formed by reacting it with a complementary base or acid. The salt will often have different properties from the parent acid, and different salts will often have different properties from each other. So, salt screening is a routine but important exercise in determining the most suitable form of a drug.

ii) The facts set out in paras 5 and 6 above.

iii) Solid salts consist of the anions and cations regularly arranged in a fixed lattice structure. Because the cations and anions are present in fixed proportions and in fixed relative positions it is possible to speak meaningfully of the salt as being present in solid form.

iv) When a salt is dissolved in water, the ions dissociate, forming free cations and anions in solution. Although the salt ceases to exist, it is common to refer to "a salt solution" or "a salt in solution".

v) The salt form can have a significant impact on the effectiveness of a drug in that it can modify many aspects of the drug.

vi) When considering a drug for intravenous chemotherapy, the solubility of the salt form is crucial, as good solubility is an indicator of how likely it is that the drug will be absorbed in the gut.

vii) But if a salt is too soluble, it cannot be made in solid form.

viii) In general, there can be many dead-ends and false leads when attempting to prepare salts of a parent molecule for the first time.

ix) One cannot predict (a) whether one could make a particular salt form of a parent molecule, (b) what its properties would be once it was made or (c) whether it would affect the efficacy of the drug.

26. The Judge made specific findings about a chemist's state of knowledge about three types of salts and about free acids:

i) Sodium was generally the preferred counter-ion, and so would be first choice. Sodium salts generally were not toxic, and would be expected to be reasonably soluble, but they were not always easy to make.

ii) Potassium salts were also generally soluble, but there were exceptions. There were concerns about the potential toxicity of such salts, which was particularly significant if large quantities of the drug were involved.

iii) There were only a small handful of examples of tromethamine salts being used in 2001. It was known that tromethamine salts might well be too soluble, so one would not be able to make and harvest the solid form.

iv) In principle, the acidic parent molecule could be administered in the form of the free acid. But it was often necessary to change from the free acid to a salt form for various reasons including solubility.

Direct infringement

27. In a nutshell, the rival contentions are these. Lilly argues that the Actavis products infringe the Patent because they are medicaments to be used as a treatment for cancer consisting of pemetrexed diacid, or a pemetrexed salt, with vitamin B12, which represents the essence of the teaching and claim of the Patent. By contrast, Actavis argues that their products do not infringe because the claims of the Patent are limited to a specific pemetrexed salt, namely pemetrexed disodium, and the Actavis products contain either pemetrexed diacid or different pemetrexed salts.

The legislative context

28. The domestic provision governing direct patent infringement is section 60(1) of the Patents Act 1977. However, section 130(7) declares that certain provisions of that Act, including section 60, are "so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of the European Patent Convention … have in the territories to which [that Convention applies]". Accordingly, it is common ground that it is appropriate to consider the present case by reference to the EPC 2000.

29. Article 69(1) EPC 2000 provides that "[t]he extent of the protection conferred by a European patent … shall be determined by the claims", although it is followed by another sentence, namely "[n]evertheless, the description and drawings shall be used to interpret the claims".

30. As a matter of ordinary language, it is quite clear that the only type of pemetrexed compound to which the Patent's claims expressly extend is pemetrexed disodium. One only needs to read claim 1 and claim 12 to justify that: as a matter of ordinary language, "pemetrexed disodium" means that particular salt, and no other salt, let alone the free acid. If the first few words of each claim were not enough to make this good, the contrast between the specific reference to pemetrexed disodium and the wider reference to "vitamin B12 or a pharmaceutical derivative thereof" underlines the point. As Floyd LJ said, this conclusion is also supported by what is said in the specification - eg in paras [0010] and [0022] quoted above. It is fair to say that para [0016] could be said to point the other way, but it is far too weak a basis for even arguing that the Patent's claims extend, as a matter of language, to pemetrexed compounds other than pemetrexed sodium.

31. In these circumstances, The Protocol on the Interpretation of article 69 as amended in 2000 ("the Protocol") is crucial to Lilly's contention that the scope of

protection afforded by the Patent extends to the Actavis products. The Protocol provides:

> "*Article 1*
>
> General principles
>
> Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.
>
> *Article 2*
>
> Equivalents
>
> For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims."

The original Protocol was agreed in 1973; the amendments made in 2000 effected very slight modifications to what is now article 1, and introduced article 2 for the first time.

32. The drafting of the Protocol bears all the hallmarks of the product of a compromise agreement. This is unsurprising. There is an inevitable conflict between the desirability of giving an inventor an appropriate degree of protection in a particular case and the need for clarity of principle as to the extent of such protection generally; and, of course, there is an unavoidable tension between the appropriateness of giving an inventor a monopoly and the public interest in

maximising competition. In addition, the EPC 2000 and the Protocol apply in many different states which have different traditions and approaches in relation to the law of patents. In that connection, as the Supreme Court observed in *Schütz (UK) Ltd v Werit (UK) Ltd (Nos 1 to 3)* [2013] Bus LR 565; [2013] RPC 16, para 40, "complete consistency of approach" between different national courts of the EPC states "is not a feasible or realistic possibility at the moment", but nonetheless "it is sensible for national courts at least to learn from each other and to seek to move towards, rather than away from, each other's approaches".

33. More specifically, two points appear to be clear from the Protocol. The first, which can be deduced from article 1, is that the scope of protection afforded to a patentee is not to be limited by the literal meaning of the claims. However, it is not at all clear how far a court is permitted to move away from the literal meaning. I do not consider that the last part of the first sentence of article 1 only enables the description (ie the specification) and the drawings to be taken into account when interpreting the claims, in cases where the claims would otherwise be ambiguous. Any doubt about this must be put to rest by the second and third sentences, which make it clear to my mind that that would be too narrow a reading. However, it is very hard to be confident how far they were intended to permit a court to go beyond the actual language of a claim when interpreting a claim. Secondly, it is apparent from article 2 that there is at least potentially a difference between interpreting a claim and the extent of the protection afforded by a claim, and, when considering the extent of such protection, equivalents must be taken into account, but no guidance is given as to precisely what constitutes an equivalent or how equivalents are to be taken into account.

34. The question of how far one can go outside the wording of a claim to enable the patentee to enjoy protection against products or processes which are not within the ambit of the actual language, construed in accordance with ordinary principles of interpretation, has been considered in three significant UK cases and in a number of significant cases decided in the courts of other Convention states.

The domestic case law

35. The UK case of *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183 was decided under the previous, purely domestic, legislation, the Patents Act 1949. At pp 242 to 243, Lord Diplock deprecated the notion that there were two types of infringement, "textual infringement" and "infringement of the 'pith and marrow' of the invention", and said that there was "a single cause of action", which involved asking the question:

> "whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that any variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked."

He continued:

> "The question, of course, does not arise where the variant would in fact have a material effect upon the way the invention worked. Nor does it arise unless at the date of publication of the specification it would be obvious to the informed reader that this was so. Where it is not obvious, in the light of then-existing knowledge, the reader is entitled to assume that the patentee thought at the time of the specification that he had good reason for limiting his monopoly so strictly and had intended to do so, even though subsequent work by him or others in the field of the invention might show the limitation to have been unnecessary. It is to be answered in the negative only when it would be apparent to any reader skilled in the art that a particular descriptive word or phrase used in a claim cannot have been intended by a patentee, who was also skilled in the art, to exclude minor variants which, to the knowledge of both him and the readers to whom the patent was addressed, could have no material effect upon the way in which the invention worked."

36. In that case, the patent was for a novel type of galvanised steel lintel, which the relevant claim described as including a rear support back plate "extending vertically" from a horizontal plate. The allegedly infringing article included a rear support member which was inclined between 6 degrees and 8 degrees from the vertical. Overruling the Court of Appeal's decision that this meant that there was no infringement, Lord Diplock said at p 244, that it would have been:

> "obvious to a builder familiar with ordinary building operations that the description of a lintel in the form of a weight-bearing box girder of which the back plate was referred to as 'extending vertically' from one of the two horizontal plates to join the other, could not have been intended to exclude lintels in which the back plate although not positioned at precisely 90 degree to

> both horizontal plates was close enough to 90 degree to make no material difference to the way the lintel worked when used in building operations."

He then added this:

> "No plausible reason has been advanced why any rational patentee should want to place so narrow a limitation on his invention. On the contrary, to do so would render his monopoly for practical purposes worthless, since any imitator could avoid it and take all the benefit of the invention by the simple expedient of positioning the back plate a degree or two from the exact vertical."

37. A few years later, Hoffmann J (as he then was) gave judgment in *Improver Corpn v Remington Consumer Products Ltd* [1990] FSR 181. The case concerned a patent for a depilator, known as the "Epilady", which worked by trapping hairs in a rotating "coiled helical spring", and the alleged infringement worked in very much the same way save that, instead of a spring, it used a slotted rubber rod. The case had already gone on an interlocutory issue to the Court of Appeal, where it was held that Lord Diplock's approach in *Catnic* [1982] RPC 183 was consistent with the 1977 Act, the EPC 1973 and the Protocol as it then was - see [1989] RPC 69.

38. At [1990] FSR 181, 189, Hoffmann J suggested the following approach, largely based on his reading of the reasoning in *Catnic* [1982] RPC 183, 242 to 243:

> "If the issue was whether a feature embodied in an alleged infringement which fell outside the primary, literal or a contextual meaning of a descriptive word or phrase in the claim ('a variant') was nevertheless within its language as properly interpreted, the court should ask itself the following three questions:
>
> > (1) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no -
> >
> > (2) Would this (ie that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes -

> (3) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.
>
> On the other hand, a negative answer to the last question would lead to the conclusion that the patentee was intending the word or phrase to have not a literal, but a figurative meaning (the figure being a form of synecdoche or metonymy) denoting a class of things which included the variant and the literal meaning, the latter being perhaps the most perfect, best-known or striking example of the class."

39. Hoffmann J then proceeded to apply those three questions to the facts of the case before him. He held that the first two questions were to be answered in the patentee's favour and then turned to the third question. On that question, he held that the patentee failed for the reasons he gave at p 197, namely that "[t]he rubber rod is not an approximation to a helical spring", that "the spring [cannot] be regarded as an 'inessential' or the change from metal spring to rubber rod as a minor variant", and that it could be appreciated that the patentee would wish to restrict his claim to helical springs as "[i]t would be obvious that the rubber had problems of hysteresis which might be very difficult to overcome".

40. Thereafter, for the next 15 years or so, this three-stage approach was almost routinely applied by judges in UK patent infringement cases, where the three "*Improver* questions" were subsequently renamed the three "Protocol questions" - see *Wheatley v Drillsafe Ltd* [2001] RPC 7, para 23.

41. Lord Hoffmann (as he had by then become) addressed the issue again in his speech in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005] RPC 9, where one of the issues was whether a protein manufactured by gene-activation infringed a patent relating to production of the same protein by recombinant DNA technology. At paras 27 to 35, Lord Hoffmann discussed "the English rules of construction". At paras 30 to 32 he effectively equated Lord Diplock's approach to patents in *Catnic* [1982] RPC 183, 243 with "purposive construction" of commercial contracts. At para 34, he said that "[t]he question is always what the person skilled in the art would have understood the patentee to be using the language of the claim to mean. And for this purpose, the language he has chosen is usually of critical importance".

42. Lord Hoffmann then turned to the doctrine of equivalents, which he explained in para 37 had been developed in the United States courts and "allow[ed]

the patentee to extend his monopoly beyond his claims", so as to prevent "the unscrupulous copyist [from making] unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law", quoting Jackson J in *Graver Tank & Manufacturing Co Inc v Linde Air Products Co* 339 US 605, 607 (1950). Lord Hoffmann expressed concern that "once the monopoly had been allowed to escape from the terms of the claims, it is not easy to know where its limits should be drawn", and concluded that, rather than adhering to literalism and adopting the doctrine, the solution was "to adopt a principle of construction which actually gave effect to what the person skilled in the art would have understood the patentee to be claiming", as Lord Diplock had done in *Catnic* [1982] RPC 183. He also said that article 69 EPC 2000 "firmly shuts the door on any doctrine which extends protection outside the claims" (see at paras 39 and 42 to 44).

43. Having considered the issue in the three preceding paragraphs of his speech, at para 48 Lord Hoffmann stated that the approach adopted by Lord Diplock was "precisely in accordance with the Protocol", as it was "intended to give the patentee the full extent, but no more than the full extent, of the monopoly which a reasonable person skilled in the art, reading the claims in context, would think he was intending to claim". He concluded his discussion by quoting with approval the passages quoted above from *Catnic* [1983] RPC 183, 243 and *Improver* [1990] FSR 181, 189, and saying in para 52 that the principle of purposive construction as Lord Diplock and he had explained it, gave "effect to the requirements of the Protocol" and was "the bedrock of patent construction, universally applicable", whereas the Protocol or *Improver* questions were simply "guidelines for applying that principle to equivalents … , more useful in some cases than in others".

The approach in the courts of other EPC states

44. In Germany, the Bundesgerichtshof has stated that a variant will infringe if (i) "it solves the problem underlying the invention with modified but objectively equivalent means", (ii) this would be recognised by the person skilled in the relevant art, and (iii) that person "focus[sing] on the essential meaning of the technical teaching protected in the patent" would regard the variant "as being equivalent to the solution" offered by the invention - see Case No X ZR 168/00, 2002 GRUR 519 (*Schneidmesser I*), para 30. (It is worth noting that in paras 36 to 38 of its judgment in that case, the Bundesgerichtshof expressly considered the approach which had been adopted in *Catnic* [1982] RPC 183 and *Improver* [1990] FSR 181.) Judge Meier-Beck of the Bundesgerichtshof, writing extra-judicially (*The Scope ofPatent Protection - The Test for Determining Equivalence* (2005) 36 IIC 339, 342 to 343) has suggested that the second step involves asking whether "the person skilled in the art, using his specialist knowledge, [would be] able to find the modified means at the priority date as having the same effect", which he then says has the "meaning that no inventive step is needed". That seems to be supported by what was said by

the Bundesgerichtshof in Case No X ZR 156/97, 1999 GRUR 977, (*Räumschild*), paras II.2(c)(aa) and III.1.

45. Further guidance as to the German approach to equivalents was very recently given by the Munich Oberlandesgericht, upholding the decision of the Landgericht, in Case No 6 U 3039/16 (*Eli Lilly & Co v ratiopharm GmbH*), when considering whether pemetrexed ditromethamine infringed the German equivalent of the Patent in this case. At para II.B.3(a), the Oberlandesgericht said that in order for "an embodiment that deviates from the literal meaning of the claim" to be within the scope of protection, "generally three requirements must be met". The first was that "the embodiment must solve the problem underlying the invention with means that are indeed modified, but are objectively equivalent". The second requirement was that "the expertise of the person skilled in the art must enable him to discover the modified embodiment with its divergent means to be equivalent". Thirdly, "the thought processes that the person skilled in the art has to perform in order to do so must be oriented on the meaning of the teaching protected in the claim". In para II.B.3(b)(aa), the Oberlandesgericht suggested that "the decisive factor" was "what individual effects the features according to the patent … provide in order to attain the object underlying the claims and whether these effects are achieved through other means by the [allegedly infringing] embodiment". The court added that the doctrine of equivalence would apply to an embodiment "if it not only essentially achieves the entire effect of the invention, but specifically also achieves the effect that the feature, which has not been literally implemented, is supposed to achieve".

46. French law, according to the expert witnesses in this case, applies the doctrine of equivalents where the variant is "different in form but perform[s] the same function" as the invention, but only where "the function [claimed in the patent] is a new one". This seems to be supported by *Azéma and Galloux, Droit de la propriété industrielle*, 7th ed (2012), which distinguishes at p 442 between two categories of patents. The first category is those which "in general terms claim the means that provide for a particular function" (*moyens généraux*), or as Arnold J put it in para 160 of his judgment, claims which cover "general means". The second category is patents "which indicate the particular means which infer such function" (*moyens particuliers*), or claims which are "narrowly worded to cover specific means" as Arnold J expressed it. The doctrine is only normally applicable to the first category of claims. Arnold J added in para 160 that the categorisation of a patent for this purpose may depend in part on what was known at the priority date - see the decisions of the Cour de Cassation in Appeal S 09-15668 *Institut Pasteur v Chiron Healthcare*, 23 November 2010 and of the Paris Tribunal de Grande Instance in Case 09/01863 *Mundipharma Laboratories GmbH v Sandoz SAS*, 2 July 2010.

47. As Arnold J also explained in para 159 of his judgment, "there is no need for the claim to be unclear or for it to be widely worded" for the doctrine of equivalents to be invoked in the French court. Thus, in the decision of the Cour de Cassation in

Appeal No 06-17915 *B2M Industries v Acome*, 20 November 2007, "the function of the particular integer that was said to be infringed pursuant to an equivalent was held to be novel, and therefore because the means that was said to be equivalent to that integer performed the same function and produced the result sought by the invention the means was equivalent to that integer", to quote from para 161 of Arnold J's judgment.

48. In the Italian courts, the expert witnesses in this case agreed that a variant would be held to infringe if (i) it reproduced the "inventive core" of the patent and (ii) it was an obvious variation, although (iii) the fact that the variant included some modifications which were not obvious and/or the fact that the variant does not include some of the elements of the patent claim does not necessarily prevent the variant infringing - see per Arnold J at para 171 of his judgment. This analysis is supported by the Corte di Cassazione decisions in Case No 257, *Forel SpA v Lisec* (13 January 2004), Case No 30234, *Barilla GER Fratelli SpA v Pastifico Fazion SpA* (30 December 2012) and Case No 622, *Entsorga Italia Srl v Ecodeco Srl* (11 January 2013).

49. At any rate at local appellate level, Spanish courts appear to have effectively adopted the approach embodied in the three questions suggested by Hoffmann J in *Improver* [1990] FSR 181 - see for instance *Laboratorios Cinfa SA v Eli Lilly &Co Ltd ("Olanzapine")* Court of Appeal of Barcelona judgment no 8/2008, 17 January 2008.

50. Following circulation of this judgment in draft, Actavis referred us to a decision of the Spanish Tribunal Supremo *Lundbeck v Cinfa*, no 223/2015, 29 April 2015. In the closely reasoned section ELEVEN of its judgment, the Tribunal Supremo (i) recorded the fact that none of the parties challenged the approach of the Court below which applied the three *Improver* questions (para 5), (ii) stated that the real issue in the case centred on the second question (para 6), (iii) cast some doubt on the applicability of the *Improver* questions in Spanish law (para 10), (iv) disapproved the notion that the test for obviousness in patentability is necessarily applicable to the second *Improver* question (paras 10 and 14), (v) disapproved the notion that, for the second *Improver* question to be answered yes, "the skilled person must be absolutely certain that the variant … would work successfully in resolving the technical problem faced by the patented invention" (paras 11 and 12), (vi) preferred instead, a test of "easy to see or comprehend" and "a degree of predictability" (paras 11 and 18), which involves "a high probability", rather than a "reasonable expectation" that the variant would work (paras 15 and 18), and (vii) concluded on this basis that the Court of Appeal was right to rule that the allegedly infringing products in that case did not infringe (paras 18 and 19).

51. As for the Netherlands, helpful guidance may be found in a lecture given in 2016 by Judge Kalden, the head of the IP division in the Court of Appeal in The Hague - *Article 69 EPC - the Scylla and Charybdis of the European Patent Convention - Which route did the Dutch courts take?* (2016 Symposium German Bundespatentgericht). She said that, although there have been subtle changes of emphasis in its decisions, the Supreme Court tends to focus on "the inventive concept in order to prevent a too literal interpretation of the claims, which could do injustice to fair protection for the patentee (or lead to an unnecessary broad interpretation)". She also explained that the doctrine of equivalents applies if (i) the variant is "foreseeable at the priority date", (ii) "the inventive concept is sufficiently broad to … cover [the] variant", (iii) "the variant makes use of - and thus benefits from - the inventive concept", and (iv) "reasonable legal certainty [is not thereby] unduly compromised". She added that, despite the first condition:

> "Variants that are not foreseeable at the priority date may well, due to later developments, become an obvious variant at a later date. This may happen in case of a pioneer invention, where at the priority date the full breadth of the possible applications could or has not been fully recognised and therefore was not sufficiently taken into account when drafting a claim. Another possibility is that a new technique becomes available after the patent was granted, which makes available an obvious variant. It would be harsh and contrary to fair protection for the patentee to deny him the right to attack those, again provided such variant falls within the inventive concept and reasonable legal certainty is taken into account. So infringement by equivalence is not limited to foreseeable variants only."

52. It may be of some significance that the product which Hoffmann J concluded in *Improver* [1990] FSR 181 was non-infringing was held by the German, Italian and Dutch courts to infringe. Of course, the fact that courts of two states reach different conclusions on the same issue does not of itself mean that there is a difference in the law of those states, let alone that one court is wrong and the other right: the evidence may be different, and there may be issues of judgment on which reasonable judges could differ. However, consideration of the judgments in those three other courts does suggest a difference of approach. Thus, in Germany, the Düsseldorf Oberlandesgericht based its conclusion on the propositions that "a person skilled in the art will not interpret the coil spring as a spring, but as an elastic body with gaps ... as it is obvious that the helical spring is not used as a spring per se", and that its only essential function, which was shared by the allegedly infringing product's slitted rubber rod, was that it could "enter between adjacent areas of the body (walls), and that the walls must approach it up to clamping it" - see Epilady Germany II (1993) 24 IIC 838. In Italy, the Milan District Court held that there was infringement because the slitted rubber rod had structural characteristics which

enabled it to perform the same function in the same way as the coiled spring referred to in the patent in suit - see Epilady Italy (1992) Giur Ann Dir Ind, Case No 2823. In the Netherlands, the Gerechtshof upheld the first instance decision that the allegedly infringing "device embodies an application of the patented invention, on the grounds that the hair-engaging component [ie the slitted rubber rod] of the device is a mechanical equivalent of the helical spring specified in the patent claims", and the rod was "not state of the art in the field of depilatory devices" - Epilady Netherlands III (1993) 24 IIC 832, paras 9 and 11.

The proper approach to infringement claims

53. Any patent system must strike a balance between the two competing factors referred to at the end of article 1 of the Protocol, namely "a fair protection for the patent proprietor [and] a reasonable degree of legal certainty for third parties". The balance cannot be struck on an *ad hoc* case-by-case basis without any guiding principles, as that would mean that there was no legal certainty. On the other hand, striking the balance by adopting a normal approach to interpretation would risk depriving patentees of a proper measure of protection; as explained in paras 37 to 39 and 52 above, that is clear from the approach of all the courts which considered the "Epilady" patent, where it could not seriously have been suggested that, as a matter of language, a slotted rubber rod falls within the expression "helical metal spring", even if one was construing those words in the context of the claim in the patent in suit. But, if one departs from ordinary language, it is necessary to have some guidance or to draw some lines, as Lord Hoffmann implied in *Kirin-Amgen* [2005] RPC 9, para 37. That is why he promulgated his three questions in *Improver* [1990] FSR 181, 189. By means of an extended version of the ordinary concept of "construction" or "interpretation", Hoffmann J explained how our domestic law, as laid down in *Catnic* [1982] RPC 183, implements article 2 of the Protocol and thus, as I see it, how it gives effect to the doctrine of equivalents. That approach was (perhaps unsurprisingly) then adopted in *Kirin-Amgen* [2005] RPC 9.

54. In my view, notwithstanding what Lord Diplock said in *Catnic* [1982] RPC 183, 242, a problem of infringement is best approached by addressing two issues, each of which is to be considered through the eyes of the notional addressee of the patent in suit, ie the person skilled in the relevant art. Those issues are: (i) does the variant infringe any of the claims as a matter of normal interpretation; and, if not, (ii) does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial? If the answer to either issue is "yes", there is an infringement; otherwise, there is not. Such an approach complies with article 2 of the Protocol, as issue (ii) squarely raises the principle of equivalents, but limits its ambit to those variants which contain immaterial variations from the invention. It is also apparent that the two issues comply with article 1 of the Protocol in that they involve balancing the competing interests of the patentee and of clarity, just as much as they seek to balance the encouragement of inventions and their disclosure

with the need for a competitive market. In my view, issue (i) self-evidently raises a question of interpretation, whereas issue (ii) raises a question which would normally have to be answered by reference to the facts and expert evidence.

55. In *Kirin-Amgen* [2005] RPC 9, Lord Hoffmann, following his approach in *Improver* [1990] FSR 181 (which itself had followed Lord Diplock's analysis in *Catnic* [1982] RPC 183) effectively conflated the two issues, and indicated that the conflated issue involved a question of interpretation. I have considerable difficulties with the notion that there is a single conflated, or compound, issue, and, even if that notion is correct, that that issue raises a question of interpretation. Indeed, in my view, to characterise the issue as a single question of interpretation is wrong in principle, and unsurprisingly, therefore, can lead to error. While normal principles of interpretation could, I think, accommodate the notion that "vertically" extended to an item which was not at precisely 90° to another item, I do not see how such principles could possibly lead to the conclusion that a slotted rubber rod was within the expression "helical metal spring". As Hoffmann J said in *Improver* [1990] FSR 181, 197, "the angle of the support member [in the allegedly infringing product in *Catnic* [1982] RPC 183] can be regarded as an approximation to the vertical", but "[t]he rubber rod is not an approximation to a helical spring". The problem with treating the issue as one of normal interpretation is thus that that point alone may be thought to have been sufficient to put an end to the patentee's infringement argument on facts such as those in *Improver* [1990] FSR 181, and there would seem to have been little purpose in going through the three questions in that case.

56. I had wondered whether the question whether issue (ii) truly involves a question of interpretation raised what was merely an arid issue of categorisation. However, I have concluded that that nettle needs to be grasped, because, so long as the issue is treated as one of interpretation, it will lead to a risk of wrong results in patent infringement cases and it will also lead to a risk of confusing the law relating to the interpretation of documents. In my opinion, issue (ii) involves not merely identifying what the words of a claim would mean in their context to the notional addressee, but also considering the extent if any to which the scope of protection afforded by the claim should extend beyond that meaning. As Sir Hugh Laddie wrote in his instructive article *Kirin-Amgen - The End of Equivalents in England?* (2009) 40 IIC 3, para 68, "[t]he Protocol is not concerned with the rules of construction of claims" but with "determining the scope of protection".

57. I might add that the notion of a product or process which infringes despite an immaterial variation from the invention as claimed is by no means new to domestic patent law. That point is convincingly demonstrated by Sir Hugh in his article at paras 33 to 39. Thus, in *Walton v Potter & Horsfall* (1843) 1 WPC 585, Tindal CJ told the jury that they had to decide whether the defendant's product was "perfectly distinct" from the patented product, or whether it varied "only in certain circumstances, which are not material to the principle and substance of the

invention". And Lord Cairns LC in *Clark v Adie* (1877) 2 App Cas 315, 320, referred to the alleged infringer having "really taken and adopted the substance of the instrument patented", and having "taken in substance the pith and marrow of the invention". The patents in these cases included relatively primitive forms of claim, but that does not undermine the fact that our domestic law has long recognised that an immaterial variation does not get an infringer off the hook. Particularly in the light of what he said in *Catnic* [1983] RPC 183, 242, it is worth mentioning that Lord Diplock himself in *Beecham Group Ltd v Bristol Laboratories Ltd* [1978] RPC 153, 200 rejected a submission that "[t]he increasing particularity with which claims are drafted … has made the doctrine [of pith and marrow] obsolete", and said that the doctrine "still remains a part of patent law".

58. Turning to the two issues identified in para 54 above, issue (i), as already mentioned, involves solving a problem of interpretation, which is familiar to all lawyers concerned with construing documents. While the answer in a particular case is by no means always easy to work out, the applicable principles are tolerably clear, and were recently affirmed by Lord Hodge in *Wood v Capita Insurance Services Ltd* [2017] 2 WLR 1095, paras 8 to 15. In the present case, there is no doubt that, according to normal principles of interpreting documents, the Actavis products do not infringe the Patent, as in no sensible way can pemetrexed free acid, pemetrexed ditromethamine, or pemetrexed dipotassium mean, ie be said to fall within the expression, "pemetrexed disodium" in claim 1 of the Patent, any more than a slotted rubber rod can be said to be within the expression "a helical metal spring" in the claim in the *Improver* patent. According to normal principles of interpreting documents, then, this would be the end of the matter.

59. However, the second issue poses more difficulties of principle: what is it that makes a variation "immaterial"? In that connection, I consider that Hoffmann J's three questions in *Improver* [1990] FSR 181 provide helpful assistance, a view supported by the fact explained in paras 44 to 52 above that similar but not identical tests have been adopted in other EPC jurisdictions. However, each of the three questions requires some exegesis, and, particularly the second question, some reformulation.

60. The first *Improver* question, which asks whether the variant has a material effect on the way in which the invention works, seems generally satisfactory. It is a question which was framed in the context of a mechanical patent, and is not wholly aptly expressed for every type of case. However, in practice, the question as framed by Hoffmann J, with its emphasis on how "the invention" works, should correctly involve the court focussing on the "the problem underlying the invention", "the inventive core", or "the inventive concept" as it has been variously termed in other jurisdictions. In effect, the question is whether the variant achieves the same result in substantially the same way as the invention. If the answer to that question is no, then it would plainly be inappropriate to conclude that it could infringe. If, by

contrast, the answer is yes, then it provides a sound initial basis for concluding that the variant may infringe, but the answer should not be the end of the matter.

61. The second *Improver* question is more problematic. In my view, it imposes too high a burden on the patentee to ask whether it would have been obvious to the notional addressee that the variant would have no material effect on the way in which the invention works, given that it requires the addressee to figure out for himself whether the variant would work. The facts of the present case serve to make that proposition good. As Floyd LJ explained in para 65 of his judgment below, because a chemist "would not be able to predict the effect of [a] substitution [for the sodium counter-ion] without testing at least the solubility of the [active ingredient in the Actavis products]", it followed that "predicting in advance whether any particular counter-ion would work was not possible", and therefore that the second *Improver* test could not be answered yes. However, as mentioned in para 25(i) above, salt screening is a routine exercise in determining suitability, and as Floyd LJ said, "the chemist would be reasonably confident that he would come up with a substitute for the sodium counter-ion". In those circumstances, given that the inventive concept of the patent is the manufacture of a medicament which enables the pemetrexed anion to be administered with vitamin B12, it appears to me that application of the second *Improver* question fails to accord "a fair protection for the patent proprietor" as required by article 1 of the Protocol.

62. In my opinion, the second question is better expressed as asking whether, on being told what the variant does, the notional addressee would consider it obvious that it achieved substantially the same result in substantially the same way as the invention. In other words, it seems to me that the second *Improver* question should be asked on the assumption that the notional addressee knows that the variant works to the extent that it actually does work. That, I think, would be a fair basis on which to proceed in terms of balancing the factors identified in article 1 of the Protocol, and it is, I think, consistent with the approach of the German, Italian and Dutch courts. It is also consistent with the fact that the notional addressee is told (in the patent itself) what the invention does.

63. This reformulated second question should also apply to variants which rely on, or are based on, developments which have occurred since the priority date, even though the notional addressee is treated as considering the second question as at the priority date. Such an approach is supported by the desirability of both consistency of approach and pragmatic justice. It seems right in principle to have the same question, including the same assumption (ie that the variant works) for all cases. As to pragmatism, the point is touched on by Judge Kalden in the passage quoted at the end of para 51 above: while the notional addressee may answer the reformulated second question affirmatively even where the variant was unforeseeable at the priority date, he is less likely to do so than in relation to a variant which was unforeseeable as at that date.

64. The second test applied by the German courts, as I understand it, at least sometimes appears to require the variation not to be inventive, but I am not sure that that is an appropriate requirement, although it is unnecessary to decide that point on this appeal. If the variation represents an inventive step, while it may render it less likely that the patentee will succeed on the second reformulated question, I find it hard to see why that alone should prevent the resultant variant from infringing the original invention. It may entitle the infringer to a new patent, in the same way as the invention of a novel use for a patented invention can itself be patented, but like such a novel use I see no reason why the variant should not infringe the original patent. Having said that, it should be added that the German version of the second test will, I suspect, usually produce the same result as the reformulated second question.

65. The third *Improver* question as expressed by Hoffmann J is whether the notional addressee would have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention. That is in my view an acceptable test, provided that it is properly applied. In that connection, I would make four points. First, although "the language of the claim" is important, consideration of the third question certainly does not exclude the specification of the patent and all the knowledge and expertise which the notional addressee is assumed to have. Secondly, the fact that the language of the claim does not on any sensible reading cover the variant is certainly not enough to justify holding that the patentee does not satisfy the third question. Hence, the fact that the rubber rod in *Improver* [1990] FSR 181 could not possibly be said to be "an approximation to a helical spring" (to quote from p 197) was not the end of the infringement issue even in Hoffmann J's view: indeed, as I have already pointed out, it was because the rubber rod could not possibly be said to be a helical spring that the allegedly infringing product was a variant and the patentee needed to invoke the three *Improver* questions. Thirdly, when considering the third question, it is appropriate to ask whether the component at issue is an "essential" part of the invention, but that is not the same thing as asking if it is an "essential" part of the overall product or process of which the inventive concept is part. So, in *Improver* [1990] FSR 181, 197, Hoffmann J may have been (and I mean "may have been") wrong to reject the notion that "the spring could be regarded as an 'inessential'": while it was undoubtedly essential to the functioning of the "Epilady", the correct question was whether the spring would have been regarded by the addressee as essential to the inventive concept, or inventive core, of the patent in suit. Fourthly, when one is considering a variant which would have been obvious at the date of infringement rather than at the priority date, it is, as explained in para 63 above, necessary to imbue the notional addressee with rather more information than he might have had at the priority date.

66. In these circumstances, given the weight that has been given by courts in this jurisdiction (and indeed in some other jurisdictions) to the three "*Improver*

questions", I think it must be right for this court to express in our own words our reformulated version of those questions. In doing so, it is right to emphasise, as Lord Hoffmann did in *Kirin-Amgen* [2005] RPC 9, para 52, that these questions are guidelines, not strict rules (as indeed the Oberlandesgericht indicated in Case No 6 U 3039/16, when saying that it was "generally" true that "three requirements must be met"). While the language of some or all of the questions may sometimes have to be adapted to apply more aptly to the specific facts of a particular case, the three reformulated questions are as follows:

> i) Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, ie the inventive concept revealed by the patent?
>
> ii) Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?
>
> iii) Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

In order to establish infringement in a case where there is no literal infringement, a patentee would have to establish that the answer to the first two questions was "yes" and that the answer to the third question was "no".

Provisional conclusion on direct infringement in the UK

67. Given that the Actavis products do not infringe on the basis of a normal interpretation of claim 1 of the Patent, it is necessary to consider whether they represent an immaterial variation on that claim. I propose to address that issue initially disregarding the prosecution history, and having reached a provisional conclusion, I will then address that history and its effect on the provisional conclusion.

68. In my view, application in the present case of the three questions just identified results in the conclusion that the Actavis products infringe. So far as the first question is concerned, there can be no doubt but that those products work in the same way as the invention: they all ultimately involve a medicament containing the pemetrexed anion and vitamin B12. Thus, they achieve substantially the same result

in substantially the same way as the invention. Indeed, as in the Court of Appeal, Actavis realistically accept that the first question is to be answered yes.

69. As to the second question, it seems to me clear that the notional addressee of the Patent would appreciate (and would have appreciated as at the priority date) that each of the Actavis products would work in precisely the same way as pemetrexed disodium when included in a medicament with vitamin B12. When it comes to different versions of pemetrexed medicaments, it is clear that the use of a free acid, and of ditromethamine and dipotassium salts was in each case well established as at the priority date - see para 26(ii) to (iv) above. Furthermore, the notional addressee of the Patent would regard investigating whether pemetrexed free acid, pemetrexed ditromethamine or pemetrexed dipotassium worked as a purely routine exercise - see para 25(i) above. The reason why I differ from the Court of Appeal and Arnold J on this second question is that, in accordance with the second question as formulated in *Improver* [1990] FSR 181, 189, they considered that the notional addressee should not be treated as knowing that the Actavis products did in fact work at all, whereas, as explained above, that seems to me to involve too strict a test.

70. Turning to the third question, the Court of Appeal considered that the notional addressee "would understand that the patent was clearly limited to the disodium salt, and did not extend to the diacid, or the dipotassium or ditromethamine salts". They based this conclusion on the fact that the specification of the Patent contains a number of passages (eg in Para [0022] of the specification, quoted in para 19 above) which refer to "anti-folates" and the like and other passages which refer to pemetrexed disodium, which is "a highly specific chemical compound", and the fact that the claim is limited to pemetrexed disodium would therefore lead the notional addressee to conclude that the claim is indeed intended to be so limited (see paras 71 and 72 of Floyd LJ's judgment).

71. In my opinion, the Court of Appeal adopted an approach which places too much weight on the words of the claim and not enough weight on article 2 of the Protocol (and it is only right to add that, in doing so, they were, like Arnold J at first instance, following Lord Hoffmann's guidance in *Kirin-Amgen* [2005] RPC 9). Thus, when considering the third test, Floyd LJ made the point at para 72(ii) of his judgment that "there is no obvious leeway as a matter of language for giving it a broad as opposed to a narrow construction". That seems to me to demonstrate the risk of treating the issue raised by the third question as being one of normal interpretation. (Another way of looking at the point is, in the language of Sir Hugh Laddie, that it involves wrongly conflating the issue of interpretation with the issue of scope of protection.) As already explained, if it was a decisive point it would make a nonsense of asking the three questions: if one cannot depart from the language of the claim when considering those questions, what is the point of the questions in the first place?

72. More specifically, I do not agree with the Court of Appeal's view that, because the specification referred to "anti-folates" and "anti-folate drugs", the fact that the claims were limited to pemetrexed disodium means that the drafter of the Patent would have been understood to intend that the other pemetrexed compounds would not infringe. As Mr Mitcheson QC contended in his well argued case, the point is neutral because there is no reference to pemetrexed salts as a class in the specification, and the contrast therefore does not help on the question whether pemetrexed salts other than pemetrexed disodium were intended to be excluded.

73. Further, contrary to the Court of Appeal's reasoning, I would have thought that if the specification had not referred to anti-folates but had only referred to pemetrexed disodium, that would have been a more powerful indication that the patentee was intending to limit himself to pemetrexed disodium. The very fact that the specification teaches that there are other anti-folate drugs which have a similar effect to pemetrexed disodium (coupled with the fact that it was generally known that cations other than sodium could be successfully used with anti-folates) highlights a point similar to that made by Lord Diplock in *Catnic* [1982] RPC 183, 244, namely "No plausible reason has been advanced why any rational patentee should want to place so narrow a limitation on his invention" as to limit the scope of protection afforded by the Patent to pemetrexed disodium - a telling but not always conclusive point. Additionally, there is no teaching in the specification which relates to the relevance or importance of the sodium cation.

74. Looking at matters more broadly, the addressee of the Patent would, as I see it, understand that the reason why the claims were limited to the disodium salt was because that was the only pemetrexed salt on which the experiments described in the specification had been carried out. However, it does not follow that the patentee did not intend any other pemetrexed salts to infringe: the suggestion confuses the disclosure of the specification of a patent with the scope of protection afforded by its claims. Particularly given the facts set out in para 25 above, it seems to me very unlikely that the notional addressee would have concluded that the patentee could have intended to exclude any pemetrexed salts other than pemetrexed disodium, or indeed pemetrexed free acid, from the scope of protection.

75. Accordingly, I would conclude that, subject to considering the prosecution history, the Actavis products infringe claim 1 of the Patent.

The effect of the prosecution history

76. The application for the patent was filed at the EPO in June 2001, and it contained claims directed to a method of treatment, claims in Swiss form, and purpose-related product claims. In January 2003, Dr Burnside, Lilly's patent

attorney, filed a revised set of claims which omitted the method of treatment claims. Claims 1 and 2 were as follows:

> "1. Use of a methylmalonic acid lowering agent in the preparation of a medicament useful in lowering the mammalian toxicity associated with an antifolate, and the medicament is administered in combination with an antifolate.
>
> 2. Use of a methylmalonic acid lowering agent in the preparation of a medicament useful in lowering the mammalian toxicity associated with an antifolate, and the medicament is administered in combination with an antifolate and a FBP binding agent."

Claim 10 was a dependent claim "wherein the antifolate is ALIMTA".

77. As Floyd LJ said, these claims are in the reverse order from the claims ultimately granted (as they start with the use of the methylmalonic lowering agent rather than pemetrexed disodium), but nothing hangs on that. The essential point is that these claims were entirely general as to the identity of the antifolate. In March 2004, the EPO examiner wrote raising various objections including some under articles 83 and 84 EPC 2000 (disclosure and clarity). The clarity and lack of disclosure objections were that the claims related to too many possible combinations of compounds by using general expressions such as "antifolate", "methylmalonic acid lowering agent" and "FBP binding agent". Moreover, the examiner was concerned that the claims covered all compounds having these characteristics or properties, whereas the application provided support and disclosure for only a very limited number of such compounds.

78. Dr Burnside replied in a letter of December 2004, under cover of which he filed new claims 1 and 2, this time starting with the use of the antifolate, now limited to "pemetrexed" in these terms:

> "1. Use of pemetrexed in the manufacture of a medicament for use in combination therapy for inhibiting tumour growth in mammals wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative thereof.
>
> 2. Use according to claim 1 wherein said medicament is to be administered in combination with vitamin B12 or a

> pharmaceutical derivative thereof and a folic binding protein binding agent [which was then defined]."

In support of these new claims, Dr Burnside said that, "in order to expedite the application proceeding to grant", Lilly had elected to amend the claims so as to reflect more closely the specific examples provided. However, he added, the amendments were made without prejudice to Lilly's right to obtain protection for other patentable subject matter in one or more divisional applications.

79. Notwithstanding these amendments, in May 2005 the EPO examiner formally objected to the admissibility of the new claims. He contended that the amendments introduced subject matter beyond the content of the originally filed documents, contrary to article 123(2) EPC 2000. Thus, he said, the inclusion in claim 1 of "use of pemetrexed ..." and similar provisions in other claims did not find any basis in the application documents as filed. According to the examiner, "pemetrexed" was a distinct compound from pemetrexed disodium. (This is supported by the Chemical Abstracts Service Registry, where the "pemetrexed" is recorded as being the free diacid.) The patent does contain one mention of the term "pemetrexed" at para [0004] of the specification, followed by a Lilly reference number which shows it to be pemetrexed disodium. It was therefore, at best, uncertain as to what the term "pemetrexed" on its own was intended to refer.

80. Dr Burnside replied in March 2006 by a letter under cover of which he filed new claims, which this time were limited to pemetrexed disodium, and are now embodied in the claims of the Patent as set out in para 21 above. Dr Burnside said:

> "The Claims have been amended to refer to the preferred embodiment, the use of pemetrexed disodium (ALIMTA®) as manufactured by Eli Lilly and Company, as the antifolate drug. The Claims have also been amended to incorporate the list of vitamin B12 derivatives set out on p 7 lines 6-7 of the application as filed."

The EPO examiner accepted the claims in this form, and the application proceeded to grant.

81. Actavis contends that the prosecution history, as summarised in paras 76 to 80 above, makes it clear that the claims of the Patent should be interpreted as being limited to pemetrexed disodium not only as a matter of language, but in the sense that the use of any other pemetrexed compound, including other pemetrexed salts and the free acid, could not infringe. This contention gives rise to two issues. The

first is one of relatively general application, namely whether and if so when it is permissible to have recourse to the prosecution history of a patent when considering whether a variant infringes that patent. The second issue is whether the prosecution history of the Patent in this case alters the provisional conclusion reached in para 75 above.

82. So far as the first issue is concerned, Lord Hoffmann said in *Kirin-Amgen* [2005] RPC 9, para 35:

> "The courts of the United Kingdom, the Netherlands and Germany certainly discourage, if they do not actually prohibit, use of the patent office file in aid of construction. There are good reasons: the meaning of the patent should not change according to whether or not the person skilled in the art has access to the file and in any case life is too short for the limited assistance which it can provide. It is however frequently impossible to know without access, not merely to the file but to the private thoughts of the patentee and his advisors as well, what the reason was for some apparently inexplicable limitation in the extent of the monopoly claimed."

83. In the absence of good reason to the contrary, it would be wrong to depart from what was said by the House of Lords. It is said by Actavis that there is good reason to depart from what Lord Hoffmann said on the ground that he was wrong in his description of the German and Dutch approaches to this issue, and that anyway he failed to have regard to the jurisprudence of other European courts.

84. In my view, Lord Hoffmann was right about the approach of the German and Dutch courts to this issue. Thus, the Bundesgerichtshof, in a decision involving the German equivalent of the instant Patent, Case No X ZR 29/15 (*Eli Lilly v Actavis Group PTC*), paras 39-40, stated that "it is permissible … to use statements made by the applicant [and the examiner] during the grant procedure as an indication of how the person skilled in the art understands the subject matter of the patent" but "such indications cannot be readily used as the sole basis for construction". And in *Ciba-Geigy AG v Oté Optics BV* (1995) 28 IIC 748, the Dutch Supreme Court said that "a court will only be justified in using clarifying information from the public part of the granting file, when it holds that even after the average person skilled in the art has considered the description and the drawings, it is still open to question how the contents of the claims must be interpreted".

85. It is argued by Actavis that this limited approach to the circumstances in which reference can be made to the prosecution file may be more restrictive than the

approach adopted in France, Italy, and Spain, as analysed by Arnold J. Thus, he said in para 162 of his judgment, that the Cour d'Appel observed in Case No 08/00882, *Hewlett Packard GmbH v Agilent Technologies Deutschland GmbH* (27 January 2010) that "the patentee who amended its clauses to give them a limited scope may not, without putting the safety of third parties at risk, claim that the amendments were not necessary, nor that the limited claims have the same scope as the broader claims". However, the court in that case had already decided on the natural meaning of the patent, and the contents of the file were merely being invoked to confirm the decision. The position in Italy, according to Arnold J in para 174 of his judgment, is that "there is no doctrine of prosecution history estoppel" and "there is no clear rule as to the relevance, if any, of the prosecution history as an aid to the interpretation of claims". In Spain there is a doctrine of *actos propios*, which as Arnold J explained in para 184, is "the doctrine of one's own acts", but it only justifies relying on the prosecution file in relation to statements which are "unequivocal, clear, precise, conclusive, undoubted and [do] not reflect any kind of ambiguity".

86. While the French courts appear to be more ready to refer to the prosecution file on issues of interpretation or scope than the German or Dutch courts, it is unclear how much, if any, difference there is in outcome. The position in relation to the Italian courts is more unclear, and it may well be that the effect of the approach of the Spanish courts is the same in outcome as that of the German and Dutch courts. In those circumstances, particularly as it may be inevitable that there is a degree of difference in the approach of different national courts on such an issue, there is nothing in the French, Italian, or Spanish jurisprudence which causes me to depart from the conclusion expressed by Lord Hoffmann.

87. In my judgment, it is appropriate for the UK courts to adopt a sceptical, but not absolutist, attitude to a suggestion that the contents of the prosecution file of a patent should be referred to when considering a question of interpretation or infringement, along substantially the same lines as the German and Dutch courts. It is tempting to exclude the file on the basis that anyone concerned about, or affected by, a patent should be entitled to rely on its contents without searching other records such as the prosecution file, as a matter of both principle and practicality. However, given that the contents of the file are publicly available (by virtue of article 128 EPC 2000) and (at least according to what we were told) are unlikely to be extensive, there will be occasions when justice may fairly be said to require reference to be made to the contents of the file. However, not least in the light of the wording of article 69 EPC 2000, which is discussed above, the circumstances in which a court can rely on the prosecution history to determine the extent of protection or scope of a patent must be limited.

88. While it would be arrogant to exclude the existence of any other circumstances, my current view is that reference to the file would only be appropriate where (i) the point at issue is truly unclear if one confines oneself to the

specification and claims of the patent, and the contents of the file unambiguously resolve the point, or (ii) it would be contrary to the public interest for the contents of the file to be ignored. The first type of circumstance is, I hope, self-explanatory; the second would be exemplified by a case where the patentee had made it clear to the EPO that he was not seeking to contend that his patent, if granted, would extend its scope to the sort of variant which he now claims infringes.

89. Turning to the second issue, I do not consider that the contents of the prosecution file in this case justify departing from the provisional conclusion expressed in para 75 above. It seems to me clear that the reason why the examiner considered that the claims in the patent should be limited to pemetrexed disodium was because the teaching in the specification did not expressly extend to any other anti-folates. It is unnecessary to decide the issue, but, at least as at present advised, I am inclined to think that the examiner was wrong in taking that view. Indeed, in the course of his well-presented argument for Actavis, Mr Alexander QC seemed to accept that Lilly could have expressed its claims more widely than it did (albeit that this was not a point which was carefully explored). However, even if the examiner was right or at least justified in taking the stance that he did, I do not consider that that consideration can have any bearing on the question whether any pemetrexed salts other than pemetrexed disodium should be within the scope of the patent pursuant to the doctrine of equivalents. The whole point of the doctrine is that it entitles a patentee to contend that the scope of protection afforded by the patent extends beyond the ambit of its claims as construed according to normal principles of interpretation.

90. This point was well made by the Dutch Court of Appeals in *Boston Scientific Ireland Ltd v Cordis Europa NV* 01/639 (unreported) 3 July 2003, when they held that the contents of the prosecution file were of no assistance, as they related to a concern which the examiner had expressed about added matter which went to disclosure, whereas that had no relevance to the point at issue which was the scope of the claim - which properly included equivalents.

91. I draw comfort from the fact that neither party was able to refer to a case where a French or Spanish Court had relied upon the patentee's response to a disclosure or added matter objection by the examining officer as being relevant to the scope of claim. It is true that the Madrid Appeal Court in *Inmobiliaria Masife SL v Vale y Tino SA* (decision 268/2013) (unreported) 27 September 2013 held that a patentee was bound by an exclusion which he had agreed during prosecution but that was "to overcome an objection of the examiner based on the prior art", a very different point. I draw even greater comfort from the fact that the Bundesgerichtshof reached the same conclusion on this very issue in relation to the German equivalent of the Patent in this case in Case No X ZR 29/15 (*Eli Lilly v Actavis Group PTC*), para 72.

Direct infringement in France, Italy and Spain

92. Having concluded that the Actavis products directly infringe the Patent as a matter of UK law, it is necessary to consider whether the same result obtains under French, Italian and Spanish law. In my judgment, direct infringement is established in those jurisdictions as well.

93. Turning first to French law, it appears to me that the answer to the question of direct infringement ultimately turns on whether the Patent in this case falls into the *moyens généraux* category or the *moyens particuliers* category, because, as discussed in para 46 above, the doctrine of equivalents is apparently only applicable to patent claims in the former category. With some diffidence, I have reached a different conclusion from Arnold J on this issue and have concluded that the Patent in this case falls into the former category. It is of course true that an appellate court should be very slow indeed to differ from the trial judge on a question of fact. However, the notion that the resolution of a dispute as to foreign law involves a factual finding rather than a legal conclusion is somewhat artificial, and in any event, the Judge did not hear any oral evidence from the expert foreign law witnesses. We are therefore in as good a position as he was to analyse the effect of the evidence as to foreign law.

94. The Judge considered that the Patent in this case represents a *moyen particulier*, because pemetrexed disodium was the relevant means and the Patent did not reveal it having a novel function: it merely revealed a new and better way in which its function could be achieved. To my mind the better analysis is that the Patent discloses that pemetrexed disodium could be used for a function for which it could not previously have been satisfactorily or safely used in practice; specifically, that pemetrexed disodium could be used with vitamin B12 to achieve an end which could not have been achieved by either chemical on its own, pemetrexed disodium because of its harmful side-effects and vitamin B12 because it would not have worked. The essential point, as I see it, is that the Patent revealed for the first time the existence of a combined means which functioned in a certain way, namely to alleviate certain cancers without serious side-effects. It would be different if the overall function of the combination of the two chemicals had not been new.

95. Support for this conclusion appears in the book referred to in para 46 above, *Droit de la propriété industrielle*, whose two authors were the expert witnesses on French law in this case. At para 719, p 443, they wrote "when the claim is over a combination of means for which global function is novel, any combination of means with a different structure but achieving the same global function is a priori equivalent and thus infringing". That passage was effectively applied by the Cour de Cassation in Appeal P08-14741, *Diffusion Equipements Loisirs v Helge*, 15 September 2009.

96. As to Italian law, Arnold J said at paras 178 and 179 of his judgment that he had concluded that the Actavis products did not infringe the Italian designation of the Patent on two grounds. The first (which he only accepted with "some hesitation") was "because on its face the patent clearly demonstrated a conscious intention of the patentee to limit the claims to pemetrexed disodium". The second ground was "because if there was any doubt about that, it was amply confirmed by the prosecution history". It is clear that (as one would expect) the Italian courts accept the doctrine of equivalents, and accordingly for the reasons given in paras 70 to 74 above, I would reject the first ground; and, for the reasons given in paras 91 to 93 above, I would reject the second ground also.

97. So far as Spanish law is concerned, it is common ground that the Spanish courts have followed the United Kingdom approach, which leads to the difficult question whether one should assume that they would follow this decision in modifying the *Improver* questions and in particular the second question. I incline to the view that judicial comity would tend to suggest that the Spanish courts would follow this court in modifying the *Improver* questions, not least because this appears to render the UK courts and therefore the Spanish courts more consistent with the German and Dutch courts, and no more inconsistent with the French and Italian courts.

98. In a written note dated 10 July 2017, Actavis applied for what would amount to a reconsideration of the conclusion expressed in para 97 above, on the ground that the reasoning of the Spanish Tribunal Supremo in the *Lundbeck* decision, discussed in para 50 above, should lead to the opposite conclusion, namely that marketing Actavis's products in Spain would not infringe the Patent.

99. In my view, it is too late for Actavis to raise such an argument. Lilly had sought to rely on the *Lundbeck* decision in its written case in this appeal, and Actavis had objected on the ground that the decision had been given after the Court of Appeal decision in these proceedings. It seems to me that in these circumstances it would be wrong to permit Actavis to raise the *Lundbeck* decision to support their case, especially as they are seeking to do so after knowing the result of this appeal and the reasons for that result. I am unimpressed by Actavis's argument that their application is nonetheless justified because the reasoning in para 97 above was not raised on this appeal. Actavis's written case stated that "Spanish law has been directly modelled on *Catnic* and *Improver*", and in paras 182 and 187 of his judgment on this case Arnold J effectively treated the *Improver* questions as part of Spanish law. It appears to me that the conclusion that, if the UK Supreme Court modifies the *Improver* questions, the Spanish courts would adopt any such modification, was therefore within the scope of the argument raised in this Court.

100. Furthermore, I consider that it would be wrong for Actavis to be permitted to raise a new ground in support of their contention that their products would not infringe in Spain, after publication of our decision, which was done with their consent and at their instigation following receipt of our draft judgment which concluded that their products would infringe in Spain. It is not as if Actavis had come across new information since they had agreed to that publication. It is true that, as explained in para 2 above, Actavis's solicitors wrote to the Court very shortly after they received the draft judgment, but thereafter they had nearly a full 24 hours within which they could have withdrawn their agreement to publication of our decision. In any event, there is obvious force in the simple point that, having agreed to publication of the decision in advance of the handing down of the judgment, they have to take the consequences. I do not suggest that, in every case where the decision is published with the consent of the parties after they have seen the draft judgment, it would be impossible for either party to invite the court to change the decision, or any aspect of it. However, it seems to me that, in the absence of a good reason, the interests of finality and certainty should prevail, and I do not consider that Actavis have come up with a good enough reason in this case.

101. It is right to add that I am by no means convinced that, even if we had permitted Actavis to re-argue their case in relation to Spain, on the basis of the *Lundbeck* decision, I would have reached a different conclusion from that expressed in para 97 above. Quite what constitutes "a degree of predictability" or "a high probability" when it comes to assessing whether the notional addressee would expect the variant to work must be fact-sensitive. Further, if, as seems likely but not, I accept, certain, the German, Dutch, French and Italian courts would all hold that Actavis's products infringed, there would have been much to be said for the view, which I have already expressed, that the Spanish courts would follow suit.

102. Accordingly, I would hold that the French, Italian and Spanish designations of the Patent are also directly infringed by the Actavis products.

Indirect infringement

103. In these circumstances, Actavis's cross-appeal, which seeks to challenge the Court of Appeal's conclusion that its products indirectly infringed does not, I think, arise in the sense that it has no practical effect on the parties (other, perhaps, than on the issue of costs). However, as the point was fully argued, gave rise to a disagreement between the Court of Appeal and the trial judge, and can be dealt with shortly, it is appropriate to consider it.

104. Indirect infringement is provided for in section 60(2) of the 1977 Act, and it states that a person infringes a patent if, without the patentee's consent, he supplies

or offers to supply in the United Kingdom to someone not authorised by the patentee with "any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect".

105. The reason why Lilly contends that, even if they did not directly infringe, the Actavis products would indirectly infringe is because, when they are supplied to a doctor or a pharmacist, they are, as Actavis would know, dissolved in a saline solution in order to enable them to be administered to patients. Saline is a solution of common salt, ie sodium chloride, in water, and when common salt is dissolved in water, it separates into sodium cations and chloride anions. Accordingly, when one of Actavis's products, say that containing pemetrexed dipotassium, is dissolved in saline, the solution contains pemetrexed anions and potassium cations plus sodium cations and chloride anions. In those circumstances, argues Lilly, even if pemetrexed dipotassium would not of itself infringe if it was administered with vitamin B12, at least provided that the ratio of sodium ions to pemetrexed ions was at least 2:1, there will be infringement when it is administered in saline solution, because the solution which is administered will contain pemetrexed disodium.

106. The Court of Appeal, disagreeing with the Judge, acceded to Lilly's argument on this point.

107. Actavis argue that a solution consisting of, or including, pemetrexed ions and sodium ions is not within the expression "pemetrexed disodium" in the Patent, because it is limited to the solid, or crystalline, chemical. I agree with Floyd LJ in rejecting that argument. There is no reason to think that the patentee intended to limit the expression in that way; quite the contrary. It is clear that solubility was an important issue, and indeed that was one of the two main reasons on which Actavis rested their contention that their products did not infringe, as discussed in paras 24 to 25, 59, and 66 above. Further, and even more in point, as Floyd LJ said, in the passages quoted in para 19 above the specification made it clear that references to pemetrexed disodium extended to that chemical in solution.

108. Actavis also argue that there is an inconsistency between the Court of Appeal holding, when considering direct infringement, that the notional addressee could not be assumed to know that pemetrexed dipotassium would dissolve, and holding, when considering indirect infringement, that pemetrexed dipotassium did in fact dissolve. Even if I had not concluded that the notional addressee should be treated as knowing that pemetrexed dipotassium could dissolve, I would have rejected that argument which seems to me to involve a non-sequitur. By the time that they were ready to market their products, Actavis knew perfectly well that they were all soluble.

109. Actavis further argue that a solution of pemetrexed dipotassium dissolved in saline does not in any event contain "pemetrexed disodium" within the meaning of that term in the Patent; it is simply pemetrexed dipotassium dissolved in saline. In my view that is a bad point. If dissolving pemetrexed disodium in an aqueous solution of potassium chloride can be said to result in a solution containing pemetrexed disodium (as Actavis's argument impliedly accepts), then it must follow as a matter of elementary chemical logic that dissolving pemetrexed dipotassium in saline also result in a solution which contains pemetrexed disodium: the two solutions are chemically identical, as each would consist of potassium and sodium cations and chloride and pemetrexed anions in water.

110. Actavis additionally argue that it is irrational to hold that there could be indirect infringement because it would all depend on the solvent in which the Actavis product is dissolved, and, even if that solvent was saline, it would depend on the proportion of sodium ions and pemetrexed ions in the solution which would vary by reference to the weight of the patient. The fact that infringement may depend on the nature of solvent and the relative amounts of ions in the solution does not seem to me to be irrational. It is simply a result of the extent of the scope of protection afforded by the patent given that (as determined by the Court of Appeal) its claims are limited to pemetrexed disodium, which, when dissolved in water produces two sodium cations to every one pemetrexed anion.

111. Finally, Actavis argue that, rather than being used in the manufacture of a medicament as described in claim 1 of the Patent, pemetrexed disodium is part of the medicament. Like the Court of Appeal, I do not agree. The pemetrexed disodium comes into the manufacturing process rather later than it would if the original medicament included pemetrexed disodium rather than pemetrexed dipotassium, but that cannot alter the fact that, before it is administered to the patient, the medicament includes pemetrexed disodium and vitamin B12.

112. Accordingly, I would uphold the Court of Appeal's determination that Actavis are liable to Lilly for indirect infringement in the United Kingdom with respect to their products if Actavis know, or it is obvious in the circumstances, that ultimate users will dilute in saline - or at least Actavis would be liable for indirect infringement if they were not liable for direct infringement. The Court of Appeal said that this conclusion would apply equally to France, Italy, and Spain, and there is no challenge to that from Actavis.

Conclusion

113. For these reasons, I would (i) allow Lilly's appeal in direct infringement and hold that the Actavis products infringe the Patent in the United Kingdom, and also

in France, Italy and Spain, (ii) dismiss Actavis's cross-appeal on the basis that if its products did not directly infringe, they would indirectly infringe to the extent held by the Court of Appeal.